TPA
Tasmanian Pharmacy Authority

TASMANIAN PHARMACY AUTHORITY

Pharmacy Guidelines

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Ph: 0417 752 348
www.pharmacyauthority.tas.gov.au

SCHEDULE OF AMENDMENTS

Version	Date	Details of Amendments
v1.0	6 February 2013	New Document- Guidelines approved
v2.0	2 December 2014	New Section 12 and update contact details
v3.0	1 April 2015	New Section 4.1
v4.0	4 October 2016	Preamble, Sections 6, 7, new Section 10A, Part D
v5.0	5 January 2017	Pharmacy Control Act 2001 amended 1 January 2017 Sections 2, 4, 5, 6, 7, 8, 10, 11, 12, 13, Part D
v6.0	November 2022	All Sections
v6.1	January 2023	Section 9
V6.2	11 June 2024	Sections 7, 8.2, 9, 12, 13

Next complete review due: February 2025

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PART A
FOREWORD

1. Effective Date

These Guidelines were first formulated and adopted on 6th February 2013. Version 6 of these Guidelines was adopted on 2 November 2022.2

2. Conventions and Definitions Used

In this document:

a. *the Act* means the *Pharmacy Control Act 2001 (as amended on 1 January 2019)*;

b. *Ahpra* means the Australian Health Practitioner Regulation Agency;

c. *Approved enclosure* means the safe or other enclosure approved by PSB for the storage of Schedule 8 substances;

d. *the Authority* means the Tasmanian Pharmacy Authority;

e. *the Guidelines* means these guidelines, as issued from time to time by the Authority;

f. *interest in a pharmacy business* means a legal or beneficial interest and includes (but is not limited to) a proprietary interest as a sole proprietor, as a partner, as a director, member or shareholder of a company and as the trustee or beneficiary of a trust;

g. *may* means that the condition is discretionary;

h. *must* means that the condition is mandatory for all pharmacists;

i. *PBS* means the Pharmaceutical Benefits Scheme governed by the *National Health Act 1953 (Commonwealth).*

j. *PGA* means the Pharmacy Guild of Australia;

k. *Pharmacy Depot* means a location other than a pharmacy where patients can drop off prescriptions for scheduled substances, and pick up dispensed scheduled substances;

l. *PharmBA* means the Pharmacy Board of Australia;

m. *Professional service area* means that area of a pharmacy reserved exclusively for activities associated with the storage and sale of medicinal products or services;

n. *PSA* means the Pharmaceutical Society of Australia;

o. *PSB* refers to the Pharmaceutical Services Branch of the (Tasmanian) Department of Health, which administers the *Tasmanian Poisons Act 1971* and the *Poisons Regulations 2018;*

p. *Regulation/s* means the *Poisons Regulations 2018*;

q. *should* means that the condition is indicative of best practice but may not be applicable to the required practice of all pharmacists;

r. *Supermarket* means any large enclosed shop that primarily sells fresh and processed foods (including beverages) and where the selection of goods is organised on a self-serve basis.

s. *Tobacco products* means tobacco in any form, any product of which tobacco is an ingredient, and any device or article designed or intended only for use in connection with tobacco BUT SPECIFICALLY EXCLUDES prescription nicotine products and associated administration devices.

3. Fees

The Authority determines fees sufficient to cover the costs of administering the legislation. Fees are reviewed annually and are published in the Government Gazette and on the Authority's website.

4. Purpose of the Guidelines

The Authority is a body corporate, established under section 6(1) of the Pharmacy Control Act 2001 (the Act). Section 11 of the Act allows the Authority to issue Guidelines for the purpose of providing practical guidance and direction with respect to pharmacy ownership, business premises registration and appropriate practice. A link to the Act is available on the Authority's website.

These Guidelines, which are subject to periodic amendment, are published on the Tasmanian Pharmacy Authority website at www.pharmacyauthority.tas.gov.au . These Guidelines represent the current policies of the Authority and should be read in conjunction with the Act, and all pharmacists must ensure they are conversant with the Act and the Guidelines.

Section 71E(3) of the Act specifies the matters that the Authority may have regard to when issuing guidelines. These include, but are not limited to:

a. the standard or proposed standard of presentation of the premises, including the external appearance and internal fittings; and
b. the physical condition of the premises, and the condition of associated amenities such as lighting, ventilation and sanitation; and
c. the security of the premises and, in particular, the security of dispensing and storage areas; and
d. key professional requirements such as the need for –
   (i) professional supervision of the sale and supply of medicines and drugs; and
   (ii) customer privacy and counselling; and
   (iii) sufficient storage for medicines and drugs; and
e. whether there is, or will be, reasonable public access to the premises and, in particular, access for disabled persons; and
f. if there is, or will be, direct access to or from adjoining premises, the nature of the activities carried out on those adjoining premises; and
g. any issues of compliance regarding State or Council legislative requirements on matters such as fire safety and occupational health and safety; and
h. in the case of leased premises, the terms of the lease.

Where these Guidelines include matters that are not the responsibility of the TPA, advice is provided as to the body responsible for those matters.

Work is underway to develop legislation regulating the operation of Pharmacy Depots. These Guidelines will be updated once this legislation takes effect.

5. Practice Standards

The Authority is not responsible for Professional Practice Standards, Code of Professional Conduct, ethical matters, or requirements for ongoing professional development. In the main, these are matters for the Pharmacy Board of Australia (PharmBA), whose functions include:

- registering pharmacists and students;
- developing standards, codes, and guidelines for the pharmacy profession;
- handling notifications, complaints, investigations, and disciplinary hearings;
- assessing overseas trained practitioners who wish to practice in Australia;
- approving accreditation standards and accredited courses of study.

The PharmBA has developed codes and guidelines for the profession. These also help to clarify its views and expectations on a range of issues.

PharmBA Guidelines may be used as evidence of what constitutes appropriate professional conduct or practice for pharmacy in proceedings under the National Law or a law of a co-regulatory jurisdiction against a health practitioner.

Pharmacists have a duty to inform Ahpra if they become aware that the professional standards or practices of a fellow pharmacist may be in breach of the Code of Conduct of Pharmacists. This includes any concerns regarding a registered pharmacist's competency to practice.

Pharmacists can access the PharmBA Guidelines, which include the Code of Conduct at *http://www.pharmacyboard.gov.au/Codes-Guidelines.aspx*

Similarly, if a pharmacist believes that a pharmacy business premises does not meet the requirements of the Act and these Guidelines, they should contact the Authority with their concerns.

The Act does not give the Authority any jurisdiction to consider or regulate advertising standards. Such matters are the responsibility of the Therapeutic Goods Administration which is responsible for the Price Information Code of Practice; and the PharmBA which regulates Guidelines for Advertising.

6. Limited Supply Notice for Pharmacies without s90 Approvals

Most community pharmacies hold approval to supply Pharmaceutical Benefits Scheme (PBS) subsidised medicine in accordance with *National Health Act 1953 s90*. There are, however, a small number of community pharmacies which do not have this s90 approval. This has implications for the supply of prescription medicines and therefore for the consumer.

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

- requires a Limited Supply Notice to be prominently displayed at all entries to the shop and in the professional services area, explaining that the pharmacy is not approved to supply pharmaceutical benefits; and
- requires persons presenting prescriptions at the pharmacy to be directed to the Limited Supply Notice and have the financial consequences of not obtaining the medicine as a Pharmaceutical Benefit explained to them.

PART B
PHARMACY BUSINESS PREMISES

The Act requires that the Authority must not approve an application for registration unless it is satisfied that the premises sought to be registered are suitable, or are being made suitable, to be used for the purposes of a pharmacy business.

The Act requires that all pharmacy business premises must be registered by the Authority and that this registration must be renewed each year by 30th June.

The Act requires that alterations to registered premises must be approved by the Authority *prior* to the commencement of work.

7. Pharmacy Business Premises Initial Registration /Relocation

If a registered pharmacist wishes to develop a new pharmacy premises, application must be made to the Authority BEFORE the development of a pharmacy premises. There are strict requirements applicable to the acceptable layout of the pharmacy which are explained in these Guidelines. The application will require professionally drawn plans to be submitted to the Authority.

Registered pharmacies which are relocating to a different address are considered to be applying for a new pharmacy premise and the same guidelines and fees apply.

Please complete Form PNR to make application and pay the appropriate fees.

If a lease is required for the pharmacy business premises, the conditions of the lease must not include any provision for the lessor (premises owner/landlord) to receive a share of turnover or profit which could be construed as the landlord having an interest in the pharmacy business.

When the Authority has considered the application, it will issue in principle approval to the owner for development of the new or relocated pharmacy premises to begin. In principle approval is granted for a period of six months. If development is not finalised in that six-month period, application should be made for an extension. If granted, the in-principle approval will then extend for a further six months. Should the pharmacy premises still not be finalised within that six-month extension, the application will be considered to have lapsed and a new application must be made and the applicable fee paid. The Authority will then consider the application again and grant an in-principle approval on the resubmitted application.

When work is completed, and **before the commencement of trading**, the Authority requires the submission of the completed and signed DOC Declaration of Completion Form and SIF Self-Inspection Form.

On the basis of the information provided in Forms DOC and SIF, if the Authority is satisfied that the premises have been made suitable to be used for the purposes of a pharmacy business, then the premises will be registered. Advice to this effect, including issuing of the Certificate of Registration of Pharmacy Business Premises, will then be formalised. Once this Certificate is issued, **trading can commence** on the date specified on the DOC Form.

The Authority will arrange to inspect the new or relocated pharmacy within one week of the commencement of trading and may direct the owner to make any remedial actions to make the premises suitable.

In the case of a relocated pharmacy, any pharmacy-related signage on the previous premises must be removed. Any websites, search engines or other internet references are to be updated with the new premises' details. A simple internet search of your pharmacy's name will assist in identifying those sites where updates may be required.

8. Pharmacy Design

When developing a design for a new pharmacy or alterations to existing premises, the following points should be taken into consideration. The Authority requires that pharmacy business premises **must** comply with the following:

- Comply with the Building Code and other State or council legislative requirements on matters such as fire safety and occupational health and safety
- At least one doorway provides access for members of the public from a street, public walkway, mall or public foyer, giving particular regard to persons with a disability
- Be constructed so as to be secure from unauthorised access, giving consideration to:
    - Doors (internal and external)
    - Windows
    - Skylights
    - Walls
    - Ceilings
    - Lighting
    - Locks
    - Other physical security measures which may be applicable to your environment (anti-vehicle bollards etc)
- Consultation, vaccination and treatment rooms should be fitted with locks to prevent unauthorised entry to the room and from the room to other areas of the pharmacy such as dispensaries or storerooms
- Windows and skylights should have substantial locks if capable of being opened. Bars or grilles should be erected internally if possible and grouted into the brickwork or bolted through wall thickness. Bolts are to be welded to bars. Roller shutters are recommended for large or recessed entry areas.
- Be fitted with a security intrusion detector alarm which is control room monitored to a central agency on a 24 hour basis. The monitoring company facilities should be graded in accordance with Australian Standard 2201.2 - 2004 (Intruder Alarm Systems – Monitoring Centres) to Grade 1, 2 or 3 and should hold a security firm licence.
- Have an alarm system with a back-up system, such that any attempts to disable or isolate the alarm system would result in a response.
- Should the premises have access to/from an (approved) adjoining business, the pharmacy premises must be separately locked and alarmed so as to prevent any unauthorised after-hours access from the adjoining premises.
- All non-public access doors to the pharmacy premises must be kept locked at all times.
- Have an area for the unpacking and storage of goods which is not in the professional service area, and which is a workable size commensurate with the size of the pharmacy and denies access to any member of the public.

- Have an area for the provision of counselling about dispensed or other medicines, so that the privacy of the person receiving the counselling can be assured.

The pharmacy premises **MUST NOT**:

- be located wholly or partly within a supermarket;
- be capable of being entered from within a supermarket;
- be capable of being used to gain entry to a supermarket;
- allow access to any other premises, *unless* it has been approved by the Authority. The Authority will not approve access to/from another premises if the business carried on in the other premises is considered to be incompatible with a pharmacy business;

8.1 Pharmacy security

The Authority encourages the use of a manual key locking system and security code entered via an on-premises keypad to ensure security of the pharmacy business premises. This creates a 'two-phase' system of something you carry and something you know.

- The use of a combined swipe card or press button system that simultaneously unlocks premises and deactivates alarms is not permitted.
- The use of a press button 'fob' system for alarm deactivation is strongly discouraged.

Pharmacy keys and alarm codes must only be held by a pharmacist, and no person is to be allowed to enter or remain in a pharmacy unless a pharmacist is present at all times.

Restricted keying systems are highly recommended as they provide the ability to control the quantity and issue of keys. Additional keys cannot be copied by hardware stores or key cutters. It is recommended that proprietors introduce and maintain a key register to ensure all keys are accounted for.

Documented procedures for the pharmacy's security must be available and accessible to all pharmacists in charge, including locums.

8.2 The Dispensary

The dispensary sits within the professional service area of the pharmacy. The professional services area may also include counselling areas, prescriptions in/out counters and storage/display locations for Schedule 2 medicines.

Definition of a Dispensary

The Authority has defined the dispensary as:

- an area within a pharmacy that a pharmacist reserves for the dispensing or preparation of prescriptions and scheduled medicines; *and*
- is enclosed by walls and/or partitions which ensure privacy for the pharmacist; *and*
- provides an environment where a pharmacist can undertake dispensing and other functions in a safe and professional manner (including measures to control and minimise distractions); *and*

- is an area where Schedule 3 and Schedule 4 medicines are stored; *and*
- is an area to which the public is denied access; *and*
- is positioned to allow a pharmacist to effectively supervise that part of the pharmacy premises where Schedule 2 and unscheduled medicines are kept, sold or supplied; *and*
- is an area where the pharmacist has ready access to required reference materials;
- is an area separate from where items other than medicines are kept or stored;
- is an area in which medicines are stored in a manner which will not promote the sale of a product or to which undue attention would be drawn; and
- is separate from the area for unpacking goods.

Dispensary Design Requirements

The Authority has not specified a minimum size for the dispensary area, although it must consider the requirements of the Regulations insofar as the storage of scheduled substances is concerned. Floor plans submitted for approval by the Authority are required to clearly show the boundary of the dispensary, as well as showing the 4 metre radius from the dispensary boundary. Schedule 2 medications are to be kept within that 4 metre radius and also must be within clear line of sight from the dispensary. All Schedule 3 medications must be within the dispensary itself. PSB regulates medicine storage requirements of pharmacy design, and the Authority takes PSB's advice on such issues.

The Authority will consider the following aspects of the dispensary design:

- The dispensary is of an adequate size to allow free and clear movement of the pharmacist when dispensing.
- Public access to the dispensary must be prevented. Staff access to the dispensary must be under the direct supervision of a registered pharmacist. Owners and pharmacists-in-charge must ensure that a pharmacist is supervising the dispensary at all times, and that dispensary access is strictly restricted to essential dispensary activities. The dispensary should be designed to prevent persons from entering the dispensary or any part of it, without being noticed by the pharmacist on duty.
- The dispensary and its surrounds should be designed to minimise interruptions and distractions to the dispensing process and also to prevent the inadvertent disclosure of documents and the identity of patients' medicines to unauthorised people. The pharmacy should be designed so that the dispensary is not used as a thoroughfare to access "back of house" areas.
- There is adequate lighting and ventilation.
- Conditions of temperature and humidity are maintainable and suitable to ensure the integrity of all drugs and medicines kept in the dispensary, and for personal comfort.
- There is a sink of stainless steel or other material approved by the Authority with an impervious surround, and supplied with hot and cold running water.
- There is a dispensing bench with an impervious covering, with not less than one (1) square metre of free working space per dispensary station.

- There is a purpose built refrigerator for the storage of those vaccines and medicines which require refrigeration. Any fridge in which vaccines are to be stored must have a data logger installed which is capable of real time temperature monitoring.
- The pharmacist on duty is able to effectively supervise the pharmacy premises where medicines are kept, sold or supplied and the persons employed therein.
- Medicines are stored in a manner that will not promote the sale of a product or draw undue attention to a product**.**
- Packing of dose administration aids is carried out in a dedicated and secure area where distractions are minimized, and complies with PSA Professional Practice Standards.

Dispensing processes

In considering the registration of a pharmacy business premises, the Authority requires evidence that the premises has in place the necessary procedures and practices to dispense medicines and drugs expected from a professional pharmacy business premises, and in accordance with the Regulations.

Premises must have:

- A documented procedure for dispensing available in the dispensary, and that those procedures are followed.
- A Dispensary Computer System, backed up daily, with an auditable trail of all amendments to patient and prescription details. There must be written procedures about the backup process, backups must be stored offsite, and retained in accordance with statutory requirements.
- Barcode scanning must be used as part of the dispensing procedures at all times.
- A documented procedure for the checking, removal, and disposal of expired stock from the pharmacy shelves which is available in the area where the stock is held.
- No expired stock on pharmacy shelves.
- Out-of-date stock awaiting disposal is marked as such and is stored away from all current stock.
- Where the batch number and/or expiry date cannot be verified, the medicine must not be supplied and should be disposed of.

9. Equipment

The pharmacy must include the following equipment:

- A means of refrigeration complying with the "Strive for Five" of the National Vaccine Storage Guidelines or equivalent minimum standards, with refrigeration of medicines totally separate from any refrigerator used for foodstuffs.
- Contingency equipment in the event of a cold chain breach (ice blocks, cooler/eski and minimum/maximum thermometer AND/OR UPS for refrigerator power supply).
- Professionally calibrated metric weighing and measuring equipment possessing capacities and precision suitable for the compounding, dispensing and sale of drugs and medicines, and which has operating instructions, including the minimum weighable mass, prominently displayed and which are stored in such a way that their accuracy is not compromised. The Authority recommends the use of

digital scales able to weigh in increments of 0.01g. Professional calibration of weighing and measuring equipment should be undertaken annually**.**

- Appropriate compounding and blending equipment for powders, liquids and pastes.
- Vessels suitable for storage and supply of commonly used pharmaceutical preparations, liquids, and powders.
- A range of equipment appropriate to specialty practice needs sufficient to comply with standards relevant to that specialty.
- Adequate facilities for heating required for dispensing and compounding drugs and medicines. Microwave ovens must not be used for dispensing or compounding purposes.

10. Reference Library

Under PharmBA Guidelines, pharmacists must have ready access to reference resources which are appropriate to their area and scope of practice. Reference materials may be in printed book form or be accessible online. The Authority recommends online access to current digital copies as a preference, as this ensures currency.

The PharmBA's Guideline 1, which specifies the required references, is accessible on the TPA website. This Guideline changes from time to time, and pharmacists should regularly check the website for updates.

In addition to the PharmBA-specified references, pharmacy business premises must also have access to the (Tasmanian) Poisons Act 1971 (and amendments) and the Poisons Regulations 2018 (and amendments).

In order to assist owners in this regard, the Authority's website has a "LINKS" tab which provides direct links to required freely available online references and to other useful sites. The Authority recommends that this page is bookmarked on each dispensing terminal.

11. Storage of Scheduled Substances

The Authority requires that storage of scheduled substances complies with legislative requirements, including the Poisons Regulations. Pharmacy business premises must be designed and practices adopted which ensure that:

- **Schedule 8 substances** – Regulation 29: All Schedule 8 items – must be stored apart from other substances in an approved enclosure in a manner approved by the Secretary.
- If a day safe or storage drawer is used:
  - it must be kept locked when not in use and the key held by the pharmacist;
  - Schedule 8s must be placed in the main approved enclosure at close of business;
  - dispensed Schedule 8s awaiting collection, including those packed in DAAs, must be stored in the day safe or approved enclosure during business hours, and in the night approved enclosure after hours;
  - the key or details of the combination for the Schedule 8s approved enclosure must be kept either on the pharmacist's person or in a place not readily accessible to other persons;
  - details of the approved enclosure's combination must not be left on the pharmacy premises when the pharmacy is closed.
  -

- Any substance specified in **Schedule 3 or 4** to the Poisons List must be kept in either of the following so that the public does not have access to the substance:

    - A store room or
    - the dispensary

- Any substance specified in **Schedule 2** of the Poisons List –

    - Must be kept behind a serving counter or in such other manner as to ensure that it is not readily accessible to the public; *or*
    - Must be on a horizontal shelf that is –
        - affixed to, or placed immediately against, an internal wall or partition separating the dispensary from the remainder of the premises; *or*
        - not more than 4 metres from, and in clear line of sight of, the dispensary

- **Pseudoephedrine Storage Requirements:**

*Note **S3 Pseudoephedrine** products from 1 April 2006 are defined as:*
Liquid preparations containing 800mg or less of pseudoephedrine hydrochloride (or its equivalent); or other preparations containing 720mg or less of pseudoephedrine hydrochloride (or its equivalent).
All other presentations of Pseudoephedrine, either as a single ingredient or in combination are Schedule 4.

- All pseudoephedrine products must be stored in the dispensary. In addition:
    - Pseudoephedrine product stock levels must be minimal.
    - Products (where possible) should be kept out of sight of general public, particularly high risk products such as single active and antihistamine combinations.
    - Recording of the supply of products should be continued where the purchaser is not a customer who is known to the pharmacist as a person of good character (bona fide regular local, account or prescription customer).
- **Nicotine e-cigarettes and nicotine vaping products** - the importation and use of nicotine e-cigarettes and liquid nicotine for vaping requires a doctor's prescription. In Tasmania, any pharmacy wishing to dispense these products is required to hold a licence under the Public Health Act 1997.

12. Compounding

Extemporaneous compounding has been a long-held practice within community pharmacy. For the purpose of these guidelines, compounding means the extemporaneous preparation and supply of a single 'unit of issue' of a therapeutic product intended for supply for a specific patient in response to an identified need.

Where a pharmacy elects not to provide simple compounding services, they must have an appropriate written referral procedure to ensure access to supply for those patients who present prescriptions for compounded products. Similarly, if a pharmacy does not have appropriate heating equipment available, an appropriate written referral procedure must be in place.

Simple Compounding

All pharmacies providing simple compounding must comply with the following:

- have adequate calibrated metric weighing and measuring equipment possessing capacities and precision suitable for simple compounding (+/- .01 g on electronic scales). The Authority strongly recommends the use of digital scales. Any scales not in service must be removed or decommissioned to disallow their use.
- each set of scales must be professionally calibrated (and weights if the scales are analogue) annually as a minimum
- have adequate compounding and blending equipment for simple compounding
- have adequate vessels suitable for storage and supply of all commonly compounded pharmaceutical preparations
- have adequate facilities for heating if required for simple compounding. Microwave ovens are not to be used.

Complex Compounding
Complex compounding involves the supply of a single 'unit of issue' of a therapeutic product intended for supply for a specific patient in response to an identified need but also involves or requires specific competencies, equipment, processes, or facilities. Examples include sterile products or those that pose an occupational health and safety hazard (e.g. hormone and cytotoxic preparation). They also encompass micro-dose single dose units and modified release preparations.

The Authority adopts the standards for complex compounding found in section G2.4.12 of the Victorian Pharmacy Authority Guidelines.

13. Vaccination services

Pharmacy businesses are able to offer immunisation/vaccination services from their premises as a means of improving the levels of immunisation in the community.

Approvals
Prior to implementing a vaccination service, approval must be obtained from the Authority for the space you wish to use to provide vaccination. This requires the submission of Form PV (Application for Approval of a Vaccination Area in a Pharmacy Business Premises) if approval is being sought for an existing room within the premises. If alterations to the premises are required to create a suitable space for vaccinations, Form PA (Application for Approval of Alterations to Pharmacy Premises) must be submitted.

Program Approval must be sought from the Communicable Diseases Prevention Unit, Department of Health.

Personnel
Vaccination services can be delivered either by a pharmacist who has met the requirements of the Tasmanian Director of Public Health (an Authorised Immuniser), or by a doctor or authorised nurse immuniser. Vaccinations undertaken by Authorised Immunisers must comply with either the PSA “Practice guidelines for the provision of immunisation services within pharmacy” or the PGA’s “Guidelines for Conducting Immunisation Services within a Community Pharmacy Environment”, and with the PharmBA’s Code of Conduct for Pharmacists and the Tasmanian Director of Public Health requirements.

There must be a second person with appropriate First Aid and CPR training present during all vaccinations and for the post-vaccination monitoring period.

Vaccination Space
The vaccination space must be approved by the Authority prior to use. The Authority requires the space to be suitable for vaccinations, having regard to size, privacy (both visible and audible), confidentiality, safety, and hygiene. The dispensary, a storeroom, packing room or staff room must not be used for vaccination services. The space may be dedicated for the vaccination purposes or may also be a consulting room.

The Authority recommends a minimum of 4m^2 of available floor space with a minimum width of 2000mm at any point. The vaccination space must be large enough to accommodate three (3) chairs or two (2) chairs and a bed, a desk or bench with an impervious surface and adequate storage for all necessary equipment and documentation. It must also provide sufficient room to manoeuvre should there be an adverse reaction and first aid be required. The Authority strongly recommends that doors should be either cavity sliding or outwards opening to facilitate retrieval of an unconscious patient.
The space must be designed such that the procedure is not visible or audible to other persons in the pharmacy, including pharmacy staff. This includes **full height walls and opaque windows.**

Temporary spaces utilising movable screens will not be approved.

Equipment & Refrigeration
A compliant anaphylaxis kit must be always readily available during vaccinations. As this kit will contain adrenaline (a Schedule 3 medicine) consideration must be given to the location and storage requirements of this kit.
Hand sanitation facilities, a sharps disposal bin (kept a minimum 1300mm off the floor and out of reach of children), and a medical waste bin are to be in the space.
A temperature-monitored fridge which meets cold chain requirements in accordance with "Strive for 5" guidelines must be used to store vaccines. The fridge can be the dispensary fridge which stores other medicines, as long as twice daily recording of temperatures occurs. The fridge used to store vaccines must also contain a data logger that facilitates real time monitoring and reporting of temperature excursions. If the fridge is located outside the dispensary, it must be secured at all times, and the key must always be under the control of the pharmacist.
Forms or method for recording/storing the results of monitored fridge(s) temperatures, time of monitoring and person who conducted the recording/reviewed the record.
Contingency equipment in the event of a cold chain breach (ice blocks, cooler/eski and minimum/maximum thermometer AND/OR UPS for refrigerator power supply).

Post-vaccination observation
Seating is to be made available post-vaccination in a position close to the dispensary (ideally within 4 metres and in direct line-of-sight) which allows the client to be observed by the pharmacist in charge or a suitably trained staff member for the required duration in accordance with vaccination guidelines. It is not appropriate for clients to be left unattended in a vaccination room for this period.

14. Inspections

An important function of the Authority is to conduct inspections of pharmacy premises. Inspections are undertaken on a regular cyclical basis and under the following circumstances:

- When a pharmacy has changed ownership
- When a pharmacy has completed alterations
- When a new pharmacy premises opens for business
- When a pharmacy relocates premises
- When the Pharmacy Authority has concerns regarding the operations of the pharmacy.

Inspectors engaged by the Authority will travel to all areas of the state to conduct inspections. Inspections may occur at any time with or without notice. The Authority encourages pharmacists to complete the Self-Inspection Form prior to their inspection to ensure all aspects of the pharmacy comply with the requirements.

Once the inspection is completed, the Inspection Report will be tabled at the next Authority Monthly

Meeting. Following that meeting, a letter to the pharmacy owner will be sent, outlining any issues found by the inspector, in particular those which need remedial action by the pharmacy owner or their representative. These issues may include those covered by the Poisons Regulations 2018.

If any issues are found which are covered by the Poisons Regulations 2018, a copy of the inspection report, and any other evidence as deemed necessary, may be forwarded to PSB for their information and action.

Additionally, if any serious issues are found, the pharmacist and/or owner may be reported to Ahpra. This includes mandatory reporting issues.

Once the pharmacy owner has received a letter outlining the inspection issues, they will have four weeks to respond to the Authority. The owner's response should indicate how they will remediate any faults and should include photographic evidence of how this has been done. Policies taken from QCP manuals will not be accepted as proof of compliance unless an accompanying procedure showing how that policy has been implemented in the pharmacy is submitted to the Authority.

When the pharmacy owner's response has been received by the Authority, it will generally be considered at the next Authority Monthly Meeting. If the owner's response is considered satisfactory, the Registrar will communicate this to the pharmacy owner and no further action will be necessary. If further information is required, the pharmacy owner will be notified accordingly.

Complex Compounding Inspections

For pharmacies which have complex compounding facilities, a specialised inspection is required. If your pharmacy is planning on introducing complex compounding to the pharmacy, please contact the Authority for advice.

15. Disruptive Events

According to the Act, a disruptive event is defined as:

- *(a) a fire, flood or other damaging event that prevents, or is likely to prevent, a pharmacy business being carried on in or from the premises for an extended period; or*
- *(b) an interruption to the supply of electricity, gas, water or another service to the premises that lasts, or is likely to last, for an extended period; or*
- *(c) an event prescribed by the regulations;*

An extended period is defined as three (3) days.

You must give the Authority written notice of the event within seven days, outlining in detail, the event/s and the consequences. Some pharmacies may be totally unable to operate after disruptive events such as fire; others may be able to operate out of temporary premises. The Authority, together with PSB, will advise how to manage the situation.

The Authority considers that the death or incapacity of a pharmacy owner should be treated in the same manner as a disruptive event.

16. Closing or relocating a pharmacy business premises

Owners who are intending to either close or relocate their registered pharmacy business premises must apply beforehand to the Tasmanian Pharmacy Authority for approval. The appropriate application forms are provided on the Authority's website.

When moving or closing a pharmacy, pharmacists need to ensure that all scheduled medicines are stored in accordance with the provisions of the Regulations or are disposed of according to accepted professional practice. Appropriate measures must also be taken to safeguard sensitive personal information such as prescription records, including the contents of a Schedule 8s register. Scheduled medicines and sensitive personal information must not be stored in locations to which the general public has (or could potentially have) access.

PART C
PHARMACY OWNERSHIP

17. Ownership of a Pharmacy Business

The Act clearly outlines the requirements for pharmacy ownership in Tasmania, and Guidelines for ownership are not issued. The Authority website provides general guidance, as well as all the relevant application forms concerning ownership.

The Authority does not offer legal advice regarding ownership structures and recommends that pharmacists seek specialist legal guidance prior to applying for ownership of a pharmacy.

18. Pharmacy Management

The PharmBA requires that a registered pharmacist who is a proprietor of, or who has a pecuniary interest in, a pharmacy business must maintain, and be able to demonstrate an awareness of, the manner in which that pharmacy business is being conducted and, where necessary, the PharmBA will intervene to ensure that the practice of pharmacy is conducted in accordance with applicable laws, standards and guidelines.

The Authority requires that key professional standards, including the presentation of the pharmacy and the professional supervision of the sale and supply of drugs and medicines, are maintained.

This means that:

- All working areas of the pharmacy are clean, sanitary, and in good repair
- The dispensary is kept tidy and uncluttered, and free of all contaminants including food/drink
- The standards of personal hygiene, dress, and appearance of all staff in the pharmacy are appropriate for a health care setting
- All staff are appropriately trained for their roles in accordance with PharmBA Guidelines, and training records are maintained
- Sufficient appropriately trained staff are rostered with consideration to workload and tasks
- The supply, sale, promotion or consumption of alcohol, tobacco or illicit drugs are not permitted within the pharmacy
- Animals are not permitted on the premises, except for guide dogs approved under the *Guide Dogs and Hearing Dogs Act 1967*, and accredited assistance dogs as defined by the *Disability Discrimination Act 1992 (Cth)*.
- Storage and display of scheduled medicines complies with all legislative requirements
- Confidential records and documents are stored in such a manner as to maintain privacy. Where records are stored off-site, they must be secured such that only a pharmacist can access them.

PART D
FORMS

All forms are available on the Authority's website. The Authority will only accept forms on the following basis:

- The current form, as listed on the Authority's website, is submitted.
- The form is completed in full with every question answered. Incomplete applications will be returned, which may cause delays in their consideration by the Authority.
- If the application pertains to a pharmacy, the form is completed in the name of the legal pharmacy owner. This may be an individual, a body corporate or a combination.. .
- The Authority recommends scanning and emailing forms to the Authority's email address. Photographs of forms are not permitted.
- Any plans lodged with forms must be professionally drawn, showing the required locations as noted on the form and dimensions of rooms and external boundaries.
- Applications must be received by the Registrar no later than 10 days prior to the Authority's monthly meeting date of the first Wednesday of the month. Forms lodged after that date will be held over to the following month for consideration.

The following table lists the Authority's forms, their uses, and helpful information. The fee units associated with each application are listed in the *Pharmacy Control (Fees) Regulations 2021*, and the value of a fee is published by Treasury HERE.

Form	Description
AAT	**Application for a Trust** – with a corporate or individual trustee or as a beneficiary. If an individual trustee, also complete Form ECI. If a corporate trustee, also complete Form ABC.
ABC	**Application for a Company Eligibility Certificate**. The company may have an associated trust. In this case, also complete Form AAT.
ACA	**Advice of Completion of Alterations** To advise the Authority that alterations, which have previously received in principle approval, have been finalised. When this form is received, final approval will be given by the Authority, subject to a subsequent satisfactory inspection.
CBC	**Change to Body Corporate Structure** Any changes to a company must be notified – directors, shareholders, type of shares, associated trusts. If a new shareholder, which is a trust, is added, then also complete Form AAT
CO	**Change of Ownership Form** To be completed by seller and signed by both seller and buyer
CT	**Change to a Trust** To notify of any changes to beneficiaries or trustee

DOC	**Declaration of Completion** To be completed when a new pharmacy or relocated pharmacy has had building work completed and is ready for trade. The pharmacy cannot begin trading until the Authority has issued an approval letter.
ECI	**Eligibility Certificate for an Individual** To apply to own a pharmacy as an individual in your own right or as an individual as trustee for a trust. If a trust is involved, also complete Form AAT
PA	**Application for Pharmacy Alterations** For use when applying for approval for structural alterations of the pharmacy. This also includes replacement of approved enclosures for S8 medicines, security systems, external structures such as windows, doors, etc. If any changes to the dispensary is made, you must complete this form. We do not require submission in the case of a change of layout of store gondolas, shelving etc, unless this involves Scheduled medicines.
PC	**Closure of Pharmacy Premises** To advise the Authority of the permanent closure of a pharmacy premises. If there is a relocation involved, you do not need to complete this form, use Form PNR instead
PNC	**Pharmacy Name Change** To advise the Authority of any name change, including the addition or deletion of a banner group name. If changing name in conjunction with alterations or sale, this can be advised by using Forms PA or CO instead
PNR	**Application for a New or Relocated Pharmacy** To apply for a new pharmacy to be established or an existing pharmacy to be relocated (even next door).
PV	**Application for a Vaccination Area** To apply to use an existing space in the pharmacy as a vaccination area. If structural alterations are required to complete an area for use as a vaccination area, use Form PA instead.
SIF	**Self-Inspection Form** For use by pharmacists as a self-check to ensure the pharmacy is adequately addressing issues which are required by the Act and these Guidelines.

PART E
LIST OF CONTACTS

Tasmanian Pharmacy Authority
The Registrar
Phone: 0417 752 348
Email: registrar@pharmacyauthority.tas.gov.au
Web: www.pharmacyauthority.tas.gov.au

Pharmaceutical Services Branch (PSB)
| Chief Pharmacist | Pharmaceutical Services Branch
Department of Health and Human Services | GPO Box 125 | Hobart | TAS 7001
Phone: 03 6166 0400
Fax: 03 6233 3904
Email: pharmserv@health.tas.gov.au
Web: www.dhhs.tas.gov.au/psbtas/

PSB Guidelines: www.dhhs.tas.gov.au/psbtas/guidelines

Australian Health Practitioner Regulation Agency (Ahpra)
The website provides an online enquiry form and has links to a range of information
Phone: Within Australia call 1300 419 495
Web: www.Ahpra.gov.au/

Pharmacy Board of Australia (PharmBA) - PharmBA functions are supported by Ahpra
Chair
Pharmacy Board of Australia | G.P.O. Box 9958 | Melbourne | VIC 3001
Web: www.pharmacyboard.gov.au/
PHARMBA Codes and Guidelines: www.pharmacyboard.gov.au/Codes-Guidelines.aspx

Pharmaceutical Society of Australia (PSA)
161 Campbell Street | Hobart | TAS 7000
Phone: 03 6231 2636
Fax: 03 6231 2669
Web: www.psa.org.au/
Tas Branch: tas.branch@psa.org.au

Pharmacy Guild of Australia (PGA) - **Tasmania Branch**:
2nd Floor Knopwood House | 38 Montpelier Retreat | Battery Point | TAS 7004
PO Box 215 | Battery Point | TAS 7004
Telephone: 03 6220 2955
Fax: 03 6220 2966
Email: guild.tas@guild.org.au
Web: www.guild.org.au/tas_branch/tasmania-branch