



**Pharmacy Council
of New South Wales**

Protecting the public
Regulating pharmacists and pharmacies

THE GUIDE

EXPLANATORY NOTES AND GUIDELINES

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INTRODUCTION

This booklet is designed to assist in the completion of the pharmacy application forms and notices. The guidelines contained in the booklet are based on the Pharmacy Council of New South Wales' ('the Council') policies and the provisions of the *Health Practitioner Regulation National Law (NSW)* ('the Law'), and the *Health Practitioner Regulation (New South Wales) Regulation 2016* ('the Regulation'). These guidelines do not overrule the Law or the Regulation, and will be revised from time to time as policies are developed or amended.

Application forms must be lodged by the appropriate lodgement date. All complete and signed applications are considered by the Council at its monthly meetings, and in accordance with Schedule 5F clause 12 of the Law.

Please refer to the Council's website for a listing of lodgement and meeting dates.

APPLICATION FORMS AND NOTICES

The NSW Register of Pharmacies record includes:

- 1) Approved premises – pharmacy businesses (and professional services rooms) can only operate on approved premises. Approved premises details are entered onto the Register on confirmation of satisfactory inspection of premises. Approval is subject to meeting the requirements provided in Clause 12 of the Regulation.

AND

- 2) Registered Financial Interest holder(s) in a pharmacy business – this includes:
 - sole trader
 - pharmacist in pharmacists' partnership
 - pharmacists' body corporate
 - shareholder and directors in a pharmacists' body corporate
 - unitholder of a Trust where a pharmacists' body corporate acts as trustee for the Trust
 - beneficiary of a Trust where a pharmacists' body corporate acts as trustee for the Trust

Details of financial interest holders are entered onto the Register of Pharmacies on receipt of a Notice of Completion (where there is a change of pharmacy ownership) or on receipt of an updated ASIC company extract (where there is a change of shareholders and/or directors of a pharmacists' body corporate).

If you are:

- (a) **opening a new pharmacy business with or without an associated professional services room**, all registration requirements must be completed, the prescribed fees paid to the Council, and premises inspected and approved by the Council ¹ **BEFORE** trading can commence.

¹ This requirement refers to a meeting of the Council members and not to an administrative approval process.

- (b) **changing any part of existing registration details**, such as business name, partners/owners/members in a pharmacists' body corporate, the acquisition or disposal of a financial interest in a pharmacy business, postal address etc., these changes must be notified (complete with all details) to the Council. Details of **acquisitions** are to be provided to Council **14 DAYS PRIOR** to the event and **disposals 14 days after the event**. Existing approval of the premises would not be affected.
- (c) **altering / renovating "substantially" or relocating the pharmacy business** without changing the ownership or the membership of a pharmacists' body corporate, registration will not be affected but the changed or new premises must be approved **BEFORE** trading can commence. The approval of an associated professional services room is not considered to be a renovation of the pharmacy premises – a separate application needs to be lodged.
- (d) **seeking approval for a professional services room** to be used in conjunction with an existing pharmacy business must be approved **BEFORE** the professional services room commences to operate. A pharmacy business and an associated professional services room are counted as one (1) pharmacy business (see Schedule 5F Clause 9(2) of the Law).

Schedule 5F, Clause 9(1) of the Law restricts the number of pharmacy businesses in which a pharmacist may hold a financial interest in NSW to five.

Schedule 5F, Clause 12 of the Law provides the procedure for consideration of applications and reasons for rejection of applications.

Schedule 5F, Clause 13 of the Law provides an appeal process for any person aggrieved by a decision under Schedule 5F, Clause 4.

Schedule 5F, Clause 4 of the Law provides for the notification of acquisition or disposal of interest in a pharmacy and lists the supporting documents to be lodged on acquisition of a financial interest in a pharmacy business, including any bill of sale, any sale of business agreement, any partnership agreement, any lease for the pharmacy business and any agreement which gives any other person a financial interest in the pharmacy business.

Application forms are to be lodged by the lodgement date prior to a Council meeting. Fees are payable at the time of lodgement. Please refer to the Council website for lodgement dates.

Notices are to be lodged on the occurrence of an event, for example, a closure of a pharmacy. There are no fees payable for Notices.

Application for new pharmacy

To be completed when a new pharmacy is to be established:

Premises application fee	\$480.00
Financial interest registration fee	\$550.00 (for each financial interest)

Note: Applications for pharmacy ownership involving trust structures may incur an additional fee. Please see Guide Note 5 for further information.

Application for a new professional services room

To be completed when a new professional services room is to be established:

Premises application fee **\$480.00**

Application for registration of holders of financial interest in a pharmacy business where the purchaser is a sole pharmacist

To be completed when a change of ownership occurs and the purchaser is a sole pharmacist.

Application fee **\$550.00 for the person acquiring the financial interest (purchaser)**

A Notice of Completion must be lodged by the purchaser within 14 days of settlement or transfer of ownership of a pharmacy business. The register of pharmacies will only be updated on receipt of the Notice of Completion.

Application for registration of holders of financial interest in a pharmacy business where the purchasers are a partnership of pharmacists

To be completed when a change of ownership is to occur and the resulting business structure will be a pharmacists' partnership of two or more pharmacists. This includes a change to partnership arrangements in an existing pharmacists' partnership.

Application fee **\$550.00 for each pharmacist acquiring a new financial interest**

A Notice of Completion must be lodged following settlement or transfer of ownership of a pharmacy business. The register of pharmacies will only be updated on receipt of the Notice of Completion.

Across NSW the way in which individual pharmacist's hold a financial interest in a pharmacy business varies. As a result of the changes made to the Regulations in July 2016, the fees payable to the Pharmacy Council for registration of a financial interest will vary. To assist with the preparation of applications to the Pharmacy Council and the calculation of fees payable examples of how to calculate fees payable have been provided.

Example One

Pharmacist A owns a pharmacy as a sole practitioner. Pharmacist A has decided to take on partner Pharmacist B. It is proposed that the two pharmacists will own the pharmacy business under a partnership arrangement. The partnership is between the individual pharmacists and is not a partnership involving companies.

While previously Pharmacist A owned the Pharmacy business as a sole trader they propose to own the same pharmacy business under partnership. Therefore fees are payable by the new partner in the business. Each partner in the partnership arrangement must lodge an application to register their own financial interest.

Fees payable = \$ 550.00 for each new partner (that is only B is required to pay the fee)

Total = \$ 550.00

Example Two

Pharmacist A and B own a pharmacy business in partnership. They propose to take on a new partner, Pharmacist C and dissolve their old partnership and form a new partnership. This amounts to a change of ownership and a change in financial interest for each person involved in the partnership.

Fees payable	= \$550.00 for the new partner (Pharmacist A and B are not required to pay \$550.00. Only Pharmacist C, the new partner is liable to pay a fee).
Total	= \$550.00

Application for registration of financial interest in a pharmacy business where the purchaser/s include a pharmacists' body corporate

To be completed when a change of ownership is to occur and the resulting business structure includes a pharmacists' body corporate. This includes a change in the shareholding or directorship of a pharmacists' body corporate where the pharmacists' body corporate retains the ownership of a pharmacy.

Application fee **\$550.00 for each new financial interest.**

Example Three

Pharmacists A and B are proposing to own a new pharmacy as shareholders in a pharmacists' body corporate.

Both Pharmacist A and B will own an equal number of shares and Pharmacist B will also have responsibility as the sole director.

Fees payable	= \$ 550.00 for each person with a financial interest.
Total	= \$1650.00 (\$550.00 for Pharmacist A and \$550.00 for Pharmacist B and \$550.00 for the Pharmacists' Body Corporate).

Example Four

Pharmacist A and B currently hold a financial interest in the AB Pharmacy under a partnership arrangement. They propose to change the ownership structure to a pharmacist body corporate. In these circumstances the pharmacist body corporate is considered to hold a financial interest in the pharmacy which is new. As Pharmacist A and B already hold a financial interest in the pharmacy, no application fee for registration of holder of a financial interest are payable in respect of Pharmacist A and Pharmacist B but a application fee of \$550 is payable in respect of the pharmacists' body corporate.

Fees payable	\$550.00
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Example Five

Pharmacist A and B currently hold a financial interest in the AB Pharmacy as directors and shareholders of a Pharmacist Body Corporate known as AB Pharmacy Pty Ltd. They are proposing the shareholding to include two other pharmacists, Pharmacist C and Pharmacist D. They do not propose the change the name of the Pharmacist Body Corporate.

Pharmacist A and B will remain directors of AB Pharmacy Pty Ltd.

On this basis the fee payable is \$1100.00, being \$550.00 by Pharmacist C and Pharmacist D as they

are making an application for registration as a holder of a financial interest in the AB Pharmacy as shareholders.

Fees payable \$1100.00 (ie \$550.00 for each **new** financial interest to be registered).

Example Six

Pharmacist A and B currently hold a financial interest in the AB Pharmacy as directors and shareholders of a Pharmacists' Body Corporate known as AB Pty Ltd. They are proposing a change of ownership structure to include two other pharmacists, Pharmacist C and Pharmacist D. They propose to change the name of the Pharmacists' Body Corporate to ABCD Pty Ltd which is a new company.

Fees payable \$1650.00 (ie \$550.00 for each new financial interest).

In the event that the pharmacy business ownership structure includes a trust, consideration must be given to identifying if the beneficiaries are required to pay an application fee for registration of a holder of financial interest. This would occur where a beneficiary of the trust, (who is a pharmacist), is not a shareholder or director of the pharmacists' body corporate.

Note: Persons with a financial interest in the pharmacists' body corporate are able to have multiple roles within the ownership structure which may change over time. Fees will be incurred in circumstances where a person who does not currently hold a financial interest is seeking to acquire the same.

Note : Applications involving trust structures may incur an additional fee. Please see Guide Note 5 for further information.

A Notice of Completion must be lodged by the purchaser within 14 days of settlement or transfer of ownership of a pharmacy business. The Register of Pharmacies will only be updated on receipt of the Notice of Completion.

Example Seven

Pharmacists A and B are proposing to own a new pharmacy as shareholders in a pharmacists' body corporate. Both Pharmacist A and B will own shares and Pharmacist A and B will also have responsibility as directors.

In addition to owning the pharmacy business as a pharmacists' body corporate it is proposed to have a trust structure under which both Pharmacist A and B will be beneficiaries. The Pharmacists' Body Corporate will be the trustee for the Trust.

Fees payable = \$550.00 for each person with a financial interest
= \$550.00 (\$550.00 for Pharmacist A plus \$550 for Pharmacist B plus \$550 for the pharmacists' body corporate)

Total fees payable = \$ 1650.00

Example Eight

Deleted – no longer applicable

Application for relocation or expansion/reduction of pharmacy premises

To be completed when an existing pharmacy is relocated to another site, resulting in a new address, or an existing pharmacy is to undergo renovations that will substantially increase or decrease the size of the pharmacy premises. This will include where the premises, as defined in the lease associated with the premises, changes. This includes moving premises within the same commercial business area and where the pharmacy business expands or reduces the footprint as defined in the lease relating to the business premises.

Application fee **\$480.00**

Application for relocation or expansion/reduction of professional services room

To be completed when an existing professional services room is relocated to another site, resulting in a new address, or an existing professional services room is to undergo renovations that will substantially increase or decrease the size of the professional services room. This will include where the premises as defined in the lease associated with the premises changes. This includes moving premises within the same commercial business area and where the pharmacy business expands or reduces the footprint as defined in the lease relating to the business premises.

Application fee **\$480.00**

Application for registration of holder of financial interest in existing Pharmacists' Body Corporate due to acquisition of shares and/or appointment of a new director

To be completed with any proposed change in the shareholding which results in a new shareholder or any proposed appointment of a new director to a pharmacists' body corporate.

Application fee **\$550.00 for each person seeking registration of a holder of a financial interest.**

Example Nine

Pharmacist A and B currently hold a financial interest in the AB Pharmacy as directors and shareholders of a Pharmacists' Body Corporate registered with ASIC as AB Pty Ltd. Pharmacist A proposes to sell their respective shareholdings to Pharmacist C and Pharmacist D. Pharmacist B is retaining their share in the company. The company name is to be retained.

As Pharmacist C and Pharmacist D do not currently hold a financial interest in the company AB Pty

Ltd they are required to pay a fee of \$550.00 each.

Fees payable \$1100.00

Example Ten

Pharmacist A and B currently hold financial interests in the AB Pharmacy as directors and shareholders of a Pharmacist Body Corporate registered with ASIC as AB Pty Ltd. Pharmacist A proposes to sell his/her respective shareholdings. Pharmacist B proposes to acquire a further 10 per cent share holding in the company. It has been agreed that Pharmacist B will remain as a Director of the company. The remaining share holding will be held in equal shares by Pharmacist C and Pharmacist D. Pharmacist C and Pharmacist D are not being appointed as Directors. The company name is to be retained.

Existing Shareholding	New shareholding
Pharmacist A 50 %	Pharmacist A Nil
Pharmacist B 50%	Pharmacist B 60 %
	Pharmacist C 20%
	Pharmacist D 20%

As Pharmacist C and Pharmacist D do not currently hold a financial interest in the company AB Pty Ltd they are required to pay a fee of \$550.00 each.

Fees payable \$1100.00

Note: In the event that Pharmacist C and Pharmacist D acquired shareholdings and were appointed as a Director, the fees payable would also be \$1100.00 as the application for registration of holder of financial interest is only payable once irrespective of the number of interests held.

Pharmacist A will need to lodge a notice of disposal of interest

Example Eleven

Pharmacist A and B currently hold a financial interest in the AB Pharmacy as directors and shareholders of a Pharmacists' Body Corporate registered with ASIC as AB Pty Ltd. They propose a new arrangement under which Pharmacist C will be appointed as a Director of the company. Pharmacist C will not be acquiring any shares in the company. Pharmacist A and B will retain their interest as shareholders only.

As pharmacist C does not currently hold a financial interest in the company he/she is liable to pay an application fee for registration of holder of financial interest.

Fees payable \$550.00

Example Twelve

Pharmacist A, B and C currently hold a financial interest in the ABC Pharmacy as directors and shareholders of a Pharmacist Body Corporate registered with ASIC as ABC Pty Ltd. It has been agreed that Pharmacist C will resign as a Director of the company.

There are no other changes occurring.

Fees payable \$NIL

Application for acquisition of financial interest by way of appointment of unitholder or beneficiary of a trust

To be completed by a new financial interest holder, a pharmacist who intends to hold the financial interest as a unitholder or beneficiary of a Trust. The financial interest holder is not an existing shareholder or director of the pharmacists' body corporate acting as trustee for that Trust.

Application fee **\$550.00 for each pharmacist acquiring a financial interest**

Example Thirteen

Pharmacist A and Pharmacist B currently hold a financial interest in a pharmacy business as shareholders and directors of a pharmacist body corporate and have an existing trust arrangement under which both Pharmacist A and Pharmacist B are beneficiaries of separate trusts. Pharmacist B has recently married Pharmacist C and proposes to add their partner, as a beneficiary of the trust.

In this case Pharmacist C is acquiring a financial interest in the pharmacy business as a beneficiary of a trust.

Fees payable \$550.00 for each person seeking registration as a holder of financial interest.

Notice for change of pharmacy name

To be completed when a pharmacy changes its name. The notice is to be provided to Council within 14 days of the name change.

Notice of disposal of financial interest in a pharmacy

To be completed when a pharmacist disposes of his/her financial interest in a pharmacy within 14 days of the disposal.

Notice of closure of pharmacy

To be completed when a pharmacy is to cease trading and close.

Notice of completion

To be completed within 14 days of the completion of the change of ownership of a pharmacy business – that is, on settlement or transfer of ownership.

GOODS AND SERVICES TAX (GST)

Under Division 81 of the Goods and Services Tax Regulations, the Treasurer has determined that the above applications and inspection fees are exempt from the Goods and Services Tax (GST).

Guide Note 1: Business name

The Council understands that pharmacy business names are required to be registered by the Australian Securities and Investments Commission (ASIC). It is in the pharmacy proprietors' best interests to make their own enquiries of ASIC.

Pharmacy names that are false, misleading, deceptive, or imply an unjustified expectation of beneficial treatment or promote unnecessary or inappropriate use of pharmacy services (see section 133 of the Law) will not be approved. Names which suggest or imply an activity or a location which cannot be supported may also be rejected by Council

If you have any doubts about a pharmacy business name, please seek the advice of ASIC, Telephone: 1300 300 630, in the first instance.

Existing Business Names

New proprietors may wish to retain the existing registered business name of the pharmacy. This may be transferred to the new proprietors.

Multiple Business Names

For various reasons, a pharmacist may wish to register more than one business name. While this is of no interest to the Council, the pharmacist must nominate the name that will be used in the operation of the pharmacy, which will become the name under which the pharmacy is registered. All pharmacy signs, stationery and advertising must be in the name registered with the Council.

The registration of a business name is subject to time limits. ASIC will be able to advise on such conditions.

Use of Business Name in Full

ASIC and the Council require that a business name, as approved by the Council and registered as a business name, be used without abbreviation wherever it is used. This particularly includes:

- * all signage inside or outside of the pharmacy
- * advertisements, including telephone directories
- * business cards, labels, stationery, prescription stamps, envelopes and computer generated documents including repeat authorisations.

Marketing Groups

Marketing Groups may require the inclusion of their marketing name in a pharmacy's registered business name e.g. **R.J. Smith (*Marketing group*) Chemist**. This name must be registered and used without abbreviation.

Display of Pharmacist' name

Wherever the display of a pharmacist's name is made, the name must be consistent with the name recorded on the Register of Pharmacies held by the Council, and the National Register of Pharmacists held by AHPRA. Nicknames, abbreviations or other versions of a pharmacist's name cannot be used unless it is registered with AHPRA, as applicable.

Display of Name of owner/s of pharmacy

Section 139D(1)(c) of the Law requires the name(s) of the owner(s) of the pharmacy business to be displayed at or near the main entrance of the pharmacy. That is,

- if you are a sole trader, it is your name that is displayed
- if you are in a pharmacists' partnership, it is the name of every partner that is displayed
- if you are in a pharmacists' body corporate, it is the name of the pharmacists' body

corporate that is displayed

The displayed name(s) must be the name(s) that is registered with the Council. Nicknames, abbreviations, or other variations of the name(s) are not permitted.

Display of Name of Pharmacist in Charge

Section 139D(1)(d) of the Law requires the pharmacist in charge of a pharmacy business to display adjacent to the area where dispensing is carried on, the name of the pharmacist in charge followed by the words "PHARMACIST IN CHARGE".

Appointment of Pharmacist responsible for compliance

In the case of a friendly society or an exempted corporate owned pharmacy, the owner of the pharmacy must appoint a pharmacist to be responsible for the display of the pharmacy owner's name [Schedule 5F Clause 6(2)(c)(i), 7(2)(a) of the Law] and the display of drug price information [Schedule 5F Clause 6(2)(c)(ii), 7(2)(b)]. The name of the appointed pharmacist must be notified to the Council.

In the case of a pharmacists' body corporate, these obligations are placed on each pharmacist who has a financial interest in the pharmacy business (section 139D(2) of the Law).

Display and Use of Approved Qualifications

A pharmacist may wish to include additional qualifications after his/her name. If you decide to do this, you must ensure you do not claim to hold a type of registration or endorsement that you do not in fact hold. To knowingly or recklessly misrepresent yourself is a breach of section 119(1) of the Law and may be grounds for a complaint of unsatisfactory professional conduct under section 139B of the Law.

Early Registration of Business Name

To avoid delay in approving a pharmacy, the earliest possible application should be made to ASIC for the registration of any pharmacy business name which is required to be registered.

Guide Note 2: Definitions

Pharmacy

A *pharmacy* is the premises upon which a pharmacy business is conducted and it includes

- (a) the portion of the premises where goods of any kind are for sale; and
- (b) a professional services room.

The definition of *pharmacy* does not include premises located in a public hospital controlled by a public health organisation (within the meaning of the *Health Services Act 1992*).

Every part of the pharmacy's operations must be on approved premises, following a satisfactory inspection by a Council Inspector. Proprietors cannot operate any part of its business, be it a pop-up stall, stand or mobile unit, that is outside the pharmacy's approved premises boundary. If you wish to operate a separate stall, stand or unit, it must be exactly that – separate, and with no association to the pharmacy. This includes any advertising, signage or displays in or on the separate stall, stand or unit.

In the event that the pharmacy operates within close proximity to a medical centre, the pharmacy premises must be separate to the medical centre which is operating and the premises must be approved by the Pharmacy Council.

Pharmacy Business

A pharmacy business is where the dispensing and compounding of prescriptions for any substance

specified in the Poisons List proclaimed under section 8 of the Poisons legislation (*Poisons and Therapeutic Goods Act 1966*) occurs.

A pharmacy business must be conducted on approved premises.

New Pharmacy

A 'new pharmacy' is one in which the site has not been occupied by a pharmacy or a site which was previously occupied by a previous pharmacy business which has been closed. A 'new pharmacy' is not an existing pharmacy business which is notifying a change of partnership, trading name or trading address, or a change of members in the pharmacists' body corporate.

Professional Services Room

The definition of 'pharmacy' in the Law includes 'a professional services room'. In turn, the definition of 'professional services room' is described as premises limited to the preparation and packaging of drugs, whether by a pharmacist in charge or by a person supervised by a registered pharmacist for supply to individual patients/residents of a health care facility as well as the storage of those drugs (see Schedule 5F, clause 1 of the Law for the definition of professional services room).

It is not the intention of the Law that this area is used for the compounding of preparations in bulk without reference to an order or prescription from a practitioner with relevant prescribing authority. One use for the professional services room would be for the preparation of dose administration aids, Webster packs etc for individual residents/patients of residential care facilities or nursing homes to which the pharmacy business provides pharmaceutical services.

An associated professional services room and the pharmacy will be treated as one pharmacy business for the purposes of counting the number of pharmacy businesses in which pharmacists can have a financial interest (Schedule 5F, clause 9(2) of the Law). This means that it is necessary in any application for a professional services room to designate the pharmacy business that it is associated with.

The standards for professional services rooms are prescribed in clause 14 of the Regulation. Please note that unlike pharmacy premises, there is a requirement to take all reasonable steps to prevent public access.

In circumstances where a pharmacy business operates a Professional Services Room which is separate from the premises with which the Professional Service Room is associated there is a requirement to have a separate pharmacist in charge of the pharmacy business at each location.

Publications required for pharmacy premises

To operate a pharmacy business and a Professional Services Room there is a requirement for certain publications to be available. The requirements are provided at Schedule 3 and 4 of the Regulations respectively.

Relocation/Change of address

A relocated pharmacy (including a professional services room) is classified as an existing pharmacy business which has simply relocated from one address to another without changing ownership. The premises of relocated pharmacies and/or professional services rooms must be approved and inspected by the Council prior to commencing business. No retail trade of any sort, including the sale of non pharmaceutical items, can occur until confirmation is given by the Council that the new premises is approved.

Renovation/Expansion or Reduction in size

If renovations to an existing pharmacy which result in a change to the size or shape of the dispensary and/or the dispensary bench, or changes the public access to the pharmacy, the pharmacy premises

must be inspected and approved before trading can either commence or recommence, even though there has been no change of ownership or address.

Similarly, any substantial changes to an existing professional services room be it an expansion or a reduction in size requires lodgement of the appropriate application, and approval is subject to a satisfactory inspection.

Security Interest

The Law makes provision for the holding of a security interest in respect of a pharmacy business. However Schedule 5F, clause 10(1) describes certain provisions of a security interest that would render such provision void or illegal. For example, any requirement that the pharmacy purchase or obtain goods from the holder of the bill of sale or any provision giving the bill of sale holder the power to control the manner in which the pharmacy business is conducted.

Schedule 5F, clause 5(2) of the Law permits the holder of security interest in the event of default by the pharmacist requiring liquidation, to have a financial interest in the pharmacy business and further provides that the holder has a maximum of six months or such further period as the Council determines, to sell or close the business.

In the event that a new bill of sale is entered into as a result of a refinance of the pharmacy business, a completed copy of the new bill of sale, appropriately signed, witnessed, stamped and registered should be forwarded to the Council for inclusion in the pharmacy file and the maintenance of correct information in the register of pharmacies.

Pharmacy Registration Numbers

Pharmacy Registration numbers issued by the Pharmacy Council have a prefix of "PC". Pharmacy registration numbers are included in letters of confirmation of approvals by the Council of ownership applications and are recorded on the receipt issued following payment of the annual pharmacy premises renewal fee. A pharmacy registration number for a particular pharmacy may also be found by conducting a search of the NSW Register of Pharmacies accessed through the Council's website. If, having searched the Register of Pharmacies, you are having difficulty in locating the registration number for a pharmacy located in NSW, please contact the Council's staff for assistance.

Pharmacy Registration numbers should not be confused with an approval number granted to a pharmacist by the Commonwealth Department of Human Services/Medicare in respect of the Pharmaceutical Benefits Scheme (PBS). Requests for information about applications for PBS approval numbers should be directed to the Australian Community Pharmacy Authority (ACPA)

www.health.gov.au/ACPA

Financial Interest

This term is defined in Schedule 5F, clause 2 of the Law and it refers to a direct or indirect monetary or financial interest in a pharmacy business. It includes, but is not limited to, the interest of a sole trader, a partner in a pharmacy business, a director and/or shareholder in a pharmacists' body corporate, an interest as a trustee or beneficiary in a pharmacy business and any interest prescribed by the Regulation.

Any interest in a pharmacy business that a person holds as a beneficiary, unitholder or trustee of a trust, where the trustees carry on or have a financial interest in the pharmacy business will be treated as a financial interest (see Schedule 5, clause 2(1)(c) and (d) of the Law). This means that if a trust is used in operating the pharmacy business and to distribute profits, then all the trustees, unitholders and beneficiaries need to be pharmacists and/or pharmacists' body corporates. Any trustee, beneficiary or unitholder of a Trust who is not a registered pharmacist or pharmacists' body corporate will be in breach of the financial interest provisions.

All shareholders and directors in the pharmacists' body corporate are required to be pharmacists. Apart from certain recognised exemptions, it is an offence for any person other than a pharmacist, a pharmacists' partnership or a pharmacists' body corporate to have a direct or indirect financial interest in a pharmacy business (see Schedule 5F, clause 5(1) of the Law).

The Council determines whether there is a financial interest, which offends Schedule 5F, clause 5(1) of the Law, on a case by case basis, having regard to the evidence placed before it and the requirements of the Law and Regulation. A breach of the financial interest provisions may result in prosecution before a Court.

Change in the ownership of a pharmacy

A person intending to acquire a financial interest in a pharmacy business is required to **lodge an application for change of ownership with Council at least 14 days prior to the next Council meeting.**

The nature of such financial interest and intended date of acquisition and the legal basis for holding such interest e.g. as a registered pharmacist, a member of a pharmacists' partnership etc (see Schedule 5F, clause 4 of the Law).

A change of partners in a pharmacists' partnership will be considered as a change in the ownership of the pharmacy business.

Notice of Completion

This form must be completed and lodged with the Council following settlement or transfer of ownership of a pharmacy business. The new financial interest holders' details will not be entered onto the Register of Pharmacies until the Council has been notified that settlement or transfer has occurred.

Acquisition of shares or appointment as director of pharmacists' body corporate

A change in the existing shareholding of a pharmacists' body corporate by way of share sale or allotment of shares may result in the acquisition of a financial interest by the incoming shareholder. Where the incoming shareholder is not already registered with the Council as the holder of a financial interest in that pharmacy business, then the shareholder will need to notify Council at least 14 days before such event (Schedule 5F, clause 4 of the Law).

Likewise the appointment of a new director in an existing pharmacists' body corporate will need to be notified to Council at least 14 days before the appointment is made because the definition of a financial interest includes a proprietary interest as a director (Schedule 5F, clause 2 of the Law).

An updated ASIC Company extract that clearly identifies the new shareholder(s) and/or director(s) must be lodged following acquisition of shares or appointment of the director(s).

If the shareholder is already registered as the holder of a financial interest in the pharmacy business and intends to increase his/her shares in the pharmacists' body corporate, then there is no need to notify the Council as the transaction will not result in an additional financial interest in the hands of the existing shareholder.

Similar notice provisions apply for the cessation of a financial interest (see Schedule 5F, clause 4(3) of the Law). Where a pharmacist is disposing of his/her financial interest in a pharmacy, the Council must be notified of that disposal of interest within 14 days of the completion.

Acquisition of financial interest by way of appointment of unitholder or beneficiary of a Trust

An appointment of a new unitholder or beneficiary of a Trust, where the trustee is a pharmacists' body corporate, results in an acquisition of a financial interest in the pharmacy business. The unitholder and or beneficiary must be a pharmacist or a pharmacists' body corporate, and is responsible for notifying the Council at least 14 days before the appointment is made by lodging the appropriate application form.

If the unitholder or beneficiary is already registered as the holder of a financial interest in the pharmacy business, then there is no need to notify the Council as the transaction will not result in an additional financial interest in the hands of the existing shareholder.

Similar notice provisions apply for the cessation of a financial interest (see Schedule 5F, clause 4(3) of the Law). Where a pharmacist is disposing of his/her financial interest in a pharmacy, the Council must be notified of that disposal of interest.

Guide Note 3: Documentation requirements

The Law requires that an application for approval of pharmacy premises or registration of a financial interest must be made to the Council in an approved form (Schedule 5F, clause 12(2) and (3) of the Law). Under Schedule 5F, Clause 12 (8) of the Law, the Council cannot approve any premises unless they comply with the standards, which are detailed in the Regulation. Additionally, the Council cannot approve pharmacy premises where the public can access the pharmacy by entering a supermarket i.e. the pharmacy is co-located within a supermarket. Clause 12(11) defines 'supermarket' to mean a retail store or market selling food and other domestic goods (whether or not self-service) but excluding a department store or a restaurant, café or coffee shop where food including prepared food and produce is sold.

As mentioned above, it is a requirement under Schedule 5F, clause 4(1) of the Law that a person who intends to acquire a financial interest in a pharmacy must give at least 14 days written notice to the Council beforehand. The documents which must accompany such notice are set out in that clause and include, but are not limited to:

- details of the nature of the financial interest intended to be acquired,
- details of the basis on which the person is entitled to hold a financial interest,
- any bill of sale in relation to the acquisition,
- any sale agreement for business ,
- any partnership agreement for the business,
- any agreement under which any other person has a financial interest in the business,
- any share sale/purchase agreement,
- any transfer of shares form (share register),
- any minutes of meeting of directors approving share sale/allotment,
- any shareholders' agreement,
- any notice of appointment of director,
- any minutes of meeting of directors regarding appointment of new director,
- any lease of the pharmacy business premises,
- any management services agreement,
- any trust deed if a pharmacists' body corporate or service entity is acting as a trustee,
- any agreement between persons having financial interests in the pharmacy business, which regulates their rights e.g. a shareholders' agreement,
- any loan or mortgage document that provides for a right to impose a charge on any assets of the pharmacy business.

Documents which are submitted to the Council must be complete (not draft) copies, which are appropriately signed, witnessed and where appropriate, stamped and/or registered.

Schedule 5F, clause 16 of the Law provides that the Council may require persons to supply such information and/or documents as it decides is relevant to any financial interest(s) held by the person in a pharmacy. Failure to supply the information/documents or knowingly furnishing false information/documents is an offence under the Law.

Guide Note 4: Pharmacists' partnership

The Law permits pharmacists' partnerships, including limited partnerships, to own or have financial interests in a pharmacy business. All partners must be registered pharmacists. No member of a pharmacists' partnership can have a financial interest in more than five (5) pharmacy businesses (see Schedule 5F, clause 9 of the Law).

Partnership Agreements

The *Partnership Act 1892* defines a partnership as a relation between persons carrying on a business in common with a view to a profit. If any member of the partnership leaves, or another is added, the partnership is dissolved and a new partnership is formed. **This amounts to a change of ownership.** New partnership agreements must be signed and re-submitted to the Council with the relevant form. Registered business names, leases and other documents must also be re-drawn reflecting the new partnership arrangements.

There is no prohibition in the Law on limited partnerships, however the Council reminds pharmacists entering into such arrangements, **there is not and cannot be, any limitation to a pharmacist's professional responsibilities.** All partners are responsible for the actions of the pharmacy business in which they hold a financial interest. The Council must be informed of any change to a partnership, limited or not.

Guide Note 5: Pharmacists' Body Corporate

The Law permits a pharmacists' body corporate as a vehicle for pharmacy ownership. The definition of financial interest in Schedule 5F, clause 2 of the Law includes a proprietary interest as a director or shareholder. Where a pharmacists' body corporate is already a registered owner of a pharmacy business, any proposed change in shareholding that results in a new shareholder or any proposed appointment of a new director will need to be notified to the Council at least 14 days before such event (Schedule 5F, clause 4 of the Law).

The term 'pharmacists' body corporate' is defined in Schedule 5F, clause 1 of the Law and it requires that all the shareholders and directors of the corporation are registered pharmacists. No pharmacists' body corporate, nor member of a pharmacists' body corporate, can have a financial interest in more than five pharmacy businesses (see Schedule 5F, clause 9 of the Law).

The legal liability of the directors of the pharmacists' body corporate is extended under the Law (see section 153 of the Law). An employer who directs an employed pharmacist to engage in conduct that would constitute 'unsatisfactory professional conduct' or 'professional misconduct' is in breach of section 136 of the Law and may be subjected to prosecution. There are also substantial monetary penalties in respect of such offences.

Guide Note 6: Trusts

If a trust is engaged in the operation of a pharmacy business e.g. the pharmacists' body corporate for the pharmacy is acting as a trustee, then it will be necessary to submit a copy of the relevant trust deed to the Council for review, regardless of whether it is a discretionary trust, fixed trust or unit trust. The trust deed needs to be a copy that has been stamped by the Office of State Revenue. The definition of financial interest in Schedule 5F, clause 2 of the Law includes a proprietary interest as a trustee, beneficiary or unit holder. If there is no trust deed in existence then a description should be provided of the parties to the trust deed and the terms of the trust – your legal advisers or accountants may be able to assist you with this aspect.

The trust deed will be reviewed for compliance with the Law. If the trust is deemed non-compliant and a Trust Certification Checklist and Schedule of Amendments is required, you will incur a fee for the drafting of the Trust Certification Checklist and Schedule of Amendments. The fee will vary according to the complexity of the arrangements and the number of trusts involved and will be in the vicinity of \$2200.00 plus GST per trust deed. If amendments are required, these amendments must be actioned before the Council can consider an application for ownership of a pharmacy. The Council cannot approve an application that contains a non-compliant Trust.

To comply with the Law, there must be appropriate restrictions on the eligibility of the Trustee, beneficiary or unitholder and the powers of the Trustee. To avoid the need for amendment of your Trust, it is recommended that the Trust deed be drafted with the financial interest provisions of the Law in mind. The following check list will assist with the preparation of trust deeds:

Trust Deed Financial Interest Checklist	No	Yes
Is the trust validly constituted at law?		
Does the trustee hold a financial interest in the pharmacy under the <i>Health Practitioner Regulation National Law (NSW)</i> ?		
Is the trustee entitled to hold a financial interest in the pharmacy under the <i>Health Practitioner Regulation National Law (NSW)</i> ?		
Does each beneficiary hold a financial interest in the pharmacy under the <i>Health Practitioner Regulation National Law (NSW)</i> ?		
Is each beneficiary entitled to hold a financial interest in the pharmacy under the <i>Health Practitioner Regulation National Law (NSW)</i> ?		
Is a person or entity that is not entitled to hold a financial interest in the pharmacy under the <i>Health Practitioner Regulation National Law (NSW)</i> eligible to be a trustee?		
Is a person or entity that is not entitled to hold a financial interest in the pharmacy under the <i>Health Practitioner Regulation National Law (NSW)</i> eligible to be a beneficiary?		

Guide Note 7: Service Entities

Service entities, which are ancillary to the operation of the pharmacy, have been found by many pharmacists to be a useful management vehicle (e.g. for taxation and superannuation purposes), to allow pharmacists to take advantage of such arrangements without contravening the Law.

Pharmacists are advised that they will be required to demonstrate that their proposals for service entities do not contravene the Law.

Pharmacists should obtain their own independent legal advice in respect of issues raised as to compliance with other relevant legislation.

Definitions:

Service Entity: The entity contracted to a pharmacy to provide a range of services to the pharmacy. The entity may be any of a number of corporate/business forms: sole trader, proprietary limited company, discretionary trust, unit trust or any other structure which can demonstrate it provides a service to the pharmacy but does not hold a financial interest.

Service Agreement: A signed document describing every component of the agreement between the pharmacy and the service entity, detailing the services provided and the fees charged, a copy of which is required to be lodged with the Council.

The service entity must be solely a business management vehicle and may not be used as an ownership or control mechanism, and must be ancillary to a professional practice.

1 Use of Management Procedures and Management Consultants

The service entity may, at its own expense, employ consultants or advisers to examine and advise on ways the service entity can improve the services it provides. The cost of such consultants or advisers must be borne by the service entity from its own accumulated funds and such cost may not be charged to the pharmacy.

The service entity may not exercise any control over, or issue any directives to the pharmacy, or otherwise directly influence the management and style of the pharmacy.

1.1 Marketing Group Services

A marketing group may provide a range of services to the pharmacy. These services must also be considered in the overall scheme of control of the pharmacy. Details of all documents to be provided to Council are listed in the document scheduled on application forms.

2. Scale of Service Fees and Surcharges

The Council cautions pharmacists to consult their financial and legal advisers so as to ensure that the Law, taxation and other statutory and civil obligations are met, with regard to the fees charged, and surcharges levied, by the service entity for the services it provides to the pharmacy. The Council neither suggests nor condones any arrangement which might amount to tax avoidance.

The Law requires control of the pharmacy to be in the hands of the pharmacist, pharmacists' partnership or pharmacists' body corporate. Thus the transfer of funds from the pharmacy to the service entity must not be such that the service entity dominates the resources of the pharmacy. The total of the payments made to the service entity is the critical factor, not the value of each element of the scale of fees.

The service fee is an amount payable at regular intervals and subject to periodic review as set out in the service agreement. The fee must be set as an actual value and NOT expressed

as a percentage of turnover, gross profit or any income related terminology.

2.1 Service Fee Declaration

The total projected annual fee to be charged by the service entity, and paid by the pharmacy, must be declared. The total projected fee may be a reasonable best estimate based on the pharmacy's anticipated income and expenditure.

Please Note:

- (a) The service fee is the estimate for the calendar or financial year and should reflect the best estimate of the pharmacist's accountant or other financial adviser, or yourself. The Council may seek clarification of major variations year on year.
- (b) This declaration to the Council is to be provided in writing or in any other format which provides the detail requested.
- (c) The Council needs to be informed of any major changes to the details provided, other than CPI or annual review adjustments.
- (d) The Total Annual Service Fee should be rounded to the nearest thousand dollars.

The Council may, at any time, direct the owners of a pharmacy business to submit information relating to financial interests. It is an offence not to comply, without reasonable excuse, with such directions.

Guide Note 8: Pre-existing non pharmacist ownership structures

Exempted Company Pharmacies

Amendments to a previous Pharmacy Act in 1940 provided that no future company ownership of pharmacies would be permitted. Those company pharmacies which existed at 27 November 1940 were "grandfathered" and are provided for in the Law (see Schedule 5F Clause 7 of the Law), and are subject to its provisions. They are not permitted to purchase pharmacies, neither may they increase in number, their numbers being required to remain static or decrease. Any transfer of shares in an exempt corporate pharmacy must now be to a registered pharmacist.

Different requirements apply to Friendly Society pharmacies, which are discussed below.

Pharmacies, other than the above, which have been set up under any kind of corporate ownership other than pharmacists' body corporates, will be contravening the Law, and such ownership must be dismantled. It is an offence to disclose information to the Council that is different from that disclosed to any other authority.

Details of the ownership of a pharmacy become known at the time of sale, when the sale contract will reveal the ownership arrangements, which might be different from those appearing in the Register. If you have any doubts, you should contact your legal advisers, or the Executive Officer of the Pharmacy Council.

Company pharmacies must be registered and approved in the same manner as all other pharmacies.

Where a change of ownership occurs a Notice of Completion of the sale of the pharmacy business must be lodged with the Pharmacy Council.

The body corporate must nominate a pharmacist to be responsible for ensuring the owner's name is displayed at the main entrance of the pharmacy, and that drug price information displayed on the

premises does not contravene the Price Information Code of Practice.

Friendly Society Pharmacies

The Law contains special provisions for the continued operation of such pharmacies. Schedule 5F Clause 6 of the Law specifically controls the operation of pharmacies operated by Friendly Societies. Friendly Societies must have the approval from the Minister for Health for the ownership of, or for having a financial interest in any pharmacy business. Such approval may be subject to such conditions (if any) as determined by the Minister.

On receipt of the approval from the Minister an application should be submitted to the Pharmacy Council with all required documentation. This includes a copy of the relevant Ministerial approval.

Guide Note 9: Financial arrangements

FORMS OF SECURITY

Bills of Sale

Bills of sale are used, generally, to support a loan from a provider of funds, such as a bank or wholesaler. Bills of sale contain conditions relating to transfer of ownership, maintenance of the operation of the pharmacy etc. Schedule 5F, clause 10 of the Law provides that certain conditions in certain bills of sale may be void, and such conditions include requiring the purchase of goods/services from the finance provider in connection with the business over which the security interest has been taken. Also listed as a void provision is any power that is given to control the manner in which the business is to be carried on.

The purpose of a bill of sale is to provide security to the grantee and to guarantee the repayment of the loan. In the event of default, the business must be appropriately re-financed or sold. The grantee may place the pharmacy under administration for a period of six months (or such longer period as the Council approves) while the pharmacy is sold, but the provisions of Schedule 5F, clause 11 of the Law relating to the presence of a pharmacist must be met, and the Council must be kept fully informed during this period. The grantee is not prevented from having a financial interest in the pharmacy business in these circumstances (Schedule 5F, clause 5(2)(a) of the Law).

Other Leases

Where equipment, fixtures and fittings are leased, the conditions of these leases must be the same as those that apply to bills of sale.

Applicant's own funds or contributions / statutory declaration

Private finance (i.e. owner's own funds,) if applicable, should be shown under 'personal contribution'. The Council requires completion of a **statutory declaration** wherever an applicant is contributing to the cost of finance through his or her own funds.

The statutory declaration should include a statement to the effect that the applicant is contributing to the cost of finance through his or her own funds, and include the amount of any such funds.

Persons eligible to be a witness to a statutory declaration in New South Wales are:

- justice of the peace (JP)

- notary public
- commissioner of the court for taking affidavits
- solicitor (with a current practising certificate issued under Part 2.4 Division 3 of the *Legal Profession Act 2004*)
- other person by law authorised to administer an oath

A statutory declaration can only be made by a natural person. A statutory declaration on behalf of a pharmacists' body corporate can be made by a director, secretary or some other authorised officer of the corporation who should state their name and source of knowledge and authority in making the statutory declaration. A statutory declaration by an attorney (that is, someone appointed under a power of attorney) must be made and signed in the name of that attorney. The attorney must only declare facts to the best of their knowledge or belief.

It may be an offence under the Law to enter into any arrangement with a lender that sets any condition/s involving the pharmacy, and not disclose such condition/s to the Council (see Schedule 5F, clause 10 (1)(a) of the Law).

Other Funds

Other funds include bank loans, vendor finance, deferred settlement and/or extended credit from suppliers. The source of the funds, term and conditions of the loan or arrangement must be disclosed. Where a contract is signed, a copy must be supplied. Where there is an exchange of letters of understanding or arrangement, copies must be made available to the Council.

The Law at Schedule 5F, clause 5(1) provides that only a registered pharmacist, a partner in a pharmacists' partnership or a pharmacists' body corporate or a member of a pharmacists' body corporate may have a financial interest in a pharmacy, and that any pharmacist who permits any arrangement in contravention of this clause may be guilty of unsatisfactory professional conduct (see section 139D(1)(a) of the Law).

Any application which includes a financial arrangement implying conditions which might amount to prohibited financial interest in a pharmacy may be rejected. If an application is rejected, Schedule 5F, clause 13 of the Law provides that an aggrieved applicant can appeal to the Administrative Decisions Tribunal for a review of the Council's decision.

Guide Note 10: Lease of premises

Except where the registered pharmacist(s) or pharmacists' body corporate owns the premises solely in their name (see next paragraph), a pharmacy must have a lease. Where partnerships exist, the names of all partners must be on the lease or, alternatively, the head lease to one partner with a special sub-lease to all partners. Where an 'oral/verbal' lease is operated, a written note of all parties to the lease, its term, and any conditions, must be supplied.

If the building is solely owned by the pharmacist(s) or pharmacists' body corporate owning the pharmacy business, it is not necessary to have a lease. In this instance, the pharmacist(s) or pharmacists' body corporate should provide proof of ownership.

The lease of the pharmacy must be for the entire pharmacy premises and cannot include a sub-lease for the dispensary or other areas within the pharmacy premises. The Law defines a pharmacy in Schedule 5F, clause 1 as premises in or on which a person carries on a pharmacy business and includes any portion where the person sells or offers for sale goods of any kind. The lease must therefore be for the entire area.

The pharmacy may not have sections closed off and re-opened at certain times. The entire premises constitute the pharmacy and the provisions of Schedule 5F, clause 11 of the Law apply at all times to the entire premises.

Percentage Turnover Rent Provisions

The definition of financial interest is discussed in Guide Note 2. Schedule 5F, clause 10 of the Law is part of the implementation of the policy of the Law regarding the control of pharmacies, which is to avoid the control of pharmacy businesses by non-pharmacists. Clause 10(1)(d) of the Law provides:

“10(1) Any of the following provisions in a lease or a licence.....in respect of a pharmacy business is void-

(d) a provision that provides that the lessor, the licensor or the grantee is to receive consideration that varies according to the profits or takings of the business.”

This provision applies to all leases of pharmacy premises. Turn over rent provisions are illegal in any lease of pharmacy premises.

Turnover rent provisions are often found in shopping centre leases. Lease documents are scrutinised as part of the approval process. Any clause in a lease that refers to a percentage of turnover or takings of the business is void.

If you are in any doubt as to whether your lease contains such a provision you should consult your legal adviser, especially during the negotiation of your lease terms and conditions or before taking an assignment or transfer of an existing lease.

Leases must be appropriately signed and stamped with the Office of State Revenue and registered with the Land Titles Office, where appropriate. Certified copies of a stamped lease must be submitted to the Council. Where stamped documents are not yet available, and to prevent delays in making and approving applications, certified copies of the original signed documents may be supplied as an interim measure.

Certified copies of the original stamped and registered lease must be supplied within six months of making application for registration.

Incomplete documents and applications will NOT be considered by the Council. Early lodgement of applications and supporting documents will assist in ensuring the application is listed before the Council for consideration at the appropriate Council meeting.

Guide Note 11: Sketch plan information

The sketch plan need not be a detailed plan, but should include the overall measurements of the pharmacy premises and/or professional service room. Specifically highlighted must be:

1. The location and overall floor area of the dispensary
2. The bench area including sink, refrigerator, barcode scanner(s) and work areas
3. Direct public access (for pharmacy premises only)

Where a new pharmacy is being constructed or where "substantial" renovations are planned for an existing pharmacy business, the builder's plans, or the plans lodged with local Councils, may be supplied for provisional approval. Final approval cannot be given until such time as the construction/renovation is completed and the premises inspected.

Guide Note 12: Pharmacy premises requirements

The Regulation requires compliance with the following standards, amongst which is the provision that the following list of equipment and reference books be kept in **every** pharmacy, as a minimum:

Schedule 3 of the Regulation – see below under Equipment and appliances.

Aside from the equipment and publications listed in Schedule 3 of the , the pharmacy is required to have any other equipment necessary for the pharmacy to provide safe and competent delivery of pharmacy services (see clause 13(1)(e)(ii) of the Regulation).

Equipment and appliances

- a refrigerator manufactured (either exclusively or principally) for the purpose of storage of vaccines
- a dispensing balance
- heavy duty scales, capable of weighing up to 1 kg and a set of metric weights compatible for use with those scales or an electronic scale capable of weighing up to 1 kg in increments of no more than 50 mg
- a 200 mL dispensing measure
- a 100 mL dispensing measure
- a 10 mL dispensing measure
- a 5 mL dispensing measure
- a funnel
- 2 mortars and pestles (at least 1 of the mortars and pestles being made of glass)
- a stirring rod
- 2 spatulas
- an ointment slab
- a tablet counting tray

The Council expects that balances, scales, weights and measures will be stamped as approved under the *National Measurement Act 1960* and the *National Measurement Regulation 1999*.

Dispensing Area

Clause 12(2) of the Regulations provide the following standards for a *dispensing area*:

- (a) it is to be adequately lit and ventilated,
- (b) it is to have adequate heating facilities for dispensing and compounding drugs,
- (c) it is to be equipped with a stainless steel or similarly impervious sink that has an impervious surround and is supplied with hot and cold running water,
- (d) it is to have a bench that is at least 40 centimetres wide, and of sufficient length to provide not less than 1 square metre of *free working space* (see below), and that has an impervious covering,
- (e) it is to have at least one dispensary barcode scanner connected to each dispensing station in the dispensing area.

N.B. 'Free working space' means free bench space, **NOT** the top of machinery, or the sink or other fixtures and must **NOT** be designated to any other full time activity.

Free working space may be used for other activities for certain periods of time, e.g. checking invoices/bookwork, or other routine activities that are part of the business of a pharmacist. The top of a printer may **not** be designated for some form of part-time activity e.g. counselling notes.

Infection Control Standards

Pharmacists should be aware of the infection control standards for pharmacy premises, which appear in Schedule 3 of the Regulation and the obligation to comply with such standards to the extent that they apply to their practice of pharmacy.

Publications for Pharmacy Premises

Schedule 5 of the Regulation provides that the following publications are required for pharmacy premises.

- the [Poisons and Therapeutic Goods Act 1966](#) and the regulations under that Act
- the Poisons List proclaimed under section 8 of the [Poisons and Therapeutic Goods Act 1966](#) or the latest edition, and all published amendments or supplements to that edition, of the [Guide to the New South Wales Medicines and Poisons Schedules](#) published by the Pharmacy Guild of Australia (New South Wales Branch)
- the [Law](#) and this [Regulation](#)
- the [Price Information Code of Practice](#)
- the latest editions, and all published amendments or supplements to those editions, of the publications listed in the [Pharmacy Board of Australia's Guidelines on practice-specific issues—Guideline 1 \(List of reference texts for pharmacists\)](#), as amended from time to time

Publications for Professional Services Rooms

Schedule 5 of the Regulation provides that the following publications are required for pharmacy premises.

- the [Poisons and Therapeutic Goods Act 1966](#) and the regulations under that Act
- the Poisons List proclaimed under section 8 of the [Poisons and Therapeutic Goods Act 1966](#) or the latest edition, and all published amendments or supplements to that edition, of the [Guide to the New South Wales Medicines and Poisons Schedules](#) published by the Pharmacy Guild of Australia (New South Wales Branch)
- the [Law](#) and this [Regulation](#)
- the latest editions, and all published amendments or supplements to those editions, of the publications listed in the [Pharmacy Board of Australia's Guidelines on practice-specific issues—Guideline 1 \(List of reference texts for pharmacists\)](#), as amended from time to time.

Guide Note 13: Professional Services Room Requirements

Clause 13 of the Regulation sets out the minimum standards required for approval of a professional services room, which include:

- (a) all reasonable steps to prevent public access to the premises are to have been taken
- (b) the premises, including any doors, windows, floors or ceilings, are to be secure to minimise the risk of unauthorised access to the premises and scheduled medicines in the premises,
- (c) the premises are to be equipped with a dispensing area of at least 8 square metres or such lesser area as the Pharmacy Council may approve in a particular case,
- (d) the premises are to be laid out and equipped so that:
 - (i) any drug stored in the premises can be stored in accordance with the relevant drug's storage conditions, and
 - (ii) all the drugs being prepared, packaged or stored in the premises, for supply to a particular patient or to a health care facility for supply to a particular patient or resident of that facility, can be stored together, and
 - (iii) any documentation physically stored in the premises relating to that patient or resident can be stored with those drugs
- (e) access to electronic publications listed in clause 15 of the Regulation should be available.

The following standards are prescribed for a *dispensing area*:

- (a) it is to be adequately lit and ventilated,
- (b) it is to be equipped with a stainless steel or similarly impervious sink that has an impervious surround and is supplied with hot and cold running water,
- (c) it is to have a bench that is at least 40 centimetres wide, and of sufficient length to provide not less than 1 square metre of free working space, and that has an impervious covering,
- (d) it is to have at least one dispensary barcode scanner connected to each dispensing station in the dispensing area.

The list of publications required to be maintained in the professional services room is the same as for the pharmacy premises. **Compliance with the Regulation will require that a separate set of publications is located within the professional services room to that maintained in the pharmacy.**

A pharmacist must be physically in charge of the associated services room (Schedule 5F, clause 11(4) of the Law). This obligation is in addition to the requirement that the pharmacy premises be in the charge of a pharmacist who must personally supervise the carrying on a business within the pharmacy premises.

Guide Note 14: Signs and sign-writing

The Regulation provides for special limitations on signs in/on pharmacy premises. Approval for trading names is obtained from the Australian Securities and Investments Commission (ASIC) by separate application.

The general rule is that the public must know with whom they are dealing. The name of the pharmacy **as registered with the Council** and name of the owner/s must be clearly visible, failure to do so may give rise to a complaint of unsatisfactory professional conduct (section 139D of the Law).

Use of multiple trading names in connection with the pharmacy business may give rise to a complaint based on a contravention of the advertising restrictions in section 133(1) of the Law in false and misleading advertising of pharmacy services.

Signs may also require separate approval/s from local government and/or other authorities. Acceptance or approval under the Law does not imply or guarantee acceptance by other authorities.

Signs must include only the registered trading name and must not be abbreviated.

The Council requires the display of:

- * the name of the owner of the pharmacy to be clearly visible to, and easily read by members of the public at or near the main entrance to the pharmacy (see section 139D (1)(c) of the Law). If the owner is a pharmacists' body corporate, the name of the pharmacists' body corporate must be displayed. It is not a requirement to display the names of the shareholder/directors and
- * the name of the pharmacist who is in charge at any given time, must be displayed adjacent to the area where dispensing is carried on. The pharmacist in charge must be physically present in the pharmacy (see section 139D (1)(d) of the Law).

Failure to observe these requirements may result in a complaint of unsatisfactory professional conduct against the pharmacy owner and/or pharmacist in charge.

Guide Note 15: Signatures

Applications and notices must be signed and dated by all applicant pharmacists, and in certain cases, witnessed by a person over the age of 18 years who is not a party to the application or notice.

The Council may require verification of produced information or documents to be supported by a statutory declaration (Schedule 5F clause 12(6) of the Law).

Guide Note 16: Closure of a pharmacy

Where a pharmacy is closed for any reason for a period longer than three months, the Council must be notified. The closure of a pharmacy and ceasing to have a financial interest in the pharmacy business should be notified on the Notice of closure of pharmacy form available from the Council, which should be completed and returned to the Council within 14 days of closure.

The Council has the power to revoke the approval of a pharmacy premises if they are no longer being used to conduct a pharmacy business (Schedule 5F, clause 12 (10)(c) of the Law). Closure may be permanent or temporary. Where temporary, **and for a period of more than three months** the Council will require complete re-registration of the business and a new inspection and approval of the premises. Where closure is temporary, **and for a period of less than three months**, the Council is to be notified in writing. The pharmacy registration will continue for the period of closure and, unless changes to the registration or the approved premises occurred in that time, registration will be automatically restored upon notification of reopening. In the event of closure for renovations, an inspection and new approval will be required.

Guide Note 17: Notification of the death of a pharmacist

The Law permits the executor, administrator, or trustee of the Estate of a deceased proprietor of a pharmacy to continue to operate the pharmacy for a period of **six** months or such further period as the Council may authorise in writing, and as provided by Schedule 5F, clause 5(2)(b)(i) of the Law. The 6 month period commences on the day of passing.

During this 6 month period the pharmacy business must be in the charge of a registered pharmacist

pursuant to Schedule 5F, clause 5(3) of the Law. By the end of the 6 months, the financial interest held by the deceased pharmacist must be transferred to a person or entity eligible to hold a financial interest in a pharmacy business.

If an extension of time is required to effect the transfer of financial interest, a request must be made to the Council prior to the expiration of the 6 month period and specifying the period of extension sought and the reason why an extension is required.

Guide Note 18: PBS Approval

Every pharmacy that dispenses Pharmaceutical Benefits prescriptions must have a Pharmaceutical Benefits Scheme (PBS) approval, issued by the Commonwealth Department of Human Services / Medicare Services. It is possible for a pharmacy to be approved and registered with the Pharmacy Council without a PBS approval.

In New South Wales, the Commonwealth Department of Human Services / Medicare Services has established a validation process for PBS approvals and will confirm with the Council details of the registered pharmacy and its ownership. Details of new owners and/or financial interest holders of a pharmacy business will only be entered into the Register of Pharmacies on the Council's receipt of a Notice of Completion, which confirms that the transfer or settlement of the change of ownership has occurred. It is also the applicant(s) responsibility to contact the Commonwealth Department of Human Services / Medicare following notification of final approval of a pharmacy application.

It is very important that the information supplied to the Council agrees completely with the application to the Commonwealth Department of Human Services / Medicare for an approval number. In the event of anomalies or inconsistencies, the issue of a PBS approval number may be delayed or refused.

Pharmacists operating a 'non approved' pharmacy are reminded of their responsibility to adhere to the Commonwealth Department of Human Services / Medicare requirements, any relevant Pharmacy Board of Australia (PBA) Guidelines and to display the required signage.

For information concerning the allocation of PBS Approval numbers, call the Commonwealth Department of Human Services / Medicare on telephone: 132 290.

Guide Note 19: Pharmacy registration

A pharmacy can operate only with a current approval of the Council. Annual pharmacy premises registration fees must be paid by 30 June to ensure approval remains current (see Guide note 16 for payment of annual renewal fees).

Registration of pharmacists working at a pharmacy

The owner/pharmacist in charge should establish a procedure for the checking of registration of the employee pharmacists, particularly locums.

- To practise pharmacy, a pharmacist must hold *general registration* status with AHPRA.
- It is possible to hold *non-practising registration* status, however such practitioners cannot practise as a pharmacist and should not be employed in the capacity of a pharmacist and/or pharmacist in charge
- It is an offence to practise as a pharmacist in a pharmacy that is not included in the Register of Pharmacies for New South Wales.

A pharmacist whose registration is cancelled or suspended and who holds a registered financial interest in a pharmacy business must within six months of such suspension or cancellation divest himself/herself of their financial interest(s) in any pharmacy business located in NSW (see Schedule 5F, clause 5(2)(c) of the Law).

Both employer and employee pharmacists should be aware of their responsibilities in matters of registration.

Guide Note 20: Payment of fees

The appropriate fee for approval of the applications must accompany each application. An application that remains incomplete, or not listed for approval, within three (3) Council meetings of the lodgement, will be considered withdrawn, and a new application and fee will need to be lodged.

All annual renewal fees for a pharmacy are to be paid before close of business on **30 June**. All accounts will be mailed to the address of the pharmacy as shown on the Register of Pharmacies.

In respect of payment the following applies:

- **Annual renewal payments of \$320 made by the 30 June due date** will result in the approval of pharmacy premises for a further 12 month period to 30 June the following year.
- **Annual renewal payments made after 30 June will incur a late fee of \$80 as provided by the regulations.** Payment of the renewal fee and the late fee will result in the approval of pharmacy premises for a further 12 month period to 30 June the following year.
- **Annual renewal payments will not be accepted after 31 July.** Approval of pharmacy premises will be revoked, the pharmacy will be removed from the Register of Pharmacies and the Department of Human Services/Medicare will be notified if Council has not received payment of the relevant fee by 31 July. Proprietors wishing to obtain a current approval will be required to submit an application for a new pharmacy.

The Council has produced a Schedule of Fees which is available on the Council's website.

Under Division 81 of the Goods and Services Tax Regulations, the Treasurer has determined that the renewal, application and inspection fees are exempt from the Goods and Services Tax (GST).

Guide Note 21: Inspections by the Council

The Council's inspectors are Authorised Persons appointed by the Secretary of NSW Health under section 164 of the Law, and they carry out routine inspections of all pharmacies in New South Wales. The powers of inspectors are detailed in section 164A of the Law and, while the Council's inspectors will make every reasonable attempt to co-operate, pharmacists should remember that the inspectors are empowered to enter pharmacy premises at any reasonable time. It is an offence under section 164C for a person to prevent, hinder or obstruct an inspector, or other authorised persons, in the carrying out of their duties.

A primary objective of routine inspections is to provide assistance to pharmacists by explaining provisions of the Law and Regulation, guidelines and rulings of the Council, as well as to help pharmacists comply with the Law, Regulation and Council guidelines and rulings.

All pharmacists should be able to demonstrate the currency of their registration as a pharmacist, if called upon to do so by an inspector.

Inspections will be as discrete and as efficient as possible and should require only a short period of the pharmacist's time. A checklist of all items being reviewed is available from the inspector. The pharmacist in charge or owner will receive a copy of the inspector's report and of any deficiencies noted by the inspector at the completion of the inspection.

The pharmacy and any associated professional services room must be inspected prior to the opening of any new business, the acquisition of an associated professional services room and immediately on completion of any substantial renovations to an existing pharmacy or professional services room. If any application is made for a separate professional services room to be approved for use in conjunction with an existing pharmacy business, the area designated as the professional services room will require inspection to ensure that it complies with the requirements and standards set out in the Regulation.

It is the responsibility of the owner of the pharmacy business to contact a Council Inspector to arrange a mutually convenient time to inspect the premises. This should be done immediately on receipt of advice of the approval of the application for a new pharmacy, relocation or renovation of a pharmacy, a new professional services room or relocation or renovation of a professional services room. The inspection must occur **within three months** of lodgement of the application.

There is no fee associated with this inspection.

Pharmacy premises should be near completion and ready for commencement of operation by the inspection date.

The Register of Pharmacies will record the date of satisfactory Council inspection as the date of commencement of the pharmacy business.

Guide Note 22: Timetable for registrations and appeals

The processing of applications and the accompanying documents is undertaken in order of their receipt by the Council. The Council meets on the second Wednesday of the month and the agenda for the meeting is prepared 7 days before the meeting.

A schedule of lodgement dates and Council meeting dates is available on the Council's website.

Applications should be submitted **by the lodgement date prior to a Council meeting** for the assessment of the application. However, where the ownership structure involves a trust then the relevant application and supporting documents should be submitted **at least 15 business days** before the Council meeting at which it is to be considered, to allow sufficient time for review of the trust.

Incomplete and unsigned applications and/or failure to submit appropriate documents in support of the application will invariably cause delays in the Council's staff initial assessment of the application, which may cause inconvenience to the applicant. The staff of the Council can advise applicants of the status of their application. An application that remains incomplete for more than three Council meetings will be deemed to have lapsed and the applicant will need to resubmit the application or submit a new application. A request for an extension of time to complete an application must be made in writing prior to the next scheduled Council meeting date. It is in the applicant's interest not to submit an application unless and until all required documents can be provided.

In the event the application for a new pharmacy or change of ownership is complex it is recommend that professional advice is sought prior to lodging the application with the Council.

The Council is not in a position to provide ‘on-the-spot’ approvals. Should Council approval be a condition of settlement, the Council is not responsible for any delays occasioned by incomplete documents.

New details of ownership of a pharmacy business will not be entered onto the Register of Pharmacies until a Notice of Completion has been submitted, clearly identifying the date that settlement or transfer of ownership occurred.

APPEALS AGAINST COUNCIL’S REFUSAL TO APPROVE PHARMACY PREMISES OR REGISTERED HOLDER OF A FINANCIAL INTEREST

Any person who is aggrieved by the Council’s decision regarding the refusal of the Council to approve pharmacy premises or to register a person or corporation as a holder of a financial interest in a pharmacy business may apply to the New South Wales Civil and Administrative Tribunal (NCAT) for a review of the Council’s decision (see Schedule 5F, clause 13 of the Law).

Guide Note 23: Online pharmacies

The Council also regulates online pharmacies, which are becoming increasingly popular. An online pharmacy can be established only in connection with an existing pharmacy, operating on approved physical premises. All financial interest holders must be registered with the Council. The online operations is considered to form part of the pharmacy business’s operations and it is therefore regarded as an online presence for an existing pharmacy, not a pharmacy business in its own right.

Practitioners should be aware that the name of all pharmacies should be registered with Council.

Guide Note 24: Contraventions and offences

The proprietors of a pharmacy are responsible for ensuring the ownership and operation of a pharmacy does not contravene the Law and Regulations, and that an offence is not committed. Where a contravention or offence is detected, all proprietors and the pharmacist in charge, if it was not a proprietor, are held responsible. A contravention of the Law or Regulation may form grounds for a complaint of unsatisfactory professional conduct, and in the case of a statutory offence, the proprietor(s) and/or pharmacist in charge will be prosecuted in Court. Most offences carry a monetary penalty and may result in a criminal conviction, if proven.

Contraventions and offences include, but are not limited to:

- the carrying on of a pharmacy business without the current approval of the Council, or where the financial interest holders are not registered
- failure to submit correct or complete information in an application before the Council
- failure to notify the Council of cessation of a financial interest in a pharmacy business
- owning of a financial interest in a pharmacy business by non-pharmacists
- owning a financial interest in more than 5 pharmacy businesses in NSW
- carrying on of a pharmacy business in the absence of a pharmacist in charge to personally supervise the carrying on of the business
- failure to submit an annual return by the due date
- failure to comply with a direction or notice given by the Council to supply information about financial interests

- failure to display at or near the main entrance of the pharmacy the name of the owner(s)
- failure to display adjacent to the area where dispensing is carried on the name of the pharmacist in charge
- failure to ensure drug price information does not contravene the Price Information Code of Practice

Guide Note 25: Application for copy of register

An application for a copy of the Register of Pharmacies may be made to the Executive Officer of the Council. The Register is also accessible online via the Council's website.

The person applying for a copy of the Register of Pharmacies must state the purpose(s) for which it will be used. The Council will not approve an application that is based purely for commercial or marketing purposes.