

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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1—Short title

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

2—Commencement

These regulations will come into operation on the day on which the *Health Practitioner Regulation National Law (South Australia) Act 2010* comes into operation.

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:

- (a) Australasian College of Podiatric Surgeons;
- (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;
- (g) Australian Medical Association (South Australia) Incorporated;
- (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;
- (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;
- (r) Health Consumers Alliance of South Australia Incorporated;
- (s) Institute of Private Practising Psychologists Inc.;
- (t) Optometrists Association Australia (SA Division) Incorporated;
- (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);
- (y) South Australian Dental Therapists' Association Incorporated;
- (z) SA Salaried Medical Officers Association.

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 Minister 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.

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 2010, deliver to the Minister a report on the activities of each prescribed body during the 2009/2010 financial year.
- (2) The report must, in relation to each prescribed body—
 - (a) contain the following information in relation to the 2009/2010 financial year:
 - (i) the number of persons registered by the prescribed body in each category of registration under its relevant Act, as at 30 June 2010;
 - (ii) the number of complaints received by the prescribed body against registered persons or service providers under its relevant Act, and the outcome of each such complaint (including, if relevant, progress on as at 30 June 2010);
 - (iii) the number of disciplinary proceedings commenced by or on behalf of, or before, the prescribed body under its relevant Act, and the outcome of each of those proceedings (including, if relevant, progress as at 30 June 2010); and
 - (b) incorporate the audited accounts of the prescribed body for the 2009/2010 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;

prescribed body means a prescribed body under Part 18 of Schedule 1 of the Act;

relevant Act, in relation to a prescribed body, means the Act under which the prescribed body was constituted (being an Act repealed under Part 17 of Schedule 1 of the Act).

Schedule 1—Revocation of regulations

1—Revocation of regulations

The following regulations are revoked:

- (a) the *Chiropractic and Osteopathy Practice (Election) Regulations 2006*;
- (b) the *Chiropractic and Osteopathy Practice (General) Regulations 2006*;
- (c) the *Dental Practice (Election) Regulations 2007*;
- (d) the *Dental Practice (General) Regulations 2007*;
- (e) the *Medical Practice (Elections) Regulations 2005*;
- (f) the *Medical Practice (General) Regulations 2005*;
- (g) the *Nursing and Midwifery Practice Regulations 2009*;
- (h) the *Optometry Practice (Elections) Regulations 2007*;
- (i) the *Optometry Practice (General) Regulations 2007*;
- (j) the *Pharmacy Practice Regulations 2007*;

- (k) the *Physiotherapy Practice (Election) Regulations 2006*;
- (l) the *Physiotherapy Practice (General) Regulations 2006*;
- (m) the *Podiatry Practice (Election) Regulations 2006*;
- (n) the *Podiatry Practice (General) Regulations 2006*;
- (o) the *Psychological Practices Regulations 1996*.

Note—

As required by section 10AA(2) of the *Subordinate Legislation Act 1978*, the Minister has certified that, in the Minister's opinion, it is necessary or appropriate that these regulations come into operation as set out in these regulations.

Made by the Governor

with the advice and consent of the Executive Council
on 1 July 2010

No 169 of 2010

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