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www.pharmacyauthority.tas.gov.au

PHARMACY GUIDELINES

VERSION 5.0

AS APPROVED BY THE TASMANIAN PHARMACY AUTHORITY 6TH FEBRUARY 2013

AMENDED 2ND December 2014

AMENDED 6th May 2016

AMENDED 5th January 2017
NB: AMENDMENTS TO THE ACT WERE PROCLAIMED ON 1 JANUARY 2017

PREAMBLE

These Guidelines replace what was the Pharmacy Code, which was administered by the Pharmacy Board of Tasmania.

Historically, the former Pharmacy Board of Tasmania had functions which included:

- registration of pharmacists; and
- registration of pharmacy premises.

The Pharmacy Board was disbanded in 2011 when each State and Territory parliament introduced the Australian Health Practitioner Regulation Agency (AHPRA) as the organisation responsible for the implementation of the National Registration and Accreditation Scheme across Australia. AHPRA services 14 registration bodies, including the Pharmacy Board of Australia.

With the creation of AHPRA, the registration of pharmacists, professional practice, complaint handling, discipline, competency, and approval of training of ancillary staff and the handling of complaints about the conduct of a pharmacist became the responsibility of the Pharmacy Board of Australia.

The regulation of pharmacy business ownership and registration of pharmacy premises, as in other States, were still to be regulated by a State body. In Tasmania, this is the Tasmanian Pharmacy Authority, which was established on 1st February 2011, and which replaced the Pharmacy Board of Tasmania.

The Tasmanian Pharmacy 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 to an applicant for registration of pharmacy business premises, or a responsible occupier in relation to the renewal of registration of pharmacy business premises in relation to matters specified in section 71E(3) of the Act. 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

Pharmacists must ensure they are conversant with the Act and the Guidelines.

Pharmacists seeking clarification or advice should contact:

The Registrar

Postal: PO Box 1082, Sandy Bay, TAS 7005

Telephone: 0417 752 348

Email: registrar@pharmacyauthority.tas.gov.au

Web: www.pharmacyauthority.tas.gov.au

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PART A
FOREWORD

1. Effective Date

This Guideline is effective from 6th February 2013.

2. Conventions and Definitions Used

In this document:

(a) *AHPRA* means the Australian Health Practitioner Regulation Agency;

(b) *may* means that the condition is discretionary;

(c) *must* means that the condition is mandatory for all pharmacists;

(d) *PBA* means the Pharmacy Board of Australia;

(e) *PSA* means the Pharmacy Society of Australia;

(f) *PGA* means the Pharmacy Guild of Australia;

(g) *Proprietary or pecuniary interest* means a legal or beneficial interest and includes 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;

(h) *PSB* refers to the Pharmaceutical Services Branch of the (Tasmanian) Department of Health and Human Services, which administers the *Tasmanian Poisons Act 1971*

(i) *Regulation/s* means the (Tasmanian) Poisons Regulations 2008

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

(k) *The Act* means the Pharmacy Control Act 2001 (as amended on 1 January 2017);

(l) *The Authority* means the Tasmanian Pharmacy Authority;

(m) *The Guidelines* means these guidelines, as issued from time to time by the Authority.

3. Purpose of the Guidelines

Section 11 of the Act empowers the Authority to issue guidelines consistent with the Act for the purpose of providing practical guidance and direction to an applicant for registration of pharmacy business premises, or a responsible occupier in relation to the renewal of registration of pharmacy business premises in relation to matters specified in section 71E(3) of the Act.

Section 71E(3) of the Act specifies the matters that the Authority may have regard to when issuing guidelines, and 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.

In order that these Guidelines provide as much assistance as possible, some matters that are not the responsibility of the Authority are included in these Guidelines in order to provide advice as to the responsible authority. These are matters that used to be included in the Pharmacy Code when the Pharmacy Board of Tasmania had broader responsibilities.

It is also important to note that, unlike the previous Pharmacy Code, the Act makes no provision for a pharmacy depot, so any person wishing to undertake depot-like functions is referred to PSB, as there may be storage of scheduled substances issues to be considered; the procedures concerning the receipt and issuing of medicines and prescriptions, either at a depot, or through internet, facsimile or similar means may also fall under PBA Codes and Guidelines, and pharmacists are to ensure their practices comply with any and all such requirements.

4. 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 (PBA), whose functions, which are administered by AHPRA, 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 PBA has developed codes and guidelines for the profession. These also help to clarify its views and expectations on a range of issues.

PBA Guidelines are approved by the National Board and 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 are able to access the PBA Guidelines, which included the Code of Conduct at http://www.pharmacyboard.gov.au/Codes-Guidelines.aspx (A link to the PBA website is provided on the Authority's web pages under "LINKS".)

Pharmacists have a duty to inform AHPRA or the PBA if they become aware that the professional standards or practices of a fellow pharmacist do not appear to meet the requirements of the Pharmacy Code. This includes any concerns regarding a registered pharmacist's competency to practice.

Similarly, if a pharmacist believes that a pharmacy business premises does not meet the requirements of the Pharmacy 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 PBA which regulates Guidelines for Advertising.

4.1 Limited Supply Notice for Pharmacies without s90 Approvals

Most community pharmacies apply to the Commonwealth Department of Health and Human Services to obtain pharmacist's approval to supply Pharmaceutical Benefits Scheme (PBS) subsidised medicine, in accordance with section 90 of the *National Health Act 1953*.

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 Tasmanian Pharmacy Authority:

- believes that the public is entitled to know if a pharmacy is not approved to supply pharmaceutical benefits; and
- requires persons presenting prescriptions at the pharmacy to be directed to the sign (**below**) and have the financial consequences of not obtaining the medicine as a Pharmaceutical Benefit explained to them; and
- understands that this message is endorsed by the Pharmacy Board of Australia, Medicare and the pharmacy approval authorities in each State or Territory; and
- requires a prominent sign displayed at all entries to the shop and in the professional services area stating as follows:

LIMITED SUPPLY NOTICE
This pharmacy cannot supply medicines subsidised under the Pharmaceutical Benefits Scheme (PBS)

What this means for you
Any medicines you have dispensed at this pharmacy will not be subsidised under the PBS.

Pharmaceutical Benefits Scheme (PBS) Safety Net
The cost of your prescriptions that you have dispensed here today cannot count towards your family's Pharmaceutical Benefits Scheme (PBS) Safety Net.

Impact on your repeats
Having your medicines dispensed here today will prevent you from having any further repeats of this prescription subsidised under the Pharmaceutical Benefits Scheme (PBS) at any pharmacy.

For further information
- Ask your pharmacist
- Contact the Department of Health and Ageing PBS Information Line on 1800 020 613 Monday to Friday from 8.30 a.m. to 5.00 p.m. (AEST), or via email at pbs@health.gov.au
- If you have a complaint, contact AHPRA (the Australian Health Practitioners Regulation Agency) on 1300 419 495 and ask to speak to a Notifications Officer in your state or territory.

PART B

PHARMACY BUSINESS PREMISES

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 also 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; and requires that alterations to registered premises must be approved by the Authority.

5. Pharmacy Design

The Authority requires that pharmacy premises comply with the Act and other relevant legislation. The Applications Forms for new, relocated or altered premises, which are available on the Authority's website, are designed to ensure all necessary information is provided to allow the Authority to provide in principle approval for the work to proceed; final approval is not given until a satisfactory inspection report is accepted by the Authority.

The Authority's processes include seeking advice from PSB regarding the storage of scheduled substances, though pharmacist owners are encouraged to liaise with PSB for any unusual or difficult medicines storage or security issues.

The Authority requires that pharmacy business premises **must**:

- Comply with the Building Code and other State or council legislative requirements on matters such as fire safety and occupational health and safety;
- Be constructed so as to be secure from unauthorised access through doors, windows, walls and ceilings. Front doors are to be fitted with a substantial lock for the type of door; a locksmith's advice is recommended as some doors require several locking systems. Other perimeter doors are to be constructed of solid core with heavy gauge metal sheeting fitted with substantial locks. A substantial metal security grille door may be installed in addition to the solid core door as an alternative to sheeting it. Bolts and bars are to be fitted into the building structure. Deterrence is enhanced by a secure perimeter that includes security lighting (particularly of rear entrances) and appropriate signs, such as "this property has security alarms". Doors to rooms in the public area of the pharmacy e.g. beauty rooms should be fitted with locks to prevent unauthorised entry to the room.
- Other 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.
- 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 after-hours access from the adjoining premises.
- 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.

- 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.
- Have access for disabled persons
- Have access for the public from a street or public walkway with at least one doorway opening from the premises to allow members of the public access to the premises from a street, public walkway, mall or public foyer
- If the premises are to be relocated, pharmacy-related signage on the previous premises should be removed and websites updated
- If a pharmacy business premises changes ownership, any signs which refer to the previous owner(s) should be removed immediately on transfer
- 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 a pecuniary interest.

The pharmacy premises **must**:

- NOT be located wholly or partly within a supermarket;
- NOT be capable of being entered from within a supermarket;
- NOT be capable of being used to gain entry to a supermarket;
- NOT allow access to any other premises, *unless* it has been approved by the Authority; the Authority will not approve access to/from another premises where the business carried on in the other premises appears to be incompatible with a pharmacy business;
- NOT have any animals present on the premises, except for exempt Guide dogs and support animal;
- NOT stock any tobacco products or alcoholic beverages.

6. The Dispensary

The dispensary is a private area dedicated to the dispensing of medicines and the secure storage of patients' records. Lighting, ventilation and temperature control are essential to maintaining the integrity of the medicines and for personal comfort. The dispensary is to be supplied with hot and cold running water and refrigeration, and provide a sufficient area for equipment and free working space. The public is not permitted access to the dispensary.

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 people who look over the dispensing bench. This may require service counters to be placed in front of the dispensary or a screen to be installed along the top of the dispensary bench. The pharmacy should be designed so that the dispensary is not used as a thoroughfare to access "back of house" areas.

Should consulting or vaccination areas need to be accessed by passing the dispensary area, clients must be escorted at all times, and steps must be taken to ensure that the placement of scheduled medicines, dispensary computer screens, documents, prescriptions and

anything which might identify patients and medical details to a passing client comply with security requirements for scheduled medication and with Privacy Principles for patients.

It is important that non-dispensary staff must not carry out activities in the dispensary area, with access strictly limited to dispensary staff. Non-dispensary clerical work such as point of sale data entry, preparation of promotional materials, storage of retail stock and storage of personal belongings and tea/meal breaks for non-dispensary staff must be carried out away from the dispensary.

There can be no access to the dispensary except 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 trained dispensary staff only.

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, and where a 4 metre boundary from that dispensary would be. Schedule 2 medications are to be kept within that 4 metre boundary 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 has defined the dispensary as:

> 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 where Schedule 2 items are stored.
>
> **The dispensary is that part which:**
>
> a) is an area within a pharmacy that a pharmacist reserves for the dispensing or preparation of prescriptions and scheduled medicines; *and*
>
> b) is enclosed by walls and/or partitions which ensure privacy for the pharmacist; *and*
>
> c) 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*
>
> d) is an area where schedule 3 and schedule 4 medicines are stored; *and*
>
> e) is an area to which the public is denied access; *and*
>
> f) 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*
>
> g) is an area where the pharmacist has ready access to required reference materials; *and*
>
> h) is an area separate from where items other than medicines are kept or stored; *and*
>
> i) 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*
>
> j) is separate from the area for unpacking goods.

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;
- There is adequate lighting and ventilation;

- Conditions of temperature and humidity suitable for the storage of all drugs and medicines kept in the dispensary are maintainable;
- There are adequate facilities for heating required for dispensing and compounding drugs and medicines;
- 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 of not less than 40 centimetres width;
- There is not less than one (1) square metre of free working space per dispensary station;
- No unauthorised person has access to the dispensary;
- 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 containers are carried out in a dedicated and secure area where distractions are minimised, complies with PSA Standards, and has adequate lighting and ventilation.

7. Reference Library

Under PBA 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, be readable from a computer disc or CD-ROM, or be accessible online. The Authority recommends online access to current digital copies as a preference, as this ensures currency.

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

The Authority considers the Reference Library is a key professional requirement in a pharmacy business premises, and therefore requires that current editions of the PBA listed references be available. If the references are accessed online, there must be bookmarked links to those references. If the Authority identifies that a premises' references are out of date or incomplete, it may draw this to the attention of AHPRA for appropriate action.

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.

In addition to the PBA-specified references, pharmacy business premises must also have access to the (Tasmanian) Poisons Act 1971 (and amendments) and the Poisons Regulations 2008 (and amendments).

Pharmacists should also have access to other references which are relevant to the pharmacist's specific area of practice.

To provide some guidance, this might involve current editions of some or all of the following references:

- A pharmacology reference
- An over-the-counter reference

- A paediatric reference
- A geriatric reference
- A herbal reference
- Subscriptions to current pharmacy journals
- An injectable drugs reference
- A drugs in pregnancy and breast feeding reference
- An immunisation reference
- References to support specialty practice

8. Pharmacy Management

The PBA 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 PBA will intervene to ensure that the practice of pharmacy is conducted in accordance with applicable laws, standards and guidelines.

The Authority is concerned with ensuring that key professional requirements, including that there is professional supervision of the sale and supply of drugs and medicines, are maintained.

The Authority requires that pharmacy business premises are professionally presented. This means that:

- The surface of the dispensing bench is kept clean, sanitary and in good repair
- The working areas and clothing of any persons working in the dispensary are kept clean and free from any contaminants
- Equipment is maintained in good working order
- Smoking of tobacco or any other substances is not permitted in the pharmacy premises
- No consumption of alcohol, alcoholic beverages or recreational drugs is permitted in the pharmacy premises
- Standards of personal hygiene, dress and appearance of all staff in the pharmacy are appropriate for a health care setting
- Any person assisting in the dispensing process is appropriately trained for the tasks being undertaken
- Control and management of keys should occur to minimise security problems. Documented procedures for the pharmacy's security must be available and accessible to all pharmacists in charge.
- A list of staff names and positions for that particular shift should be available. Procedures should be in place so that a smooth handover occurs at the end of a shift or on a day to day basis. A communications book should be used to record any information which may be needed by the next rostered pharmacist.

9. Equipment

The pharmacy must include the following equipment:

- A means of refrigeration complying with the "Cold Chain Management Standard" of the Quality Care Pharmacy program (QCPP) or equivalent minimum standards, with refrigeration of medicines totally separate from any refrigerator used for foodstuffs;

- Accurately 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;
- 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.

10. Dispensing

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, regularly backed up, with an auditable trail of all amendments to patient and prescription details ; there must be written procedures about the backup process, and backups should be stored offsite, and retained in accordance with statutory requirements;
- Barcode scanning must be used as part of the dispensing procedures at all times;
- If packing single or multiple dose containers, there must be a dedicated area within the registered pharmacy premises, free of distractions and not accessible to the public, to permit the packing procedure to be undertaken in compliance with PSA standards. Pharmacy owners must ensure that the area has adequate lighting and ventilation;
- 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 it stored away from all current stock;
- A Drugs of Dependence Register which is maintained in accordance with the requirements of the Poisons Act and Regulations; the Register must be regularly reconciled against stock and entries to the Register must be made within the legislated timeframes;
- All dispensed containers must be labelled with:
    - the words "Keep out of reach of children" in red on a white background; and
    - the name of the patient (or, in the case of an animal, the name of the owner of the animal); and
    - the name and address of the pharmacy; and
    - cautionary labels as required by the Regulations; and
    - particulars set out in the prescription; and
    - the initials of the dispensing pharmacist

  Numbers or letters on a label must be –
    - at least 1.5 mm high; and
    - in clear and distinct contrast to the background

- Prescriptions must be dispensed in accordance with the Regulations and recorded in the approved system and produced on request
- Hard copies of all cancelled prescriptions must be retained for 2 years
- Correct procedures for retaining Schedule 8 Prescriptions:
  Where repeats are authorised, prescriptions are retained at the pharmacy and repeats are made from same pharmacy as original dispensing. Transfer of repeats are done only after authorisation from Pharmaceutical Services Branch.
- Correct procedures for Dispensing of Narcotic Prescriptions in accordance with Regulation 23; Prescriptions are verified in accordance with Regulation 24
- Prescriptions must be marked with in accordance with Regulation's including:
  - dated and initialled on duplicate at each supply; and
  - at last supply, prescription is cancelled; and
  - repeat intervals as required on S4D and S8 prescriptions

10A. Vaccination services offered from Pharmacy Business Premises

Pharmacy businesses are able to offer immunisation/vaccination services from their premises as a means of improving the levels of immunisation in the community. Vaccination services can be delivered either by a pharmacist who has met the requirements of the Tasmanian Director of Public Health, or by a Doctor or authorised nurse practitioner. Regardless of who is administering the vaccination service, or whether the vaccination area in the pharmacy is permanent or temporary, the Authority requires the vaccination area within the pharmacy business premises to be approved.

The Authority requires the room or area to be suitable for vaccinations, having regard to privacy (both visible and audible), confidentiality, safety and hygiene. The dispensary, a storeroom or staff room cannot be used for immunisation services. The room or area may be dedicated for the vaccination purposes or may also be a consulting room.

Hand sanitation facilities and a sharps disposal bin (kept off the floor and out of reach of children) are to be in the room/area. The vaccination room/area must be large enough that the floor area, clear of equipment and furniture, accommodates the client, a carer and the practitioner, allowing sufficient room to manoeuvre. It must have sufficient space, should there be an adverse reaction, for the patient to lie down (ideally on a first aid couch) and have first aid administered. The room/area must be designed such that the procedure is not visible or audible to other persons in the pharmacy, including pharmacy staff.

A temperature-monitored fridge (which meets usual cold chain requirements and records twice daily monitoring 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 occurs. If the fridge is in the vaccination area, it must be fitted with a lock.

Seating is to be made available post-vaccination in a positon which allows the client to be observed in accordance with vaccination guidelines.

For pharmacies where an existing area (such as a consultation room) is to be used for administering the vaccination service, or where a short term temporary area is to be established (such as by use of suitably soundproofed privacy screens), the Authority requires Form PV "Application for Approval of a Vaccination Area in a Pharmacy Business Premises" to be submitted. For those pharmacies where there will be an alteration to the layout, such as the addition of a new consulting/vaccination room, this would constitute an

alteration to the premises, and therefore Form PA "Application for Approval of Alterations to Pharmacy Premises" would be required.

Vaccinations undertaken by approved pharmacist 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 PBA Code of Conduct for Pharmacists and with the Tasmanian Director of Public Health requirements.

11. Storage of Scheduled Substances

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

- Narcotic substances – Regulation 25: All **Schedule 8** items – must be stored apart from other substances in a level 4 safe which is securely locked (torch and drill resistant in-floor or 500kg free standing safe bolted and glued to floor);
- 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
    - narcotics must be placed in the main safe at the end of the day
    - dispensed narcotics awaiting collection, including those packed in DAA’s must be stored in the day or night safe during business house, and in the night safe afterhours
- The key or details of the combination for the Narcotics Safe must be kept either on the pharmacist’s person or in a place not readily accessible to other persons;
- Keys or details of the safe’s combination must not be left on the pharmacy premises while 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 storeroom; 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 Pseudephedrine** products from 1 April 2006 are defined as:
>
> a) Liquid preparations containing 800mg or less of pseudoephedrine hydrochloride (or its equivalent); or
> b) 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 **Schedule 3** pseudoephedrine products must be stored in the dispensary or pharmacy storeroom. 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).

12. 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 narcotics 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

13. 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 and ownership changes.

The information below is provided as a summary of what the Act mandates in terms of pharmacy business ownership. This is not definitive advice, and interested parties are referred to the Act for complete information.

No person, including a body corporate and including an individual in his or her capacity as a trustee or beneficiary or as a partner is able to have an interest, including a propriety interest, in more than four (4) pharmacy businesses in Tasmania (s65 of the Act).

Definitions: For the purposes of pharmacy business ownership:

close relative*, of a pharmacist, means –*

(a) *the spouse of the pharmacist; or*

(b) *the son, daughter, grandson or granddaughter of the pharmacist; or*

(c) *any child of the spouse of the pharmacist, of whom the pharmacist is not the natural parent; or*

(d) *the father, stepfather, mother or stepmother of the pharmacist; or*

(e) *the brother, step-brother, sister or step-sister of the pharmacist;*

spouse*, in relation to a pharmacist, includes a person who is in a significant relationship with the pharmacist within the meaning of the Relationships Act 2003.*

Meaning of "interest in a pharmacy business"

(1) *For the purposes of this Act, the expression* ***interest in a pharmacy business*** *means any legal or beneficial interest in the business, including an interest as –*

(a) *a sole proprietor; or*

(b) *a partner; or*

(c) *a director, member or shareholder of a company as defined in the Corporations Act; or*

(d) *a trustee or beneficiary of, or unit holder in, a trust.*

NB The term "close relative**" came into effect on 1st January 2017, and replaces the previous term "**related parties".***

Pharmacy businesses can be owned by:

1. **An individual** who is a pharmacist who holds general registration under the Health Practitioner Regulation National Law (Tasmania) in the pharmacy profession, *provided that* the pharmacist does not have an interest in any more than 4 pharmacy businesses (Sections 62(1) and 65 of the Act);

2. **A partnership** where all partners are registered pharmacists, *provided that* none of the pharmacists has an interest in any more than 4 pharmacy businesses (Sections 62(1) and 65 of the Act);

3. **A body corporate** where the controlling interest (i.e. more than 50% of the voting shares) is held by one or more registered pharmacists and **all** the other members

of the body corporate are “close relatives” of the pharmacist(s); *and* each Director is a registered pharmacist (section 61C(1)(c)). **NB**: None of the shareholders can be another body corporate.

The controlling interest in a body corporate which owns a pharmacy business may be held by a registered pharmacist as the trustee of a discretionary trust or a unit trust, *provided that*:

- the deed which establishes the trust specifies that all beneficiaries of the trust (or, in the case of a unit trust, the unitholders) must be the registered pharmacist or "close relatives" of the registered pharmacist; *and*
- the Authority is satisfied that the trustee of the trust exercises effective control over the voting rights which attach to the shares which make up the controlling interest.

Effective control of the pharmacy business must be exercised by the registered pharmacist or pharmacists (section 61C(1)(ii)(C) of the Act).

4. An individual or a body corporate as trustee of a <u>discretionary</u> trust, *provided that*:

- the class of beneficiaries is limited to the registered pharmacist or "close relatives" of the registered pharmacist (and so cannot be a body corporate, even if that body corporate is the trustee); *and*
- the trustee is either an individual registered pharmacist or a body corporate which meets the above requirements (See section 61C(2)of the Act); *and*
- neither the trustee nor any beneficiaries have an interest in any more than 4 pharmacy businesses (Sections 62(1) and 65 of the Act)

5. An individual or a body corporate as trustee of a <u>unit</u> trust, *provided that*:

- the deed which establishes the trust provides that all unit holders must be registered pharmacists or "close relatives" of the registered pharmacist(s) (and so cannot be a body corporate, even if that body corporate is the trustee); *and*
- the trustee is either an individual registered pharmacist or a body corporate which meets the above requirements (Section 61C(2) of the Act); *and*
- neither the trustee nor any beneficiaries have an interest in any more than 4 pharmacy businesses (Sections 62(1) and 65 of the Act)

PART D
LIST OF CONTACTS

Tasmanian Pharmacy Authority

The Registrar
PO Box 1082 | Sandy Bay | TAS 7005
Phone: 0417 752 348
Email: registrar@pharmacyauthority.tas.gov.au
Web: www.pharmacyauthority.tas.gov.au

Pharmaceutical Services Branch (PSB)

Peter Boyles | 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: Peter.Boyles@dhhs.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 (PBA) - PBA functions are supported by AHPRA

Chair
Pharmacy Board of Australia | G.P.O. Box 9958 | Melbourne | VIC 3001
Web: www.pharmacyboard.gov.au/
PBA Codes and Guidelines: www.pharmacyboard.gov.au/Codes-Guidelines.aspx

Pharmacy 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
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Email: guild.tas@guild.org.au
Web: www.guild.org.au/tas_branch/tasmania-branch