South Australia

Pharmacy Practice Regulations 2007

under the Pharmacy Practice Act 2007

Contents

- 1 Short title
- 2 Commencement
- 3 Interpretation
- 4 Representative bodies
- 5 Annual report
- 6 Authority conferred by registration as pharmacy student
- 7 Fees and returns
- 8 Registration of premises as pharmacy
- 9 Registration of premises as pharmacy depot
- 10 Provision of restricted pharmacy services by unqualified persons—prescribed circumstances
- 11 Obligation to report medical unfitness or unprofessional conduct of pharmacist or pharmacy student
- 12 Registered person etc must declare interest in prescribed business
- 13 Information relating to claim against registered person to be provided
- 14 Fees

Schedule 1-Revocation and transitional provision

Part 1-Revocation of Pharmacists Regulations 2006

1 Revocation of regulations

Part 2—Transitional provision

2 Transitional matter

1—Short title

These regulations may be cited as the Pharmacy Practice Regulations 2007.

2—Commencement

These regulations will come into operation on the day on which the *Pharmacy Practice Act 2007* comes into operation.

3—Interpretation

In these regulations—

Act means the Pharmacy Practice Act 2007;

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

4—Representative bodies

For the purposes of the definition of *representative body* in section 3(1) of the Act, each of the following is a representative body:

- (a) Australian Friendly Societies Pharmacies Association Incorporated;
- (b) Australian Pharmacy Council Incorporated;
- (c) Pharmaceutical Society of Australia (South Australian Branch) Incorporated;
- (d) The Pharmacy Guild of Australia (SA Branch);
- (e) The Society of Hospital Pharmacists of Australia (SA & NT Branch);
- (f) Health Consumers Alliance of South Australia Incorporated.

5—Annual report

- (1) For the purposes of section 23(2)(a)(iv) of the Act, the following information is to be included in the Board's annual report in relation to the relevant financial year:
 - (a) the number of persons registered in each category of registration;
 - (b) the number of persons in each category of registration registered with limited registration;
 - (c) the number of pharmacy services providers who have given notice to the Board under section 42(1) of the Act;
 - (d) the number of complaints received by the Board against registered persons, pharmacy services providers or persons who occupy positions of authority in corporate pharmacy services providers from persons of Aboriginal or Torres Strait Islander descent;
 - (e) the number of persons included on the register of persons who have been prohibited by order of the Board from carrying on business as a pharmacy services provider or occupying a position of authority in a corporate pharmacy services provider;
 - (f) the number of disciplinary proceedings commenced before the Board and the outcomes of those proceedings;
 - (g) a statement of whether codes of conduct or professional standards for registered persons or codes of conduct for pharmacy services providers have been prepared or endorsed by the Board and, if so, a summary of the codes or standards;
 - (h) a statement of whether practice rules of the kind referred to in section 13(1)(e) of the Act have been prepared or endorsed by the Board and, if so, a summary of the practice rules;
 - (i) a description of any committees established by the Board and the purposes for which they were established;
 - (j) the number of persons in each category of registration in respect of whom reports have been received by the Board under section 51(1) of the Act;
 - (k) the number of persons in each category of registration in respect of whom reports have been received by the Board under section 51(2) of the Act;

- (1) the number and nature of orders made by the Board under section 52 of the Act;
- (m) the number of persons in each category of registration who have submitted information to the Board under section 63(1) of the Act;
- (n) the number of persons in each category of registration in respect of whom notices have been received by the Board under section 68 of the Act;
- (o) the number of claims in respect of which information has been provided to the Board under section 71(1) of the Act;
- (p) the number of claims in respect of which information has been provided to the Board under section 71(2) of the Act;
- (q) the number of persons found guilty of an offence against the Act, the nature of the offences and the penalties imposed.
- (2) Information presented in relation to the relevant financial year should be presented in a manner enabling it to be compared with statistical data from previous years.

6—Authority conferred by registration as pharmacy student

For the purposes of section 25(1)(a) of the Act, registration on the pharmacy student register authorises the person to provide pharmacy services under the direct supervision of a pharmacist who holds a current practising certificate.

7—Fees and returns

Section 31(2) of the Act does not apply to a person registered on the pharmacy student register.

8—Registration of premises as pharmacy

- (1) For the purposes of section 37(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 37(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.

9—Registration of premises as pharmacy depot

For the purposes of section 41(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.

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

Pursuant to section 43(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.

11—Obligation to report medical unfitness or unprofessional conduct of pharmacist or pharmacy student

- (1) For the purposes of section 51(1) of the Act, the following information is required to be included in a report to the Board:
 - (a) the diagnosis of the condition of the pharmacist or pharmacy student and its likely duration and prognosis;
 - (b) if the person making the report is of the opinion that the pharmacist or pharmacy student may be medically unfit to provide pharmacy services only in a particular branch of pharmacy—a statement specifying the particular branch of pharmacy and the reasons for the opinion.
- (2) For the purposes of section 51(2) of the Act, the following information is required to be included in a report to the Board:
 - (a) the date, time and place at which it is alleged the pharmacist or pharmacy student engaged in unprofessional conduct;
 - (b) the nature of the alleged unprofessional conduct.

12—Registered person etc must declare interest in prescribed business

- (1) For the purposes of section 63(1) of the Act, the information that must be given to the Board by a person who has an interest in a prescribed business is—
 - (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) For the purposes of section 63(2) of the Act, details of the change in the information referred to in subregulation (1) must be given to the Board by the person.
- (3) For the purposes of the definition of *health service* in section 63(7) of the Act, naturopathy services are declared to be a health service.

13—Information relating to claim against registered person to be provided

- (1) For the purposes of section 71(1)(a) and (2)(a) of the Act, the information relating to a claim referred to in that section to be provided to the Board 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 71(1)(b) and (2)(b) of the Act, the information relating to the claim referred to in that section to be provided to the Board 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 the Board relating to the claim; and
 - (c) details of the order or agreement (including the amount ordered or agreed to be paid).

14—Fees

- (1) The Board may fix—
 - (a) fees or charges for the purposes of the Act;
 - (b) fees or charges for services provided by the Board in the exercise of its functions under the Act.
- (2) However, no fee may be charged for registration on the pharmacy student register.

(3) The Board may recover a fee or charge fixed under this regulation by action in a court of competent jurisdiction as a debt due to the Board from the person liable for payment of the fee or charge.

Schedule 1—Revocation and transitional provision

Part 1—Revocation of Pharmacists Regulations 2006

1—Revocation of regulations

The Pharmacists Regulations 2006 are revoked.

Part 2—Transitional provision

2—Transitional matter

A person who was a member of the Board immediately before the commencement of Schedule 1 clause 5(2) of the Act may continue to act as a member of the Board for the purpose of continuing and completing proceedings under the repealed Act.

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 8 November 2007

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