**PHARMACY PREMISES COMMITTEE**

**OF THE**

**NORTHERN TERRITORY**

**PS2**

**PREMISES STANDARD**

**FOR NORTHERN TERRITORY PHARMACY BUSINESSES**

***Version* 5.2**

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| **Table of Contents Page** | |
| 1. **General Information** | **3** |
| 1. **Overview** | **3** |
| 1. **Pharmacy Signage** | **3** |
| 1. **Security** | **3** |
| **4.1 Physical Security** | **3** |
| **4.2 Alarm Systems** | **4** |
| 1. **Pharmacy Access** | **4** |
| 1. **Lighting** | **4** |
| 1. **Temperature Control** | **4** |
| 1. **Professional Services Area** | **5** |
| **8.1 Dispensary** | **5** |
| **8.2 Schedule 3 Medicines Storage** | **5** |
| **8.3 Schedule 2 Medicines Storage** | **6** |
| **8.4 Counselling Area** | **6** |
| **8.4.1 Semi-private Booths** | **6** |
| **8.4.2 Counselling Rooms** | **6** |
| **8.5 Non-approved Pharmacies** | **7** |
| **8.6 Computer and Information Technology** | **7** |
| 1. **Schedule 8 Safe** | **8** |
| 1. **Refrigerator** | **8** |
| 1. **Sinks** | **8** |
| 1. **Hygiene and Pest Control** | **8** |
| 1. **Storerooms** | **8** |
| 1. **Dose Administration Aid (DAA) Program** | **9** |
| 1. **Opioid Pharmacotherapy Program (OPP)** | **9** |
| 1. **References** | **9** |
| 1. **Acknowledgements** | **10** |
| 1. **Disclaimer** | **10** |
| **Appendix A Determination of Risk for Pharmacy Premises** | **11** |

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| 1. **GENERAL INFORMATION** |
| 1. Pursuant to the *Health Practitioners Act 2004 (*HPA*),* Schedule 7, Clause 4the Pharmacy Premises Committee (the Committee) prescribes that all pharmacy businesses must comply with the premises standards |
| **1.2** Pharmacy businesses found to be in compliance with the premises standards will be issued a Certificate of Compliance under the following conditions:   * effective for two years unless deemed to be of high risk at which a Certificate of Compliance will be issued by the committee for one year (Appendix A); * valid only for the address listed * not transferrable from the current ownership structure; and * not valid if the premises undergoes major retrofitting. |

1. **OVERVIEW**

The premises must consist of an enclosed area with sufficient space for the safe provision of therapeutic products and pharmacy services. The premises must:

* provide adequate security for the storage of scheduled medicines;
* provide the necessary lighting, temperature and humidity control to ensure the integrity of medicines;
* allow an appropriate level of public access; and
* protect consumer privacy.

1. **PHARMACY SIGNAGE**

The pharmacy must have appropriate signage to inform the public of relevant details. Details on the requirement for signage can be found in **PS3 Display of Names for Pharmacy Premises Standard.**

Upon closure or relocation of a pharmacy, all signage indicating that the premise was a pharmacy must be immediately removed.

1. **SECURITY**

**4.1 PHYSICAL SECURITY**

Pharmacies must be constructed to prevent unauthorised access through walls, doors windows and ceilings.

External walls should be of solid construction to ensure they cannot be breached.

Measures need to prevent entry through the ceiling. It is recommended that the ceiling spaces above pharmacies are secured to ensure the crawl spaces cannot be accessed from adjoining areas. It is recommended that walls are continued to the roof line or security grills are installed to cordon off the ceiling space.

External doors are to be constructed of a solid core. Where this is not possible heavy gauge roller door or security grill may be used in addition to a lockable door.

All external entry points, including windows and skylights, must be lockable with additional security grills or roller doors. High security glass providing an equivalent level of security as a security grill or roller door will be accepted.

It is recommended that external bollards are considered if the pharmacy is at high risk of ram raid.

**4.2 ALARM SYSTEMS**

Pharmacies must be protected by a back to base electronic alarm which meets Australian Standards. Alarm detectors should cover the entire pharmacy space. Where this is not possible, priority should be given to areas that store scheduled medicines. The alarm system must undergo regular testing and be monitored by a licensed security firm on a 24 hour basis.

Duress alarms are also recommended.

1. **PHARMACY ACCESS**

The pharmacy must allow public access through at least one doorway, but the *Health Practitioners Act 2004*, Schedule 7, Clauses 5, 6 and 9 requires that:

* pharmacy business must be under the direct supervision of a pharmacist at all times while it is open to the public;
* non-pharmacists must not enter or remain in a pharmacy unless under the direct supervision of a pharmacist *(Note: this applies even when the pharmacy is not open for business)*; and
* a pharmacy key holder must be the pharmacist-in-charge or a pharmacist nominated by the pharmacist-in-charge. Codes or swipe cards used to access the pharmacy premises are considered keys.

The premises must allow 24 hour access to the pharmacy by the pharmacist-in-charge.

1. **LIGHTING**

All working areas used for the selection, preparation and supply of medicines must have adequate lighting in the range of 320 to 400 Lux.

Undue exposure of medicines to direct sunlight, or ultraviolet light, must be prevented.

1. **TEMPERATURE CONTROL**

The pharmacy must have the facility to ensure that recommended storage conditions for medicines are maintained at all times. For room temperature stable medicines, temperatures must not exceed 25°C. Where 24 hour temperature control is not possible, the pharmacy must have a documented process to monitor and evaluate temperatures to ensure stock viability. The use of data loggers or minimum/maximum recording thermometers with appropriate documentation, are considered acceptable methods of monitoring temperatures.

The pharmacy must also have the facilities to ensure that temperature conditions are maintained during periods of power outages. A backup generator allowing uninterrupted power supply to critical items is recommended. Alternatively facilities that allow temperature monitoring and recording can be used to inform evaluation of stock viability after a power interruption.

Consideration should also be given to control of humidity to ensure medicines integrity.

1. **PROFESSIONAL SERVICES AREA**

The pharmacy must have a clearly delineated and marked professional service area restricted only to the provision of therapeutic goods and services. The area should be designed and located such that consumers are able to access the advice of the pharmacist to assist in their safe and effective use of therapeutic goods. The professional service area contains the dispensary, counselling booths, prescription drop off and collection points and Schedule 2 (except in clause 8.3) and Schedule 3 medicine storage areas. The professional service area must be free of information, products and services that are not health related.

**8.1 DISPENSARY**

The dispensary must consist of an area of at least 16m2 and must ensure the security and integrity of medicines stored within it. Smaller dispensary sizes may be considered by individual application to the Committee.

It must be constructed in such a manner as to minimise deliberate or inadvertent public access. Design should also prevent members of the public from entering the area directly in front of the dispensary to maintain confidentiality and minimise distraction. For these reasons the dispensary design must also limit it from being used as a staff thoroughfare.

The dispensary must contain at least one dispense station. For further detail on the requirements for a dispense station see **PS6 Mandatory Equipment for Pharmacy Premises Standard**.

The dispensary must contain at least 1m2 of free bench space for the preparation of dispensed medicines. This bench space does not include the tops of machinery, sinks or fixtures and must not be designated for any other activity. It is strongly recommended that the bench space be immediately adjacent to the dispense station.

The dispensary must have access to a sink for the preparation of medicines and maintenance of medicine preparation equipment.

**8.2 SCHEDULE 3 MEDICINES STORAGE**

Schedule 3 medicines must be stored in such a manner as to minimise unauthorised access. It is recommended that Schedule 3 medicines are stored behind the service counter in the professional service area. They must be stored a sufficient distance behind the service counter for items to be out of reach of members of the public. Medicines must be stored within or in close proximity to the dispensary to allow appropriate security and pharmacist oversight.

Where pharmacies are experiencing issues with Schedule 3 medicines which are subject to abuse, such as codeine containing analgesics or pseudoephedrine based products, consideration should be given to storing products within the dispensary. In these circumstances minimal stock levels should be held with stock limited to one shelf facing.

**8.3 SCHEDULE 2 MEDICINES STORAGE**

Schedule 2 medicines may be stored outside the professional service area, but must be stored within 6m of, and within sight of, the dispensary (measured from the closest point of the dispensary) to allow effective oversight by the pharmacist.

Schedule 2 medicines stored within 4m of the dispensary may be stored in such a manner as to be not within line-of-sight of the dispensary.

**8.4 COUNSELLING AREA**

The pharmacy must have an area for the provision of counselling in relation to dispensed or other medicines. This area must be separated from other areas of the premises to minimise interruption to client interactions and protect client confidentiality. The design of the counselling area must minimise risk of conversations being overheard and ensure that medicines and documents cannot be seen by other persons.

**8.4.1 COUNSELLING BOOTH (SEMI-PRIVATE) – all pharmacies**

* + Fitted with opaque privacy screens that rise to at least 0.6m above the bench to form a booth or that are otherwise arranged or located to provide and equivalent level of privacy;
  + The width of each area shall be such that only one person can fit comfortably – 0.9m to 1.2m;
  + Must be incorporated in to the workflow design to encourage routine use for all prescription transactions;
  + It is recommended that there should be as many counselling points as there are dispensing stations; and
  + Additionally, it is recommended that there is access to electronic devices in each ‘booth’ to assist in the counselling process.

**8.4.2 COUNSELLING ROOM (PRIVATE) – if fitted**

* + It is recommended that the minimum floor area be 7m2. Smaller areas may be considered on application;
  + Must be constructed in such a manner as to allow privacy to the client;
  + Contain a bench area equivalent to or greater than 0.6m2;
  + Allow sufficient space to accommodate the consumer, their carer and staff member;
  + The room must be compliant with all relevant Australian Standards including AS 1428.1 Design for access and mobility;
  + The room must have access to hand washing or hand sanitising facilities;
  + Sufficient lighting for ‘routine office tasks’ eg: reading, writing and typing having an illumination range of 320-400 Lux. – AS/NZS 1680.1 Interior workplace lighting; and
  + Access to electronic devices to assist in the counselling process.
  + If utilised as an immunisation service – seating outside the counselling room for patient waiting/observation.

**8.5 NON-APPROVED PHARMACIES**

The public is entitled to know if a pharmacy is not approved to supply pharmaceutical benefits.

There must be a sign stating that:

* pharmaceutical Benefits are not available from the pharmacy; and
* repeat authorisation forms for Pharmaceutical Benefits are not issued.

Persons presenting prescriptions at the pharmacy are to be directed to the sign (below) and have the financial consequences of not obtaining the medicine as a Pharmaceutical Benefit explained to them.

1. Signage:

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| **ATTENTION**  This pharmacy is unable to provide prescription medicines under the Pharmaceutical Benefits Scheme (PBS)  What this means to you:   * prescriptions dispensed at this pharmacy do not count towards your (family) Pharmaceutical Benefits Scheme Safety Net; and * any subsequent prescription repeats will not be included in your (family)Pharmaceutical Benefits Scheme Safety Net.   For further information:   * ask your pharmacist; * contact the Australian Government Department of Health PBS Information Line on 1800 020 613, or via email at [pbs@health.gov.au](mailto:pbs@health.gov.au) |

1. Display of Signage:
   1. Minimum size requirement – A4
   2. Minimum font size – 26pt on A4
   3. Must be on public display in the Professional Services Area (Standard 8)
2. All prescription interactions must include reference to the above notice and acknowledgement from the patient must be obtained.
   1. **COMPUTER AND INFORMATION TECHNOLOGY**

The pharmacy must have adequate software, hardware and information technology (IT) to meet the requirements of professional guidelines and legislation for dispensing and managing patient records appropriately and securely.

All software, hardware and IT must be maintained and up to date to ensure conformance and usability.

It is strongly recommended that the pharmacy have procedural guidelines in place for the management of these IT processes.

1. **SCHEDULE 8 SAFE**

The pharmacy must have a minimum of one safe for the storage of Schedule 8 substances. All safes used for storing S8 substances must comply with the **Code of Practice for the Transport and Storage of Schedule 8 Substances.**

1. **REFRIGERATOR**

The pharmacy must have a minimum of one refrigerator for the storage of temperature sensitive medicines. All refrigerators used for the storage of medicines must comply with **National Vaccine Storage Guidelines (*Strive for 5*)** and must be dedicated to the storage of pharmaceutical products.

1. **SINKS**

The pharmacy must have a sink with running hot and cold water dedicated to support hand hygiene practices.

*Note: this sink must be separate, with dedicated water source and drainage, to sinks used for other purposes.*

If the pharmacy has an area for staff breaks and meal preparation, this area must have a sink with hot and cold running water that is separate to the sink for hand hygiene practices.

Where the pharmacy extemporaneously prepares medicines onsite, it must have a separate sink for the cleaning of medicines preparation equipment.

*Note: A double bowl sink, with one bowl restricted for cleaning of meal preparation equipment and the other for cleaning of medicines preparation equipment is considered acceptable providing the two bowls have separate draining areas, separate water sources and separate drainage points (including s-bends).*

Pharmacies must have access to a cleaner’s sink, floor waste or other similar facility connected to drainage to dispose of mop water and other liquid waste. Sinks used for the maintenance of floor cleaning equipment must be separate from those used for hand washing, food and medicines preparation.

1. **HYGIENE AND PEST CONTROL**

The building must be constructed in a manner to minimise the ingress of debris. Buildings and fixtures must be kept clean, tidy and well maintained.

All cleaning equipment must be maintained to support hygiene and infection control.

The building must be constructed and maintained to minimise entry of rodents, vermin, birds and pests. Animals including pets are not permitted in the pharmacy, with the exception of guide dogs and other assistance animals.

1. **STOREROOMS**

All storerooms must meet the same security, access, supervision and temperature control standards as the pharmacy.

Storerooms containing scheduled medicines in a location separate to the pharmacy must be approved by the Committee and will only be considered in exceptional circumstances.

1. **DOSE ADMINISTRATION AID (DAA) PROGRAM**

Where a pharmacy regularly provides a DAA service to more than 15 clients per week, the pharmacy must have a dedicated preparation area. This area must:

* meet requirements for security, lighting and temperature control;
* provide at least 1m2 of free bench space;
* be tidy and free from distractions;
* provide access to and appropriate security for patient records; and
* access to hand washing facilities.

Where the pharmacy provides DAA services to less than 15 clients per week, the same requirements must be met, but bench space within the dispensary may be used for DAA preparation.

For information on equipment required for DAA services see **PS6 Mandatory Equipment for Pharmacy Premises Standard**.

1. **OPIOID PHARMACOTHERAPY PROGRAM (OPP)**

**Where a facility provides treatment to more than 20 clients per day the pharmacy must have an area designated exclusively to the dosing of clients**. This area must:

* meet requirements for security, lighting and temperature control;
* protect the privacy of OPP clients;
* be fitted with a safe for the storage of OPP medicines;
* have lockable storage for client records; and
* contain suitable storage for the equipment necessary for provision of this service.

Where the pharmacy provides treatment for less than 20 clients per day, the same requirements must be met, but the counselling area may be used for the dosing of patients.

For information on equipment required for OPP services see the **PS6 Mandatory Equipment for Pharmacy Premises Standard**.

1. **REFERENCES**

The pharmacy must have access to all references described in the **PS7 Mandatory References for all Pharmacies Standard**.

1. **ACKNOWLEDGEMENTS**

This standard was developed with reference to:

* Victorian Pharmacy Authority Guidelines, The Victorian Pharmacy Authority
* The Guide, Pharmacy Council of New South Wales;
* Pharmacy Guidelines, Pharmacy Regulation Authority of South Australia;
* Australian Code of Good Wholesaling Practice of Medicines in Schedules 2, 3, 4 and 8, The Therapeutic Goods Administration 2011;
* Quality Care Pharmacy Program, The Pharmacy Guild of Australia;
* Pharmacy Board of Australia, Guidelines for Dispensing;
* Pharmacy Board of Australia, Communique 27 June 2014;
* National Vaccine Storage Guidelines (Strive for 5); The Australia Government, Department of Health and Aging;
* Code of Practice for the Storage and Transport of Schedule 8 Substances, Northern Territory Department of Health, 2018.

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| 1. **DISCLAIMER** |
| In case of any conflict or discrepancy between this document and legislation, the legislation prevails. |

**APPENDIX A DETERMINATION OF RISK FOR PHARMACY PREMISES.**

All pharmacy premises in the Northern Territory are administered by the Pharmacy Premises Committee which must ensure compliance with the *Health Practitioners Act 2004*. The Committee has determined all pharmacies are to be categorised in to ~~two distinct~~ three risk categories. These are normal, high risk and pharmacy premises undergoing desktop or remote assessment.

1. **Normal Risk** pharmacies and professional services premises and pharmacies which fit into the following criteria:
   1. attained a QCPP Certificate (or for the accompanying pharmacy); and
   2. undertake a normal range of pharmacy products and services as deemed by the Pharmacy Premises Committee.
2. **High Risk** pharmacies and professional services premises which fit in to the following criteria:
   1. not assessed by QCPP; and/or
   2. compounding utilising a Compounding Laboratory; and/or
   3. undertake activities which the Pharmacy Premises Committee determines to be high risk; and/or
   4. have been the subject of a substantiated complaint; and/or
   5. found to have significant non-compliance during a routine inspection.
3. **Pharmacy premises undergoing desktop / remote assessment:** 
   1. **For existing premises** – the pharmacy’s certificate of compliance may be extended for up to six (6) months.
   2. **For new, relocated and / or refurbished premises** - a new certificate of compliance may be issued for up to six (6) months
   3. Any extension beyond six (6) months will be at the discretion of the Pharmacy Premises Committee.

**For Items one and two - Inspection and issuing of a Certificate of Compliance:**

**Normal Risk** – pharmacies will be inspected every two years and once deemed compliant, issued with a Certificate of Compliance valid for two (2) years.

**High Risk** – pharmacies will be assessed once a year and if deemed compliant, issued with a Certificate of Compliance valid for one year.