



**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 guide is primarily designed to assist in the completion and lodgement of pharmacy application forms and notices. The guide also provides information about the regulatory framework within which the Pharmacy Council of New South Wales ('the Council') operates in respect of pharmacies and pharmacy ownership in New South Wales.

This guide is based on the Council's 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'). This document does not overrule the Law or the Regulation, and is revised from time to time.

Schedule 5F of the Law requires applications to be made in the form approved by the Council.

Only complete and signed applications will be considered for approval. It is the applicant's responsibility to ensure the application is accurate, complete and in accordance with the Law.

It is recommended that a professional advisor (lawyer, accountant, pharmacy broker) assist in the preparation of applications, particularly those involving complex business structures. Additional assistance from a shop fitter or draftsman may aid in the preparation of premises' floor plans and locational plans, where these are required.

This document is not intended to provide guidance on the Pharmaceutical Benefits Scheme (PBS) or the Pharmacy Location Rules, both of which are administered by the Commonwealth Government. Information on the PBS may be found at <https://www.humanservices.gov.au> and Location Rules at <http://www.pbs.gov.au>

REGISTER OF PHARMACIES

The Law requires the Council to maintain a Register of Pharmacies. The NSW Register of Pharmacies records approved premises (pharmacies and professional services rooms) and holders of financial interests in pharmacy businesses.

The Register of Pharmacies is accessible online via the Council's website:
<https://www.pharmacycouncil.nsw.gov.au/>

A person must not carry on a pharmacy business unless the premises are approved and all holders of financial interests are recorded in the Register of Pharmacies.

Approved premises means premises that have been inspected and approved by the Council as suitable for carrying on a pharmacy business by a pharmacist.

Details of approved premises are entered onto the Register of Pharmacies on confirmation of satisfactory inspection of premises. An inspection is required prior to a new pharmacy opening for trade; or an existing pharmacy business resuming trade at relocated premises or existing premises which have undergone substantial renovation or resizing.

The Register of Pharmacies also includes details of all persons holding financial interests in a pharmacy business including as shareholders and directors in a pharmacists' body corporate, and as trustees or as beneficiaries under a trust.

Details of financial interest holders are entered onto the Register of Pharmacies:

- following approval of an application and satisfactory inspection of premises (for a new

pharmacy)

- on receipt of a Notice of Completion (where there is a change of pharmacy ownership)
- on receipt of a Notice of Completion and updated ASIC company extract (where there is a change of shareholders and/or directors of a pharmacists' body corporate).

FINANCIAL INTEREST

Financial interest refers to a direct or indirect monetary or financial interest in a pharmacy business. It includes 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.

Apart from certain recognised exemptions, it is an offence for any person other than a pharmacist 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).

A pharmacist is an individual who is registered with general registration by the Pharmacy Board of Australia in the Register of Pharmacies under the Law. Individual who holds provisional, limited or non-practising registration is not entitled under the Law (see Schedule 5F, clause 25(6) of the Law) to hold a financial interest in a pharmacy business.

A pharmacist's body corporate is defined under the Law as a body corporate where all the shareholders and directors of which are pharmacists. This means that a pharmacist's body corporate cannot hold a financial interest as shareholder of a pharmacist's body corporate.

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 5F, 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.

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.

Schedule 5F, Clause 4 of the Law provides for the notification of acquisition or disposal of a financial interest in a pharmacy business 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.

Clause 5 of Schedule 5F of the Law allows the following non-pharmacists to hold a financial interest in a pharmacy business for a period of six months (or such further period as the Council may authorise in writing):

- A person appointed or authorised under the laws relating to bankruptcy to administer the property of a pharmacy proprietor who has become bankrupt
- the executor, administrator or trustee of the estate of a deceased pharmacy proprietor (see also Guide Note 17)

A pharmacist whose registration is cancelled or suspended should have regard to Clause 5(2)(c) of Schedule 5F of the Law.

Annual declaration of financial interest

The Law requires anyone who held a financial interest in a pharmacy business for 12 months from 1 May to 30 April to make a declaration to the Council about the interest. This is an annual requirement with declarations due by 1 June each year. This applies whether or not the holder sold, or otherwise divested themselves of that interest during the relevant 12 month period from 1 May to 30 April.

Each April, annual declaration notices are emailed to all persons listed on the Register of Pharmacies as holding a financial interest in a pharmacy business at any time during the preceding 12 months. Annual declarations are completed on line via the Council's website and must be completed for each pharmacy in which the holder held a financial interest during the relevant period.

Failure to submit a completed annual declaration by the due date is a contravention of Clause 15 of Schedule 5F of the Law and is considered an offence.

APPLICATION FORMS AND NOTICES

An application for approval of premises or registration of a financial interest must be made in the form approved by the Council and accompanied by the applicable fee.

The following Application Forms and Notices are available to download from the Council's website:

Application Forms:

- Application for New Pharmacy
- Application for New Professional Services Room
- Application for relocation or expansion/reduction of pharmacy premises
- Application for relocation or expansion/reduction of professional services room
- Application for change of pharmacy ownership as a sole pharmacist or Friendly Society
- Application for change of pharmacy ownership where the purchaser/s is a partner in a partnership of pharmacists
- Application for change of pharmacy ownership where the new ownership structure includes a pharmacists' body corporate
- Application for acquisition of financial interest in a pharmacy business as shareholder in a pharmacists body corporate and /or as a new director
- Application for acquisition of financial interest by way of appointment of unitholder or beneficiary of a trust

Notices:

- Notice for change of pharmacy name
- Notice of disposal of financial interest in a pharmacy business
- Notice of closure of pharmacy
- Notice of completion

The following information will help identify the appropriate Form or Notice and the timing for submission depending on the individual circumstance. See *Application Fees* for assistance in calculating the relevant fee.

If you are:

- (a) **establishing a new pharmacy**, a completed *Application for New Pharmacy* form with adequate supporting documentation must be submitted, application fees paid, application approved by the Council and premises inspected **BEFORE** trading can commence.
- (b) **establishing a new professional services room** to be used in conjunction with an existing pharmacy business, an *Application for New Professional Services Room* must be submitted, approved and the premises inspected **BEFORE** it commences operation.

The pharmacy and its associated professional services room are counted as one (1) pharmacy business (see Schedule 5F Clause 9(2) of the Law).

- (c) **changing any aspect of the ownership of an existing pharmacy business**, including acquiring or disposing of a financial interest as a sole owner, partner, director or member in a pharmacists' body corporate, or unitholder or beneficiary of a trust, all details of an acquisition of financial interest in the pharmacy business must be provided to the Council **14 DAYS PRIOR** to the event and disposals of financial interest **14 days after the event**.

Refer to the relevant form and/or notice depending on the particular circumstance: *Application for change of pharmacy ownership* (where purchaser is sole owner, partner, or includes a pharmacist body corporate in the business structure), *Application for acquisition of financial interest*, *Notice of disposal of financial interest in a pharmacy*.

A *Notice of Completion* must be submitted within 14 days of the completion of the change of ownership of a pharmacy business – that is, on settlement or transfer of ownership. No fee will apply.

- (c) **relocating an existing pharmacy business or "substantially" altering / renovating existing premises** (without changing any aspect of the ownership of the business), an *Application for relocation or expansion/reduction of pharmacy premises* or *Application for relocation or expansion/reduction of professional services room* must be submitted, approved and premises inspected **BEFORE** trading can commence.
- (d) **changing the name of a pharmacy**, a *Notice for Change of Pharmacy Name* must be submitted within 14 days of the name change. No fee will apply.
- (e) **ceasing trade and closing a pharmacy**, a *Notice of Closure of Pharmacy* must be submitted. No fee will apply.

APPLICATION FEES

Fees are payable at the time of lodgement of an application. An application is not considered complete until the correct fee has been received.

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

There are no fees payable for notices.

Calculating the fee payable

Pharmacy application fees are prescribed in Clause 15 of the *Health Practitioner Regulation (New South Wales) Regulation 2016*:

Type of application	Fee
Application for approval of premises as suitable for carrying on pharmacy business by a pharmacist	\$550
Application for registration of holder of financial interest in pharmacy business	\$615

The fee payable will be determined by the type of application and number of proposed new financial interests in the pharmacy business.

Fee examples provided will assist with the preparation of applications and calculation of fees.

Application for new pharmacy

To be completed when establishing a **new pharmacy**.

Premises application fee	\$550.00
Financial interest registration fee	\$615.00 (for each financial interest)

See Examples One, Two, Three, Four and Five

Application for a new professional services room

To be completed when establishing a **new professional services room**

Premises application fee	\$550.00
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Application for relocation or expansion/reduction of pharmacy premises

To be completed when an **existing pharmacy business 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 premises**. This will include where the premises as defined in the lease associated with the premises changes. This includes moving to new premises within the same commercial business area and expansion or reduction of the footprint of the pharmacy as defined in the relevant lease.

Premises application fee	\$550.00
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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 to new premises within the same commercial business area and expansion or reduction of the footprint of the professional services room as defined in the relevant lease.

Premises application fee	\$550.00
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Application for change of pharmacy ownership as a sole pharmacist or Friendly Society

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

Financial interest registration fee	\$615.00 for the pharmacist or Friendly Society acquiring the financial interest (purchaser)
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See Example Six

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

Application for change of pharmacy ownership where the purchaser/s is a partner in a partnership of pharmacists

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

Financial interest registration fee	\$615.00 for each pharmacist acquiring a new financial interest
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See Examples Seven and Eight

Note: 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.

Application for change of pharmacy ownership where the new ownership structure includes a pharmacists' body corporate

To be completed when a **change of ownership is to occur and the new business structure will include a pharmacists' body corporate.**

Financial interest registration fee	\$615.00 for each new financial interest.
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See Example Nine

Application for acquisition of financial interest in a pharmacy business as shareholder in a pharmacists body corporate and /or as a new director

To be completed when proposing a **change to a pharmacists' body corporate by adding a new shareholder or appointing a new director.**

Financial interest registration fee	\$615.00 for each new financial interest
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See Examples Ten, Eleven, Twelve and Thirteen

Note: The definition of a pharmacists' body corporate provides that all the shareholders and directors must be pharmacists.

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.

Financial interest registration fee	\$615.00 for each pharmacist acquiring a financial interest
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See Example Fourteen

FEE EXAMPLES

Example One

Pharmacist A is proposing to establish a **new pharmacy** and operate it as sole proprietor.

Premises application fee	\$550.00
Financial interest registration fee	\$615.00 (Pharmacist A)
Total	\$1165.00 (Premises application fee, plus 1 financial interest registration fee)

Example Two

Pharmacist A and Pharmacist B are proposing to establish a **new pharmacy**. They will hold financial interests in the pharmacy business as partners.

Premises application fee	\$550.00
Financial interest registration fee	\$615.00 for each financial interest (Pharmacist A and Pharmacist B)
Total	\$1780.00 (Premises application fee, plus 2 financial interest registration fees)

Example Three

Pharmacist A and Pharmacist B are proposing to establish a **new pharmacy** as shareholders in a Pharmacists' Body Corporate.

Both Pharmacist A and Pharmacist B will own shares and have responsibilities as directors.

Premises application fee	\$550.00
Financial interest registration fee	\$615.00 for each financial interest (Pharmacist A, Pharmacist B and the Pharmacists' Body Corporate)
Total	\$2395.00 (Premises application fee, plus 3 financial interest registration fees)

Example Four

Pharmacist A, Pharmacist B and Pharmacist C are proposing to establish a **new pharmacy**.

Pharmacist A and Pharmacist B are shareholders/directors of a Pharmacists' Body Corporate 'AB Pty Ltd'. It is intended that AB Pty Ltd own the pharmacy with Pharmacist C.

Premises application fee	\$550.00
Financial interest registration fee	\$615.00 for each financial interest (Pharmacist A, Pharmacist B, Pharmacist C and AB Pty Ltd.)
Total	\$3010.00 (Premises application fee, plus 4 financial interest registration fees)

Example Five

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 have responsibilities 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.

Premises application fee	\$550.00
Financial interest registration fee	\$615.00 for each financial interest (two pharmacists and the Pharmacists' Body Corporate)
Total	\$2395.00 (Premises application fee, plus three financial interest registration fees)*

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

Example Six

Pharmacist A and Pharmacist B are proposing to sell their pharmacy to Pharmacist C. This will be a **change of ownership**. Pharmacist C will hold his/her interest in the business as sole proprietor. Pharmacist C will need to submit an *Application for change of pharmacy ownership as a sole pharmacist*.

Financial interest registration fee	\$615.00 for Pharmacist C's new financial interest
Total	\$615.00 (one financial interest registration fee)

Pharmacist A and Pharmacist B are each required to submit a *Notice of disposal of financial interest in a pharmacy business* within 14 days of the disposal.

Example Seven

Pharmacist A owns a pharmacy and holds the financial interest in the business as sole proprietor. Pharmacist A has decided to take on partner Pharmacist B. The two pharmacists intend owning the pharmacy business under a partnership arrangement. This amounts to a **change of ownership** and a change in the nature of Pharmacist A's financial interest in the business from sole proprietor to partner in a pharmacists' partnership.

Pharmacist B will need to submit an *Application for change of pharmacy ownership where the purchaser/s is a partner in a partnership of pharmacists*.

While Pharmacist A's financial interest in the business is already registered with the Council, Pharmacist B's financial interest is not. Therefore a registration of financial interest fee is payable by the new partner in the business.

Financial interest registration fee	\$615.00 for the new partner (Pharmacist B)
Total	\$615.00 (one financial interest registration fee)

Example Eight

Pharmacist A and B own a pharmacy business in partnership. They propose to dissolve their old partnership and form a new partnership by taking on a new partner, Pharmacist C. This amounts to a **change of ownership** and a new financial interest for Pharmacist C.

Pharmacist C will need to submit an *Application for change of pharmacy ownership where the purchaser/s is a partner in a partnership of pharmacists*.

The financial interests of pharmacists A and B are already registered with the Council for this business so they are not required to pay a fee.

Financial interest registration fee	\$615.00 for the new partner (Pharmacist C)
Total	\$615.00 (one financial interest registration fee)

Example Nine

Pharmacist A currently holds a financial interest in the AB Pharmacy as sole proprietor. Pharmacist A has registered AB Pharmacy Pty Ltd, a Pharmacists' Body Corporate, with ASIC. Pharmacist A is the sole director /shareholder of AB Pharmacy Pty Ltd. The Pharmacists' Body Corporate will become the proprietor of the pharmacy. This amounts to a **change of ownership**. The nature of Pharmacist A's financial interest will change from sole proprietor to director/shareholder of a Pharmacists' Body Corporate.

An *Application for change of pharmacy ownership where the new ownership structure includes a pharmacists' body corporate* will need to be submitted.

Pharmacist A already holds a financial interest in the business so is not required to register a new financial interest or pay a fee. AB Pharmacy Pty Ltd will incur a financial interest registration fee.

Financial interest registration fee	\$615.00 for AB Pharmacy Pty Ltd's new financial interest.
Total	\$615.00* (one financial interest registration fee)

*Applications involving a new trust structure may incur an additional fee. Please see Guide Note 5 for further information.

Notes:

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

Example Ten

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. AB Pty Ltd is the proprietor of the pharmacy. Pharmacist A proposes to sell his/her respective shareholdings to Pharmacist C. This amounts to Pharmacist C's **acquisition of a financial interest as a shareholder in a pharmacists body corporate**. Pharmacist B is retaining their share in the company. The company name is to be retained.

Pharmacist C will need to submit an *Application for acquisition of financial interest in a pharmacy business as shareholder in a pharmacists body corporate and /or as a new director*

As Pharmacist C does not currently hold a financial interest in the company AB Pty Ltd he/she is required to pay a fee of \$615.00 to register a new financial interest in the pharmacy business.

Financial interest registration fee	\$615.00 for Pharmacist C's new financial interest
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Total	\$615.00* (one financial interest registration fee)
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Pharmacist A will need to lodge a *Notice of disposal of interest in a pharmacy business*

*Applications involving new trust structures or amended trusts may incur an additional fee. Please see Guide Note 5 for further information.

Notes:

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

Example Eleven

Pharmacist A and B currently hold financial interests in AB Pharmacy as directors and shareholders of a Pharmacist Body Corporate known as AB Pharmacy Pty Ltd. They are proposing to bring two other pharmacists, Pharmacist C and Pharmacist D into the business (**acquiring financial interests**) as new shareholders of the Pharmacist Body Corporate. The name of the Pharmacist Body Corporate will not change.

Pharmacist A and B's financial interests in the business will not change. They will remain directors and shareholders of AB Pharmacy Pty Ltd.

Pharmacists A and B will need to submit an *Application for acquisition of financial interest in a pharmacy business as shareholder in a pharmacists body corporate and /or as a new director*.

On this basis the fee payable is \$1230.00, being \$615.00 each for Pharmacist C and Pharmacist D to register their new financial interests in AB Pharmacy as shareholders in AB Pharmacy Pty Ltd, the existing Pharmacist Body Corporate.

Financial interest registration fee	\$615.00 for each new financial interest (Pharmacist C and Pharmacist D).
Total	\$1230.00* (two financial interest registration fees)

*Applications involving new trust structures or amended trusts may incur an additional fee. Please see Guide Note 5 for further information.

Notes:

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

As the ACN for the Pharmacists' Body Corporate has not changed, it is considered that AB Pharmacy Pty Ltd already has a registered financial interest in the pharmacy business. If AB Pharmacy Pty Ltd is to have a different ACN, then this is considered a new financial interest and the application will incur an additional \$615.

Example Twelve

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 acquired by Pharmacist C and Pharmacist D in equal shares. They are **acquiring financial interests** as new shareholders of the Pharmacist Body Corporate. 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%

Pharmacists C and D will need to submit an *Application for acquisition of financial interest in a pharmacy business as shareholder in a pharmacists body corporate and /or as a new director*. 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 \$615.00 each to register their interests.

Financial interest registration fee	\$615.00 for each new financial interest (Pharmacist C and Pharmacist D).
Total	\$1230.00* (two financial interest registration fees)

Notes:

If Pharmacist C (or Pharmacist D) was also appointed as a Director, the fee to register their financial interest would remain at \$615 as the fee is only payable once irrespective of the number of interests held in that business by that financial interest holder.

Pharmacist A will need to lodge a *Notice of disposal of interest in a pharmacy business*

Example Thirteen

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 to appoint Pharmacist C as a Director of the company. Pharmacist C will not be acquiring any shares in the company. Pharmacist A and B will retain their interests as shareholders only.

As Pharmacist C does not currently hold a financial interest in the company, this is **new financial interest**. Pharmacist C will need to submit an *Application for acquisition of financial interest in a pharmacy business as shareholder in a pharmacists body corporate and /or as a new director*.

Financial interest registration fee	\$615.00 (Pharmacist C's new financial interest)
Total	\$615.00 (one financial interest registration fee)

Example Fourteen

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 spouse, 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. Pharmacist C will need to submit an *Application for acquisition of financial interest in a pharmacy business by way of appointment of unitholder or beneficiary of a trust*

Financial interest registration fee	\$615.00 for Pharmacist C's new financial interest
Total	\$615.00 (one financial interest registration fee)

Example Fifteen

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. Pharmacist C is to resign as a director of the company but will retain his/her share holding.

There are no other changes occurring.

Financial interest registration fee	\$NIL
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Guide Note 1: Definitions**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 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.

Notice of Completion

The form which 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.

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. Proprietors cannot operate any part of the pharmacy business, be it a pop-up stall, stand or mobile unit, outside the boundary of the pharmacy. Proprietors wishing to operate a separate stall, stand or unit, must establish and operate the stall, stand or unit separately from the pharmacy business, and with no association to the pharmacy. This applies to any advertising, signage or displays in or on the stall, stand or unit.

Pharmacy Business

A pharmacy business means the business of a pharmacist or pharmaceutical chemist in which 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 and all financial interest holders in the business must be registered with the Council.

Pharmacy - New

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 pharmacy which ceased operating and closed.

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

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).

A professional services room and the associated pharmacy premises will be treated as one pharmacy business for the purposes of counting the number of pharmacy businesses in which a pharmacist can have a financial interest (Schedule 5F, clause 9(2) of the Law). This means that it is necessary to identify the pharmacy premises that a proposed new professional services room is to be 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 this Guide a reference to a professional services room is not a reference to a room within a pharmacy where patient services such as vaccinations are delivered.

The Law requires a pharmacy business carried on in approved premises to be in the charge of a pharmacist who must personally supervise the carrying on of the business. This means that if a pharmacy business includes pharmacy premises and an associated professional services room, a minimum of one pharmacist must be present at each location to be in charge and personally supervise the carrying on of the 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.

Renovation/Expansion or Reduction in size

If renovations to an existing pharmacy 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.

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.

Guide Note 2: 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 should not be misleading or imply an unjustified expectation of beneficial treatment or promote unnecessary or inappropriate use of pharmacy services (see section 133 of the Law). Names should not suggest or imply an activity or a location which cannot be supported.

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 will usually be addressed in the sale of business agreement if the existing owners consent to the transfer of the business name 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 under which the pharmacy will operate. This will become the name under which the pharmacy is registered.

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.**

Use of Business Name

All pharmacy signs, stationery and advertising must be in the name registered with the Council.

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.

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

DISPLAY OF NAMES

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, your name must be displayed
- if you are in a pharmacists' partnership, the name of every partner must be displayed
- if you are in a pharmacists' body corporate, the name of the pharmacists' body corporate must be displayed

The displayed name(s) must be the name(s) registered with the Council.

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".

Display of Pharmacist' name

Wherever the display of a pharmacist's name is made, the name should be consistent with the name recorded on the Register of Pharmacies held by the Council, and the National Register of Pharmacists held by AHPRA.

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 may be 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.

Guide Note 3: Documentation requirements

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:

- 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 copies, which are appropriately signed, witnessed and where appropriate, stamped and/or registered. Applications which include draft, unsigned or otherwise incomplete documents will not be approved.

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 (Schedule 5F, clause 16 of the Law). Failure to supply the information/documents or knowingly furnishing false information/documents is an offence under the Law.

Guide Note 4: Pharmacists' partnership

All partners in a pharmacist's partnership must be registered pharmacists. No member of a pharmacists' partnership can have a financial interest in more than five (5) pharmacy businesses (Schedule 5F, clause 9 of the Law).

There is no prohibition in the Law on limited partnerships, however the Council reminds pharmacists entering into such arrangements, that **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.

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 in a pharmacists' body corporate. All shareholders and directors of the pharmacists' body corporate must be registered pharmacists (see Schedule 5F, clause 1 of the Law).

If a pharmacy business is to be legally and beneficially owned by a pharmacists' body corporate a copy of the company constitution that is compliant with the Law is to be provided for Council's review. The following general checklist may assist with your incorporation and preparation of documentation that reflects the financial provisions of the Law:

Constitution Certification Checklist	No	Yes
Is the body corporate validly constituted at law?		
Are all directors and shareholders pharmacists?		
Is a person that is not entitled to hold a financial interest in the pharmacy business under the Law eligible to be a director and/or shareholder of the pharmacists' body corporate?		

If the constitution is found to be non-compliant then a Constitution Certification Checklist and Schedule of Amendments will be required, and you will incur a fee for the drafting of the Constitution Certification Checklist and Schedule of Amendments. The fee will vary according to the complexity of the arrangements and will be in the vicinity of \$2, 200.00 plus GST per document. Amendments must be made before the application will be considered for approval.

Where a pharmacists' body corporate is already a registered owner of a pharmacy business, any proposed change in shareholding that results in a new shareholding 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).

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). Notification is by way of submitting an *Application for acquisition of financial interest in a pharmacy business as shareholder in a pharmacists body corporate and /or as a new director*.

Likewise the appointment of a new director in an existing pharmacists' body corporate will need to be notified to Council by way of submitting the abovementioned form at least 14 days before the appointment is made. This is 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 the number of 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.

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, and is responsible for notifying the Council at least 14 days before the appointment is made by lodging the appropriate application form - *Application for acquisition of financial interest by way of appointment of unitholder or beneficiary of a trust*.

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 business, the Council must be notified of that disposal of interest within 14 days of the completion.

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 - by way of a *Notice of disposal of financial interest in a pharmacy business*.

Guide Note 6: Trusts

If a trust is included in a proposed pharmacy business structure, a copy of the relevant Deed of Trust will need to be submitted to the Council for review. If operating in NSW, the trust deed needs to be stamped by the Office of State Revenue prior to lodgement for consideration by the Council. The definition of financial interest in Schedule 5F, clause 2 of the Law includes a proprietary interest as a trustee, beneficiary or unit holder.

The trust deed will be reviewed for compliance with the Law. An application containing a non-compliant trust will not be approved. If the trust is found to be 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 \$2,200.00 plus GST per trust deed. If amendments are required, these amendments must be actioned before the associated application will be considered for approval.

Trustees must be either registered pharmacists or pharmacists' body corporates. Beneficiaries must be registered pharmacists. It is recommended that the trust deed be drafted with the financial interest provisions of the Law in mind to ensure compliance.

The following checklist 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 each trustee either <ul style="list-style-type: none"> • a registered pharmacist, or • a pharmacists' body corporate? 		
Does each beneficiary hold a financial interest in the pharmacy under the <i>Health Practitioner Regulation National Law (NSW)</i> ?		
Is each beneficiary either <ul style="list-style-type: none"> • a registered pharmacist, or • a pharmacists' body corporate? 		
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

Pharmacists will be required to provide a copy of any Service Agreement with an application for acquisition of a financial interest. The Service Agreement will be reviewed to determine if it provides any persons with a financial interest in the pharmacy business.

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

Guide Note 8: 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.

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 operation of Friendly Society pharmacies. 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 (new pharmacy or change of ownership) should be submitted to the Pharmacy Council with all required supporting 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.

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*)

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.

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 practises pharmacy for remuneration at a pharmacy in the course of employment by a non-pharmacist or in association with a non-pharmacist is guilty of unsatisfactory professional conduct (see section 139D(1)(a) of the Law).

Any application which includes a financial arrangement with conditions that amount to prohibited financial interest in a pharmacy will be refused

Guide Note 10: Lease of premises

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.

In the event that the lease is not in the name of the pharmacist, the partnership or the pharmacists' body corporate, Council must be provided with an explanation of the commercial arrangements which exists.

The address of the premises as described on the lease must be consistent with the address of the premises as described on the application form submitted to Council for approval.

If the building is solely owned by the pharmacist(s) or pharmacists' body corporate the owner of 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.

Percentage Turnover Rent Provisions

Schedule 5F, clause 10 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.”

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 where required stamped by the Office of State Revenue and registered with the NSW Land Registry Services. Certified copies of the completed 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, with certified copies of the original stamped and registered lease supplied within six months from completion.

Guide Note 11: Premises plan information

The Council requires a Floor Plan and a Locational Plan to be submitted in support of the following applications:

- New pharmacy;
- New professional services room;
- Relocation or expansion/reduction of a pharmacy;
- Relocation or expansion/reduction of a professional services room.

It is important to ensure that the proposed premises are identified clearly and described accurately, with full details of shop, floor, suite or lot number provided along with the building name (*e.g. x shopping centre*) and street number, name and suburb.

It is also important that address details on supporting documentation provided with the application are consistent with the address nominated for the proposed premises on the application form. This will enable the Council to have a clear understanding of the location and layout of the premises.

Details of the plan requirements are set out below. Assistance from a shop fitter or draftsman may aid in the preparation of premises floor plans and locational plans, where these are required.

A Council Inspector will inspect premises as part of the approval process for new or relocated/resized premises with reference to plans submitted with the application. The premises' address and layout of the premises must be described consistently throughout the application and supporting documentation. Accordingly, the premises as inspected should be consistent with the plans and any other supporting documentation provided, such as the lease.

Plan requirements

1. A **Floor Plan** of the premises, drawn to an indicated scale, showing: -
 - a) the entire premises of the pharmacy / professional services room with the perimeter of the premises highlighted to distinguish the premises from any other areas shown on the plan;
 - b) the total area of the premises expressed in square metres;
 - c) the entry/exits clearly marked. Public access points are to be indicated (not applicable to professional services rooms);
 - d) the dispensary with the perimeter of the dispensary marked to distinguish the dispensary from other areas of the pharmacy / professional services room;
 - e) the total area of the dispensary expressed in square metres;
 - f) the layout of the dispensary including:
 - location of dispensing benches;
 - location of benches for general compounding of medicines;
 - location of hot and cold water sink with drainer;
 - location of vaccine refrigerators(s);
 - location of dispensing stations (dispensing computers);
 - location of shelving in the dispensary - including 'rhombic', 'carousel' units and automated robotic delivery machines;
 - g) the location of the area or areas for the storage for sale of any Pharmacist Only Medicines (S3 medicines) that must not be accessible to the public. Note: This area may be in the dispensary (not applicable to professional services rooms);
 - h) the confidential counselling area with the perimeter of the confidential counselling area marked to distinguish it from other areas of the pharmacy and with privacy arrangements indicated (not applicable to professional services rooms);
 - i) the location of any laboratory area for complex compounding or preparation of sterile/cytotoxic products, including the location of specific equipment such as sink and powder containment cabinet;
 - j) the location of treatment or patient consulting rooms or areas *e.g. treatment/vaccination room, beauty treatment room, ear-piercing room, pregnancy testing room* (not applicable to professional services rooms);
 - k) the location of other general areas (*eg office, staffroom, storeroom, toilets*).
2. A **Locational Plan**, showing the premises in relation to the surrounding area.
 - a) The Locational Plan should include any adjacent buildings, roadways with name of roadway marked, footpaths, walkways and car parks. If located within a shopping centre, a layout plan of the shopping centre with premises highlighted should be provided;
 - b) The door/entrance providing public access is to be clearly marked (not applicable to professional services rooms).

Guide Note 12: Pharmacy premises requirements

The Regulation requires compliance with standards which includes equipment and publications that must be kept in **every** pharmacy (see below).

Aside from the equipment and publications listed in Schedule 5 of the Regulation, the pharmacy is required to have any other equipment necessary for the pharmacy to provide safe and competent delivery of pharmacy services (see clause 12(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 Regulations 1999*.

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.

Dispensing Area

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

- it is to be adequately lit and ventilated,
- it is to have adequate heating facilities for dispensing and compounding drugs,
- 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,
- 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,
- 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.

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:

- all reasonable steps have been taken to prevent public access to the premises
- 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,
- the premises are to be equipped with a dispensing area of at least 8 square metres or such lesser area as the Council may approve in a particular case,
- the premises are to be laid out and equipped so that:
 - any drug stored in the premises can be stored in accordance with the relevant drug's storage conditions, and
 - 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) publications listed in Schedule 6 of the Regulation should be available onsite or accessible electronically from the premises

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.

Publications required for a professional services room and a pharmacy are the same with the exception of the Price Information Code of Practice which is not required for a professional services room. **The set of publications held within the professional services room must be in addition to and separate from the set of publications held within the associated pharmacy.**

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

Guide Note 14: Signs and sign-writing

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.

The Law 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. Electronic signatures are acceptable.

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

A Notice of closure must be completed and lodged with the Council within 14 days of the closure, for any reason, of a pharmacy.

The Council has the power to revoke the approval of a pharmacy premise 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.

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 (see Schedule 5F, clause 5(2)(b)(i) of the Law). The 6 month period commences on the day of the pharmacist's death.

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

Pharmacies that dispense Pharmaceutical Benefits prescriptions must have a Pharmaceutical Benefits Scheme (PBS) approval. The Pharmacy Council's process of approving premises and financial interests is independent of the PBS approval process. A pharmacy does not need to have PBS approval to be registered with the Council.

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

It is very important that the information supplied to the Council agrees completely with an application to the Commonwealth Department of Human Services / Medicare for a PBS approval number. Anomalies or inconsistencies may delay the issuing of a PBS approval number.

Pharmacists operating a 'non approved' pharmacy must adhere to the Commonwealth Department of Human Services / Medicare requirements, any relevant Pharmacy Board of Australia (PBA) Guidelines and 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. The Council sends out an Annual Renewal of Pharmacy Premises Registration Notice to the 'proprietor' of each pharmacy in NSW every year in May with the annual renewal fee due for payment by 30 June. Payment by the due date will result in the approval of pharmacy premises for a further 12 month period to 30 June the following year (see also Guide Note 20 Payment of annual renewal fees).

Renewal of pharmacy registrations may be completed online through the Council's website. Users will be requested to login using the username and password provided with the renewal notice.

Should payment not be made by 30 June, the pharmacy will lose its current approval status and the Register of Pharmacies will indicate the registration as 'Expired'. The Council reminds proprietors that operating a pharmacy without a current approval is a breach of Clause 3(1) of Schedule 5F of the Law for which penalties apply.

If payment is not made by the due date, the pharmacy should not operate until payment of the late fee is made. Payment will result in renewal of premises registration and Council approval to 30 June the following year.

Following renewal of registration fee payment, a Certificate of Pharmacy Registration will be posted to the proprietors at the address listed for the pharmacy on the Register of Pharmacies. It is therefore important that you notify the Council when changing the postal address details of your pharmacy. Doing so will ensure that the annual renewal notice is posted to the correct address.

Registration of pharmacists working at a pharmacy

The owner/pharmacist in charge should establish a procedure for the checking of the registration of the employee pharmacists, particularly locums. The Pharmacy Board of Australia maintains an online register of pharmacists which can be accessed via www.ahpra.gov.au.

- To practise pharmacy, a pharmacist must hold *general registration or provisional registration* status with the Pharmacy Board of Australia.
- It is possible to hold *non-practising registration* status, however such practitioners cannot practise as a pharmacist, should not be employed in the capacity of a pharmacist and/or pharmacist in charge and are not entitled to hold a financial interest in a pharmacy business in New South Wales

A pharmacist whose registration is cancelled or suspended and who holds a registered financial interest in a pharmacy business needs to consider Schedule 5F, clause 5(2)(c) of the Law.

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

Guide Note 20: Payment of fees

Pharmacy fees are prescribed in Clause 15 of the Regulation.

Type of application	Fee
Application for approval of premises as suitable for carrying on pharmacy business by pharmacist:	\$550
Application for registration of holder of financial interest in pharmacy business:	\$615

Annual renewal of pharmacy premises registration (if lodged on or before due date):	\$320
Annual renewal of pharmacy premises registration (if lodged after the due date):	\$400

The appropriate fee must accompany each application. For guidance on calculating an application fee see the examples provided under 'Applications Forms and Notices' in this Guide.

Annual renewal of pharmacy premises registration fees are due by 12 midnight on **30 June**. (see also Guide Note 19). In respect of renewal payments the following applies:

- Annual renewal of pharmacy premises registration 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.
- Should payment not be made by 30 June, the pharmacy will lose its current approval status and the Register of Pharmacies will indicate the registration as 'Expired'. Payment of the \$400 fee will result in the renewal of premises registration and Council approval to 30 June the following year.

Under Division 81 of the Goods and Services Tax Regulations, the Treasurer has determined that application and renewal 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. The powers of inspectors are detailed in section 164A of the Law. Under section 164C of the Law it is an offence for a person to prevent, hinder or obstruct an inspector, or other authorised person, in the carrying out of their duties.

Premises must be inspected prior to the opening of a new pharmacy or associated professional services room, relocation of an existing pharmacy or professional services room, and immediately on completion of any substantial renovations to an existing pharmacy or professional services room to ensure compliance with the requirements and standards set out in the Regulation.

It is the responsibility of the applicant (for a new pharmacy or professional services room, or relocation or renovation of a pharmacy or professional services room) to nominate a date for inspection of the premises. Once the application has been conditionally approved by the Council, the applicant should contact the Council inspector to confirm the premises are ready for inspection and to arrange a mutually convenient time for the inspection.

The premises should be complete and ready for commencement of operation by the inspection date.

There is no fee associated with an inspection.

Inspections will be conducted as efficiently as possible and with reference to the Floor Plan and Locational Plan submitted with the relevant application. Information on items being checked for compliance is available from the inspector. The pharmacist in charge or owner will receive a copy of the inspector's report at the completion of the inspection. Following a satisfactory inspection, correspondence will be sent to the applicant confirming approval of the application and details entered into the Register of Pharmacies.

The Register of Pharmacies will record the date of satisfactory inspection as the date of commencement of (current) approval by the Council to operate the pharmacy business.

Compliance inspections

Pharmacies across NSW are also routinely inspected every 18 months to ensure compliance with the Law.

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

Drug destructions

Pharmacy inspectors are authorised by the NSW Ministry of Health Pharmaceutical Services to destroy and dispose of unusable Schedule 8 medications.

Guide Note 22: Timetable for registrations and appeals

The processing of applications is undertaken in order of their receipt by the Council.

It is recommended that independent professional advice and/or assistance (lawyer, accountant, pharmacy broker) be sought in the preparation of applications, and particularly those involving complex business structures.

Only applications that are complete, accompanied by final and completed supporting documents and comply with all legislative requirements will be considered for approval. Applicants will be notified within 5 business days of lodgement of an application if their application is incomplete and/or non compliant and will be given an opportunity to rectify any anomalies.

For the purpose of calculating the timeframe to rectify anomalies, it should be noted that an application that has not been dealt with by Council is taken to have been refused on the day that is one month after the application was lodged, or a later date as decided by the Council and communicated to the applicant (see Clause 13 of the Law).

The Council is not in a position to provide ‘on-the-spot’ approvals. The Council is not responsible for any delays caused by submission of incomplete documents in circumstances where Council approval is a condition of settlement.

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 to register a financial interest

Any person who is aggrieved by the Council’s decision to refuse an application 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).

For the purposes of a review, an application that has not been dealt with by Council is taken to have been refused on the day that is one month after the application was lodged.

Appeals are dealt with in the Administrative Division of NCAT. The Administrative Division is not a “costs jurisdiction” and ordinarily parties pay their own legal costs.

Guide Note 23: Online pharmacy operations

An online pharmacy can be established only in connection with an existing pharmacy business, operating on approved pharmacy premises. All financial interest holders must be registered with the Council. The online operation 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.

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. 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 may 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 supply specified information or a specified document relating to a financial interest the person has in a pharmacy business
- 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 declaration by the due date
- failure to comply with a direction or notice given by the Council to supply information about financial interests

Matters constituting unsatisfactory professional conduct include:

- practising pharmacy for remuneration at a pharmacy in the course of employment by, or in association with, a non-pharmacist
- 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