

South Australia

Health Practitioner Regulation National Law (South Australia) Regulations 2010

under the *Health Practitioner Regulation National Law (South Australia) Act 2010*

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Legislative history

1—Short title

These regulations may be cited as the *Health Practitioner Regulation National Law (South Australia) Regulations 2010*.

3—Interpretation

In these regulations—

Act means the *Health Practitioner Regulation National Law (South Australia) Act 2010*;

PRASA means the Pharmacy Regulation Authority SA constituted under Part 4 of the Act;

therapeutic goods has the same meaning as in the *Therapeutic Goods Act 1989* of the Commonwealth.

4—Representative bodies

The following bodies are declared to be *representative bodies* for the purposes of the Act:

- (aaa) Ambulance Employees Association SA Inc;
- (a) Australasian College of Podiatric Surgeons;
- (aa) Australian Acupuncture and Chinese Medicine Association;
- (ab) Australian and New Zealand Society of Nuclear Medicine (SA Branch) Limited;
- (b) Australian College of Mental Health Nurses (SA Branch) Incorporated;
- (c) Australian College of Midwives (SA Branch) Incorporated;
- (d) Australian Dental Association South Australian Branch Incorporated;
- (e) Australian Dental Prosthetists Association (SA) Incorporated;
- (f) Australian Friendly Societies Pharmacies Association Incorporated;
- (fa) Australian Institute of Radiography;
- (g) Australian Medical Association (South Australia) Incorporated;
- (ga) Australian Natural Therapists Association;
- (h) Australian Nursing and Midwifery Federation (SA Branch);
- (i) Australian Osteopathic Association;
- (j) Australian Pharmacy Council Ltd;
- (k) Australian Physiotherapy Association;
- (l) Australian Physiotherapy Council;
- (m) Australian Podiatry Association SA Incorporated;
- (n) The Australian Psychological Society (SA Branch) Ltd;
- (na) Australian Traditional-Medicine Society;
- (nb) Chinese Medicine and Acupuncture Society of Australia;
- (o) Chiropractors' Association of Australia (South Australia) Limited;
- (p) Council on Chiropractic Education Australasia Incorporated;
- (q) The Dental Hygienists' Association of Australia (SA Branch) Incorporated;
- (qa) Federation of Chinese Medicine and Acupuncture (SA Branch);
- (r) Health Consumers Alliance of South Australia Incorporated;
- (s) Institute of Private Practising Psychologists Inc.;
- (sa) National Aboriginal and Torres Strait Islander Health Worker Association;
- (sb) Occupational Therapy Australia Limited, South Australia Division;
- (t) Optometry South Australia Incorporated;
- (ta) Paramedics Australasia Ltd (SA Chapter);

- (u) Pharmaceutical Society of Australia (South Australian Branch) Incorporated;
- (v) The Pharmacy Guild of Australia (SA Branch);
- (w) Royal College of Nursing, Australia;
- (x) The Society of Hospital Pharmacists of Australia (SA & NT Branch);
- (xa) Society of Natural Therapists and Researchers Incorporated;
- (y) South Australian Dental Therapists' Association Incorporated;
- (z) SA Salaried Medical Officers Association.

4A—Prescribed body

For the purposes of section 82(3)(c) of the Act, Standards Australia is a prescribed body.

5—Restricted pharmacy services

For the purposes of the definition of *restricted pharmacy services* in section 26(1) of the Act, the following services are declared to be restricted pharmacy services:

- (a) the assessment of a medication, whether on account of a prescription, recommendation or request, followed by the selection and preparation of the medication and its supply (with or without information about health outcomes associated with the medication);
- (b) the custody, control or dispensing, provision and management of therapeutic goods, health care products and other products or items commonly associated with the practice of a pharmacist;
- (c) the provision of information and other services commonly associated with the practice of a pharmacist.

6—Registration of premises as pharmacy

- (1) For the purposes of section 41(3)(a) of the Act, premises proposed to be registered as a pharmacy must—
 - (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 kept in a hygienic condition and be adequately ventilated; and
 - (d) have provision for adequate lighting; and
 - (e) have provision for temperature control of therapeutic goods and health care products; and
 - (f) contain adequate provision for the safe, secure and hygienic storage of therapeutic goods and health care products; and
 - (g) contain adequate provision for the safe and secure storage of confidential and sensitive information; and

- (h) 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 provision of restricted pharmacy services and the activities of persons in that part of the premises.
- (2) For the purposes of the definition of **supermarket** in section 41(10) of the Act, a supermarket is a store or market the primary business of which is the sale of a range of food, beverages, groceries and other domestic goods.

7—Registration of premises as pharmacy depot

For the purposes of section 45(2)(a) of the Act, premises proposed to be registered as a pharmacy depot must—

- (a) have provision for temperature control of therapeutic goods and health care products; and
- (b) contain adequate provision for the safe, secure and hygienic storage of therapeutic goods and health care products; and
- (c) contain adequate provision for the safe and secure storage of confidential and sensitive information.

8—Registration as pharmacy services providers

- (1) For the purposes of section 49 of the Act, the following information must be provided to PRASA by a pharmacy services provider if the pharmacy services provider, or a prescribed relative of the pharmacy services provider, has an interest in a prescribed business:
 - (a) the full name and residential and postal address of the person who has the interest; and
 - (b) if the person who has the interest is a prescribed relative of a registered person—the relationship of the person to the registered person; and
 - (c) the name, address and nature of the prescribed business in which the person has the interest; and
 - (d) the nature of the interest and of any benefit derived from the interest; and
 - (e) if the interest consists of a shareholding in a prescribed business—the number, nominal value and class of shares held and particulars of any voting rights exercisable by the holder at a meeting of shareholders.
- (2) A pharmacy services provider must, within 30 days after a change in the nature or extent of an interest under subregulation (1), give to PRASA information about the change (in accordance with any requirements determined by PRASA).

Maximum penalty: \$5 000.

- (3) In this regulation—

health product means a pharmaceutical product;

health service means—

- (a) hospital, nursing home or aged care facility services; or
- (b) medical, dental or pharmaceutical services; or

- (c) chiropractic, occupational therapy, optometry, osteopathy, physiotherapy, podiatric or psychology services;

prescribed business means a business consisting of or involving—

- (a) the provision of a health service; or
- (b) the manufacture, sale or supply of a health product;

prescribed relative has the same meaning as in Part 4 of the Act.

9—Provision of restricted pharmacy services by unqualified persons—prescribed circumstances

Pursuant to section 51(3)(a) of the Act, restricted pharmacy services may be provided by the Little Company of Mary Health Care Limited at Calvary Hospital at North Adelaide through the instrumentality of a pharmacist who holds a current practising certificate.

10—Information relating to claim against pharmacy services provider to be provided

- (1) For the purposes of section 69(1)(a) of the Act, the information relating to a claim referred to in that section to be provided to PRASA within 30 days after the claim is made is—
 - (a) the nature of the pharmacy service that is alleged to have been carried out negligently; and
 - (b) full details of the alleged negligence; and
 - (c) the address of the premises at which the negligence is alleged to have occurred; and
 - (d) the time at which and the date on which the negligence is alleged to have occurred; and
 - (e) full details of the injury suffered or allegedly suffered by the claimant as a result of the alleged negligence; and
 - (f) the date of the claim.
- (2) For the purposes of section 69(1)(b) of the Act, the information relating to the claim referred to in that section to be provided to PRASA within 30 days after any order is made by a court to pay damages or other compensation in respect of that claim or any agreement has been entered into for payment of a sum of money in settlement of that claim (whether with or without a denial of liability) is—
 - (a) information adequate to identify the claim; and
 - (b) details of any change in information previously provided to PRASA relating to the claim; and
 - (c) details of the order or agreement (including the amount ordered or agreed to be paid).

11—Fees

- (1) The PRASA may fix—
 - (a) fees or charges for the purposes of Part 4 of the Act;

- (b) fees or charges for services provided by PRASA in the exercise of its functions under Part 4 of the Act.
- (2) PRASA may recover a fee or charge fixed under this regulation by action in a court of competent jurisdiction as a debt due to PRASA from the person liable for payment of the fee or charge.

11AA—Sale of glasses—section 74

- (1) For the purposes of section 74(2)(c) of the Act and subject to the modifications set out in subregulation (2), glasses are manufactured to the prescribed standard if they are manufactured in accordance with *Australian/New Zealand Standard ISO 16034:2011* (as in force from time to time).
- (2) *Australian/New Zealand Standard ISO 16034:2011* is modified such that—
 - (a) clause 4.2 does not apply; and
 - (b) the following requirements of clause 5.2 do not apply:
 - (i) the requirement that a warning of the unsuitability of the glasses for driving or road use be indicated by the symbol given in Figure 1;
 - (ii) the requirement that a legible warning notice (as set out in the box entitled "WARNING" in clause 5.2) be given in the form of a label or swing tag affixed to the glasses.

Note—

Regulation 11AA(3) sets out the prescribed warning to be attached to the glasses.

- (3) For the purposes of section 74(2)(d) of the Act—
 - (a) the following warning is prescribed:

WARNING

These glasses are for near-vision and reading use only.

The lenses in these glasses are NOT prescription lenses. They are not intended as a substitute for glasses specifically prescribed for you.

These glasses are not suitable—

- for use whilst driving or operating a vehicle; or
- for use as eye protection.

Poor vision may be the result of a disease of the eye and a regular examination by an optometrist is recommended to ensure that any eye disease is detected early.

- (b) the prescribed warning in paragraph (a) must be attached to the glasses—
 - (i) by a string or cord; or
 - (ii) by sticking the warning onto the glasses; or
 - (iii) in any other manner such that the warning does not detach from the glasses in the ordinary course of inspecting and selecting the glasses.

12—Transitional provision—staff

- (1) For the purposes of the definition of ***designated period*** in clause 37(4) of Schedule 1 of the Act, the period of 3 months from the day on which the person is determined by the National Agency to be excess to the requirements of the National Agency is prescribed.
- (2) For the purposes of the definition of ***qualifying member of the staff of a prescribed body***, 30 June 2010 is prescribed in relation to each prescribed body.

13—Transitional provision—annual reports

- (1) The National Agency must, on or before 30 September 2012, deliver to the Minister a report on the activities of the Occupational Therapy Board of South Australia during the 2011/2012 financial year.
- (2) The report must—
 - (a) contain the following information in relation to the 2011/2012 financial year:
 - (i) the number of persons registered by the Board in each category of registration under the *Occupational Therapy Practice Act 2005*, as at 30 June 2012;
 - (ii) the number of complaints received by the Board against registered persons or service providers under the *Occupational Therapy Practice Act 2005*, and the outcome of each complaint (including, if relevant, progress as at 30 June 2012);
 - (iii) the number of disciplinary proceedings commenced by or on behalf of, or before, the Board under the *Occupational Therapy Practice Act 2005*, and the outcome of each of those proceedings (including, if relevant, progress as at 30 June 2012); and
 - (b) incorporate the audited accounts of the Board for the 2011/2012 financial year.
- (3) The Minister must, within 12 sitting days after receiving the report under subregulation (1), have copies of the report laid before both Houses of Parliament.
- (4) In this regulation—

National Agency means the Australian Health Practitioner Regulation Agency.

14—Transitional provisions—occupational therapy

- (1) The Occupational Therapy Board of South Australia is brought within the ambit of the definition of ***prescribed body*** in clause 29 of Schedule 1 of the Act.
- (2) No application may be made to the Occupational Therapy Board of South Australia under Part 3 Division 2 of the *Occupational Therapy Practice Act 2005* on or after 1 July 2012.
- (3) For the purposes of clauses 42 and 43 of Schedule 1 of the Act, the *Occupational Therapy Practice Act 2005* will be taken to be a relevant Act that has been repealed under that schedule on 1 July 2012.

Schedule 1—Revocation of regulations

1—Revocation of regulations

The following regulations are revoked:

- (a) the *Occupational Therapy Practice (Election) Regulations 2006*;
- (b) the *Occupational Therapy Practice (General) Regulations 2006*.

Legislative history

Notes

- Please note—References in the legislation to other legislation or instruments or to titles of bodies or offices are not automatically updated as part of the program for the revision and publication of legislation and therefore may be obsolete.
- Earlier versions of these regulations (historical versions) are listed at the end of the legislative history.
- 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.

Legislation revoked by principal regulations

The *Health Practitioner Regulation National Law (South Australia) Regulations 2010* revoked the following:

Chiropractic and Osteopathy Practice (Election) Regulations 2006

Chiropractic and Osteopathy Practice (General) Regulations 2006

Dental Practice (Election) Regulations 2007

Dental Practice (General) Regulations 2007

Medical Practice (Elections) Regulations 2005

Medical Practice (General) Regulations 2005

Nursing and Midwifery Practice Regulations 2009

Optometry Practice (Elections) Regulations 2007

Optometry Practice (General) Regulations 2007

Pharmacy Practice Regulations 2007

Physiotherapy Practice (Election) Regulations 2006

Physiotherapy Practice (General) Regulations 2006

Podiatry Practice (Election) Regulations 2006

Podiatry Practice (General) Regulations 2006

Psychological Practices Regulations 1996

Principal regulations and variations

New entries appear in bold.

Year	No	Reference	Commencement
2010	169	<i>Gazette 1.7.2010 p3363</i>	1.7.2010: r 2
2012	168	<i>Gazette 28.6.2012 p2935</i>	1.7.2012: r 2
2012	275	<i>Gazette 20.12.2012 p6251</i>	20.12.2012: r 2
2014	225	<i>Gazette 14.8.2014 p4042</i>	1.9.2014: r 2

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2018	47	<i>Gazette 13.2.2018 p797</i>	12.3.2018: r 2
2018	230	<i>Gazette 29.11.2018 p4094</i>	1.12.2018: r 2
2019	38	<i>Gazette 16.5.2019 p1293</i>	1.7.2019: r 2—disallowed on 16.10.2019 (<i>Gazette 24.10.2019 p3547</i>)

Provisions varied

New entries appear in bold.

Entries that relate to provisions that have been deleted appear in italics.

Provision	How varied	Commencement
r 2	<i>omitted under Legislation Revision and Publication Act 2002</i>	1.7.2012
r 4	varied by 168/2012 r 4(1)—(7)	1.7.2012
	varied by 47/2018 r 4(1), (2)	12.3.2018
r 4A	inserted by 47/2018 r 5	12.3.2018
r 11		
r 11(1)	varied by 275/2012 r 4	20.12.2012
r 11AA	inserted by 47/2018 r 6	12.3.2018
r 11A	<i>inserted by 225/2014 r 4</i>	1.9.2014
	<i>deleted by 230/2018 r 4</i>	1.12.2018
	<i>inserted by 38/2019 r 4</i>	1.7.2019—disallowed 16.10.2019
rr 11B—11F	<i>inserted by 38/2019 r 4</i>	1.7.2019—disallowed 16.10.2019
r 13		
r 13(1) and (2)	substituted by 168/2012 r 5(1)	1.7.2012
r 13(4)		
<i>prescribed body</i>	<i>deleted by 168/2012 r 5(2)</i>	1.7.2012
<i>relevant Act</i>	<i>deleted by 168/2012 r 5(2)</i>	1.7.2012
r 14	inserted by 168/2012 r 6	1.7.2012
Sch 1		
cl 1	substituted by 168/2012 r 7	1.7.2012

Historical versions

1.7.2012
20.12.2012
1.9.2014
12.3.2018
1.12.2018
1.7.2019