

Pharmacy Registration Board of Western Australia Guidelines

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PHARMACY REGISTRATION BOARD OF WESTERN AUSTRALIA

(As at 10 April 2018)

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1. FOREWORD

1.1 Overview of legislative framework

The *Health Practitioner Regulation National Law (WA) Act 2010* ("the National Law") came into operation on 18 October 2010. Corresponding identical legislation has been passed in all states and territories but in no sense is the National Law a Commonwealth law. The National Law creates ten health registration boards including the Pharmacy Board of Australia.

Under the Council of Australian Governments agreement that led to the passing of the National Law, pharmacy ownership and approval of premises were specifically excluded from it. The Parliament of Western Australia has therefore established the Pharmacy Registration Board of Western Australia ("Board") under the *Pharmacy Act 2010* ("Act") to assume these functions. The Board is the successor in law to the Pharmaceutical Council of Western Australia in relation to pharmacy businesses, pharmacy premises, or any other pharmacy related entity that is not an individual and in essence, carries out the latter's functions other than those related to registration, professional practice, complaint handling, discipline, competency, and approval of training of ancillary staff, each of which is the responsibility of the Pharmacy Board of Australia.

The Pharmaceutical Council of Western Australia no longer exists.

1.2 Functions

The Board registers premises to carry on a pharmacy business and monitors, and enforces compliance with the Act through its application, inspection and other processes.

In licensing a person to carry on a pharmacy business, the Board must be satisfied that the facilities, equipment, security, management and operation of the pharmacy business at the premises comply with minimum standards of fitness for the competent and safe practice of pharmacy, the requirements of the Act and any other requirements that are prescribed. Despite practice matters having become the responsibility of the Pharmacy Board of Australia, there are some subjects that combine both premises and practice elements, such as works of reference. This standard should be read in conjunction with any guidelines produced by the Pharmacy Board of Australia.

In this document:

- "Act" means the *Pharmacy Act 2010*.
- "Regulations" means the *Pharmacy Regulations 2010*.
- "Board" means the Pharmacy Registration Board of Western Australia.
- "the National Law" means The *Health Practitioner Regulation National Law (WA) Act 2010*.

1.3 Powers

Inspections of pharmacy businesses are carried out by the Board's staff who are authorised under Section 44 of the Act. Section 44 sets out the power of entry during business hours.

Inspections will be conducted within 12 months after new premises have been registered, after existing premises have been renovated or extended or on a routine cyclical basis. Typically an inspection will cover issues such as security, privacy, layout and equipping of the premises, including reference documents.

1.4 Standards, guidelines, codes and policies issued by the Pharmacy Board of Australia

The Board recognises the registration standards, guidelines, codes and policies issued by the Pharmacy Board of Australia.

2. APPLICATION FOR REGISTRATION

2.1 Registration of Premises

2.1.1 Application process

A person must not own, or hold a proprietary interest in, a pharmacy business unless the business is carried on at premises that are registered as a pharmacy.

“Registered” means registered with the Board under Part 4 of the Act to an eligible person to own, or hold a proprietary interest in, the pharmacy business. Regulation 4 of the Regulations lists the documents and other information to accompany an application for registration of premises.

In considering an application for registration of pharmacy premises, the Board must ensure that the premises comply with the minimum standards of fitness for the competent and safe practice of pharmacy referred to in Schedule 1 of the Pharmacy Regulations 2010 and any other requirements that are prescribed.

(NB. The registration of pharmacists and the handling of notifications about the performance or impairment of pharmacists and students is the responsibility of the Pharmacy Board of Australia which is supported by the Australian Health Practitioner Regulation Agency.)

Guidelines

The owner or proprietary interest holder is required to:

1. complete the appropriate application form obtained from the Board's office or website; and
2. forward the completed application to the Board at least 10 working days prior to the next meeting for it to be considered at that meeting.

Application forms may be downloaded from:

<http://www.pharmacyboardwa.com.au/?n=Main.Guidelines>. The forms are:

- Application for Registration of a Premises as a Pharmacy
- Authority to Notify Australian Government Department of Health – Pharmaceutical Benefits Scheme – Approved Suppliers and the Department of Health WA

The Board will not consider any application until all documentation has been provided. No application for registration of premises as a pharmacy by a pharmacist controlled company (as trustee or otherwise) will be approved without a copy of the Constitution and/or Trust Deed accompanying the application.

The Board also seeks the inclusion in any Constitution or Trust Deed words to the effect:

- Any amendment to this Constitution/Trust Deed where the effect of the amendment is to allot additional shares, allot separate classes of shares, or in any other way enlarge the shareholders or the class of beneficiaries will require the approval of the Pharmacy Registration Board of Western Australia.

The Board strongly recommends that any person contemplating applying for registration of premises as a pharmacy obtain legal advice to ensure any company's Constitution or Trust Deed for a pharmacy trust does not contravene the provisions of the Act.

For significant alterations, relocations or applications for a new pharmacy, the Board will give approval to commence activities, however final approval will not be given until a satisfactory Notification of Completion of Significant Alterations to Existing Registered Premises, or Notification of Completion of New Pharmacy Premises (as appropriate) is approved by the Board.

Definition of Significant Alteration:

The Board considers that a significant alteration is any alteration to the pharmacy that affects:

1. the construction of any part of the premises;
2. the structure of any part of the premises;
3. any entry to or exit from the premises, including the way the general public accesses any entry or exit;
4. any change to the floor area of the premises;
5. the layout or floor area of the area(s) for private consultation, including access to or from the area(s) and refurbishment of the area(s);
6. the layout or floor area of the professional services area(s), including access to or from the area(s), the storage area(s) for scheduled medicines and refurbishment of the area(s); and
7. the layout or floor area of the dispensary, including access to or from the dispensary or the ability of a pharmacist working in the dispensary to supervise the storage, sale or supply of Schedule 2 and Schedule 3 medicines.

The Board usually approves significant alterations by considering the *Notification of Completion of Significant Alterations to Existing Pharmacy Premises* submitted by the applicant but may also inspect a pharmacy if there is a concern over any matter relating to the initial application or the final notification.

2.1.2 Other persons carrying on a business in the pharmacy

A business carried on within the pharmacy business (by a person other than the owner of the pharmacy business), is prohibited.

Premises may not be located wholly or partly within a supermarket, or capable of being entered from a supermarket, or capable of being used to gain entry to a supermarket.

2.1.3 Limit on Ownership of Pharmacy Business

Section 55 of the Act states that a pharmacist must not own, or hold a proprietary interest in, more than four pharmacy businesses at any one time. Further, a close family member of a pharmacist must not hold a proprietary interest in more than four pharmacy businesses at any one time.

2.1.4 Local Council planning permits

The Board may refuse to register premises if the planning permit prevents the pharmacy from:

1. Providing a pharmacy service to any members of the public: e.g. by restricting the pharmacy to providing goods and services only to clients of a co-located medical business: and
2. Stocking certain goods. At a minimum, the permit must allow the pharmacy to stock and supply a range of goods consistent with the practice of pharmacy, including prescription medicines, non-prescription medicines, medical devices, dressings, first aid and sick room supplies and specialised infant foods.

2.2 Additional Requirements

When submitting an application form with the Board, applicants should be aware of these additional requirements.

2.2.1 Plans

Applicants must submit a floor plan and specifications of the intended premises unless the application is only for a change of ownership or change of pharmacy name.

Please refer to Appendix 1 “Guidelines for Plans of Registered Premises”

Applications will not be considered where the proposed commencement date is later than six months from the date of the Board's approval.

2.2.2 Quotation from Builder/Cost to Fitout

When approval is being sought for anything other than change of ownership or change of pharmacy name, a quotation from the builder/contractor on the cost to fit out the premises is required. If self-funding these costs, please refer to requirements for "letter of self-funding"; otherwise, refer to "finance documentation" requirements, as per below.

2.2.3 Lease documents

Provide a copy of the Head Lease and all lease documents connected to it, down the line to the final fully executed Assignment of Lease or other deed of lease, placing the premises directly within the applicant's control.

Please also note the final, fully executed lease should include a clause giving the pharmacist unrestricted access to the premises at all times, in order to be able to dispense emergency prescriptions.

2.2.4 Finance Documentation

When finance is being sought, provide a copy of the fully executed Letter of Offer, which should include the details of the loan facility approved and list the security being offered to secure the loan facility.

2.2.5 Guarantee Documentation

When guarantees are being sought from wholesalers or other sources, provide a copy of the fully executed security document.

2.2.6 Letter of Self-Funding

Written confirmation and evidence must be submitted at the time of applying for pharmacy registration, if the venture is being funded in whole or in part from the applicant/s own resources. Evidence includes copies of bank statement and/or letter from the bank manager confirming sufficient funds available for the venture.

2.2.7 Sale Agreement

If the application results from a change of ownership, a copy of any sale agreement for the premises or the pharmacy must be provided. This also includes changing ownership from an individual/partnership to a Company/Trust.

2.2.8 Expiry of Applications

Applications will not be considered where the proposed commencement date is later than six months from the date of the Board's approval.

2.3 Notification of Completion

Notification of Completion of new pharmacy premises, and Notification of Completion of significant alterations to existing registered pharmacy premises, along with a photograph document, are required to be completed and lodged with the Board upon completion of works, as they form part of the documentation upon which the Board will grant or refuse Registration. Notification must be completed and provided to the Board **at least 20 working days prior** to the Board meeting you wish it to be considered at.

These forms can be downloaded from the Board's website at:

<http://www.pharmacyboardwa.com.au/?n=Main.Forms>

In the case of Relocations, the form "*Preliminary Notification of Relocation of Pharmacy Premises*", along with a photograph document, is to be completed when the relocated premises do not yet have all the required equipment and/or reference material at the relocated premises and will not have the required equipment/reference material until the move is completed.

This is generally the case when the equipment and reference materials from the existing pharmacy are to be used within the relocated pharmacy.

As above, this document must be completed and provided to the Board **at least 20 working days prior** to the Board meeting you wish it to be considered at. Meeting dates therefore must be kept in mind by applicants so that approval is not delayed. The fully completed "*Notification of Completion of New Pharmacy Premises*", including the entire suite of required photographs, must be submitted to the Board prior to 8:00 am on the morning of the proposed opening date. If this form and the required photographs are not submitted prior to the opening date, a condition may be placed on the premises that the pharmacy has matters outstanding and the time frame for resolution of these outstanding matters. If the matters outstanding are considered to be major, the Board may cancel the registration of the premises.

When providing photographic evidence in support of these Notifications, please refer to **Appendix 2 "Guidelines for Photographs to be submitted with Notification of Completion Form"**.

The Board will also arrange for an inspection by the Board's Compliance Pharmacist, which may either occur as a condition of registration, or following registration to ensure compliance.

With regard to new or relocated premises, it is highly recommended that you base your opening date at least 5 working days following the Board meeting date.

3. GENERAL RESPONSIBILITIES

3.1 Appointments and duties of owners and pharmacists with overall responsibility

In accordance with the Act, the owner of a pharmacy business must appoint a pharmacist to have overall responsibility for the pharmacy business carried on at the pharmacy.

The pharmacist with overall responsibility is either:

1. the person in whose name the pharmacy is registered;
2. a pharmacist who has been appointed by the owner(s) of the pharmacy if owned by other than an individual;
3. a pharmacist who is appointed to be in charge of a pharmacy business for the executors, administrator or trustee of the estate of a deceased pharmacist; or
4. a pharmacist who is appointed to administer the property of a pharmacist who is bankrupt, or under the terms of a mortgage, bill of sale or security interest.

The responsibilities of the pharmacist with overall responsibility of a pharmacy includes:

1. ensuring compliance with statutory obligations and ethical standards;
2. the general security of the premises, including control of the keys or other entry devices and intrusion alarm systems;
3. ensuring the correct supervision of students, pre-registrants and dispensary assistants;
4. ensuring that in his or her absence, another pharmacist is in charge for the time being;
5. the maintenance at the premises of the required references and equipment; and
6. maintenance of a record of all prescriptions dispensed at, or from, the pharmacy, ensuring such records are secured safely, are dealt with in a confidential manner and are retained for a period of 24 months.

Upon making an appointment of a pharmacist with overall responsibility for a pharmacy the person who appointed the pharmacist must give written notice to the Board within 7 days specifying:

1. the name and address of the person appointed;
2. the date on which the appointment is to commence; and
3. evidence that the pharmacist has agreed to the appointment.

Either the person registered under the Act, or the person with overall responsibility for the pharmacy business is to ensure that the pharmacy business carried on at a pharmacy is at all times under the personal supervision of a pharmacist.

3.2 Responsibilities of proprietors

Every owner, partner or director of a pharmacy business, if that pharmacist is not the pharmacist with overall responsibility of that pharmacy, must on a regular basis make himself or herself sufficiently aware of the manner in which the pharmacy is being conducted to determine that it is being carried on in accordance with the Act and good pharmaceutical practice. If the proprietor finds that it is not, he or she must intervene to ensure that the pharmacy is properly conducted.

For the purposes of this paragraph, being aware of how the pharmacy business is being conducted includes maintaining a direction over the kinds of goods being sold - particularly those known to be subject to abuse or misuse - and that the owner's procedures and policies are being followed. The procedures and policies should be documented and available within the pharmacy.

In a partnership or other business structure, a member cannot abdicate his or her professional obligations even if that partner is essentially silent or absent.

4. PHARMACIES

4.1 Premises

4.1.1 Access to the premises

The public is entitled to have reasonable access to registered pharmacy premises.

Guidelines

To be registered, pharmacy premises must have 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.

For the purposes of section 43 of the Act, the Board will refuse to register premises as a pharmacy if the premises has other access points that would enable a member of the public to gain unauthorised access to scheduled medicines, or direct access to any adjoining premises.

A proprietor of a pharmacy business who wishes to have the Board approve access to pharmacy premises from other premises should apply to the Board in writing and provide:

1. a description of the business from which access is proposed; and
2. a completed application for approval of the pharmacy premises. Application forms are available from the Board's office or website.

4.1.2 Parts of the premises

The design and equipping of pharmacies are to ensure that the premises:

1. are secure and sanitary;
2. are suitable for the safe dispensing and supply of therapeutic products;
3. provide an environment that ensures confidentiality in dealings with the public; and
4. are directly accessible from a public place.

4.1.2.1 Security

Pharmacies are required to be constructed to prevent, as far as is reasonable, unauthorised access through doors, windows, walls and ceilings.

Roller shutters are recommended for large or recessed entry areas.

Patrols are supplementary to physical security and are not a substitute for it.

The intrusion detector must at least cover any area where drugs are kept, including the dispensary, drug safe, professional service area and storerooms.

Silent "hold up" alarms (panic buttons) are recommended.

Schedule 4 poisons must be stored in a manner that they can be supervised; particular attention therefore, needs to be paid to the contents of, and accessibility to, storerooms and refrigerators.

There should be periodic checking of physical security items such as locking systems and electronic devices should be tested to see that they are functioning. Advice from a security expert and/or a locksmith is recommended.

4.1.2.2 Professional service area in a pharmacy

To reflect the professional nature of a pharmacist's dealings with the public, a professional service area is required. It is a distinct area, distinguished by décor and sign(s) stating "Professional Service Area". The area is solely for the purposes of displaying and storing products for therapeutic use and information about them.

4.1.2.3 Counselling area

A distinct area (which may be part of the professional service area) is required that permits the pharmacist to discuss any matter with a member of the public on a private and confidential basis. The area must be positioned such that any conversations are out of the hearing of other persons and without distractions or interruptions.

As a minimum, dedicated prescription reception and counselling points fitted with privacy screens at least 800 mm apart and rising not less than 600 mm above the bench or that are otherwise arranged or located to provide privacy are required. They should be designed to encourage routine use for all prescription transactions. A password-protected screen and keyboard is recommended in each. The counselling area must be located such that there is a minimum of 2 metres from any area accessed by other members of the public. In all cases, please ensure all fixtures and fittings to be used in this area are included on the plan.

The Board notes that a number of pharmacies are incorporating more than one counselling area within the pharmacy, as they expand services into such areas as vaccinations, blood glucose testing etc. When these rooms/areas are being used for long consultations, clinics or for other uses, it is essential there is another area in the pharmacy which is suitable for private counselling of prescriptions. Where any of these consultation rooms/areas are being used as an area for private consultation, as per Clause 7 of Schedule 1 of the *Pharmacy Regulations 2010*, then adequate arrangements should be in place to ensure that:

- confidential discussions can occur between a pharmacist and a consumer in privacy; and
- consumers' medicines are not able to be seen by a third party while being stored or provided to the client.

4.1.2.4 Dispensary

4.1.2.4.1 Definition of a Dispensary

The dispensary **sits within or is ideally located near** the professional service area of the pharmacy. The professional service area may also include counselling areas, prescriptions in/out counters and where Schedule 2 medicines and Schedule 3 medicines 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) ensures privacy for the pharmacist and the activities conducted in the dispensary; 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 3R medicines 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 supervise effectively that part of the pharmacy premises where Schedule 2 medicines and Schedule 3 medicines are stored, sold or supplied; and
- g) is an area where the pharmacist has ready access to required reference materials; and
- h) 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
- i) is separate from the area for general unpacking of goods; and

j) is separate from any designated staff area.

4.1.2.4.2 General dispensary requirements

The dispensary is a private area dedicated to the dispensing of medicines. 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 pharmacy should be designed so that the dispensary is not used as a thoroughfare.

Therapeutic products are not to be removed from the dispensary without the express permission of a pharmacist unless by a student, intern or trained dispensary assistant under the supervision of a pharmacist.

A dispensary in a pharmacy is to include:

1. provision for the storage of S4 poisons that facilitates the accurate selection of medicines and restricts access to dispensary staff only;
2. a hot and cold water sink of a size large enough to clean the largest equipment used for dispensing.

A safe or drug cabinet for the storage of S8 poisons that facilitates the accurate selection of medicines should be placed in an area not accessible to the public and ideally located in the dispensary.

4.1.2.4.3 Dispensary size in pharmacies

Applications for registration of new pharmacy premises or approving alterations to existing pharmacy premises should provide a dispensary to be of an area not less than 10 square metres.

4.1.2.5 Client waiting area in pharmacies

A pharmacy should include at least one client waiting area. Its use should be encouraged to minimise congestion at the serving counter where privacy may be compromised, and to reduce pressure on the dispensing staff. In the interests of safe dispensing, chairs should be positioned in such a way that dispensing staff are not subject to staring or body language that indicates impatience. Provision of reading matter is suggested.

4.1.3 Point of Sale (POS) data entry station

POS data entry stations, non-dispensary clerical work areas and staff areas are to be located outside of the dispensary.

4.1.4 Display of names

The public is entitled to know the names of the pharmacists with whom they are dealing in a professional capacity.

Guidelines

The name or names of the proprietor(s) of a pharmacy, natural or corporate as the case may be, must be displayed on a sign at all entries accessed by the public so as to be clearly visible.

The name of the pharmacist who is regularly and usually in charge of the pharmacy and the name or names of other pharmacists on duty are to be visibly displayed in the professional service area or the place where medicines are usually collected by the public.

In all instances, the given and family names of all pharmacists should be shown as they appear on their *Pharmacy Board of Australia Certificate of Registration*. The Board will accept the inclusion of a commonly used name in brackets between the given and family names.

There is neither a requirement for, nor objection to, the wearing of name badges.

4.1.5 Removal of signs / Closure of Pharmacy Business

The Board must be advised of the closure of any premises. Please refer to the Board's website for information required. The public is entitled to know that a pharmacy has ceased to operate.

Guidelines

When a pharmacy ceases to operate, the owner or the pharmacist who is regularly and usually in charge of the pharmacy or pharmacy department, or the administrators, trustees or executors must remove all signs that indicate that the premises were a pharmacy.

Please refer to Appendix 4 "Guidelines for Closure of Pharmacy Business"

4.1.6 Unapproved pharmacy notice

The public is entitled to know if a pharmacy is not approved to claim Australian Government subsidies for PBS and RPBS prescription medicines.

Guidelines

There should be prominent notices at all public entries to the shop and in the professional services area, with a minimum of A3 size for external notices and A4 for internal.

Please refer to Appendix 5 'Unapproved Pharmacy Notice'

For ease of use, go to [Unapproved Pharmacy Notice](#) on the Board's website, for a downloadable pdf version of this Notice, suitable for printing.

4.1.7 Workloads

Section 43 of the Act requires the Board to be satisfied that, *inter alia*, the operation of the pharmacy business meets the minimum standards of fitness for the competent and safe practice of pharmacies. Accordingly, a pharmacy should be staffed to meet the expected workload.

4.1.8 Controlled temperature storage

Pharmacies are required to provide facilities in which medicines are stored at temperatures within their recommended temperature range.

Guidelines

Regulation 15 requires all premises to be well lit, adequately ventilated and air conditioned. Air conditioners should be set to maintain temperatures not exceeding 25°C during periods when the pharmacy is not open for business.

Refrigerators used to store medicines should be dedicated to this purpose.

Due regard must be paid to maintaining the integrity of the “cold chain” when stock is received and before it is supplied. It follows that the patient or agent should be informed of the storage conditions both verbally and by labelling.

4.2 Equipment

4.2.1 References

The pharmacist with overall responsibility for a pharmacy must keep at that pharmacy the current edition, together with any supplements, addenda or amendments to the references specified in Schedule 1 of the Regulations. The references may be in the form of a published document (hard copy) or in an electronic form provided the information is immediately available to the pharmacist during the dispensing process.

4.2.2 Dispensing equipment

Schedule 1 of the Regulations prescribes the equipment and reference documents required at premises to meet the minimum standards of fitness for the competent and safe practice of pharmacy. Schedule 1 has been reproduced and included in these guidelines at Appendix 3.

4.2.3 Schedule 8 poisons – storage

Schedule 8 poisons (Controlled Drugs) are to be stored in accordance with the *Medicines and Poisons Act 2014/Medicines and Poisons Regulations 2016*.

Guidelines

Requirements for Pharmacy Safes

For information on the storage of Schedule 8 medicines:

- go to [Medicines and Poisons Regulation Branch - Department of Health WA](#)
- open Health professionals
- expand Storage, transport and disposal
- open Storage of Schedule 8 medicines
- open **What type of safe is required**

The increased use of Schedule 8 poisons (including substitution therapies) and bulkier packaging indicate the need for installing safes or lockers that are large enough to store all S8 poisons on hand (taking into account future needs) and to facilitate accurate selection of the medicines from the safe or locker.

5. MISCELLANEOUS

5.1 Service Companies

Pharmacists who engage companies to provide services to a pharmacy business may do so provided:

1. the company does not enjoy any proprietary interest in the pharmacy business;
2. there is a written agreement, contract, memorandum of understanding or other document between the parties setting out the details of the services and how they are paid for; and
3. any documentation is made available for inspection by the Board at any reasonable time.

Notes

1. A "proprietary 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.
2. Section 3(2) of the Act makes void a provision in any arrangement, franchise or in any other commercial arrangement that gives a right to anyone (other than a person approved under the Act) the right to receive any consideration that varies according to the profits or takings of the business.

Guidelines

The documentation and practice must not give any suggestion that the service company has any ownership rights in connection with the pharmacy business or that it shares in the income or profits of a pharmacy business.

If the service company maintains customer accounts on behalf of the pharmacy or provides computer services, the pharmacist must not supply the company with any information about a person's medication.

The purchase of any stock (especially scheduled poisons) for or on behalf of the pharmacy business is indicative of ownership in the assets of the pharmacy business. Subject to any licensing requirements imposed by law, a service company may carry on a *bona fide* business as a wholesaler but in such circumstances, it is a separate and distinct entity having its own premises and books of account.

5.2 Pharmacy Trusts

Some pharmacists have obtained advice about pharmacy trusts from persons who may not have fully understood the ownership provisions of the *Pharmacy Regulation Act 2010*. The Act defines proprietary interest as: "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*" (italics added).

A pharmacy trust must not have as a trustee or beneficiary a person or company unless that person or company is:

- (a) a registered pharmacist; or
- (b) a close family member; or
- (c) a company registered under the Corporations Act –
 - a. in which-
 - (i) at least one director is a registered pharmacist; and
 - (ii) whose directors are either all registered pharmacists, or a registered pharmacist or a close family member of a pharmacist who is a director; and
 - b. where each holder of shares, or of a beneficial or legal interest in those shares are held by registered pharmacist or a close family member of such a pharmacist; and

- c. in which a pharmacist is, or pharmacists are, entitled to control the exercise of more than 50% of the voting power at meetings of the directors of the company or attaching to voting shares issued by the company.;
- (d) an eligible trust (An eligible trust is a trust which may be a beneficiary of another trust by reason of the General Beneficiaries of the first trust having the sole interest in that trust.)

Additionally, a trustee or a beneficiary of a pharmacy trust must not own or have a proprietary interest in more than four separate pharmacy businesses.

The Board strongly recommends that pharmacy proprietors obtain advice from a lawyer to ensure that the deed to any pharmacy trust they operate does not contravene the ownership provisions of the *Pharmacy Regulation Act 2010*.

APPENDIX 1 – GUIDELINES for PLANS of REGISTERED PREMISES

ALL PLANS of premises are required to –

1. be drawn in black ink, on one side only, on A3 paper
2. have clear margins of at least 10mm on all sides with no printing, drawing or writing extending into any margin
3. show a north point
4. be drawn to scale in metric measurement, preferably 1:50 or 1:100. If the premises size up to 150m², the scale should be 1:50
5. include the following TITLE information in BLOCK lettering on the bottom right corner-
 - a. BUSINESS NAME of premises
 - b. for existing premises, REGISTRATION NUMBER of premises
 - c. type of plan such as PREMISES, BUILDING or LOCATION.
 - d. style of plan such as FLOOR or ELEVATION
 - e. SCALE of plan
 - f. DATE of plan
 - g. for registered premises, the NAME of the pharmacist with overall responsibility for the pharmacy business carried on at the pharmacy
 - h. for premises to be registered, the NAME of the applicant

A SET of plans comprises -

1. the **PREMISES**
2. if the premises do not comprise the whole of a building, the **BUILDING** where the premises are situated that highlight the location of the premises within the building
3. the **LOCATION**

A plan of the PREMISES must clearly show -

1. the perimeter and total area of the premises in square metres
2. the perimeter of the dispensary outlined with a coloured border and total area of the dispensary in square metres
3. the perimeter for private consultation between a pharmacist and consumer including the dimensions of any privacy screens
4. if applicable, the perimeter and total area of each non pharmacy business operating at the premises in square metres
5. all entry and exit points and the purpose of each entry and/or exit point
6. fixed and mobile fittings including a description and the dimensions of any barriers used to prevent consumer access to Schedule 2 medicines and Schedule 3 medicines
7. the storage area(s) for Schedule 2 medicines
8. the storage area(s) for Schedule 3 medicines
9. the storage area(s) for Schedule 3 Restricted medicines (if applicable) and Schedule 4 medicines
10. the storage area(s) for Schedule 8 medicines
11. the dispensary sink, confirming hot and cold water available
12. the refrigerator
13. all dispensing stations

Notes:

- With respect to Item 2, a minimum floor area of 10 square metres is required for new premises and registered premises undergoing a significant alteration
- With respect to Item 3, an area for private consultation is required for new premises and registered premises undergoing a significant alteration. As a minimum, dedicated prescription reception and counselling points fitted with privacy screens at least 800 mm apart and rising not less than 600 mm above the bench or that are otherwise

arranged or located to provide privacy are required. They should be designed to encourage routine use for all prescription transactions. A password-protected screen and keyboard is recommended in each. The counselling area must be located such that there is a minimum of 2 metres from any area accessed by other members of the public. In all cases, please ensure all fixtures and fittings to be used in this area are included on the plan.

- The Board notes that a number of pharmacies are incorporating more than one counselling area within the pharmacy, as they expand services into such areas as vaccinations, blood glucose testing etc. When these rooms/areas are being used for long consultations, clinics or for other uses, it is essential there is another area in the pharmacy which is suitable for private counselling of prescriptions. Where any of these consultation rooms/areas are being used as an area for private consultation, as per Clause 7 of Schedule 1 of the *Pharmacy Regulations 2010 (WA)*, then adequate arrangements should be in place to ensure that:
 - confidential discussions can occur between a pharmacist and a consumer in privacy; and
 - consumers' medicines are not able to be seen by a third party while being stored or provided to the client.
- With respect to Item 6, refer to the Board's *Guidelines for the Safe Storage of Scheduled Medicines*. The use of fins as barriers are looked at on a case by case basis.

In addition, please refer over, for the requirements for additional information to be submitted with Applications for Significant Alterations, New Premises and Relocations.

Requirements for Additional Information to be Submitted with Applications for Significant Alterations, New Premises and Relocations

Please provide a separate document that covers off the nine items listed below, in short answer format and signed by:

- the pharmacist who has, or will have, overall responsibility for the pharmacy business; and
 - each pharmacist who has, or will have, a proprietary interest in the pharmacy business.
1. What steps will you take to ensure compliance with Schedule 1 of the *Pharmacy Regulations 2010 (WA)* (the Minimum Standards)?
 2. What steps will you take to ensure at all times all medicines are stored in accordance with manufacturer requirements?
 3. What steps will you take to ensure at all times Schedule 2 and Schedule 3 medicines are stored in accordance with the Premises Plan approved by the Board?
 4. What steps will you take to ensure at all times Schedule 4 medicines are stored in accordance with the Premises Plan approved by the Board?
 5. What steps will you take to ensure the supervision of Schedule 2 and Schedule 3 medicines when the pharmacist/s on duty is/are unavailable, such as when engaged in counselling, attending to an emergency situation or on a comfort break?
 6. What steps will you take to ensure the supervision of Schedule 4 medicines when the pharmacist/s on duty is/are unavailable?
 7. What steps will you take to ensure at all times returned and unwanted medicines are secure?
 8. What steps will you take to ensure a pharmacist consultation conducted in the proposed area for private consultation is not reasonably likely to be overheard by a person who is not a party to the consultation?
 9. For each professional service, where will it be carried out and why are you satisfied the allocated area provides adequate space and an appropriate environment to effectively deliver the service?
 - Professional services include, but are not limited to:
 - Complex compounding
 - Screening, risk assessment and disease state management
Examples of services include asthma management, the Community Program for Opioid Pharmacotherapy (CPOP), diabetes support, sleep apnoea and weight management support.
 - Dose administration aids
 - Vaccination

APPENDIX 2 – GUIDELINES for PHOTOGRAPHS to be submitted with NOTIFICATION of COMPLETION FORM

Attach a set of referenced colour photographs of the following items to a copy of the FLOOR PLAN of the registered PREMISES that uses the same reference to show the location of each photograph.

The photographs must be presented in document format, with each photograph labelled as to what it represents.

1. Consumer view(s) of exterior of premises.
2. View from each entry and/or exit showing the area beyond that entry and/or exit.
3. Consumer view of dispensary.
4. Consumer view of area(s) for private consultation between pharmacist and consumer including surrounding area.
5. Consumer view of storage area(s) for Schedule 2 medicines including counter or barrier.
6. Consumer view of storage area(s) for Schedule 3 medicines including counter or barrier.
7. a) Storage area(s) for Schedule 3 Restricted medicines (if applicable).
b) Storage area(s) for Schedule 4 medicines.
8. Storage area(s) for Schedule 8 medicines.
9. Storage area for equipment for extemporaneous dispensing and surrounding area. Ensure that all equipment is visible.
10. Storage area for reference documents and surrounding area. Ensure that all documents are visible. If a document is accessed online, include screenshots.
11. Each dispensing station with bar code scanner and work space.
12. Dispensary sink and surrounding area.
13. Hot water system for dispensary sink.
14. Refrigerator and surrounding area.
15. Air conditioning unit(s).
16. Signage at all entries accessed by the public displaying the name(s) of the proprietor(s) of the pharmacy, natural or corporate, as the case may be, so as to be clearly visible. If the proprietor(s) of the pharmacy are owned in a natural capacity, the names of all pharmacists should be shown as they appear on their *Pharmacy Board of Australia Certificate of Registration*. The Board will accept the inclusion of a commonly used name in brackets between the given and family names.
17. Signage showing the name the pharmacist who is regularly and usually in charge of the pharmacy and the name or names of other pharmacists on duty are to be visibly displayed in the professional service area or the place where medicines are usually collected by the public. The names of all pharmacists should be shown as they appear on their *Pharmacy Board of Australia Certificate of Registration*. The Board will accept the inclusion of a commonly used name in brackets between the given and family names.
18. Consumer view of each non pharmacy business.
19. Pharmacies that do not supply pharmaceutical benefits: signage at all public entries to the shop and in the professional services area advising the public that the pharmacy cannot supply medicines subsidised under the PBS. The signage should be easily identifiable and a minimum of A3 size for external signage and A4 for internal. Refer to the Board's *Guidelines* for requirements of this.

Notes:

- The pharmacy registration number and date of the photograph should appear on the bottom left corner of each photograph.
- Identification of the item(s) should appear on the bottom right corner of each photograph.
- The set of photographs should demonstrate that the premises comply with the minimum standards of fitness for the competent and safe practice of pharmacy. For example, photograph 9 should include equipment required for extemporaneous dispensing.
- If a single photograph is submitted for more than one listed item, identify the photograph with all relevant numbers. For example, if Schedule 2 and Schedule 3 medicines are stored in the same area then number the single photograph as 5 & 6.
- If more than one photograph of a listed item is submitted, follow the allocated number with a sequential capital letter starting at the beginning of the alphabet. For example, if there are two consumer views of the exterior of the premises then number the separate photographs as 1A & 1B and mark the location of each view on the floor plan.

PHARMACY REGISTRATION INFORMATION							
Pharmacy Name							
Pharmacy Registration Number							
PHOTOGRAPH REFERENCE GUIDE							
If one photograph of an item is submitted, tick over that item number.							
If more than one photograph of an item is submitted, tick the relevant letters to the right of that item number.							
If a single photograph is submitted for more than one item, write REFER ITEM “#” to the right of the subsequent item number(s).							
If an item is not applicable, tick the NA column to the left of that item number.							
NA	No.	A	B	C	D	E	ITEM
	1						Consumer view(s) of exterior of premises
	2						View from each entry and/or exit showing the area beyond that entry and/or exit
	3						Consumer view of dispensary
	4						Consumer view of area(s) for private consultation between pharmacist and consumer including surrounding area
	5						Consumer view of storage area(s) for Schedule 2 medicines including counter or barrier
	6						Consumer view of storage area(s) for Schedule 3 medicines including counter or barrier
	7 a)						Storage area(s) for Schedule 3 Restricted medicines (if applicable)
	7 b)						Storage area(s) for Schedule 4 medicines
	8						Storage area(s) for Schedule 8 medicines
	9						Storage area for equipment for extemporaneous dispensing and surrounding area
	10						Storage area for reference documents and surrounding area
	11						Each dispensing station with bar code scanner and work space
	12						Dispensary sink and surrounding area
	13						Hot water system for dispensary sink
	14						Refrigerator and surrounding area
	15						Air conditioning unit(s)
	16						Signage at all entries accessed by the public displaying the name(s) of the proprietor(s) of the pharmacy, natural or corporate, as the case may be, so as to be clearly visible. If the proprietor(s) of the pharmacy are owned in a natural capacity, the names of all pharmacists should be shown as they appear on their <i>Pharmacy Board of Australia Certificate of Registration</i> . The Board will accept the inclusion of a commonly used name in brackets between the given and family names
	17						Signage showing the name the pharmacist who is regularly and usually in charge of the pharmacy and the name or names of other pharmacists on duty are to be visibly displayed in the professional service area or the place where medicines are usually collected by the public. The names of all pharmacists should be shown as they appear on their <i>Pharmacy Board of Australia Certificate of Registration</i> . The Board will accept the inclusion of a commonly used name in brackets between the given and family names
	18						Consumer view of each non pharmacy business such as Post Office agency or newsagency
	19						Pharmacies that do not supply pharmaceutical benefits: Signage at all public entries to the shop and in the professional services area advising the public that the pharmacy cannot supply medicines subsidised under the PBS. The signage should be easily identifiable and a minimum of A3 size for external signage and A4 for internal.
Total number of photographs submitted:							<input style="width: 40px; height: 20px;" type="text"/>

APPENDIX 3 – SCHEDULE to the PHARMACY REGULATIONS 2010

1. Premises generally

The premises are to —

- (a) have at least one door allowing direct access to members of the public from a street or thoroughfare; and
- (b) have no direct access to any adjoining premises.

2. Premises, fixtures and fittings to be clean etc.

- (1) The premises and all fixtures and fittings at the premises are to be in a safe, clean and hygienic condition and in good repair.

[The Board considers this to mean:

- **safe, clean and hygienic condition**

The premises and all fixtures and fittings at the premises are to be in a condition that would be considered safe, clean and hygienic by a reasonable person.

- **good repair**

The premises and all fixtures and fittings at the premises are to be in a state of repair that is considered good/satisfactory by a reasonable person.

This view is also take for Regulation 15 (b)]

- (2) The premises are to have such devices and systems provided and maintained in good working order as is necessary to ensure that the premises are reasonably secure against burglary, robbery, theft and unexplained loss.

3. Equipment on premises

The premises are to be equipped with the equipment referred to in the Table.

Table

Item	Equipment	Number required
1.	Bar code scanner	one at each dispensing station
2.	Beakers: 100 ml 250 ml	one of each
3.	Appropriate heating device (e.g. gas, microwave or electric hotplate)	one
4.	Funnel (glass or plastic)	one
5.	Measures graduated (dispensing glass): 10 ml 25 ml 50 ml 100 ml 250 ml	one of each

Item	Equipment	Number required
6.	Mortars and Pestles: Glass 75 mm Ceramic	one of each
7.	Refrigerator	one
8.	Scales Either: Dispensing Beam type to weigh to 50 g Counter Beam type to weigh to 1 kg with metric weights 5 mgm to 500 gm inclusive OR Electronic balance to weigh to at least 200 gm, with a readability of not less than 0.01 gm and standard deviation $\leq \pm 0.01$ gm	one set of each
9.	Slabs-ointment: 250 mm x 250 mm (minimum size)	one
10.	Spatulas: Stainless Steel	at least 2 different sizes
11.	Stirring Rods: Glass	one

4. Access to reference documents

The premises are to have a copy of, or immediate electronic access to, the latest editions, and all published amendments or supplements to those editions, of each of the following documents —

- (a) the Australian Medicines Handbook (also known as *AMH*);
- (b) the Australian Pharmaceutical Formulary and Handbook;
- (c) the MIMS annual or eMIMS or AusDI;
- (d) the Therapeutic Guidelines (complete series);
- (e) the *Pharmacy Act 2010* and the *Pharmacy Regulations 2010*;
- (f) the *Medicines and Poisons Act 2014* and the *Medicines and Poisons Regulations 2016*.

5. Records

The premises are to have a safe and secure location for the keeping of records made under regulation 16.

6. Dispensary

- (1) The premises are to have an area for the dispensing of medicines or drugs that has a minimum floor area of 10 square metres (the **dispensary**).
- (2) The dispensary is to have a suitable sink that has hot and cold running water connected.

7. Area for private consultation

The premises are to have an area in which a consultation conducted by a pharmacist is not reasonably likely to be overheard by a person not a party to the consultation.

APPENDIX 4 – GUIDELINES for CLOSURE OF PHARMACY BUSINESS

Closure of a pharmacy business includes:

- **CLOSURE OF A PHARMACY BUSINESS AND RELOCATION TO NEW PREMISES**
Ceasing the operation of a pharmacy business at registered premises and commencing the operation of the pharmacy business at new registered premises.
- **CLOSURE OF A PHARMACY BUSINESS AND VACATION OF PREMISES**
Ceasing the operation of a pharmacy business at registered premises and vacating the premises.
- **CLOSURE OF A PHARMACY BUSINESS AND STAYING AT PREMISES**
Ceasing the operation of a pharmacy business at registered premises and continuing or commencing the operation of another business at the same premises.

The Pharmacy Registration Board of Western Australia requires a pharmacy proprietor who is ceasing the operation of a pharmacy business at registered premises to:

- Advise the Registrar in writing of this intention at least 14 days before the planned date for closure. (Section 52, Pharmacy Act 2010)
- Remove or obliterate all signs and notices referring to the practice of pharmacy within seven (7) days of closing the pharmacy business and provide the Registrar with photographic evidence of this action within 10 days of closing the pharmacy business. (Section 60 Pharmacy Act 2010)
- Return the *Certificate of Registration as a Pharmacy* to the Registrar within 10 days of closing the pharmacy business. (Section 65, Pharmacy Act 2010)
- Forward correspondence to The Registrar, Pharmacy Registration Board of Western Australia, Post Office Box 8124, Perth Business Centre WA 6849.

The Pharmacy Registration Board of Western Australia recommends a pharmacy proprietor who is ceasing the operation of a pharmacy business at registered premises advises all relevant authorities including:

- The Medicines and Poisons Regulation Branch, Department of Health, Western Australia.
- The Department of Human Services, Australian Government. (Pharmaceutical Benefits Scheme)
- The Australian Securities and Investments Commission. (Business Name Registration)

This document is not intended in any way to replace or paraphrase any Act or Regulation. The onus of meeting the obligations imposed upon all pharmacists under the various Act and Regulations falls on the pharmacists concerned.

APPENDIX 5 – UNAPPROVED PHARMACY NOTICE

IMPORTANT PUBLIC INFORMATION

This pharmacy is **not** approved to claim Australian Government subsidies for Pharmaceutical Benefits Scheme (PBS) and Repatriation Pharmaceutical Benefit Scheme (RPBS) prescription medicines.

The PBS is a program of the Australian Government that provides subsidised medicines to:

- residents of Australia who present their current Medicare Card; and
- overseas visitors from countries with a Reciprocal Health Care Agreement who present their passport.

The RPBS is a program of the Australian Government that provides additional subsidised medicines to eligible veterans.

PBS & RPBS PRESCRIPTION MEDICINES DISPENSED HERE:

- **will not be subsidised;**
- **will not count towards the PBS Safety Net Scheme; and**
- **MAY COST YOU MORE.**

The PBS Safety Net Scheme is a program of the Australian Government that provides additional subsidies to individuals and families who require a large volume of PBS or RPBS medicines in a calendar year.

If a repeat prescription for a PBS medicine is issued here, all future repeat prescriptions are not eligible to be subsidised at any pharmacy.

The Pharmacy Registration Board of Western Australia:

- considers consumers are entitled to know a pharmacy is not approved to claim Australian Government subsidies for PBS medicines and, in the public interest, requires such pharmacies to display this sign; and
- refers consumers with queries or concerns to the following information.

QUERIES

Ask the Pharmacist on Duty.

Contact the Department of Health by:

- calling the PBS Information Line 1800 020 613 - Monday to Friday 8:30am to 5pm (AEST); or
- emailing pbs@health.gov.au.

CONCERNS

Ask the Pharmacist on Duty.

Contact Health Providers Compliance by:

- calling the Provider Benefits Integrity Hotline 1800 314 818; or
- emailing provider.benefits.integrity@health.gov.au; or
- completing the Tip-off Form at www.health.gov.au.