



New South Wales

Pharmacy (General) Regulation 1998

under the

Pharmacy Act 1964

His Excellency the Lieutenant-Governor, with the advice of the Executive Council, has made the following Regulation under the *Pharmacy Act 1964*.

ANDREW REFSHAUGE, M.P.

Minister for Health

Explanatory note

The object of this Regulation is to repeal and remake the provisions of the *Pharmacy (General) Regulation 1993*. The new Regulation makes provisions with respect to the following matters:

- (a) the registration of pharmacists (Part 2),
- (b) the requirements to be observed in the conduct of pharmacies (Part 3),
- (c) other matters of a minor, consequential or ancillary nature (Parts 1 and 4).

This Regulation is made under the *Pharmacy Act 1964*, including section 38 (the general regulation-making power) and various other sections referred to in the Regulation.

This Regulation is made in connection with the staged repeal of subordinate legislation under the *Subordinate Legislation Act 1989*.

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Clause 1 Pharmacy (General) Regulation 1998

Part 1 Preliminary

Pharmacy (General) Regulation 1998

Part 1 Preliminary

1 Name of Regulation

This Regulation is the *Pharmacy (General) Regulation 1998*.

2 Commencement

This Regulation commences on 1 September 1998.

3 Notes

The explanatory note and table of contents do not form part of this Regulation.

4 Definitions

In this Regulation:

pecuniary interest includes a direct or indirect pecuniary interest.

pharmacy business means the business of a pharmacist carried on in a pharmacy.

the Act means the *Pharmacy Act 1964*.

Part 2 Registration of pharmacists

5 Applications for registration

An application for registration as a pharmacist is to be made in a form approved by the Board.

6 Qualifications for registration: prescribed university (section 13)

For the purposes of section 13 (1) (a) of the Act, Charles Sturt University is a prescribed university.

7 Qualifications for registration: prescribed period of work as assistant (section 13)

- (1) For the purposes of section 13 (1) (b) of the Act, the prescribed period as an assistant is 2,000 hours.
- (2) In calculating the number of hours that a person has served as an assistant, the following periods are not to be included:
 - (a) in the case of a person who has commenced a course leading to a first degree in pharmacy between 1 September 1993 and 1 October 1995:
 - (i) any period served before the person's successful completion of the first academic year of the course, and
 - (ii) any hours above 300 served during the period between the person's successful completion of that year and the person's successful completion of the course,
 - (b) in the case of a person who commences a course leading to a first degree in pharmacy after 1 October 1995, any period served before the person's successful completion of the course,
 - (c) in all cases:
 - (i) any period of less than 30 hours served in any one week, and
 - (ii) any hours above 45 served in any one week, and
 - (iii) any period of less than 150 hours served in any one location.

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Part 2 Registration of pharmacists

- (3) Subclauses (1) and (2) do not apply to persons who commenced a course for a degree in pharmacy before 1 September 1993.
- (4) Regulation 30A of the Pharmacy Regulations (as in force immediately before 1 September 1993) continues to apply to persons who commenced a course for a degree in pharmacy after 22 February 1991 and before 1 September 1993.

8 Qualifications for registration: interstate and overseas applicants (section 14)

For the purposes of section 14 of the Act, the qualifications listed in Schedule 1 are prescribed qualifications.

9 Certificates of registration (sections 17, 17A)

- (1) For the purposes of section 17 (2) of the Act, the prescribed form for a certificate of registration is the form set out as Form 1 in Schedule 2.
- (2) For the purposes of section 17A (1) and (2) of the Act, the prescribed form for a certificate of provisional registration is the form set out as Form 2 in Schedule 2.
- (3) The Board may issue a duplicate certificate of registration or certificate of provisional registration, on payment of the fee fixed by the Board, if it is satisfied that the original certificate has been lost, destroyed or mutilated.

10 Certificates of identity

The Registrar may, at the request of a pharmacist, issue a certificate of identity, in a form approved by the Board, on payment of the fee fixed by the Board.

11 Applications for restoration of name to register (section 19)

- (1) An application for restoration of the name of a pharmacist to the register must be in a form approved by the Board.
- (2) The Board may waive such part of the fee payable under section 19 (4) of the Act as it may, in any particular case, consider proper.

Part 3 Pharmacies

12 Approval of pharmacy premises: standards to be complied with (section 24A)

- (1) For the purposes of section 24A (4) of the Act, the following standards for premises are prescribed:
 - (a) at least one doorway allowing direct public access to the premises is to be provided,
 - (b) secure doors, windows and roof are to be provided,
 - (c) the premises are to be equipped with a dispensing area of at least 8 square metres or such lesser area as the Board may approve in a particular case,
 - (d) a refrigerator suitable for the storage of biological and pharmaceutical products at appropriate temperatures is to be provided.
- (2) The dispensing area referred to in subclause (1) (c):
 - (a) must have adequate lighting and ventilation, and
 - (b) must have adequate heating facilities for dispensing and compounding drugs and medicines, and
 - (c) must be equipped with a stainless steel or similarly impervious sink, being a sink that has an impervious surround and is supplied with hot and cold running water, and
 - (d) must have a dispensing 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.

13 Branch pharmacies (section 26)

- (1) An application for an approval of premises as suitable for a branch pharmacy is to be made to the Registrar in a form approved by the Board and is to be accompanied by the fee fixed by the Board.
- (2) The Board may reject the application or may approve the premises concerned as being suitable for carrying on a pharmacy business.

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Part 3 Pharmacies

- (3) Premises are not to be approved:
 - (a) if they fail to comply with the standards set out in clause 12, or
 - (b) if they are to operate as a branch pharmacy for more than 25 hours a week, or
 - (c) if they are on or near premises approved by the Board under section 24A of the Act, or
 - (d) if they fail to comply with such other conditions or requirements as the Board determines.
- (4) An approval remains in force for the period of 12 months from the date on which it was given.
- (5) The Board may, by written notice served on the pharmacist in charge of a branch pharmacy, revoke an approval at any time if the premises concerned are found not to comply with any condition referred to in subclause (3).

14 After-hours pharmacies: changes in partnership agreements etc

- (1) If the members of a partnership conducting an after-hours pharmacy execute an agreement relating to the conduct of the pharmacy, a copy of the agreement must be lodged with the Registrar within 14 days after execution.
- (2) If there is an alteration in the name, place of business or residential address of a member of a partnership conducting an after-hours pharmacy, particulars of the alteration must be lodged with the Registrar within 14 days after it occurs.
- (3) Before being lodged, a copy of an agreement or particulars of an alteration must be certified as correct by each member of the partnership.
- (4) Each member of the partnership must ensure that the requirements of this clause are complied with.
Maximum penalty (subclause (4)): 2 penalty units.
- (5) Compliance with the requirements of subclauses (1) and (2) by any one of the members of the partnership is taken to be compliance by them all.

15 Notice of acquisition or disposal of interest in pharmacy

- (1) A person who intends to acquire any pecuniary interest in a pharmacy business (whether by purchase or otherwise) must cause written notice of the intended acquisition to be given to the Board at least 14 days before acquiring the interest.

Maximum penalty: 2 penalty units.

- (2) A person who ceases to have a pecuniary interest in a pharmacy business must, within 14 days after doing so, cause written notice of that fact to be given to the Board.

Maximum penalty: 2 penalty units.

- (3) The notices referred to in subclauses (1) and (2) must be in a form approved by the Board and must be accompanied by copies of the following:

- (a) any bill of sale referred to in the notice,
- (b) any sale agreement for the business,
- (c) any partnership agreement for the business,
- (d) any lease for the pharmacy,
- (e) any agreement under which any other person has a pecuniary interest in the business.

- (4) Subclause (2) does not apply to a person who has ceased to have an interest in a pharmacy business because the person's name has been removed from the Register or because the person is suspended from practising as a pharmacist.

- (5) A company carrying on a pharmacy business must, within 14 days after any change in composition of the board of directors of the company, cause written notice of that fact to be given to the Board.

Maximum penalty: 2 penalty units.

- (6) The notice must be in a form approved by the Board.

- (7) A person must not, in any notice under this clause, make any statement that the person knows to be false or misleading in a material particular.

Maximum penalty: 2 penalty units.

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Clause 16 Pharmacy (General) Regulation 1998

Part 3 Pharmacies

16 Advertising

- (1) The owner of a pharmacy must cause to be displayed:
 - (a) at or near the main entrance of the pharmacy, the name of the owner of the pharmacy business, and
 - (b) adjacent to the area where dispensing is carried on, the name of the pharmacist in charge of the pharmacy followed by the words "PHARMACIST IN CHARGE".

Maximum penalty: 2 penalty units.

- (2) An advertisement that relates to a pharmacy or pharmacy services must not:
 - (a) be false, misleading or deceptive, or
 - (b) create an unjustified expectation of beneficial treatment or give any warranty of satisfaction, or
 - (c) promote the unnecessary or inappropriate use of pharmacy services, or
 - (d) claim or imply superiority for a pharmacist in the practice of pharmacy.
- (3) A person who publishes, or causes to be published, an advertisement in contravention of subclause (2) is guilty of an offence.

Maximum penalty: 2 penalty units.

17 Equipment etc to be kept in pharmacy

A person carrying on a pharmacy business must install and maintain in the pharmacy the equipment, appliances and publications listed in Schedule 3.

Maximum penalty: 2 penalty units.

Part 4 Miscellaneous

18 Registrar to be Secretary to the Board etc

The Registrar is also the Secretary to the Board and any committee (other than a professional standards committee) established by the Board.

19 Dispensing by medical practitioners: when permitted (section 28)

For the purposes of section 28 (2) (c) of the Act, each of the following are prescribed circumstances in which a medical practitioner may dispense medicine in the ordinary course of medical practice:

- (a) that the practitioner is issued with an approval number for dispensing by the Commonwealth Health Insurance Commission.
- (b) that the practitioner is employed by the Family Planning Association of New South Wales, practises in a clinic or premises operated by that Association and dispenses medicine (for use in connection with family planning) to persons attending the clinic or premises.

20 Death of pharmacist to be notified (section 29)

- (1) This clause applies to the executor of the will, or the administrator or trustee of the estate, of a deceased person who was carrying on a pharmacy business at the date of his or her death, being an executor, administrator or trustee who carries on the business, or proposes to carry on the business, pursuant to section 29 of the Act.
- (2) An executor, administrator or trustee to whom this clause applies must, within 90 days after the death of the pharmacist, cause written notice to be sent to the Registrar of:
 - (a) the fact that the pharmacist has died, and
 - (b) the date of the pharmacist's death, and
 - (c) the fact that the executor, administrator or trustee carries on the business, or proposes to carry on the business, pursuant to section 29 of the Act.

Maximum penalty: 2 penalty units.

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Clause 21 Pharmacy (General) Regulation 1998

Part 4 Miscellaneous

21 Savings provision: pecuniary interests before 5.10.1990 (section 25)

- (1) For the purposes of section 25 (2) (c) of the Act, an individual, a body corporate or an unincorporated body is not prevented from having a pecuniary interest in a pharmacy business:
 - (a) if the interest in the business is of a kind referred to in section 25 (2) (b)–(f) of the Act as in force immediately before 5 October 1990 (the day on which those provisions were repealed), and
 - (b) if the pecuniary interest is the same interest in the same business as the individual, body corporate or unincorporated body had immediately before 5 October 1990.
- (2) This clause does not apply to a person whose name has been removed from the Register or who is suspended from practising as a pharmacist.

22 Repeal

- (1) The *Pharmacy (General) Regulation 1993* is repealed.
- (2) Any act, matter or thing that, immediately before the commencement of this Regulation, had effect under the *Pharmacy (General) Regulation 1993* is taken to have effect under this Regulation.

Schedule 1 Interstate and overseas qualifications

(Clause 8)

<i>Qualification</i>	<i>Granted by:</i>
<i>Victoria</i>	
Final Examination Certificate	Pharmacy Board of Victoria
<i>Queensland</i>	
Prescribed Certificate of Fitness issued after examination	Pharmacy Board of Queensland
Degree or Diploma in Pharmacy	University of Queensland
<i>South Australia</i>	
Standard Certificate issued prior to 9 December 1965	Pharmacy Board of South Australia
Bachelor of Pharmacy	University of South Australia
Degree in Pharmacy	University of Adelaide
Diploma in Pharmacy	South Australian Institute of Technology
Degree in Pharmacy	South Australian Institute of Technology
Diploma in Pharmacy	University of Adelaide
Degree in Pharmacy of Joint Faculty of University of Adelaide	South Australian Institute of Technology
<i>Western Australia</i>	
Bachelor of Pharmacy	Curtin University, Western Australia
Diploma in Pharmacy	Perth Technical College, Western Australia
Associateship in Pharmacy	Western Australian Institute of Technology
Bachelor of Science in Pharmacy	Western Australian Institute of Technology
<i>Tasmania</i>	
Qualifying Examination Pass	Pharmacy Board of Tasmania
Bachelor of Pharmacy	University of Tasmania
Diploma in Pharmacy	Tasmanian College of Advanced Education
Bachelor of Applied Science in Pharmacy	Tasmanian College of Advanced Education

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Schedule 1 Interstate and overseas qualifications

New Zealand

Qualifying Examination Pass prior to 1963	Pharmacy Board of New Zealand
Pharmacy Professional Examination Pass	A board of Examiners constituted under the Pharmacy Act 1939 of the General Assembly of New Zealand
Bachelor of Pharmacy	University of Otago, New Zealand
Diploma in Pharmacy	Central Institute of Technology, New Zealand

Schedule 2 Forms

(Clause 9)

Form 1

Certificate of Registration

(Pharmacy Act 1964)

(section 17 (2))

Pharmacy Board of New South Wales

This is to certify that the name of
was entered in the Register of Pharmacists for New South Wales under the
Pharmacy Act 1964 on the day of 19.....

.....

Registrar

Form 2

Certificate of Provisional Registration

(Pharmacy Act 1964)

(section 17A)

Pharmacy Board of New South Wales

No

This is to certify that
is provisionally registered as a Pharmacist until the day of
..... 19.....

.....

(President/Board Member)

Date

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Schedule 3 Equipment, appliances and publications to be installed and maintained
in a pharmacy

**Schedule 3 Equipment, appliances and
publications to be installed and
maintained in a pharmacy**

(Clause 17)

Equipment and appliances

Dispensing balance

Heavy duty scales, capable of weighing up to 1 kg

1 set of metric weights

Dispensing measures:

1 x 500 ml measure

1 x 200 ml measure

 x 100 ml measure

1 x 20 ml measure

1 x 10 ml measure or graduated pipette

1 x 5 ml measure or graduated pipette

Adequate supplies of filter paper

2 Funnels

2 Mortars and pestles (one, at least, of glass)

2 Stirring rods

2 Spatulas

1 Ointment slab

1 Table counting tray

Publications

Poisons and Therapeutic Goods Act 1966, and the Regulations under that Act. together with the Poisons List proclaimed under section 8 of that Act or the Guide to the New South Wales Poisons Schedules published by the Pharmacy Guild of Australia (New South Wales Branch)

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Equipment, appliances and publications to be installed and maintained in a pharmacy Schedule 3

Pharmacy Act 1964, and Pharmacy (General) Regulation 1998

The latest editions of, and all published amendments and supplements to, the following publications, or other equivalents approved by the Board:

Martindale -The Extra Pharmacopoeia
Australian Pharmaceutical Formulary
Australian Prescription Products Guide or MIMS Annual or
Drugs on Disk
Handbook for Patient Medication Counselling