Pharmacy Practice Regulation 2008

[2008-39]

New South Wales

Status Information

Currency of version

Repealed version for 22 February 2008 to 30 June 2010 (accessed 17 July 2024 at 19:18)

Legislation on this site is usually updated within 3 working days after a change to the legislation.

Provisions in force

Some, but not all, of the provisions displayed in this version of the legislation have commenced.

Notes—

- **Does not include amendments by**
  Cl 42 of this Regulation (not commenced — to commence on the commencement of Sch 15 to the *Parliamentary Electorates and Elections Amendment Act 2006*)
  Cl 2 (2) of this Regulation (cl 42 to be repealed on the day following the day on which that clause commences)
- **Repeal**
  The Regulation was repealed by Sch 3 to the *Health Practitioner Regulation Amendment Act 2010* No 34 with effect from 1.7.2010.

Authorisation

This version of the legislation is compiled and maintained in a database of legislation by the Parliamentary Counsel's Office and published on the NSW legislation website, and is certified as the form of that legislation that is correct under section 45C of the Interpretation Act 1987.

File last modified 1 July 2010

Pharmacy Practice Regulation 2008

New South Wales

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Pharmacy Practice Regulation 2008

New South Wales

Her Excellency the Governor, with the advice of the Executive Council, has made the following Regulation under the *Pharmacy Practice Act 2006*.

REBA MEAGHER, M.P.,Minister for Health

Part 1 Preliminary

1 Name of Regulation

This Regulation is the *Pharmacy Practice Regulation 2008*.

2 Commencement

(1) This Regulation commences on 25 February 2008, except as provided by subclause (2).

(2) Clause 42 commences on the later of:

(a) the day on which Schedule 15 to the *Parliamentary Electorates and Elections Amendment Act 2006* commences, or

(b) 25 February 2008,

and is repealed on the day following the day on which that clause commences.

3 Interpretation

(1) In this Regulation:

in the premises includes on the premises.

Price Information Code of Practice means the *Price Information Code of Practice* published by the Therapeutic Goods Administration of the Commonwealth, as in force on 25 February 2008.

the Act means the *Pharmacy Practice Act 2006*.

Note—

Section 11 of the *Interpretation Act 1987* provides that expressions defined in the Act have the same meanings in this Regulation.

(2) Notes included in this Regulation do not form part of this Regulation.

Part 2 Practice of pharmacy

Division 1 Conduct of practice

4 Standards for approval of pharmacy premises

(1) The following standards are prescribed for the purposes of clause 1 (8) (a) of Schedule 2 to the Act for premises other than professional services rooms:

(a) at least one doorway allowing direct public access to the premises is to be provided,

(b) the premises (including any doors, windows, floors or ceilings) are to be secure,

(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) there is a part of the premises in which a consultation conducted by a pharmacist is not reasonably likely to be overheard by a person not party to the consultation,

Note—

Other legislation may impose obligations in respect of customer privacy that apply in addition to obligations imposed under the Act and this Regulation.

(e) the premises are to be equipped with:

(i) the equipment listed in Schedule 1, and

(ii) any other equipment necessary to ensure the safe and competent delivery of the pharmacy services delivered in those premises,

installed and maintained in accordance with the manufacturer's instructions or if no such instructions exist, to the standard necessary for the safe and competent delivery of pharmacy services,

(f) the publications listed in Schedule 1 are to be kept in the premises or are to be accessible by electronic means from the premises in accordance with clause 6.

(2) The following standards are prescribed for the purposes of clause 1 (8) (a) of Schedule 2 to the Act for a dispensing area referred to in subclause (1) (c):

(a) it is to be adequately lit and ventilated,

(b) it is to have adequate heating facilities for dispensing and compounding drugs,

(c) it is to be equipped with a stainless steel or similarly impervious sink that has an

impervious surround and is supplied with hot and cold running water,

(d) it is to have a 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,

(e) it is to have at least one dispensary barcode scanner connected to each dispensing station in the dispensing area.

(3) Subclause (1) (d) does not apply to a pharmacy before 25 February 2009.

(4) Subclause (1) (d) does not apply to a pharmacy before 25 February 2010 if:

(a) the Board has served on the owner of the pharmacy a notice exempting the pharmacy for the purposes of this subclause and specifying the date the exemption ceases (not being a date later than 25 February 2010), and

(b) a copy of the notice is displayed adjacent to the area where patient consultations are carried on in the pharmacy, and

(c) the exemption has not ceased.

(5) The Board is to maintain a list of all pharmacies subject to an exemption under subclause (4) and to make that list publicly available, by publication on the Board's website or otherwise.

5 Standards for approval of professional services room premises

(1) The following standards are prescribed for the purposes of clause 1 (8) (a) of Schedule 2 to the Act for professional services rooms:

(a) all reasonable steps to prevent public access to the premises are to have been taken,

(b) the premises (including any doors, windows, floors or ceilings) are to be secure,

(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) the premises are to be laid out and equipped so that:

(i) any drug stored in the premises can be stored in accordance with the relevant drug's storage conditions, and

(ii) all the drugs being prepared, packaged or stored in the premises, for supply to a particular patient or to a health care facility for supply to a particular patient or resident of that facility, can be stored together, and

(iii) any documentation physically stored in the premises relating to that patient

or resident can be stored with those drugs,

(e) the publications listed in Schedule 2 are to be kept in the premises or are to be accessible by electronic means from the premises in accordance with clause 6.

(2) The following standards are prescribed for the purposes of clause 1 (8) (a) of Schedule 2 to the Act for a dispensing area referred to in subclause (1) (c):

(a) it is to be adequately lit and ventilated,

(b) it is to be equipped with a stainless steel or similarly impervious sink that has an impervious surround and is supplied with hot and cold running water,

(c) it is to have a 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,

(d) it is to have at least one dispensary barcode scanner connected to each dispensing station in the dispensing area.

6 Access to electronic versions of publications

The following provisions apply to access by electronic means to publications referred to in clauses 4 (1) (f) and 5 (1) (e) that are not kept in the premises:

(a) any relevant software or data licence in respect of the publication is to provide for access for each pharmacist in the premises (including a locum),

(b) a document is to be kept, in the premises and available to each pharmacist in the premises (including a locum), setting out how each pharmacist can readily access the current version of the publication,

(c) if the publication is accessed via the internet—access to the internet is to be maintained while any pharmacist is dispensing or compounding drugs in the premises and the current version of the publication is to be readily accessible (by way of web browser bookmarks or otherwise).

7 Displaying name of owner and pharmacist in charge

(1) The owner of a pharmacy business must ensure that the name of the owner is displayed at or near the main entrance of each premises in which the business is carried on.

Maximum penalty: 2 penalty units.

(2) The pharmacist in charge of a pharmacy must ensure that the name of the pharmacist in charge followed by the words “PHARMACIST IN CHARGE” is displayed adjacent to the area where dispensing is carried on in the pharmacy.

Maximum penalty: 2 penalty units.

8 Displaying prices

The owner of a pharmacy business must ensure that drug price information displayed in any premises in which the business is carried on does not contravene the Price Information Code of Practice.

Maximum penalty: 2 penalty units.

9 Owner to appoint pharmacist to be responsible for compliance with clauses 7 (1) and 8

(1) This clause applies to a pharmacy business that is carried on by a body corporate.

(2) The owner of a pharmacy business to which this clause applies must, by notice in writing to the Board, appoint a pharmacist to be responsible for compliance with clauses 7 (1) and 8. There must be such an appointment in force at all times, otherwise the owner of the pharmacy business is guilty of an offence.

Maximum penalty: 2 penalty units.

(3) To be effective the notice of appointment must be accompanied by a notice of acceptance of the appointment signed by the appointed person.

(4) An appointment may be revoked by notice in writing to the Board given either by the owner of the pharmacy business or by or on behalf of the appointed person. The appointment is automatically revoked if the person appointed ceases to be a pharmacist.

(5) If the owner of a pharmacy business contravenes clause 7 (1) or 8, the person appointed under this clause in respect of the pharmacy business at the time of the contravention is taken to have contravened the provision that the owner contravened.

(6) A person may be proceeded against and convicted under a provision pursuant to this clause whether or not the owner has been proceeded against or convicted.

(7) This clause does not affect any liability imposed on an owner of a pharmacy business for an offence committed by the owner.

(8) In this clause, a reference to the owner of a pharmacy business that has more than one owner is a reference to each owner.

Division 2 Control of pharmacies

10 Interests prescribed as constituting pecuniary interests

(1) For the purposes of paragraph (b) of the definition of ***pecuniary interest*** in section 4 (1) of the Act, the following interests are, without limiting the generality of the definition as expressed in the Act, prescribed as constituting pecuniary interests:

(a) any interest (whether proprietary or otherwise) in a pharmacy business that a person has by virtue of being a member or shareholder of:

(i) an exempted body corporate, or

(ii) a holding company (whether a listed corporation or not) of an exempted body corporate that is not a listed corporation,

(b) any interest (whether proprietary or otherwise) in a pharmacy business that a person has by virtue of being a trustee or beneficiary of a trust, the trust property of which includes shares in:

(i) an exempted body corporate, or

(ii) a holding company (whether a listed corporation or not) of an exempted body corporate that is not a listed corporation,

(c) any interest (whether proprietary or otherwise) in a pharmacy business that a person has by virtue of being a trustee or beneficiary of a trust, being a trust the trustees of which, in their capacity as the trustees of that trust, carry on or have a pecuniary interest in such a business.

Note—

The interests prescribed in this clause are subject to paragraphs (c) and (d) of the definition of ***pecuniary interest*** in section 4 (1) of the Act.

(2) In this clause:

exempted body corporate means a body corporate that carries on or has a pecuniary interest in a pharmacy business under section 27 of the Act.

holding company has the meaning it has in the *Corporations Act 2001* of the Commonwealth.

listed corporation has the meaning it has in the *Corporations Act 2001* of the Commonwealth.

11 Interests prescribed as not constituting pecuniary interests

(1) For the purposes of paragraph (e) of the definition of ***pecuniary interest*** in section 4 (1) of the Act, any interest a person has in the profits of a pharmacy business by virtue of the person being an employee employed in that business does not, subject to subclause (2), constitute a pecuniary interest in a pharmacy business for the purposes of the Act.

(2) Any interest constituted by legal or beneficial ownership of shares or other securities of a body corporate (issued as part of an employee share scheme or otherwise) is excluded from the interests prescribed by subclause (1).

12 Notice of acquisition or disposal of interest in pharmacy

For the purposes of section 24 (4) of the Act, the matters set out in Schedule 3 are prescribed as additional matters to be included in a notice under section 24 of the Act in respect of a pharmacy business.

13 Circumstances in which person not prevented from having pecuniary interest

(1) For the purposes of section 25 (2) of the Act, a person may have a pecuniary interest in a pharmacy business if the person comes into possession of the business or any of the assets of the business as a consequence of a default on an obligation secured by a security interest.

(2) Subclause (1) applies to a person for the period of 6 months from the date the person comes into possession of the pharmacy business or assets or any longer period that the Board specifies by notice in writing served on the person.

Part 3 Infection control standards

14 Infection control standards

(1) A pharmacist must not, without reasonable excuse, fail to comply with the infection control standards set out in Schedule 4 to the extent that they apply to the pharmacist in the practice of pharmacy.

(2) In determining whether or not a pharmacist has a reasonable excuse for failing to comply with a standard, particular consideration is to be given to the following:

(a) whether the circumstances involved the provision of emergency treatment,

(b) whether the pharmacist's employer failed to provide the necessary equipment, including providing access to it and training in its use, that would have enabled the pharmacist to comply with the standard (and whether the failure to provide such equipment was reported by the pharmacist to the Director-General of the Department of Health).

Note—

While some types of health professional may not necessarily provide direct patient care as frequently as other types, the various Acts regulating health professionals in NSW apply infection control standards that are substantially consistent.

Part 4 Advertising of pharmacy services

15 Advertising

For the purposes of section 155 (2) (i) of the Act, a person (including a corporation) may advertise pharmacy services in any manner except in a manner that:

(a) is false, misleading or deceptive, or

(b) creates an unjustified expectation of beneficial treatment, or

(c) promotes the unnecessary or inappropriate use of pharmacy services, or

(d) contravenes the Price Information Code of Practice.

Maximum penalty: 10 penalty units.

Part 5 Election of members of Board

16 Definitions

In this Part:

close of nominations, in relation to an election, means the final time and date fixed by the returning officer for the close of nominations in the election.

close of the poll, in relation to an election, means the final time and date fixed by the returning officer for the close of the poll in the election.

election means an election conducted for the purposes of section 100 (1) (a) of the Act to elect members of the Board.

returning officer—see clause 18.

17 Manner of conduct of election

For the purposes of section 100 (1) (a) of the Act, the election of elected members of the Board is to be held and conducted in the manner set out in this Part.

18 Returning officer

(1) The Electoral Commissioner for New South Wales appointed under the *Parliamentary Electorates and Elections Act 1912* is to be the returning officer at an election.

(2) The Electoral Commissioner may delegate to any member of staff of the Office of the New South Wales Electoral Commission any of the returning officer's functions under this Regulation, other than this power of delegation.

19 Notice of election

(1) The returning officer must, as soon as practicable after being notified in writing by the Minister that an election is required to be held, cause to be published in the Gazette and in at least one daily newspaper published and circulated in New South Wales a notice that:

(a) states that an election is to be held, and

(b) invites nominations from pharmacists to fill the vacancies for elected members of the Board, and

(c) advises where nomination forms may be obtained, and

(d) fixes the time and date of the close of nominations, and

(e) fixes the time and date of the close of the roll, and

(f) fixes the time and date of the close of the poll.

(2) A notice referred to in subclause (1) must be published at least 60 days before the close of the poll for the election to which it relates.

(3) The returning officer may, by a notice published in accordance with subclauses (1) and (2), fix a later time and date for the close of nominations for an election than those fixed by a previous notice published in relation to the election.

20 Nominations

(1) A nomination must be made in writing and must set out the following particulars:

(a) the full name of the candidate nominated,

(b) the residential address of that candidate,

(c) an endorsement of that candidate's consent to his or her nomination,

(d) the full names, residential addresses and signatures of at least 2 nominators, being pharmacists other than that candidate.

(2) A candidate may withdraw his or her nomination for an election by notification in writing delivered to the returning officer at any time until the close of nominations for the election.

21 Candidate information sheet

(1) A candidate for election may, at any time before the close of nominations for the election, submit to the returning officer a statutory declaration containing information, not exceeding 100 words, intended for inclusion in a candidate information sheet referred to in subclause (2).

(2) As soon as practicable after the close of nominations for an election, the returning officer must, if clause 22 (2) requires that a poll be taken, draw up a candidate information sheet consisting of the information in the statutory declarations, if any, submitted to the returning officer by candidates pursuant to subclause (1).

(3) Despite subclause (2), the returning officer may, when drawing up a candidate information sheet, omit or alter so much of the information contained in a statutory declaration submitted to the returning officer pursuant to subclause (1):

(a) as appears necessary or desirable to prevent the sheet containing information

that is inappropriate for inclusion in a candidate information sheet, or

(b) as appears necessary or desirable to prevent the sheet containing information that is misleading in a material particular, or

(c) as exceeds 100 words.

(4) Information concerning candidates must appear on a candidate information sheet referred to in subclause (2) in the same order in which the candidates are listed on the ballot-paper relating to them.

22 Procedure on close of nominations

(1) If, after the close of nominations, there is not a greater number of pharmacists nominated than are required for election, the returning officer is to declare those pharmacists duly elected.

(2) If, after the close of nominations, the number of pharmacists nominated is greater than the number required for election, a poll must be taken.

23 Closing of roll

(1) If, by the close of nominations, the returning officer has received more than the required number of nominations, the returning officer must immediately notify the Registrar that a poll is to be taken and that the returning officer requires the Registrar to deliver to the returning officer within 7 days after the close of the roll:

(a) a roll, certified by the Registrar as true and correct, which contains:

(i) the name of each person whose name is entered in the Register, and

(ii) an address, nominated by the person, to which a ballot-paper in respect of an election may be sent to the person, and

(b) a label for each person whose name is entered in the Register as at the close of the roll, of a size suitable for fixing to an envelope, upon which the name and address of that person is written.

(2) The Registrar is to comply with a requirement of the returning officer under subclause (1).

24 Conduct of ballot

(1) Where a poll is to be taken, the returning officer must:

(a) hold a ballot, in the manner prescribed for the purposes of section 82A of the *Parliamentary Electorates and Elections Act 1912*, to determine the order in which the candidates' names are to be entered on the ballot-paper, and

(b) cause ballot-papers to be drawn up in accordance with subclause (2), and

(c) cause the ballot-papers to be printed, and

(d) cause any candidate information sheet drawn up under clause 21 relating to the candidates to be printed.

(2) The ballot-paper must contain:

(a) the names of the candidates, arranged in the order determined in accordance with subclause (1) (a), with a small square opposite each name, and

(b) if the returning officer considers that the names of 2 or more candidates are so similar as to cause confusion, such other matter as the returning officer considers will distinguish between the candidates, and

(c) such directions, as to the manner in which a vote is to be recorded and returned to the returning officer, as are required by subclause (3), and

(d) such further directions as to the manner in which a vote is to be recorded and returned to the returning officer as the returning officer considers appropriate.

(3) The directions to voters must include the following:

(a) that the voter must record a vote for at least 5 candidates by placing the numbers “1”, “2”, “3”, “4” and “5” in the squares opposite the names of the candidates in the order of the voter’s preferences for them,

(b) that the voter may, if the voter so wishes, vote for additional candidates by placing consecutive numbers (beginning with the number “6”) in the squares opposite the names of the additional candidates in the order of the voter’s preferences for them,

(c) that the ballot-paper is to be rejected by the returning officer if it contains any matter by which the voter may be identified,

(d) that, having completed the ballot-paper, the voter is to:

(i) fold the ballot-paper so that the vote cannot be seen, and

(ii) seal the ballot-paper, and only the ballot-paper, in the reply-paid envelope addressed to the returning officer, and

(iii) legibly print the voter’s name and address on the reply-paid envelope’s rear flap and sign the flap, and

(iv) send the reply-paid envelope to the returning officer so that the envelope is received by the returning officer before the time and date appointed for the closing of the poll,

(e) the time and date appointed for the closing of the poll,

(f) that it is an offence to:

(i) vote, or attempt to vote, more than once in an election, and

(ii) vote, or attempt to vote, in an election in which the voter is not entitled to vote.

(4) The returning officer must, not later than 20 days before the date fixed for a poll, post to the address, nominated in the roll referred to in clause 23 (1), of each pharmacist registered at the date of the close of nominations to which the poll relates:

(a) a ballot-paper printed in accordance with subclause (1) and initialled by the returning officer, and

(b) an unsealed reply-paid envelope addressed to the returning officer, and

(c) the candidate information sheet (if any) drawn up under clause 21.

(5) A reply-paid envelope referred to in subclause (4) must contain, on the rear flap, spaces for the insertion of a voter's name, address and signature.

(6) A pharmacist who has been forwarded a ballot-paper and a reply-paid envelope under subclause (4) and who wishes to vote must complete the ballot-paper, fold the ballot-paper so that the vote cannot be seen and send or deliver to the returning officer the ballot-paper enclosed and sealed in the reply-paid envelope addressed to the returning officer.

(7) The returning officer may, on written application made to the returning officer, and if satisfied that a ballot-paper has been lost or destroyed, supply a duplicate ballot-paper to the person to whom the lost or destroyed ballot-paper was issued.

(8) An election is not invalid because:

(a) a person whose name is on the Register did not receive a ballot-paper, or

(b) the returning officer did not receive a ballot-paper sent to the returning officer.

25 Examination of envelopes

(1) The returning officer must, as soon as practicable after the receipt of a reply-paid envelope purporting to contain a ballot-paper, examine the envelope for the purpose of deciding whether to accept or reject the envelope.

(2) The returning officer is to reject a reply-paid envelope purporting to contain a ballot-paper issued in respect of an election if:

(a) the rear flap of the reply-paid envelope does not bear the legibly printed name and address of a pharmacist to whom the returning officer supplied a ballot-paper or has not been signed, or

(b) the reply-paid envelope is not sealed, or

(c) the reply-paid envelope is not received by the returning officer at or before the time and date fixed for the close of the poll under clause 19.

26 Dealing with ballot-papers

(1) On the day fixed for the close of the poll, the returning officer must:

(a) open all the reply-paid envelopes received (except those envelopes rejected under clause 25 (2)) and extract the ballot-papers and, without unfolding them, place the ballot-papers in the ballot-box, and

(b) mix the ballot-papers and draw the ballot-papers at random, and

(c) unfold the ballot-papers and count, in accordance with clause 27, the votes recorded on the ballot-papers (except any ballot-papers rejected under subclause (2)).

(2) The returning officer is to reject a ballot-paper as being informal if:

(a) the ballot-paper contains any matter by which the voter may be identified, or

(b) the ballot-paper was received in a reply-paid envelope that contained more than one ballot-paper, or

(c) the ballot-paper is not completed in accordance with the directions printed on the ballot-paper.

(3) Each candidate may appoint, in writing, a scrutineer to represent that candidate.

(4) A scrutineer appointed in accordance with subclause (3) may be present during the examination, opening and counting of votes by the returning officer.

27 Method of voting and counting

(1) At an election a voter is:

(a) required to record a vote for 5 candidates, and

(b) permitted to record a vote for as many more candidates as the voter pleases,

so as to indicate, in such manner as is required by this Part, the candidates for whom the voter votes and the order of the voter's preference for them.

(2) Ballot-papers must be counted, and the candidates who are elected determined, by the returning officer according to an optional multi-preferential system in which the first, second, third, fourth and fifth preference votes (represented by the numbers "1", "2", "3", "4" and "5", respectively, marked on the ballot-paper) are regarded as primary votes.

28 Report of election

When the returning officer first ascertains the result of an election, the returning officer must furnish a report, in writing, of the result to the Minister and must cause the result to be published in the Gazette and in at least one daily newspaper published or circulated in New South Wales.

29 Returning officer's decision final

If the returning officer is by this Regulation permitted or required to make a decision on any matter relating to the conduct of an election under this Part, the decision of the returning officer on that matter is final.

30 Candidate dying or ceasing to be pharmacist

(1) If a candidate dies or ceases to be a pharmacist and, as a result, at any time after the close of nominations but before the close of the poll, there is not a greater number of pharmacists nominated than are required for election, the returning officer is to declare those pharmacists duly elected and is not to proceed with the poll.

(2) Without limiting the operation of subclause (1), an election under this Part is not invalid merely because a candidate or a Board member-elect died or ceased to be a pharmacist after the close of nominations.

(3) Without limiting the operation of subclause (1), a vote cast in an election under this Part is not informal merely because the person, for whom the vote was cast, died or ceased to be a pharmacist after the close of nominations.

(4) If a person elected in an election under this Part has, after the close of nominations but before assuming office, died or ceased to be a pharmacist, the Minister may nominate a pharmacist to assume office in the person's place.

(5) The person who assumes office after being so nominated by the Minister is taken to be an elected member.

(6) In this clause, ***Board member-elect*** means a member elected at an election who is yet to assume office.

31 Offences

A person must not:

(a) vote, or attempt to vote, more than once in an election, or

(b) vote, or attempt to vote, in an election in which the person is not entitled to vote.

Maximum penalty: 2 penalty units.

Part 6 Miscellaneous

32 Forms

Any application made, or notice given, to the Board under the Act or this Regulation must be in a form approved by the Board.

33 Additional information to be included in pharmacist annual return

For the purposes of section 31 (1) (n) of the Act, the following information is to be specified in a return furnished by a pharmacist:

(a) the name of any insurer who has issued a policy of professional indemnity insurance to the pharmacist that is current at the time that the pharmacist furnishes the return,

(b) whether the pharmacist has practised as a pharmacist during the return period,

(c) if so, the period of practice, and whether the pharmacist practised full-time or part-time,

(d) if the pharmacist practised part-time, the estimated number of hours per week that the pharmacist practised.

34 Notice of mental incapacity

(1) For the purposes of section 34 of the Act, the person required to cause notice of mental incapacity to be given to the Registrar is:

(a) in the case of a pharmacist who is a mentally incapacitated person and becomes a patient at an institution because of that incapacity—the medical superintendent of the institution, or

(b) in the case of a pharmacist who is a protected person under the *Protected Estates Act 1983*—the Protective Commissioner.

(2) Notice for the purposes of section 34 of the Act is to be given by telephone by the next business day, and by post within the next 7 business days, after the day on which the pharmacist is admitted to the institution or becomes a protected person, and is to specify the following:

(a) the name and residential address of the pharmacist,

(b) the date on which the pharmacist:

(i) was admitted to the institution at which the pharmacist is a patient, or

(ii) became a protected person.

(3) In this clause, ***business day*** means any day other than a Saturday, a Sunday or a public holiday throughout New South Wales.

35 Excluded offences

(1) Sections 31 (1) (a), 32 (1) (a) and 33 of the Act do not apply in respect of an excluded offence.

(2) In this clause, ***excluded offence*** means any offence relating to the parking of motor vehicles or any offence under the road transport legislation (within the meaning of the *Road Transport (General) Act 2005*) except for the following offences:

(a) any offence under section 9 of the *Road Transport (Safety and Traffic Management) Act 1999* (which relates to presence of prescribed concentration of alcohol in a person's breath or blood),

(b) any offence under section 12 (1) of the *Road Transport (Safety and Traffic Management) Act 1999* (which relates to the use or attempted use of a vehicle while under the influence of alcohol or any other drug),

(c) any offence under section 42 (1) of the *Road Transport (Safety and Traffic Management) Act 1999* (which relates to driving a motor vehicle negligently on a road or road related area) if the pharmacist is, by way of penalty, sentenced to imprisonment or fined a sum of $200 or more,

(d) any offence under section 42 (2) of the *Road Transport (Safety and Traffic Management) Act 1999* (which relates to driving a motor vehicle furiously, recklessly or at a speed or in a manner dangerous to the public on a road or road related area),

(e) any offence under section 43 of the *Road Transport (Safety and Traffic Management) Act 1999* (which relates to menacing driving),

(f) any offence under section 70 of the *Road Transport (Safety and Traffic Management) Act 1999* (which relates to failing to stop and assist after an impact causing injury),

(g) any offence under section 171 (2) of the *Road Transport (General) Act 2005* (which relates to failing to comply with a requirement to produce a driver licence, or to state name and home address, or stating a false name or home address),

(h) any offence under section 25A (1), (2) or (3) of the *Road Transport (Driver Licensing) Act 1998* (which relates to driving while unlicensed),

(i) any other offence under the road transport legislation if the court orders the disqualification of the pharmacist from holding a driver licence.

36 Appeal on point of law

An appeal referred to in section 90 of the Act is to be made:

(a) by causing a notice of appeal, specifying the grounds on which the appeal is made, to be given to the Chairperson (or, if a Deputy Chairperson is nominated under section 90 (1) of the Act, to the Deputy Chairperson so nominated), and

(b) by causing a copy of the notice of appeal to be given to each other party to the proceedings from which the appeal has arisen.

37 Fee for inspection of Register

For the purposes of clause 15 (5) of Schedule 1 to the Act, the prescribed maximum fee for an inspection of the Register is $30.

38 Fee for additional information to be recorded in Register

For the purposes of clause 16 (3) of Schedule 1 to the Act, the prescribed fee for recording additional particulars in the Register is $50.

39 Fee for inspection of Register of Pharmacies

For the purposes of clause 2 (4) of Schedule 2 to the Act, the prescribed maximum fee for an inspection of the Register of Pharmacies is $30.

40 Replacement certificates

(1) The Registrar may issue a replacement certificate of registration if satisfied that:

(a) the original certificate has been lost, stolen, destroyed or mutilated or the information that it certifies is no longer correct, and

(b) the person to whom the replacement certificate is to be issued is entitled (under subclause (2) or by other lawful entitlement) to be issued with it.

(2) A pharmacist who has been issued with a certificate of registration is entitled to be issued with a replacement of the certificate under subclause (1) on:

(a) application to the Registrar, and

(b) payment of any relevant fee fixed by the Board.

(3) The Registrar may require an application under this clause for a replacement for a lost, stolen, destroyed or mutilated certificate to be verified by a statutory declaration as to the circumstances in which the certificate was lost, stolen, destroyed or mutilated.

41 Transitional provision regarding certain provisions in certain instruments

Pursuant to clause 2 of Schedule 8 to the Act, section 29 (1) (d) of the Act does not, before 25 February 2009, affect a provision of a lease or a licence, or an arrangement that creates a security interest, in respect of a pharmacy business if the lease, licence or arrangement was entered into before 25 February 2008.

42 Amendment consequential on enactment of Schedule 15 to the Parliamentary Electorates and Elections Amendment Act 2006

This Regulation is amended by omitting clause 18 and inserting instead:

18 Returning officer

The Board may appoint an accredited election service provider (referred to in Part 6A of the *Parliamentary Electorates and Elections Act 1912*) to be the returning officer for the purposes of this Regulation.

Schedule 1 Equipment and publications required for pharmacy premises

(Clause 4 (1) (e) and (f))

1 Equipment

The following equipment is listed for the purposes of clause 4 (1) (e) of this Regulation:

(a) a refrigerator manufactured (either exclusively or principally) for the purpose of storage of vaccines,

(b) a dispensing balance,

(c) heavy duty scales, capable of weighing up to 1 kg and a set of metric weights compatible for use with those scales or an electronic scale capable of weighing up to 1 kg in increments of no more than 50 mg,

(d) a 200 ml dispensing measure,

(e) a 100 ml dispensing measure,

(f) a 10 ml dispensing measure,

(g) a 5 ml dispensing measure,

(h) a funnel,

(i) 2 mortars and pestles (at least 1 being made of glass),

(j) a stirring rod,

(k) 2 spatulas,

(l) an ointment slab,

(m) a tablet counting tray.

2 Publications

The following publications are listed for the purposes of clause 4 (1) (f) of this Regulation:

(a) the *Poisons and Therapeutic Goods Act 1966* and the Regulations under that Act,

(b) the Poisons List proclaimed under section 8 of the *Poisons and Therapeutic Goods Act 1966* or the latest edition, and all published amendments or supplements to that edition, of the *Guide to the New South Wales Poisons Schedules* published by the Pharmacy Guild of Australia (New South Wales Branch),

(c) the Act and this Regulation,

(d) the Price Information Code of Practice,

(e) the latest editions, and all published amendments or supplements to those editions, of:

(i) *MIMS Annual* or *Drugs on Disk* or *AusDI* or a publication approved by the Board for the purposes of this subparagraph, and

(ii) *Martindale—The Extra Pharmacopoeia* or *AusDI* or *Micromedex* or a publication approved by the Board for the purposes of this subparagraph, and

(iii) *Australian Pharmaceutical Formulary and Handbook* (also known as *APF*) or a publication approved by the Board for the purposes of this subparagraph, and

(iv) *Australian Medicines Handbook* (also known as *AMH*) or the *Pharmacy Self Care Cards* published by the Pharmaceutical Society of Australia or a publication approved by the Board for the purposes of this subparagraph.

Note—

Section 68 of the *Interpretation Act 1987* provides that, in any Act or instrument, a reference to some other Act or instrument extends to the other Act or instrument as in force for the time being. Section 69 of that Act makes provision for how a reference to a publication that is not an Act or instrument is to be construed.

Schedule 2 Publications required for professional services room premises

(Clause 5 (1) (e))

The following publications are listed for the purposes of clause 5 (1) (e) of this Regulation:

(a) the *Poisons and Therapeutic Goods Act 1966* and the Regulations under that Act,

(b) the Poisons List proclaimed under section 8 of the *Poisons and Therapeutic Goods Act 1966* or the latest edition, and all published amendments or supplements to that edition, of the *Guide to the New South Wales Poisons Schedules* published by the Pharmacy Guild of Australia (New South Wales Branch),

(c) the Act and this Regulation,

(d) the latest editions, and all published amendments or supplements to those editions, of:

(i) *MIMS Annual* or *Drugs on Disk* or *AusDI* or a publication approved by the Board for the purposes of this subparagraph, and

(ii) *Martindale—The Extra Pharmacopoeia* or *AusDI* or *Micromedex or a publication approved by the Board for the purposes of this subparagraph*, and

(iii) *Australian Pharmaceutical Formulary and Handbook* (also known as *APF*) or a publication approved by the Board for the purposes of this subparagraph, and

(iv) *Australian Medicines Handbook* (also known as *AMH*) or the *Pharmacy Self Care Cards* published by the Pharmaceutical Society of Australia or a publication approved by the Board for the purposes of this subparagraph.

Note—

Section 68 of the *Interpretation Act 1987* provides that, in any Act or instrument, a reference to some other Act or instrument extends to the other Act or instrument as in force for the time being. Section 69 of that Act makes provision for how a reference to a publication that is not an Act or instrument is to be construed.

Schedule 3 Additional matters to be included in notification of pecuniary interest

(Clause 12)

For the purposes of clause 12, the following additional matters are prescribed:

(a) a copy of any bill of sale referred to in the notice,

(b) a copy of any sale agreement for the business,

(c) a copy of any partnership agreement for the business,

(d) a copy of any lease for the pharmacy,

(e) a copy of any agreement under which any other person has a pecuniary interest in the business,

(f) a copy of any agreement, between persons who have pecuniary interests in the business, that makes provision for any rights the persons possess by virtue of having the pecuniary interests,

(g) a copy of any agreement for the provision of management services to the business or to any pharmacists' body corporate that owns an interest in the business,

(h) a copy of any agreement (except a contract of employment) between any person who has a pecuniary interest in the business and any entity in respect of the provision of accounting, information technology, human resources or other support services to the business,

(i) if a pharmacists' body corporate is acting as a trustee (whether of a fixed trust, unit trust, discretionary trust or other kind of trust), a copy of the relevant trust deed (if any exists),

(j) a copy of any security interest in respect of the business.

Schedule 4 Infection control standards

(Clause 14)

Part 1 Preliminary

1 Definitions

(1) In this Schedule:

body substance includes any human bodily secretion or substance other than blood.

invasive procedure means any one or more of the following:

(a) any procedure during which a patient's skin is penetrated or cut or otherwise rendered non-intact,

(b) treatment of a wound.

patient includes a person who is accessing pharmacy services.

sharps means any object capable of inflicting penetrating injury, and includes hollow bore needles, suture needles, scalpel blades, wires, trocars, auto lancets, stitch cutters and broken glassware.

(2) The requirements set out in this Schedule apply to a pharmacist who is assisting in performing a procedure in the same way as they apply to a pharmacist who is actually performing the procedure.

Part 2 Standards applying to pharmacists

2 General precautions and aseptic techniques

(1) Precautions must be taken to avoid direct exposure to a patient's blood or other body substances. This requirement applies regardless of whether there is any perceived risk of infection.

(2) Aseptic techniques must be used in the course of complying with the requirements of this Schedule.

3 Hand and skin cleaning

(1) Hands must be cleaned:

(a) immediately before and after performing any invasive procedure, and

(b) immediately before and after performing any procedure during which direct contact is anticipated or occurs with a patient's blood or other body substance, mucous membranes or non-intact skin, and

(c) immediately after handling blood or other body substances.

(2) Subclause (1) does not apply in circumstances where treatment is required to be performed urgently and cleaning facilities are not readily available.

(3) Hands may be cleaned by:

(a) using washing facilities involving water and a soap or antiseptic, or

(b) using non-water cleansers or antiseptics.

(4) Hands or other skin surfaces that are contaminated with a patient's blood or other body substances must be cleaned as soon as it is practicable to clean them.

(5) The requirement to clean hands applies regardless of whether gloves are also required to be worn.

4 Protective gowns and aprons

A gown or apron made of impervious material must be worn during any procedure where there is a likelihood of clothing being splashed or contaminated with blood or other body substances.

5 Gloves

(1) Gloves must be worn while handling blood or other body substances.

(2) In particular, gloves must be worn:

(a) during any procedure where direct contact is anticipated with a patient's blood or other body substances, mucous membranes or non-intact skin, and

(b) while handling items or surfaces that have come into contact with blood or other body substances, and

(c) while performing an invasive procedure.

(3) Sterile gloves must be worn if the procedure involves contact with tissue that would be sterile under normal circumstances.

(4) Gloves must be discarded:

(a) as soon as they are torn or punctured, and

(b) after contact with each patient.

(5) Nothing in subclause (4) affects the operation of subclauses (1)–(3).

(6) Gloves must be changed if separate procedures are being performed on the same patient and there is a risk of infection from one part of the body to another.

6 Masks and protective eye wear

(1) A fluid repellent mask and protective eye wear must be worn while performing any procedure where there is a likelihood of splashing or splattering of blood or other body substances.

(2) A mask must be worn when in close contact with patients known by the pharmacist to have an infectious disease (or suspected by the pharmacist of having such a disease) if the disease is capable of being transmitted by the airborne or droplet route. If the disease is tuberculosis, the mask must be a particulate mask that is capable of filtering to 0.3µm.

(3) In cases where a mask is required to be worn, it must be worn and fitted in accordance with the manufacturer's instructions.

(4) A mask must be discarded once it has been worn and it must not be used again.

(5) In cases where protective eye wear is required to be worn, it must be worn and fitted in accordance with the manufacturer's instructions.

(6) Protective eye wear must be discarded once it has been worn and not used again unless it is reusable (in which case it is to be cleaned in accordance with the manufacturer's instructions).

7 Sharps

(1) Sharps must not be passed by hand between a pharmacist and any other person unless the sharps are contained in a puncture resistant container.

(2) A puncture resistant tray must be used to transfer sharps that are not contained in a puncture resistant container.

(3) A needle must not be removed from a disposable syringe for disposal, or be purposely broken or otherwise manipulated by hand, unless it is necessary to remove the needle for technical reasons.

(4) A needle must not be bent after it is contaminated with blood or other body substances.

(5) In any case where resheathing of a needle is required:

(a) the needle must be properly recapped, and

(b) the sheath must not be held in the fingers, and

(c) either a single handed technique or forceps, or a suitable protective guard designed for the purpose, must be used.

(6) Reusable sharps must, immediately after being used, be placed in a puncture

resistant container specially kept for that purpose and labelled as such.

(7) Non-reusable sharps must, immediately after being used, be disposed of in a puncture resistant container.

8 Management of waste

(1) Clinical waste must be properly packaged to protect against potential exposure to infectious agents and to facilitate the proper handling, storage and treatment or disposal of the waste.

(2) Splashing or contamination of skin while disposing of blood or other body substances must be avoided as far as practicable.

(3) Nothing in this clause limits any other requirement under this Part.

9 Sterile medications and solutions

(1) A sterile needle and syringe must be used to withdraw any medication or solution from a vial or ampoule (or other similar container).

(2) The needle and syringe must be discarded once the needle and syringe have been used.

(3) A medication or solution may be taken from a multi-dose vial or ampoule (or other similar container) only if the medication or solution is not reasonably available in another form.

(4) Precautions must be taken to ensure that contaminated material or fluid is not injected into a multi-dose vial or ampoule (or other similar container).

Part 3 Processing of instruments and equipment

10 Interpretation

In this Part:

AS/NZS 4187 means AS/NZS 4187:2003*, Cleaning, disinfecting and sterilizing reusable medical and surgical instruments and equipment, and maintenance of associated environments in health care facilities*.

AS/NZS 4815 means AS/NZS 4815:2006*, Office-based health care facilities—Reprocessing of reusable medical and surgical instruments and equipment, and maintenance of the associated environment*.

11 Cleaning of instruments and equipment

(1) Any instrument or equipment that comes into contact with intact skin must be cleaned before it is used.

(2) Any instrument or equipment that is required under this Part to be sterilised or disinfected must be cleaned before it is sterilised or disinfected.

(3) The process of cleaning:

(a) must involve water and mechanical or physical action (such as washing machines) and a cleaning agent (with the cleaning agent being removed from instruments and equipment by rinsing), and

(b) must be consistent with AS/NZS 4187 or (in the case of a pharmacy) AS/NZS 4815.

(4) In this clause, ***cleaning agent*** means a detergent and includes proteolytic enzyme substances.

12 Disinfection of instruments and equipment

(1) Any instrument or equipment that comes into contact with non-sterile tissue (other than intact skin) must, before it is used, be disinfected with a disinfectant specified in the Australian Register of Therapeutic Goods that is maintained under the *Therapeutic Goods Act 1989* of the Commonwealth, and the relevant manufacturer's instructions must be followed.

(2) The process of disinfection:

(a) must involve either thermal methods or (if thermal methods are unsuitable) chemical methods, and

(b) must be consistent with AS/NZS 4187 or (in the case of a pharmacy) AS/NZS 4815.

13 Sterilisation of instruments and equipment

(1) Any instrument or equipment used to enter, or that is capable of entering, tissue that would be sterile under normal circumstances, or the vascular system of a patient, must be sterilised before it is used.

(2) The method of sterilisation must be:

(a) compatible with the particular type of instrument or equipment concerned, and

(b) consistent with AS/NZS 4187 or (in the case of a pharmacy) AS/NZS 4815.

(3) If a steriliser is used (whether it is a benchtop or portable steriliser or a permanently plumbed or wired steriliser), the following criteria must be met:

(a) the relevant manufacturer's instructions must be followed,

(b) an ongoing monitoring program must be followed which reflects the requirements of Table 7.1 Calibration, Monitoring and Maintenance of Sterilizers of AS/NZS 4187 or (in the case of a pharmacy) Table 7.1 Performance Testing, Monitoring, Calibration and Maintenance of Sterilizers of AS/NZS 4815.