

Australian Capital Territory

Health (Community Pharmacy Premises) Approved Standard 2010 (No 1)*

Notifiable instrument NI2010–349

made under the
Health Act 1993, Section 128B

1. Name of instrument

This instrument is the Health (Community Pharmacy Premises) Approved Standard 2010 (No 1).

2. Commencement

This instrument commences on 1 July 2010.

3. Standard

In accordance with Section 128B of the *Health Act 1993* I approve the following Standards for community pharmacy premises.

Katy Gallagher
Minister for Health

29 June 2010

*Name amended under Legislation Act, s 60

Health (Community Pharmacy Premises) Approved Standard 2010 (No 1)

STANDARDS OF COMMUNITY PHARMACY PREMISES

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Disclaimer

In the case of any conflict or discrepancy between this document and legislation, the legislation prevails.

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STANDARDS OF PHARMACY PREMISES

1. PREMISES AND REFERENCE WORKS

1.1 Premises

Premises at which a business consisting of or involving pharmacy should:

- 1.1.1 Consist of an enclosed area with direct access to a public place
- 1.1.2 Contain an area set aside for the dispensing of items on prescription that is not less than 8 square metres
- 1.1.3 Have at least 1 square metre of free working space, which is not less than 40cm wide for the dispensing of prescriptions
- 1.1.4 Be in a hygienic condition and be adequately ventilated
- 1.1.5 Have adequate lighting
- 1.1.6 Contain facilities for the secure and appropriate storage of medicines and pharmaceutical products, including refrigeration
- 1.1.7 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 practice of pharmacy and the activities of persons in that part of the premises
- 1.1.8 Have appropriate equipment for the accurate dispensing of all prescriptions including the compounding of extemporaneous preparations
- 1.1.9 Be so constructed such that the pharmacist can supervise the sale of the scheduled medicines and that a space is provided for the confidential counselling of patients
- 1.1.10 Have a dedicated fax facility for the receipt of urgent communications

Note: These requirements are in addition to any provisions under ACT legislation such as the *Medicines, Poisons and Therapeutic Goods Act 2008*

1.2 Legislation

1.2.1 Access to the following legislation must be in place at any premises at which pharmacy is practised.

- (a)** Medicines, Poisons and Therapeutics Act 2008
- (b)** Medicines, Poisons and Therapeutics Regulation 2008
- (c)** Drugs of Dependence Act 1989
- (d)** Drugs of Dependence Regulation 2009
- (e)** Public Health Act 1997
- (f)** Public Health Regulation 2000
- (g)** Work Safety Act 2008
- (h)** Work Safety Regulation 2008
- (i)** Health Practitioner Regulation National Law (ACT) Act 2010
- (j)** Health Practitioner Regulation National Law Act 2009 (Qld)
- (k)** Health Act 1993
- (l)** Health Regulation 2004

1.2.2 The legislation may be kept in hard copy form or in electronic form or via the Internet. All ACT legislation is accessible at www.legislation.act.gov.au.

1.2.3 The legislation may be kept in hard copy form or in electronic form on CD-ROM or on a Disk or via the Internet.

1.3 Reference Works

1.3.1 Current editions of the following reference works, together with any supplements, addenda or amendments, are compulsory and must be kept at any premises at which pharmacy is practised:

- (a)** The Australian Pharmaceutical Formulary and Handbook (APF)
- (b)** The Australian Medicines Handbook (AMH)
- (c)** MIMS Annual together with bi-monthly addenda or eMIMS.
- (d)** Copies of the legislation controlling the practice as listed in previous section on Legislation

- (e)** A scheduling guide – one of either
 - (i)** The Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP)
 - or**
 - (ii)** The Guide to the ACT Poisons and Drugs Schedules (Pharmacy Guild of Australia ACT Branch)

1.3.2 A reference work on drug interactions – one of either

- (a)** Drug Interaction Facts – Facts and Comparisons (the edition with quarterly amendments not the soft cover annual publication)
- or**
- (b)** Drug Interaction Analysis and Management, Hansten and Horn
- or**
- (c)** Drug Interactions, Stockley

1.3.3 A reference work on therapeutics – one of either

- (a)** The Merck Manual of Diagnosis and Therapy, Merck, Sharp and Dohme
- or**
- (b)** Goodman and Gilman's Pharmacological Basis of Therapeutics
- or**
- (c)** Applied Therapeutics: Clinical Use of Drug, Koda-Kimble (not the accompanying handbook)
- or**
- (d)** Therapeutic Guidelines Limited Series including:
 - Analgesic Guidelines
 - Antibiotic Guidelines
 - Cardiovascular Guidelines
 - Dermatology Guidelines
 - Endocrinology Guidelines
 - Gastrointestinal Guidelines
 - Neurology Guidelines
 - Palliative Care Guidelines
 - Psychotropic Guidelines
 - Respiratory Guidelines

- (e) An evidence-based reference work on complementary and alternate medicines – one of either:
 - Herbs and Natural Supplements: An Evidence Based Guide. Braun and Cohen
 - or**
 - Herbal Medicines. A Guide for Health Care Professionals, Phillipson
 - or**
 - Professionals Handbook of Complementary and Alternate Medicines. Fetrow and Avila
 - or**
 - The Review of Natural Products. Facts and Comparisons.
- (f) The Paediatric Pharmacopeia. Royal Children's Hospital.
- (g) A medical dictionary (various available e.g Dorland's, Stedman's, Mosby's)
- (h) *Professional Practice Standards*. Pharmaceutical Society of Australia.
- (i) *Quality Care Pharmacy Standards*. The Pharmacy Guild of Australia.
- (j) *Standards for the Provision of Pharmacists Only and Pharmacy Medicines*. Pharmaceutical Society of Australia

1.3.4 The information must be available to the pharmacist immediately during the dispensing process.

1.3.5 Substitution of the compulsory references listed above with unlisted texts is not acceptable.

1.3.6 These may be kept in hard copy form or in electronic form.

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2. NOTIFICATION OF OWNERSHIP

- 2.1** A pharmacist who has, or who acquires, or who changes an ownership interest in a community pharmacy or a hospital pharmacy must advise the Chief Health officer. The advice must be in writing and provided within the 30 days prior to the proposed change. The advice needs to state the names, addresses, contact numbers and registration numbers of all parties who have an ownership interest in the pharmacy and it needs to state the address and contact number of the pharmacy.

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3. CONDUCT OF BUSINESS

- 3.1** Names of all persons practicing as a pharmacist in a community pharmacy must be displayed in a public place in a clearly legible notice in the premises. The name of the pharmacist in charge must be displayed followed by the words 'Pharmacist in Charge'.
- 3.2** A registered pharmacist who is an individual must not—
- 3.2.1** Keep or maintain any shop for selling or supplying medicines or drugs, or for compounding or dispensing prescriptions unless the shop is, while open for business, constantly under his or her own control or that of some other registered pharmacist who is an individual
- 3.3** A complying pharmacy corporation must -
- 3.3.1** comply with the provisions of its constitution as set out in section 128A of the *Health Act 1933* and must notify the Chief Health Officer in writing within 10 business days of any failure to do so
- 3.3.2** if it intends to change its name or constitution notify the Chief Health Officer in writing. The notification must be provided in writing within 30 days of the proposed change.
- 3.3.3** on or before 31 October each year provide the Chief Health Officer with a written return. The return is to specify the names and addresses of the complying pharmacy corporation all directors and all shareholders
- 3.3.4** provide the Chief Health Officer with a copy of all returns submitted to ASIC
- 3.3.5** ensure that the business of the complying pharmacy corporation is conducted under the actual personal supervision of a registered pharmacist who is an individual.
- 3.3.6** notify the Chief Health Officer in writing if membership of the complying pharmacy corporation or the board of directors changes. The notification must be provided in writing within 30 days of the proposed change.

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4. OPERATION OF PHARMACY ON DEATH OF PHARMACIST

4.1 This section applies if—

4.1.1 A pharmacist dies

and

4.1.2 At the time of the pharmacist's death, the pharmacist was operating a pharmacy.

4.2 A person who is an executor of the estate, or a close relative, of the pharmacist, but who is not qualified to be a pharmacist, may apply to the Chief Health Officer for approval to operate the pharmacy. The application must be in writing outlining the circumstances of the request, including details about the executor or close relative. The application must be sent within 10 working days of the death of the pharmacist.

4.3 The Chief Health Officer may approve the person to operate the pharmacy for not longer than 12 months to allow for the sale or disposal of the pharmacy. The approval will be issued on the conditional that the pharmacy is under the direct, personal control of a pharmacist at all times when the pharmacy is being operated.