victorian pharmacy authority

Victorian Pharmacy Authority Standards

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VICTORIAN PHARMACY AUTHORITY STANDARDS

INTRODUCTION & INTERPRETATION

About the Victorian Pharmacy Authority

The Victorian Pharmacy Authority ('the Authority') has important functions and powers under the *Pharmacy Regulation Act 2010* ('the Act') which regulates the ownership and operation of pharmacy businesses, pharmacy departments and pharmacy depots.

The Authority's functions and powers under the Act include:

- licensing a person to carry on a pharmacy business or a pharmacy department
- registering the premises of pharmacy businesses, pharmacy departments and pharmacy depots, herein collectively referred to as registered premises unless specified individually
- maintaining a public register of all licensees and registered premises
- issuing standards in relation to the operation of pharmacies, pharmacy businesses, pharmacy departments and pharmacy depots
- inspecting registered premises to ensure that standards are being met and maintained.

Scope and application of the Standards

These standards, issued by the Authority ('the Standards'), have been approved by the Victorian Minister for Health as required under section 86 of the Act.

The Standards reflect the requirements of the Act, including the Schedule to the Act and are supported by the Victorian Pharmacy Authority Guidelines ('the Guidelines'). They should be read in conjunction with these documents.

In undertaking its functions under the Act, the Authority must have regard to the need to maintain standards, which help to ensure the facilities, equipment, security, management and operation of the registered premises comply with the Act and good pharmacy practice.

In relation to good pharmacy practice, the Authority recognises the standards, codes, guidelines and policies issued by the Pharmacy Board of Australia and has regard to standards, codes and guidelines issued by the Pharmaceutical Society of Australia, The Society of Hospital Pharmacists of Australia, Victorian Department of Health and Therapeutic Goods Administration.

These Standards apply to all registered premises in Victoria, except where specifically excluded. The licensee is responsible for meeting the Standards.

What happens if the Standards are not met?

The Authority may investigate a matter based on a notification of an alleged contravention of an Authority standard or if there is evidence of a contravention (sections 53 and 54 of the Act). The Authority may, among other things, convene a panel hearing in respect of matters that have been the subject of an investigation (section 57 of the Act).

The Authority may revoke a license or a registration if the licensee has contravened a standard on one or more occasions and the Authority believes it is against the public interest for that person to continue carrying on a pharmacy business or pharmacy department, or a breach of the Standards presents a serious risk to public safety (section 55 of the Act).

Structure of the Standards

The Standards are grouped into categories and sub-categories as follows:

1. Licensee responsibilities

1.1 Compliance
1.2 Management
1.3 Records
1.4 Policies and procedures
1.5 Quality improvement and risk management

2. Premises

2.1 Essential and ongoing requirements
2.2 Alterations
2.3 Security
2.4 Design, layout and condition
2.5 Equipment
2.6 Reference texts

The categories include an overlying principle which describes the desired outcome which will be achieved by compliance with the Standards.

KEY TERMS

Term	Meaning in the document
Complex compounding	refers to compounding, which is the extemporaneous preparation and supply of a single 'unit of issue' of a therapeutic product intended for supply for a specific patient in response to an identified need, and which requires or involves special competencies, equipment, processes and/or facilities [or as defined in the current edition of the Australian Pharmaceutical Formulary and Handbook (APF)]. Examples of complex compounded products include: • sterile products • products containing ingredients that pose a work health and safety hazard (e.g., cytotoxics, hormones, gene therapy) • monoclonal antibodies • single-unit dosage forms containing less than 25 mg (or up to 25% by weight or volume) of active ingredient • sustained-release or other modified-release products • capsules that contain more than one ingredient • tablets • troches, suppositories or pessaries.
Current reference texts	include any essential reference texts specified by the Pharmacy Board of Australia.
Drugs and Poisons legislation	refers to the *Drugs, Poisons and Controlled Substances Act 1981* and any regulations made under this Act.
Pharmacist regularly and usually in charge (PRUIC)	is the pharmacist who is regularly and usually in charge of the registered premises and can be the proprietor or a pharmacist appointed to that position.
Pharmacy services	includes the supply, compounding and dispensing of medicines, the provision of advice and counselling on the effective and safe use of medicines and a wider range of specific pharmacy services to support these functions, including those which may emerge as practice evolves, such as, but not limited to: • compounding (including complex compounding) • medication assisted treatment for opioid dependence (MATOD) • dose administration aids • administration of medicines by injection.
Registered premises	refers to pharmacies, pharmacy departments or pharmacy depots, as defined under the Act, which are registered by the Authority.

THE STANDARDS

1. Licensee responsibilities

Principle

The licensee is responsible for the delivery of pharmacy services that, through appropriate governance and oversight, are consistent with the law and good pharmacy practice. Public safety is paramount and the risk of causing harm must always be considered as part of the delivery of pharmacy services.

The licensee holds responsibility for the carrying on of a pharmacy business, pharmacy department or pharmacy depot in accordance with the Act.

Where there is a partnership, the responsibility is not held just by one single individual, but by each of the partners.

Governance arrangements include having clear definitions of the roles and accountabilities for the people involved in providing and managing pharmacy services. It also includes the arrangements for managing risks, and the way the registered premises is managed and operated.

1.1. Compliance

The licensee is responsible for:

1.1.1. compliance with the requirements of the Act, the Standards and any conditions imposed by the Authority

1.1.2. ensuring that the delivery of pharmacy services complies with relevant legislation, and follows good pharmacy practice

1.1.3. ensuring that all medicines and poisons are managed in accordance with legislation and good pharmacy practice.

1.2. Management

The licensee shall provide for the appropriate management of the pharmacy business, pharmacy department or pharmacy depot by:

1.2.1. a) acting as the pharmacist regularly and usually in charge, or
b) appointing a pharmacist to be regularly and usually in charge, and
c) notifying the Authority, in each case

1.2.2. ensuring that employed pharmacists hold appropriate and current registration

1.2.3. ensuring that all staff are suitably qualified and trained

1.2.4. ensuring that there are enough suitably qualified and trained staff to support service demands and the safe and effective provision of pharmacy services

1.2.5. ensuring that staff comply with professional and legal obligations

1.2.6. ensuring that staff have access to current reference texts.

1.3. Records

The licensee is responsible for ensuring that:

1.3.1. records relating to pharmacy services are created, stored and retained in accordance with relevant legislation and good pharmacy practice

1.3.2. records containing consumers' personal and health information are secure from theft, misuse, interference, loss, unauthorised access, modification or disclosure

1.3.3. records for Schedule 8 and 9 poisons are in accordance with Drugs and Poisons legislation.

1.4. Policies and procedures

The licensee is responsible for ensuring that:

1.4.1. there are policies and procedures in place which are relevant to the services provided and activities being undertaken at the registered premises

1.4.2. policies and procedures are clearly documented, easily accessible, regularly reviewed and updated as part of effective governance arrangements

1.4.3. policies and procedures are readily available to all staff and are being followed.

1.5. Quality improvement and risk management

The licensee is responsible for ensuring that there are appropriate systems in place to:

1.5.1. monitor and review the safety and quality of pharmacy services as part of ongoing improvement activities

1.5.2. identify, investigate and monitor incidents, adverse events and near misses

1.5.3. identify and manage the risks associated with providing pharmacy services.

2. Premises

Note: This category does not apply to pharmacy depots (refer to section 48 of the Act and the Schedule to the Act)

Principle

The design, condition, facilities and security of registered premises provide an appropriate environment for the safe custody of medicines and poisons and provision of pharmacy services.

The licensee holds responsibility for ensuring that registered premises comply with the Standards.

2.1. Essential and ongoing requirements

The Schedule to the Act sets out matters required in relation to registered premises such as layout, hygiene, temperature control and security and access.

2.1.1. Registered premises shall comply with relevant requirements of the Schedule to the Act on an ongoing basis.

2.1.2. Registered premises shall be maintained in an organised, uncluttered state.

2.2. Alterations

Registered premises should be suitable for the provision of pharmacy services. By approving significant alterations to registered premises, the Authority can ensure that the premises remain suitable and do not present a risk to public safety. The Authority provides information regarding significant alterations in the Guidelines.

2.2.1. Authority approval shall be obtained prior to making any significant alteration to registered premises.

2.3. Security

Registered premises shall be secure and safeguarded from unauthorised access.

2.3.1. The doors, windows, skylights, walls and ceilings of registered premises shall be substantially constructed and secured to prevent unauthorised access.

2.3.2. There shall be adequate perimeter security measures in place to prevent and deter unauthorised access.

2.3.3. The registered premises shall be fitted with a functional, 24-hour monitored intrusion detector alarm which:

a) is monitored by an appropriately graded monitoring centre or an onsite security service approved by the Authority in special circumstances, and

b) covers all areas where medicines and poisons are kept.

2.4. Design, layout and condition

2.4.1. The dispensary shall be a private area, dedicated to tasks associated with the dispensing, supply and compounding of medicines and secure storage of medicines and patient records.

2.4.2 The dispensary shall be fitted with:

a) a sink with integrated drainer, that is supplied with hot and cold running water and connected to an appropriate waste outlet

b) refrigeration which is dedicated to and appropriate for the storage of medicines, with adequate temperature monitoring

c) an appropriate number of suitably equipped dispensing stations

d) sufficient free working space and area/s for equipment storage and use

e) a storage system which provides for the safe custody and accurate selection of medicines

f) a dedicated storage facility for Schedule 8 and 9 poisons which complies with legislation, provides adequate storage for poisons on hand at all times and facilitates their accurate selection.

2.4.3 The dispensary shall be well lit, adequately ventilated and temperature controlled, to maintain the integrity of medicines and provide for personal comfort.

2.4.4. There shall be hygiene and infection prevention measures in place which are appropriate for the pharmacy services being provided.

2.5. Equipment

2.5.1. Equipment shall be safe to use and fit for purpose.

2.5.2. Equipment shall undergo regular maintenance, including routine calibration or servicing.

2.5.3. Equipment shall be operated safely, in accordance with standard operating procedures, and within the manufacturer's specified operating range.

2.5.4. Equipment shall be routinely cleaned.

2.5.5. Maintenance records shall be kept and standard operating procedures shall be current and readily available.

2.5.6. Registered premises shall be equipped with the minimum equipment required for simple compounding.

2.5.7. Appropriate equipment shall be used for the handling and compounding of hazardous materials to ensure that staff and the public are not put at risk and the integrity of the product is maintained.

2.6. Reference texts

2.6.1. There shall be a range of current reference texts relevant to the pharmacy services provided, at the premises.

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