

South Australia

Pharmacists Regulations 2006

under the *Pharmacists Act 1991*

Contents

- 1 Short title
- 2 Commencement
- 3 Interpretation
- 4 Non-derogation from *Controlled Substances Act 1984*
- 5 Eligibility for registration
- 6 Prescribed additional qualifications
- 7 Exemptions from obligation to be registered
- 8 Prohibition on use of certain words
- 9 Name of registered company
- 10 Business or trading names
- 11 Information relating to claim against pharmacist to be provided
- 12 Obligation to report incapacity of pharmacist
- 13 Standard of premises to be used in practice of pharmacy
- 14 Access to registered premises
- 15 Reference works to be kept by pharmacists
- 16 Ceasing to practise pharmacy at registered premises
- 17 Other businesses not to be carried on at registered premises
- 18 Dispensing of prescriptions received by facsimile
- 19 Dispensing of expired prescription
- 20 Dispensing of suspected forgeries etc
- 21 Labelling of items dispensed on prescription etc
- 22 Delivery of dispensed items
- 23 Records of prescriptions
- 24 Advertising by pharmacists
- 25 Fees

Schedule 1—Qualifications

Part 1—Australia

Part 2—New Zealand

Schedule 2—Forms

Schedule 3—Revocation of *Pharmacists Regulations 1991*

Legislative history

1—Short title

These regulations may be cited as the *Pharmacists Regulations 2006*.

2—Commencement

These regulations will come into operation on 1 September 2006.

3—Interpretation

In these regulations, unless the contrary intention appears—

Act means the *Pharmacists Act 1991*;

approved pharmacist means—

- (a) a registered pharmacist (other than a person who has limited or provisional registration); or
- (b) a person unconditionally registered as a pharmacist, or otherwise unconditionally authorised to practise pharmacy, under the law of another State or a Territory of Australia or New Zealand.

4—Non-derogation from *Controlled Substances Act 1984*

These regulations do not derogate from regulations made under the *Controlled Substances Act 1984*.

5—Eligibility for registration

- (1) An applicant for registration under section 18(1) of the Act must have the following qualifications and experience and fulfil the following requirements:
 - (a) —
 - (i) a degree or diploma in pharmacy awarded by an Australian or New Zealand educational institution listed in Schedule 1; and
 - (ii) satisfactory completion of a period of practical experience in pharmacy under the supervision of an approved pharmacist of at least 1 year or such lesser period as the Board determines having regard to post-graduate academic qualifications held by the applicant; and
 - (iii) satisfactory completion of a first aid course and a forensic examination; or
 - (b) unconditional registration as a pharmacist, or other unconditional authorisation to practise as a pharmacist, under the law of another State or a Territory of Australia or New Zealand; or
 - (c) —
 - (i) a certificate granted by the Australian Pharmacy Examining Council certifying that the person has the necessary qualifications to practise pharmacy in this State; and
 - (ii) satisfactory completion of at least the period recommended or required by the Australian Pharmacy Examining Council of practical experience in pharmacy under the supervision of an approved pharmacist; and

- (iii) if an applicant has obtained his or her qualifications in pharmacy in a non-English speaking country, the applicant must satisfy the Board that the applicant has sufficient knowledge of the English language with which to carry on the practice of pharmacy; and
- (iv) satisfactory completion of a first aid course and forensic examination.

(2) In this regulation—

first aid course means—

- (a) the senior first aid certificate course conducted by St. John Ambulance Australia South Australia Incorporated; or
- (b) the senior first aid certificate course conducted by Australian Red Cross Society South Australian Division; or
- (c) a course in first aid that is, in the opinion of the Board, of equivalent standard to a course referred to in a preceding paragraph;

forensic examination means a multiple choice examination conducted by the Board on the law applying in this State in relation to the sale or supply of poisons and other pharmaceutical items.

6—Prescribed additional qualifications

For the purposes of section 24(2) of the Act, the following qualifications are prescribed:

- (a) any degree or diploma relating to the practice of pharmacy awarded by a university;
- (b) any degree, diploma or other qualification in a medical or health field awarded by an educational institution;
- (c) membership of an association that—
 - (i) is established under a law of a State or Territory of Australia or New Zealand; and
 - (ii) has objects relating to pharmacy.

7—Exemptions from obligation to be registered

(1) Section 26(1) of the Act does not apply in relation to—

- (a) the practice of pharmacy by the personal representative of a deceased pharmacist within 1 year (or such longer period as the Board may allow) after the date of death; or
- (b) the practice of pharmacy, for a period of 1 year (or such longer period as the Board may allow), by the official receiver of a bankrupt or insolvent pharmacist; or
- (c) the practice of pharmacy, for a period of 1 year (or such longer period as the Board may allow), by a person vested by law with power to administer the affairs of a company that is registered as a pharmacist and is under administration, receivership or official management; or

- (d) the practice of pharmacy by a person who has obtained academic qualifications in pharmacy and who is undergoing a period of experience under the supervision of an approved pharmacist with a view to applying for registration as a pharmacist and has obtained the approval of the Board to do so; or
 - (e) the practice of pharmacy by Little Company of Mary Health Care at Calvary Hospital, North Adelaide.
- (2) A person who practices pharmacy pursuant to subregulation (1)(a), (b) or (c) must, within 7 days after commencing to do so, give notice in writing of that fact to the Board.
- Maximum penalty: \$2 000.

8—Prohibition on use of certain words

For the purposes of section 28 of the Act, the word "druggist" is prescribed.

9—Name of registered company

The name of a company that is to be registered as a pharmacist must be approved by the Board.

10—Business or trading names

A person must not practise pharmacy under a business or trading name unless that name has been approved by the Board.

Maximum penalty: \$2 000.

11—Information relating to claim against pharmacist to be provided

For the purposes of section 31 of the Act, the information relating to a claim referred to in that section to be provided to the Board is as follows:

- (a) the nature of the act that is alleged to have been carried out negligently;
- (b) full details of the alleged negligence;
- (c) the address of the premises at which the negligence is alleged to have occurred;
- (d) the time at which and the date on which the negligence is alleged to have occurred;
- (e) full details of the injury or loss suffered or allegedly suffered by the claimant as a result of the alleged negligence;
- (f) details of any court judgment or order made in respect of the claim, including any amount ordered to be paid by the pharmacist by way of damages or compensation;
- (g) details of any agreement entered into to pay a sum of money in settlement of the claim, including the amount agreed to be paid.

12—Obligation to report incapacity of pharmacist

For the purposes of section 42(c) of the Act, the following information is required to be included in a report to the Board:

- (a) the diagnosis of the illness of the pharmacist and its likely duration and prognosis;
- (b) a description of any treatment being received by the pharmacist for the illness;
- (c) a description of any form of pharmacy that, in the opinion of the medical practitioner making the report, the pharmacist is not fit to provide.

13—Standard of premises to be used in practice of pharmacy

- (1) Premises at which a business consisting of or involving pharmacy is carried on must, unless the Board otherwise approves under this regulation—
 - (a) consist of an enclosed area with access to a public place; and
 - (b) contain an area set aside for the dispensing of items on prescription that is not less than 9 square metres; and
 - (c) be in a hygienic condition and be adequately ventilated; and
 - (d) have provision for adequate lighting; and
 - (e) contain adequate provision for the secure and hygienic storage of drugs and pharmaceutical products; and
 - (f) be constructed in such a manner as to allow a pharmacist to supervise effectively the whole of that part of the premises used in the practice of pharmacy and the activities of persons in that part of the premises.
- (2) The Board may approve premises that do not comply with subregulation (1) (and register the premises under section 32 of the Act) if satisfied—
 - (a) that the premises are used as a delivery and collection point for drugs, medicines or other pharmaceutical products that have been pre-packaged for specific customers outside Metropolitan Adelaide (as defined in the Development Plan under the *Development Act 1993*) and are not otherwise used in the practice of pharmacy; and
 - (b) that an adequate pharmaceutical service cannot otherwise be provided in the locality.
- (3) Premises at which a business consisting of or involving pharmacy is carried on must be kept, at all times, in a hygienic and tidy condition.
- (4) A person who carries on a business of or involving the practice of pharmacy at premises that do not comply with subregulation (3) is guilty of an offence.
Maximum penalty: \$2 000.

14—Access to registered premises

A person who carries on a business consisting of or involving pharmacy at registered premises must ensure that the name and telephone number of a pharmacist who can, at all times, gain ready access to the premises is displayed at the entrance to the premises.

Maximum penalty: \$2 000.

15—Reference works to be kept by pharmacists

- (1) Current editions of the following reference works must be kept at any premises at which pharmacy is practised:
 - (a) *Martindale—The Complete Drug Reference* published by Pharmaceutical Press;
 - (b) *The Australian Pharmaceutical Formulary and Handbook* published by the Pharmaceutical Society of Australia;
 - (c) the *Australian Prescription Products Guide* published by the Australian Pharmaceutical Publishing Company or the *MIMS Annual* published by CMPMedica Australia Pty Ltd;
 - (d) *The Australian Medicines Handbook* published by Australian Medicines Handbook Pty Ltd or another reference work on therapeutics.
- (2) Copies of the following legislation as in force from time to time must be kept at any premises at which pharmacy is practised:
 - (a) the Act and these regulations;
 - (b) the *Controlled Substances Act 1984* and all regulations made under that Act that are relevant to the practice of pharmacy.
- (3) It is sufficient for the purposes of this regulation if the required reference work or legislation is stored by computer, microfilm or other process and is readily accessible.
- (4) If the requirements of this regulation are not complied with, the person who carries on the business consisting of or involving pharmacy at the premises is guilty of an offence.

Maximum penalty: \$2 000.

16—Ceasing to practise pharmacy at registered premises

A person must, within 7 days after ceasing to carry on a business of or involving the practice of pharmacy at registered premises, give written notice of that fact to the Registrar.

Maximum penalty: \$1 000.

17—Other businesses not to be carried on at registered premises

- (1) A person must not, without the approval of the Board, carry on a business other than the practice of pharmacy, or a business commonly associated with the practice of pharmacy, at registered premises.

Maximum penalty: \$2 000.

- (2) A person must not carry on a business commonly associated with the practice of pharmacy at registered premises unless—
- (a) the person is the person in whose name the premises are registered; or
 - (b) the approval of the Board has been obtained.

Maximum penalty: \$2 000.

18—Dispensing of prescriptions received by facsimile

A pharmacist must not dispense an item on a prescription received by means of a facsimile machine or other electronic or photographic means unless he or she has first verified the authenticity of the prescription.

Maximum penalty: \$2 000.

19—Dispensing of expired prescription

A pharmacist must not dispense an item on prescription more than 1 year after the date of the issue of the prescription.

Maximum penalty: \$2 000.

20—Dispensing of suspected forgeries etc

- (1) A pharmacist must not dispense an item on prescription if there are reasonable grounds for suspecting that the prescription has been altered, forged or obtained on false pretences.

Maximum penalty: \$2 000.

- (2) It is a defence to a charge of an offence against subregulation (1) if the defendant proves that the offence did not result from any failure on his or her part to take reasonable care to avoid the commission of the offence.

21—Labelling of items dispensed on prescription etc

- (1) A pharmacist must not dispense an item on prescription unless—

- (a) the item is labelled with—

- (i) the name (or approved business or trading name), address and telephone number of the person carrying on the practice of pharmacy at the premises at which the item is dispensed; and
- (ii) the name of the person for whose use the item is dispensed; and
- (iii) the trade name and the generic name of the item dispensed, or, if it does not have either a trade or generic name, its ingredients; and
- (iv) adequate directions for the safe and proper use of the item; and
- (v) a unique identifier enabling the item to be linked with the prescription; and
- (vi) the date on which the item is dispensed; and

- (b) the prescription is marked with—

- (i) the unique identifier applicable to the item; and

- (ii) the name (or approved business or trading name), address and telephone number of the person carrying on the practice of pharmacy at the premises at which the item is dispensed.

Maximum penalty: \$2 000.

- (2) If a prescription has been issued in duplicate, it is sufficient compliance with subregulation (1)(b) if the required information is marked on the duplicate prescription.
- (3) The information required to be displayed under this regulation may be displayed on a label containing information required to be displayed under the *Controlled Substances Act 1984*.

22—Delivery of dispensed items

- (1) An item dispensed by a pharmacist on a prescription must not be given or sent to a person, or left for collection by a person, at any premises except—
 - (a) registered premises; or
 - (b) premises occupied by a pharmacist; or
 - (c) premises occupied by the person for whose use the item is dispensed.
- (2) If an item dispensed by a pharmacist on a prescription is to be given or sent to a person, or left for collection by a person, at premises other than premises occupied or supervised by a pharmacist, the item must be packaged, wrapped and addressed to the person for whose use the item is dispensed.
- (3) If an item is given, sent or left for collection in contravention of this regulation, the pharmacist who dispensed the item is guilty of an offence.

Maximum penalty: \$2 000.

- (4) It is a defence to a charge of an offence against subregulation (3) if the defendant proves that the offence did not result from any failure on his or her part to take reasonable care to avoid the commission of the offence.

23—Records of prescriptions

- (1) A person who carries on a business consisting of or involving pharmacy must keep an accurate record of each prescription on which an item is dispensed in the course of that business, together with the following details:
 - (a) the unique identifier applicable to the item dispensed on the prescription;
 - (b) the name or initials of the pharmacist who dispensed the item;
 - (c) the date on which the item was dispensed;
 - (d) the trade name and the generic name of the item, or, if it does not have either a trade or generic name, its ingredients, and the form, strength and quantity of the item dispensed;
 - (e) the name and address of the person for whose use the item was dispensed;
 - (f) the directions for the safe and proper use of the item given in accordance with these regulations;
 - (g) the name of the person who prescribed the item.

- (2) Records kept under this regulation—
 - (a) must be retained for at least 2 years; and
 - (b) must be kept at the premises at which the items to which the records relate were dispensed or at other premises approved for that purpose by the Board; and
 - (c) must be readily accessible; and
 - (d) must be made available for inspection at any reasonable time at the request of the Board.
- (3) If the information contained in a record is accessible only after the record is subjected to electronic or other process, it is sufficient for the purposes of this regulation for the person to produce for inspection a reproduction or computerised record of an entry in the records.
- (4) If a requirement of this regulation is contravened, the person who carries on the business in relation to which the records must be kept is guilty of an offence.
Maximum penalty: \$2 000.

24—Advertising by pharmacists

- (1) A person must not advertise in respect of the practice of pharmacy except under the name of a registered pharmacist or a business or trading name approved by the Board.
Maximum penalty: \$2 000.
- (2) A person must not advertise in respect of the practice of pharmacy—
 - (a) in a manner that is likely to bring discredit on the profession of pharmacy; or
 - (b) in a manner that draws invidious comparison between pharmacists or groups of pharmacists; or
 - (c) in a manner that is likely to mislead.
Maximum penalty: \$2 000.

25—Fees

- (1) The Board may fix fees or charges for the following:
 - (a) the registration of pharmacists (including provisional or limited);
 - (b) the renewal of registration of pharmacists;
 - (c) entering in the register any new or additional qualifications;
 - (d) the issue of duplicate certificates of registration;
 - (e) the preparation of statements verifying registration;
 - (f) other extracts from the register;
 - (g) inspection of the register;
 - (h) approval of a company, trading or business name;
 - (i) approval of the alteration of the memorandum and articles of association of a company;
 - (j) the registration of premises;

- (k) the renewal of registration of premises;
 - (l) other authorisations or approvals under the Act or these regulations.
- (2) Fees for registration or renewal of registration may vary according to whether the applicant is a natural person or a company, and in the case of a company, may vary according to whether or not the memorandum and articles of association of the company are in a standard form approved by the Board.
- (3) The Board may recover a fee or a charge as a debt.

Schedule 1—Qualifications

(Regulation 5)

Part 1—Australia

Charles Darwin University
Charles Sturt University
Curtin University of Technology
Griffith University
James Cook University
La Trobe University
Monash University
Murdoch University
Queensland University of Technology
South Australian Institute of Technology
University of Adelaide
University of Canberra
University of Newcastle
University of Queensland
University of South Australia
University of Sydney
University of Tasmania
University of Western Australia

Part 2—New Zealand

Central Institute of Technology, Heretaunga
University of Auckland
University of Otago

Schedule 2—Forms

The forms included in this Schedule are to be used for the purposes indicated.

Form 1 (Section 19)

Application for registration of a natural person as a pharmacist

1 I
[full name]

of
[residential address]

apply for registration as a pharmacist under the *Pharmacists Act 1991*.

2 I have the following academic qualifications:

.....
[degree or diploma]

awarded by
[university or college]

3 I have completed the following period of practical experience as required under the Act:

Period	Supervising pharmacist	Address of practice
.....
.....

4 I have entered into an agreement with *Pharmaceutical Defence Ltd*
(or)
to compensate me for loss by reason of civil liability incurred in the practice of pharmacy.

OR

I claim exemption under section 30(2) of the *Pharmacists Act 1991* on the following basis:

I am employed at
[hospital or industrial establishment]

Other:

Date

Signed

Witness

[JP or Commissioner for taking Affidavits in Supreme Court of SA]

Please fill in the following for inclusion in the register:

Title

Additional qualifications

.....
.....

Phone (H)

(W)

Business address

.....
.....

Date of birth

I am also registered in the following jurisdictions:

.....
.....

Form 2

(Section 19)

Application for registration of a company as a pharmacist

- 1 (a) Company's name:
 - (b) Registered office:
 -
 - (c) Business address:
 -
 - (d) Telephone number:
- 2 Date of incorporation:
- 3 State whether the company intends to practise in South Australia under its own name, or under a business name and, if so, state the business name proposed to be used.
- 4 (a) State the intended place of business or places of business of the company.
 - (b) State the intended principal place of business of the company.
- 5 State in relation to each director—
 - (a) the director's full name and usual residential address; and
 - (b) whether the director is registered under the Act; and
 - (c) if the director is not registered under the Act whether the director is a prescribed relative of a director who is registered and, if so, the particulars of the relationship; and
 - (d) whether the director is a director of any other company which is registered under the Act and, if so, full particulars of that other directorship.
- 6 Give particulars of the issued capital of the company specifying the number, class and nominal value of all shares on issue.
- 7 State in relation to each person who is a member of the company or the beneficial owner of shares in the company—
 - (a) the person's full name and usual residential address; and
 - (b) whether the person is registered under the Act; and
 - (c) whether the person is a director or employee of the company or a prescribed relative of a person who is a director or employee of the company; and
 - (d) the following particulars of all shares in the company held or owned beneficially by the person:
 - (i) a description of the shares (including the number, nominal value and class); and
 - (ii) particulars of the voting rights (if any) exercisable at a meeting of the members of the company attached to the shares; and

- (iii) if the person is not the holder of shares, the name and address of the holder and particulars of the nature of the beneficial ownership of the shares of the person.

I,, declare

[insert full name and address]

- (a) that the above particulars are true in every respect to the best of my knowledge, information and belief; and
(b) that I am authorised by the company to make this application on its behalf.

Dated this day of 20

Signature

Witness

[JP or Commissioner for taking Affidavits in the Supreme Court of SA]

(A copy of the Memorandum and Articles of Association of the company must be attached)

Form 3

(Section 39)

Annual return of a company

1 Name and particulars

- (a) Name of company:
- (b) Registered office:
- (c) Principal address at which the practice is conducted:
-
- (d) Full address of all other places where the practice is conducted:
-
- (e) Business name (if any) under which the practice is conducted:
-
- (f) Telephone number:
- (g) This return relates to the period from 20.... to 30 June 20...

2 Memorandum and Articles of Association

Have there been any amendments to either the Memorandum or Articles of Association of the company during the period to which this return relates? If so, give particulars.

3 Directors

In relation to every person who was at any time during the period to which this return relates a director of the company state—

- (a) the director's full name and last usual residential address;
- (b) whether the director was a director during the whole of such period and, if not, the date on which the director became or ceased to be a director (as the case may be);
- (c) whether the director was registered under the Act for the whole or part of any such period and, if part only, the period during which the director was so registered;
- (d) in the case of a director permitted to hold office by virtue of section 18 of the Act not being a registered pharmacist, particulars of the director's relationship to a director who is registered during the period to which the return relates;
- (e) whether the director was at any time during the period to which the return relates a director of any other company and, if so, full particulars of that other directorship.

4 Shareholders

In relation to each person who was at any time during the period to which this return relates a member of the company or the beneficial owner of shares in the company state—

- (a) the person's full name and last usual residential address;
- (b) in the case of a member, whether he or she was a member during the whole of such period and, if not, the date on which he or she became or ceased to be a member;
- (c) whether the person was registered under the Act and whether such registration was for the whole or part of such period and, if part only, the period during which such registration applied;
- (d) in the case of a person being a prescribed relative of a registered person who is a director or employee of the company, particulars of the person's relationship to such director or employee;
- (e) the following particulars of all shares owned beneficially by such person at any time during such period:
 - (i) a description of the shares (including the number, nominal value and class); and
 - (ii) particulars of the voting rights (if any) exercisable at a meeting of the members of the company attached to the shares; and
 - (iii) if the person was not the holder of the shares, the name and address of the holder and particulars of the nature of the beneficial ownership of the shares of such person; and
 - (iv) if such person became the beneficial owner of the shares at any time during such period, particulars of the date on which and circumstances in which such person became the beneficial owner of the shares; and
 - (v) if such person ceased to become the beneficial owner of the shares at any time during such period, particulars of the date on which and circumstances in which such person ceased to be the beneficial owner of the shares.

5 Practice in partnership

Has the company at any time during the period to which this return relates practised as a pharmacist in partnership with any other person including any other company? If so, give particulars.

I DECLARE that the above statements are true in every particular to the best of my knowledge, information and belief.

Dated this day of 20

Signature of director:

Form 4

(Section 22)

Application for renewal of registration

I
[full name]

of
[residential address]

apply (on behalf of)
[insert company name if applicable]

for renewal of registration as a pharmacist under the *Pharmacists Act 1991* for the
year

Date

Signed

Form 5

(Section 32)

Application for registration of premises

- 1 I
[full name]
of
[residential address]
apply for registration under the *Pharmacists Act 1991* of premises situated at.....
.....
.....
- 2 The following are particulars of the business carried on or proposed to be carried on at those premises:
Type of business:
.....
Name under which business carried on:
.....
If the business is carried on by a company, the name of that company:
.....
If the business is carried on by a partnership, the names of the partners:
.....
.....
The names and addresses of any other persons taking part in the control or management of the business:
.....
.....
- 3 No part of the premises has previously been registered under the *Pharmacists Act 1991* or the *Pharmacy Act 1935*.
OR
The premises or part of the premises has previously been registered. Set out details of the registration including the person under whose name the premises were registered, any structural alterations to the premises that have taken place since that previous registration and any other relevant information:
.....
.....

- 4 A plan of the premises showing the floor area of the space (if any) in which items are to be dispensed on prescription is attached.

[This item should be deleted if the application is made only because of the transfer of a business]

- 5 The premises comply with the requirements of the regulations under the *Pharmacists Act 1991*.

OR

I seek the Board's approval of the premises as a depot on the following basis:

Name of occupier:

Name of person nominated to receive pharmaceutical items:

.....

Proposed method of delivery of pharmaceutical items to depot:

.....

Proposed method of communication between depot and any premises from which pharmaceutical items dispatched:

.....

Closest registered premises (pharmacy):

.....

Area to which pharmaceutical services expected to be provided through depot:

.....

I DECLARE that the above statements are true in every particular to the best of my knowledge, information and belief.

Date

Signed

Form 6

(Section 32)

Application for renewal of registration of premises

I
[full name]

of
[residential address]

apply (on behalf of)
[insert company name if applicable]

.....
for renewal of registration of premises at

.....
for the year

Date

Signed

Schedule 3—Revocation of *Pharmacists Regulations 1991*

The *Pharmacists Regulations 1991* are revoked.

Legislative history

Notes

- For further information relating to the Act and subordinate legislation made under the Act see the Index of South Australian Statutes or www.legislation.sa.gov.au.

Revocation of regulations

The *Pharmacists Regulations 2006* were revoked by Sch 1 cl 1 of the *Pharmacy Practice Regulations 2007* on 8.11.2007.

Principal regulations

Year	No	Reference	Commencement
2006	219	<i>Gazette 31.8.2006 p3096</i>	1.9.2006: r 2