

Victorian Pharmacy Authority Guidelines

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PART 1

FOREWORD

1.1 OVERVIEW OF THE LEGISLATIVE FRAMEWORK

The *Health Practitioner Regulation National Law (Victoria) Act 2009* (“the National Law”) came into operation on 1 July 2010. The National Law governs registration of health practitioners through 14 boards, including the Pharmacy Board of Australia, but it does not provide for ownership, approval or inspection of pharmacies. The Victorian Parliament therefore passed the *Pharmacy Regulation Act 2010* (“the Act”) to regulate these functions. The Act created the Victorian Pharmacy Authority, which is the successor in law to the Pharmacy Board of Victoria.

Despite practice matters having become the responsibility of the Pharmacy Board of Australia, there are some subjects that combine both premises and practice elements, such as workloads, privacy and works of reference.

1.2 MEMBERSHIP OF THE VICTORIAN PHARMACY AUTHORITY

Members are appointed for three years by the Governor in Council on the nomination of the Minister for Health. Three of the members must be pharmacists, one must be a lawyer and one is a person who is not a pharmacist.

1.3 FUNCTIONS

The Authority *licenses* persons (natural or corporate) to carry on a pharmacy business or a pharmacy department and *registers* the premises of pharmacy businesses, pharmacy departments and pharmacy depots. It is authorised to issue standards about the operation of pharmacy businesses, pharmacy departments and pharmacy depots and to appoint inspectors. It also advises the Minister on any matters relating to its functions.

In licensing a person and registering the premises, the Authority must be satisfied that the facilities, equipment, security, management and operation of the pharmacy business or pharmacy department at the premises comply with good pharmacy practice, the requirements of the Schedule to the Act and any other requirements that are prescribed.

1.4 POWERS

1.4.1 Inspections

Inspections of pharmacy businesses, pharmacy departments and pharmacy depots are carried out by the Authority’s staff who are authorised under section 65 of the Act. Section 68 sets out the powers of entry without warrant during business hours.

Inspections are conducted shortly after new premises have been registered, after existing premises have been renovated or extended or on a routine cyclical basis. Typically, an inspector will examine security, records, staffing, privacy, layout and equipping of the premises. Particular attention will be paid to the assembly of dose administration aids, opioid replacement therapy and compounding. An inspector may also enter the premises to conduct an investigation.

Following an inspection, the licensee will be issued with a report of any matters that require attention. The licensee or pharmacist in charge must rectify the deficiencies, truthfully certify accordingly and return the form to the Authority by the date specified.

A report may also be referred to the Authority for its consideration.

1.4.2 Receipt of notifications (complaints)

Any person may submit a notification to the Authority in cases where there are allegations concerning the licensee's character or ability to carry on the business competently, if there appear to be contraventions of the Act or if the premises do not meet the mandatory conditions for licensing and registration.

1.4.3 Investigations

As well as responding to notifications, the Authority may investigate a matter on its own motion. Even if a notification is withdrawn, the Authority may proceed to conduct an investigation.

1.4.4 Revocation of licence and registration

The Authority may revoke a licence if the licensee:

- is no longer eligible to hold a licence; or
- has been convicted of an offence under the Act or regulations; or
- has contravened a standard; or
- has been found guilty of an offence that affects the suitability of the person to carry on the business; or
- is of such a character that affects the licensee's suitability to carry on the business or department and where it would be against the public interest.

Further grounds for revoking the licence are:

- if there has been a failure of security that presents a serious risk to public health or safety; or
- if the premises are unhygienic or are no longer suitable for the purpose; or
- if there has been a failure of good pharmaceutical practice that presents a serious risk to public health and safety.

Similar criteria apply to revocation of registration of premises.

1.4.5 Panel hearings

The Authority may convene a panel to hear a matter which has been the subject of an investigation. Hearings are held in private with little formality or technicality but procedural fairness must be observed. There is no right to legal representation but the licensee may be accompanied by another person, who may be a lawyer.

At the conclusion of the hearing, the panel may insert conditions in the licence or the registration of the premises. It may also caution or reprimand the licensee or revoke the licence or the registration of the premises. The decision of the panel is the decision of the Authority.

1.4.6 VCAT review

In the event of a revocation, or a refusal to grant a licence or registration of premises, or the imposition of conditions in the licence or registration, the person affected may seek a review by the Victorian Civil and Administrative Tribunal (VCAT).

1.4.7 Fixing fees

The Authority fixes fees such that the amount of money is sufficient to cover the costs of administering the legislation. Fees are reviewed annually and are published in the Government Gazette.

PART 2

PUBLICATIONS

2.1 VICTORIAN PHARMACY AUTHORITY GUIDELINES

The Guidelines of the Victorian Pharmacy Authority (this document) represent the current policies of the Authority and any departure from them must be justified on a case by case basis. Where applicable, the guidelines should be read in conjunction with any standards, guidelines, codes and policies produced by the Pharmacy Board of Australia.

In this document:

- "the Act" means the *Pharmacy Regulation Act 2010*.
- "the Authority" or "the VPA" means the Victorian Pharmacy Authority.
- "the Board" means the Pharmacy Board of Australia.
- "the National Law" means The *Health Practitioner Regulation National Law (Victoria) Act 2009*.

2.2 STANDARDS, GUIDELINES, CODES AND POLICIES ISSUED BY THE PHARMACY BOARD OF AUSTRALIA

The Authority recognises the registration standards, guidelines, codes and policies issued by the Pharmacy Board of Australia.

2.3 STANDARDS AND GUIDELINES ISSUED BY PROFESSIONAL ORGANISATIONS

The Authority has regard to the standards, codes and guidelines issued by the Pharmaceutical Society of Australia and The Society of Hospital Pharmacists of Australia.

2.4 SPECIALISED COMPOUNDING REFERENCES

The Authority has regard to Chapters <795> and <797> of the most recent edition of the *United States Pharmacopeia* for Pharmaceutical Compounding – Non-sterile Preparations and Pharmaceutical Compounding – Sterile Preparations, respectively; and to the Pharmaceutical Inspection Convention's (PIC/S) publication, *PIC/S Guide to Good Practices for the Preparation of Medicinal Products in Health Care Establishments*.

2.5 PUBLIC REGISTER OF LICENSEES AND PREMISES

The Authority may publish the register of licensees and premises on its website and may also publish a list of persons whose licence or registration has been revoked.

GENERAL RESPONSIBILITIES

3.1 RESPONSIBILITIES OF LICENSEES AND PHARMACISTS IN CHARGE

3.1.1 Appointments and duties of owners and pharmacists in charge

In accordance with the Act, the owner of a pharmacy business or the board of management of a hospital or other institution that operates a pharmacy department must appoint a pharmacist to be regularly and usually in charge of the pharmacy or pharmacy department.

Guidelines

The pharmacist who is regularly and usually in charge of a pharmacy or pharmacy department is either:

1. the owner or in the case of a partnership, one (or more) of the owners of that pharmacy;
2. a pharmacist who has been appointed by the owner(s) of the pharmacy or in the case of a pharmacy department, the board of management (however titled);
3. a pharmacist who is appointed to be in charge of a pharmacy business for the executors, administrator or trustee of the estate of a deceased pharmacist; or
4. a pharmacist who is appointed to administer the property of a pharmacist who is bankrupt, or under the terms of a mortgage, bill of sale or security interest.

The pharmacist who is regularly and usually in charge of a pharmacy or pharmacy department is responsible for:

1. ensuring compliance with statutory obligations and ethical standards;
2. the general security of the premises, including control of the keys or other entry devices and intrusion alarm systems;
3. ensuring the correct supervision of students, pre-registrants and dispensary assistants;
4. ensuring that in his or her absence, another pharmacist is in charge for the time being;
5. the preparation and maintenance of an operations manual for use in the pharmacy; and
6. the maintenance at the premises of the required references and equipment.

The pharmacist who is regularly and usually in charge of a pharmacy or pharmacy department:

1. may not practise as such in more than one pharmacy or pharmacy department at a time; and
2. must notify the Authority as soon as practicable when appointed to the position at a hospital or at a pharmacy business.

The owner of a pharmacy business who is not regularly and usually in charge of the pharmacy must notify the Authority as soon as practicable of the name of the pharmacist so appointed. The notification may be supplied electronically or other means.

A pharmacist who has been appointed to be the pharmacist regularly and usually in charge of a pharmacy department of a hospital or institution or a friendly society pharmacy must notify the Authority as soon as practicable of that appointment. The notification may be supplied electronically or other means.

If a pharmacist regularly and usually in charge is absent for more than 28 days, another pharmacist is to be appointed as the pharmacist regularly and usually in charge.

Extra pressures can affect the performance of locums who are working in new surroundings. Locums should be given a full briefing before commencing, with particular attention being paid to computer

software, opening and closing procedures, and dispensary layout. Contact telephone numbers should be made available.

3.1.2 Death or bankruptcy of a pharmacist – duty of manager

The pharmacist who is appointed to manage a pharmacy business of a deceased or bankrupt pharmacist or of a pharmacist whose property is subject to a mortgage, bill of sale or security interest under the terms of section 6 of the *Pharmacy Regulation Act 2010* must inform the Authority as soon as practicable of the circumstances of the appointment.

3.1.3 Responsibilities of proprietors

The Act permits non-practising pharmacists to have a proprietary interest in a pharmacy. Other pharmacists with general registration may have a proprietary interest in a particular pharmacy business but choose neither to attend nor work in it.

Every owner, partner or director of a pharmacy business, if that pharmacist is not the pharmacist who is regularly and usually in charge of that pharmacy, must on a regular basis make himself or herself sufficiently aware of the manner in which the pharmacy is being conducted to determine that it is being carried on in accordance with the law and good pharmaceutical practice. If the proprietor finds that it is not, he or she must intervene to ensure that the pharmacy is properly conducted.

For the purposes of sub-section 3.1.3, being aware of how the pharmacy business is being conducted includes maintaining a direction over the kinds of goods being sold - particularly those known to be subject to abuse or misuse - and that the owner's procedures and policies are being followed. The procedures and policies should be documented and available within the pharmacy.

In a partnership or other business structure, a member cannot abdicate his or her professional obligations even if that partner is essentially silent or absent. [see: *David Loewy and Sandra Lowey v The Pharmacy Board of Victoria*, [1991] VSC 11301].

PART 4

PHARMACIES, PHARMACY DEPARTMENTS AND DEPOTS

4.1 LICENCE TO CARRY ON A PHARMACY BUSINESS OR PHARMACY DEPARTMENT

4.1.1 Application process

For further information about application processes please refer to “Assistance with applications” under the “Resources” tab on the Authority website at www.pharmacy.vic.gov.au.

The proprietor or governing body must be licensed to carry on a pharmacy business or pharmacy department.

“Licence” means a licence granted or taken to be granted under Part 3 [of the Act] by the Authority to an eligible person to carry on a pharmacy business or pharmacy department.

Guidelines

The proprietor or governing body is required to:

1. complete the **current** application form obtained from the Authority's office or website; and
2. forward the completed application to the Authority by the last working day of the month for it to be considered by the Authority at its meeting during the following month.

Correctly completed applications will be considered by the Authority at its meeting in the calendar month following receipt of the application.

Application forms may be downloaded from www.pharmacy.vic.gov.au>Forms>Licences. The forms are:

Application for a licence to carry on a Pharmacy Business - Pharmacist, Form VP11
Application for a licence to carry on a Pharmacy Business - Company, Form VP12
Application for a licence to carry on a Pharmacy Business - Friendly Society, Form VP13
Application for a licence to carry on a Pharmacy Department, Form VP17

If the Authority determines it is appropriate and that the applicant is eligible, the Authority will issue:

1. a letter approving the application; and
2. a “Notice of Commencement” form.

When the applicant commences to carry on the pharmacy business or pharmacy department, the applicant must complete and sign the “Notice of Commencement” form, include the fee and send the completed notice and the fee to the Authority.

The Authority will then write to the applicant setting out the next steps.

4.1.2 Other persons carrying on a business in the pharmacy

A business carried on within the pharmacy business (by a person other than the owner of the pharmacy business), must be compatible with the pharmacy business.

Guidelines

For the purposes of section 24 of the Act, the Authority may approve a business other than a pharmacy business to be carried on in a pharmacy by a person other than the owner of the pharmacy business.

The Authority will not approve any such business that it believes to be incompatible with a pharmacy business.

If the Authority approves another business to be carried on, it may impose conditions on the proprietor(s) of the pharmacy business.

The other business must be adequately identified as a separate and distinct business by signs; partitions, cubicles or rooms may also be provided.

The other business is not to sell or supply therapeutic goods within the pharmacy.

So that the pharmacist and staff are not distracted from providing a service in accordance with good pharmacy practice and the statutory provisions, the other business must be located so that the security of the pharmacy, privacy of pharmacy records or transactions, access to Schedule 4 and Schedule 8 poisons and access to the dispensary are not compromised. Access by clients and staff of the other business to toilets and hand basins must not be through the dispensary. The waiting area for the other business is to be situated away from the professional service area.

Any lease or agreement between the owner of the pharmacy business and the proprietor or operator of the other business should include a condition that the owner of the pharmacy business may terminate the lease or agreement if the proprietor or operator of the other business does not meet the above conditions.

An owner of a pharmacy business who wishes to have the Authority approve the carrying on of another business in the pharmacy premises should apply to the Authority in writing and provide:

1. details of the proposed business including a description of the goods and services to be offered by that business;
2. a plan of the approved premises showing where the business is to be located within the premises; and
3. details of signs to identify the business and its proprietor.

4.1.3 Notification of business names

Licensees are to notify the Authority within 14 days of any changes to the registered business name of the pharmacy.

4.2 REGISTRATION OF PREMISES

4.2.1 Application process

The practice of pharmacy must be carried out in premises that are registered by the Authority.

“Registration” means a registration granted or taken to be granted under Part 3 [of the Act] to a licensee to register the premises of a pharmacy business, pharmacy department or pharmacy depot.

Guidelines

For new premises to be registered as a pharmacy business or pharmacy department, or for existing premises to be altered, the proprietor or governing body is required to:

1. complete the appropriate application form obtained from the Authority’s office or website; and
2. forward the completed application to the Authority by the last working day of the month for it to be considered by the Authority at its meeting during the following month.

Application forms may be downloaded from www.pharmacy.vic.gov.au>Forms>Registration.

The forms are:

Application for registration of Pharmacy Premises - Form VP21

Application for registration of a Pharmacy Department - Form VP22

Application for registration of a Pharmacy Depot - Form VP23

When the Authority has considered the application and agrees to the plan “in principle”, the Authority will issue:

1. an “Agreement in Principle” letter; and
2. a “Notice of Completed Premises” form.

When the work has been completed in accordance with the approved application, the Authority must be notified.

Notification forms may be downloaded from www.pharmacy.vic.gov.au>Forms>Notifications.

The forms are:

Notification of Completion of Alterations/extensions to Pharmacy Premises - Form VP35

Notification of Completion of New Premises - Form VP36

The Authority will then write to the applicant setting out the next steps.

4.2.2 Alterations to registered premises

An application for alterations to an existing registered premises must be approved by the Authority prior to making significant alterations to a pharmacy or pharmacy department. Significant alterations include any of the following:

- alterations to the perimeter or perimeter security of the premises
- alterations affecting public access to the premises
- alterations to the dispensary including changes to the perimeter and access to the dispensary
- addition of a compounding room or dose administration aid filling room separate to the dispensary
- alterations to counselling areas

This list is not exhaustive. All applications are considered on a case-by-case basis. If clarification is required applicants are advised to speak to an Authority officer for advice.

4.3 PREMISES

4.3.1 Access to the premises

The public is entitled to have reasonable access to registered pharmacy premises.

Guidelines

To be registered, pharmacy premises must have:

1. in the case of a pharmacy business, at least one doorway opening from the premises to allow members of the public access to the premises from a street, public walkway, mall or public foyer; or
2. in the case of a pharmacy department, access from a public place within the institution, except where the department does not provide services directly to the public.

For the purposes of section 46(2) of the Act, the Authority will refuse to register premises as a pharmacy or pharmacy department if it is freely accessible to persons from other premises where the business carried on in the other premises appears to be incompatible with a pharmacy business.

Registration issued under section 46(2) is conditional on the business in the other premises remaining of the same or similar character. If the business changes in character or to another form of business, the owner of the pharmacy business must advise the Authority immediately.

A proprietor of a pharmacy business who wishes to have the Authority approve access to pharmacy premises from other premises should apply to the Authority in writing and provide:

1. a description of the business from which access is proposed; and
2. a completed application for approval of the pharmacy premises. Application forms are available from the Authority's office or website.

4.3.2 Local council planning permits

The Authority may refuse to register premises if the planning permit prevents the pharmacy from:

1. providing a pharmacy service to any member of the public; e.g. by restricting the pharmacy to providing goods and services only to clients of a co-located medical business; and
2. stocking certain goods. At a minimum, the permit must allow the pharmacy to stock and supply a range of goods consistent with the practice of pharmacy, including prescription medicines, non-prescription medicines, medical devices, dressings, first aid and sick room supplies and specialised infant foods.

4.3.3 Parts of the premises

The design and equipping of pharmacies and pharmacy departments are to ensure that the premises:

1. are secure and sanitary;
2. are suitable for the safe dispensing and supply of therapeutic products;
3. provide an environment that ensures confidentiality in dealings with the public; and
4. are directly accessible from a public place.

Pharmacy departments should refer to the *Australasian Health Facilities Guidelines*, – Health Facility Briefing and Planning B.0560 – Pharmacy Unit. [see: <https://healthfacilityguidelines.com.au> >Health Planning Units>B.0560 - Pharmacy]

4.3.3.1 Security

Pharmacies and pharmacy departments are required to be constructed to prevent, as far as is reasonable, unauthorised access through doors, windows, walls and ceilings. They are to be fitted with a security intrusion detector alarm which is control room monitored to a central agency on a 24 hour basis. The monitoring company facilities should be graded in accordance with Australian Standard 2201.2 - 2004 (Intruder Alarm Systems - Monitoring Centres) to grade 1, 2 or 3 and should hold a security firm licence.

Deterrence is enhanced by a secure perimeter that includes security lighting (particularly of rear entrances) and signs, such as "this property has security alarms", "all narcotics and cash stored in a substantial safe".

Front doors are to be fitted with a substantial lock for the type of door; a locksmith's advice is recommended as some doors require several locking systems.

Other perimeter doors are to be constructed of solid core with heavy gauge metal sheeting fitted with substantial locks. A substantial metal security grille door may be installed in addition to the solid core door as an alternative to sheeting it. Bolts and bars are to be fitted into the building structure.

Dispensary doors that cannot be readily supervised at all times should close automatically and not be able to be opened from outside the dispensary without a key, code or swipe card.

Where the building code permits, perimeter doors must be fitted with a locking system that prevents the doors from being opened by hand from the inside when the premises are *not lawfully occupied*. Otherwise, measures are needed to prevent entry through ceilings or roofs, e.g. floor to roof walls or ceiling space alarm sensors.

Doors to rooms in the public area of the pharmacy e.g. beauty rooms should be fitted with locks to prevent unauthorised entry to the room. This does not apply if the room can be readily supervised by the pharmacist on duty.

Other windows and skylights should have substantial locks if capable of being opened. Bars or grilles should be erected internally if possible and grouted into the brickwork or bolted through wall thickness. Bolts are to be welded to bars.

Roller shutters are recommended for large or recessed entry areas.

Patrols are supplementary to physical security and are not a substitute for it.

The intrusion detector must at least cover any area where drugs are kept, including the dispensary, drug safe, professional service area and storerooms.

Silent "hold up" alarms (panic buttons) are recommended.

Schedule 4 poisons must be stored in a manner that they can be supervised; particular attention therefore, needs to be paid to the contents of, and accessibility to, storerooms and refrigerators.

There should be periodic checking of physical security items such as locking systems. Electronic devices should be tested to see that they are functioning. Advice from a security expert and/or a locksmith is recommended.

4.3.3.2 Professional service area in a pharmacy

To reflect the professional nature of a pharmacist's dealings with the public, a professional service area is required. It is a distinct area, distinguished by décor and sign(s) stating "Professional Service Area". The area is solely for the purposes of displaying and storing products for therapeutic use and information about them.

4.3.3.3 Counselling area

A distinct area (which may be part of the professional service area) is required that permits the pharmacist to discuss any matter with a member of the public on a private and confidential basis. The area must be positioned such that any conversations are out of the hearing of other persons. Care must also be exercised in ensuring that third parties do not see a patient's medicines, the packaging of which is indicative of the medicines' identity and potentially its purposes.

Dedicated prescription reception and counselling points fitted with opaque privacy screens that rise to at least 600 mm above the bench to form a booth or that are otherwise arranged or located to provide privacy are required. There should be as many counselling points as there are dispensing stations. They should be designed to encourage routine use for all prescription transactions. A password-protected screen and keyboard is recommended in each.

A separate room or office may also be used for the above purposes and for the provision of extended services such as disease screening, prolonged consultations or structured patient programs that, to be effective, require privacy and freedom from interruptions. Pharmacists should determine if a level of privacy, as achieved in a counselling room, is required to undertake the more extensive professional activities, compared with the level of privacy that can be achieved in the Professional Service Area for the more routine patient interactions.

4.3.3.4 Dispensary

4.3.3.4.1 General dispensary requirements

The requirements for dispensaries set out in this section apply to all existing and new pharmacies. Pharmacists should regularly assess the adequacy of the dispensary to ensure compliance in the face of changed business circumstances including business growth. Compliance with dispensary standards will be a priority of Authority officers during all inspections.

In particular circumstances demonstrated by the applicant, the Authority may approve variations to the requirements of this section.

The dispensary is a private area dedicated to the dispensing of medicines and the secure storage of patients' records. Lighting, ventilation and temperature control are essential to maintaining the integrity of the medicines and for personal comfort. The dispensary is to be supplied with hot and cold running water and refrigeration, and provide a sufficient area for equipment and free working space. The public is not permitted access to the dispensary.

The dispensary should be designed to prevent persons from entering the dispensary or any part of it, without being noticed by the pharmacist on duty. e.g. rear entrances to the dispensary should be avoided but if necessary, doors should be fitted with a self-closing device and a lock so that they cannot be opened to enter the dispensary without a key or key code.

The dispensary and its surrounds should be designed to prevent clients from approaching and standing directly and immediately in front of the dispensary (except at designated service points), in order to minimise interruptions and distractions to the dispensing process and also to prevent the inadvertent disclosure of documents and the identity of patients' medicines to people who look over the front of the dispensing bench. This may require service counters to be placed in front of the dispensary or a screen to be installed along the top of the dispensary bench.

Where the dispensing stations are designed for forward dispensing, there should be at least one additional non-forward dispensing station which is not accessible to the public.

The pharmacy should be designed so that the dispensary is not used as a thoroughfare to access "back of house" areas.

Therapeutic products are not to be removed from the dispensary without the express permission of a pharmacist unless by a student, intern or trained dispensary assistant under the supervision of a pharmacist.

A dispensary in a pharmacy is to include:

1. provision for the storage of S4 poisons that facilitates the accurate selection of medicines and restricts access to dispensary staff only;
2. a safe or drug cabinet for the storage of S8 poisons that facilitates the accurate selection of medicines;
3. a bench or bench area of at least 0.6 m² for the unpacking and sorting of dispensary orders received;
4. one dispensing station for each 150 prescriptions or part thereof dispensed on a typical day between 9 am and 6 pm;
5. a hot and cold water sink with drainer;
6. a bench or bench area of at least 0.6 m² located near to the sink for the compounding or preparation of medicines that provides storage for measuring and weighing equipment; and
7. a bench or bench area of at least 0.6 m² for dispensary or clerical and research use;

AND

if the pharmacy provides pharmacotherapy to 20 or more persons per day:

8. a bench or bench area dedicated to the pharmacotherapy program of at least 0.6 m² that is not accessible to the public and provides for the secure storage of "in use" S8 medicines.

The pharmacotherapy area may be located away from the dispensary provided:

9. it is air-conditioned;
10. it is alarmed;
11. it is fitted with a hot and cold water sink with drainer;
12. it is fitted with a safe or drug cabinet to store S8 poisons;

13. it is fitted with lockable storage for client records; and
14. suitable arrangements are in place in the pharmacy to protect the privacy of pharmacotherapy clients;

AND

if the pharmacy regularly fills dose administration aids (DAAs) for 15 or more persons per week;

15. there is a bench or bench area of at least 1 m² dedicated to the filling of DAAs; and
16. a secure storage for dispensed medicines.

The area for the filling of DAAs may be located away from the dispensary provided:

17. it is air-conditioned;
18. it is alarmed;
19. it has access to hand washing facilities;
20. it has a 'patient history look-up' computer terminal and DAA printing equipment;
21. it provides lockable storage for dispensed medicines;
22. it provides secure storage for patient records; and
23. it is free from interruption and distraction.

A dispensing station is to include a dispensing bench of at least 0.6 m² (e.g. 1000 mm x 600 mm) equipped with a screen, a keyboard, a dedicated scanner, a dedicated printer for labels, a dedicated printer for repeat forms and adequate stationery. Each station must be convenient to a printer that prints Consumer Medicine Information (CMI). The CMI printer may be located at or away from the dispensing station and may service multiple dispensing stations.

If a dispensary assistant is involved with dispensing at a dispensing station, then an additional bench area of at least 0.6 m², equipped with a keyboard and screen without label and printing capability, is recommended for the dispensing station. The bench area may be separate from, or an extension of the dispensing bench.

4.3.3.4.2 Dispensary area in pharmacies

The area of the dispensary should be in keeping with the level of service provided by the pharmacy. The area of the dispensary should be not less than 10 per cent of the total trading area to a maximum required area of 30 m² but not less than 20 m².

Examples:

- A pharmacy up to 200 m², the dispensary area will be not less than 20 m².
- A pharmacy of 260 m², the dispensary area will be not less than 26 m².
- A pharmacy of 300 m², the dispensary area will be not less than 30 m².
- A pharmacy of 400 m², the dispensary area will be not less than 30 m².

In calculating the area of the dispensary;

1. the total trading area is the sum of the areas of the professional trading area and the general trading area;
2. a pharmacotherapy area that is located away from the dispensary may not be included in the calculation of the dispensary size; and
3. a dose administration aid filling area that is located away from the dispensary may not be included in the calculation of the dispensary size.
4. a laboratory set aside for complex compounding may not be included in the calculation of the dispensary area.

4.3.3.4.3 Dispensary area in hospital pharmacy departments

The area set aside for each of the functional areas in a pharmacy department should be in keeping with the level of service to be provided by the department and the needs of the hospital in which it operates.

In considering the area required for a pharmacy department, the Authority has regard to:

1. the level classifications described in Appendix 4 to these Guidelines, as adapted from the New South Wales Department of Health's Guide to the Role Delineation of Health Services;
2. The Australasian Health Infrastructure Alliance's *Australasian Health Facilities Guidelines – Health Planning Unit – B.0560 Pharmacy Unit*. [see: <https://healthfacilityguidelines.com.au> >Part B: Health Facility Briefing and Planning Units > B.0560 – Pharmacy Unit];
3. the Authority's experience; and
4. the relevant parallels with community pharmacies.

The Authority requires appropriate space to be allocated to all functional areas such as the dispensing area, offices, staff amenities, bulk storage, clinical trials, drug information, intravenous and/or cytotoxic preparation areas.

Based on 1-4 (above), the minimum dispensary area (i.e. the area allocated for dispensing only) as appropriate to departments fitting the levels described in Appendix 3 are:

Level 3:	45 m ²
Level 4:	85 m ²
Levels 5 and 6:	180 m ²

The Authority, at its discretion may approve a smaller dispensary area provided the hospital can demonstrate to the Authority's satisfaction that it is appropriate for the needs of the hospital and in the public interest. Conversely, the Authority may decline to approve an area meeting the minimum requirements if it considers that they are insufficient for the range or type of services required.

4.3.3.5 Client waiting area in pharmacies

A pharmacy should include at least one client waiting area. Its use should be encouraged to minimise congestion at the serving counter where privacy may be compromised, and to reduce pressure on the dispensing staff. In the interests of safe dispensing, chairs should be positioned in such a way that dispensing staff are not subject to staring or body language that indicates impatience. Provision of reading matter is suggested.

4.3.3.6 Client waiting area in hospital pharmacy departments

The requirements of paragraph 4.3.2.5 also apply to hospital pharmacy departments in cases where patients may be required to collect dispensed medicines from the pharmacy department.

4.3.4 Point of Sale (POS) data entry station

POS data entry stations, non-dispensary clerical work areas and staff areas are to be located outside of the dispensary.

4.3.5 Display of names

The public is entitled to know the names of the pharmacists with whom they are dealing in a professional capacity.

Guidelines

The name or names of the proprietor(s) of a pharmacy, natural or corporate as the case may be, must be displayed on a sign at eye height placed at all the entrances to the pharmacy where the public has access so as to be clearly visible at all times from the street or public thoroughfare. The font size should be at least 72 points (25 mm).

The name of the pharmacist who is regularly and usually in charge of the pharmacy or pharmacy department and the name or names of other pharmacists on duty are to be displayed in the professional service area or the place where medicines are usually collected by the public.

In the case of pharmacy departments, it is sufficient compliance with this standard if the name of the director or pharmacist-in-charge is displayed.

There is neither a requirement for, nor objection to, the wearing of name badges.

4.3.6 Removal of signs

The public is entitled to know that a pharmacy or pharmacy department has ceased to operate.

Guidelines

When a pharmacy or pharmacy department ceases to operate, the owner or the pharmacist who is regularly and usually in charge of the pharmacy or pharmacy department, or the administrators, trustees or executors must remove all signs that indicate that the premises were a pharmacy or a pharmacy department.

4.3.7 Pharmacies that do not supply pharmaceutical benefits

The public is entitled to know if a pharmacy is not approved to supply pharmaceutical benefits.

Guidelines

There should be a prominent sign stating that:

- Pharmaceutical Benefits (of all kinds) are not available from the pharmacy; and
- Patient Record Forms cannot be completed; and
- Repeat Authorisation forms for Pharmaceutical Benefits are not issued.

Persons presenting prescriptions at the pharmacy are to be directed to the sign (above) and have the financial consequences of not obtaining the medicine as a Pharmaceutical Benefit explained to them.

4.3.9 Display of medicines containing pseudoephedrine

Pseudoephedrine is a precursor that is highly sought after for the illicit manufacture of methylamphetamine in clandestine drug laboratories. It is an essential ingredient in the most common methods of illicit amphetamine manufacturing processes in Victoria.

Current police intelligence clearly indicates that pharmacies are targeted by individuals and criminal organisations seeking to acquire pseudoephedrine.

On-line decision support tools are available and the Authority encourages their use.

Guideline

All stocks of medicines containing pseudoephedrine should be kept out of view of the public. This guideline is in addition to those published by the Pharmacy Board of Australia.

4.3.10 Workloads

Section 38(1)(b) of the Act requires the Authority to be satisfied that, *inter alia*, the operation of the pharmacy business and pharmacy departments complies with good pharmacy practice and the Schedule to the Act [see: Appendix 2]. Accordingly, a pharmacy or pharmacy department should be staffed to meet the expected workload.

4.3.10.1 Community pharmacies

Guidelines

As a benchmark, not less than one full-time equivalent pharmacist dispensing an average of 150 prescriptions over a 9.00am to 6.00pm day, and pro rata at weekends and on public holidays, is regarded as the *minimum* staffing level. Attention should be paid to predictable spikes in activity during specific times, days or months. Sustainable workload may also be affected by other factors such as dispensing technologies, staff familiarity with systems and other non-dispensing responsibilities.

The preparation of each take-away dose of methadone or buprenorphine and each administration of either drug is counted as being the equivalent of one prescription.

An individual pharmacist must not supervise more than two dispensary assistants or dispensary technicians engaged in the selection, processing and labelling of prescription medicines at a time. Other trained dispensary assistants or dispensary technicians can be engaged in duties that do not require direct supervision outside of this ratio (e.g. in dispensary stock control or preparing dose administration containers).

If dispensing levels are in the range of 150-200 prescriptions per day, a trained dispensary assistant and/or an intern pharmacist may assist the pharmacist. If the workload is in the range of 200 to 220 prescriptions daily, a second dispensary assistant may be used but above this workload, a second pharmacist will be necessary for at least part of the day.

The Authority acknowledges that a pharmacist may be required to dispense above this rate in unforeseen circumstances such as staff shortage due to sudden illness. The Authority recognises that in such circumstances the pharmacist can take effective short term measures to allow him or her to deal with the workload and meet his or her professional obligations.

4.3.10.2 Hospital pharmacy departments

Guidelines

The workload principle in paragraph 4.3.8.1 applies to hospital pharmacy departments modified in recognition of the more varied functions and complexity of the work. To this end, the Authority takes into account the dispensing, in-ward clinical activities, bed ratios for classes of patients (e.g. critical care, surgical, rehabilitation, hospice), drug information and clinical trial management to arrive at a comparable workload.

A clinical service appropriate to the classification and patient acuity of the hospital should be provided. As a minimum, a "basic clinical service" (as defined by The Society of Hospital Pharmacists of Australia) is required during normal weekday business hours. In the case of a pharmacy department that does not routinely provide a clinical pharmacy service to all overnight beds then a documented procedure should be in place to identify and refer to the pharmacy department those patients who warrant a clinical pharmacy service.

4.3.11 Controlled temperature storage

Pharmacies and pharmacy departments are required to provide facilities in which medicines are stored at temperatures within their recommended temperature range.

Guidelines

Temperatures in a pharmacy or pharmacy department should not exceed 25^o; to this end, thermostatically controlled air conditioning or cooling by other means is necessary unless the premises are so situated or constructed as not to allow this temperature to be exceeded. Air conditioners should be set to maintain temperatures not exceeding 25^o during periods when the pharmacy is not open for business.

Temperatures may vary considerably between different parts of a refrigerator.

A continuously reading thermometer is required with the sensor (known as a data logger) connected to the computer (or functionally similar arrangements) to alert staff to any malfunction when the premises

are unoccupied and provide sufficient information to allow the effect of the malfunction on the integrity of the medicines to be assessed. Appendix 5 expands on data loggers and cold chain management.

Refrigerators used to store medicines should be dedicated to this purpose.

Due regard must be paid to maintaining the integrity of the “cold chain” when stock is received and before it is supplied. It follows that the patient or agent should be informed of the storage conditions both verbally and by labelling.

4.3.12 Privacy and confidentiality

Schedule 1 of the *Health Records Act 2001* sets out the Privacy Principles applicable to health providers in Victoria; [see: www.legislation.vic.gov.au and follow the prompts].

Information about a person that a pharmacist obtains in the course of professional practice is confidential and may be disclosed only:

1. with that person's permission; or
2. to other persons authorised to the extent of the latter person's lawful jurisdiction or;
3. on a court order; or
4. if, in the pharmacist's opinion, it is in the patient's best interest to divulge pertinent information to another health practitioner who is treating the patient.

Authorised persons include:

1. an inspector or investigator of the Australian Health Practitioner Regulation Agency;
2. an officer of the Victorian Pharmacy Authority;
3. a person authorised under the *Drugs, Poisons and Controlled Substances Act 1981* (including a member of the Victoria Police in accordance with section 42 of that Act);
4. a member of the Victoria Police or other enforcement agency in accordance with the *Privacy Act 1988* (Cth) or the *Health Records Act 2001*;
5. an authorised officer of Medicare Australia for the purposes of examining prescriptions supplied as pharmaceutical benefits under the *National Health Act 1953* (Cth); and
6. an authorised officer of the Victorian WorkCover Authority (WorkSafe Victoria) or the Transport Accident Commission (TAC).

The *Pharmacy Regulation Act 2010* obliges proprietors, as a condition of their licence, to have arrangements in place that enable confidential discussions to take place in private and to ensure that the identity of a client's medicines cannot be known to other persons in the premises.

Guidelines

Particular care should be exercised if other official bodies seek information. The Office of the Victorian Commissioner of Privacy and Data Protection (Privacy and Data Protection Victoria) should be contacted in cases of uncertainty. (tel: 1300 666 444; email: enquiries@privacy.vic.gov.au)

Members of staff at a pharmacy are to be informed of the need to observe confidentiality in all their dealings with the public.

The name or details of a therapeutic product (medicines and devices) should not be identified in information given to other than the person for whom it was intended, unless the person waives that right. Examples of persons to whom information may be inadvertently disclosed could include a person paying a family account or to third party organisations (including service companies) that process accounts, and organisations collecting statistical data.

The inadvertent disclosure of the identities of patients' medicines (and therefore the patients' medical conditions) to third parties is to be avoided. Ensuring that dispensed medicines are not transferred to checkouts in open baskets for other people to look at or comment on, is essential. Similarly, dispensed medicines that are waiting collection should be stored in a manner that prevents third parties from relating them to the person for whom the medicines are intended. The Schedule to the *Pharmacy*

Regulation Act 2010 makes specific mention of these matters; see Appendix 2, paragraphs 9(g) and 9(h).

Dispensary counters should be designed so that privacy is not compromised and in such a way that members of the public cannot view private information.

4.3.13 Facilities for immunisation services

Immunisation services may be provided in pharmacies and stand-alone pharmacy depots as a means of improving the current level of immunisation in the community. Immunisation services are to be carried out in a room or area suitable for the purpose, ensuring privacy, confidentiality and hygiene standards are maintained. These guidelines apply only to premises and equipment and not procedures.

Pharmacists may only administer vaccines in accordance with the Secretary Approval – Pharmacist Immuniser and the *Victorian-Pharmacist Administered Vaccination Guidelines* as issued by the Department of Health and Human Services [see: <https://www2.health.vic.gov.au/public-health/immunisation/immunisers-in-victoria/pharmacist-immunisers>]

A copy of the Certificate of Training Completion should be displayed in the vaccination area to assure consumers that the pharmacist-immuniser has successfully completed an immuniser program of study that has been recognised by the Chief Health Officer.

Guidelines

The dispensary is not to be used for immunisation services.

The room or area may be dedicated to the purpose or an existing consulting room may be used. It is not to be used as a storeroom or staff room. Hand sanitisation facilities are to be in the room.

The room or private consultation area is to:

1. be designed such that the procedure is not visible or audible to other persons in the pharmacy;
2. have sufficient floor area, clear of equipment and furniture, to accommodate the client and an accompanying person, and to allow the practitioner room to manoeuvre;
3. have a bench with an impervious surface of an **adequate area**, a chair, a first aid couch or similar*;
and
4. have an emergency response protocol (preferably laminated) on display, an emergency response kit, and the most recent editions of the *Australian Immunisation Handbook* and the *National Vaccine Storage Guidelines: Strive for 5*.

*The purpose of the first aid couch or similar, **such as a reclining chair**, is for people who prefer to recline or lie down because they may feel faint before, during or after the injection. The first aid couch is not intended to be used for CPR.

Seating is to be made available post-vaccination so that the client may be observed in accordance with professional guidelines.

Only a temperature-monitored refrigerator manufactured exclusively for the purpose of storage of vaccines may be used but the same refrigerator may also be used for the storage of other medicines. If the refrigerator is not in the dispensary, it must be fitted with a lock. Cold chain requirements, including the use of a data logger, apply to all refrigerators used for storing refrigerated medicines.

Note: Pharmacists providing immunisation services are exempt from the requirement to register the premises with the municipal council, but this exemption does not apply where other skin penetration procedures, such as ear piercing, are carried out.

4.3.14 Dispensary assistants' certificates

The Pharmacy Board of Australia sets out detailed requirements for the training, activities and competencies of dispensary assistants. [see: Pharmacy Board of Australia: *Guidelines for the*

Dispensing of Medicines; para 12, “Dispensary assistants/dispensary technicians and hospital pharmacy technicians”].

Guideline

For the purposes of inspection of pharmacies and pharmacy departments, the licensee should ensure that copies of the dispensary assistants’ certificates or other evidence of training are kept at the registered premises.

4.4 EQUIPMENT

4.4.1 References

The pharmacist regularly and usually in charge of a pharmacy or pharmacy department must keep at that pharmacy or pharmacy department the current edition, together with any supplements, addenda or amendments to the references specified in the Pharmacy Board of Australia’s *Guidelines on practice-specific issues – Guideline 1 (List of References)*. The references may be in the form of a published document (hard copy) or in an electronic form provided the information is immediately available to the pharmacist during the dispensing process.

The: *Drugs, Poisons and Controlled Substances Act 1981*
Drugs, Poisons and Controlled Substances Regulations 2017
Pharmacy Regulation Act 2010
Health Practitioner Regulation National Law (Victoria) Act 2009

may be accessed from www.legislation.vic.gov.au and clicking on Victorian Law Today.

The Codes and Guidelines of the Pharmacy Board of Australia may be accessed at www.pharmacyboard.gov.au

The Guidelines of the Victorian Pharmacy Authority (i.e. this document) may be accessed at www.pharmacy.vic.gov.au

Notes

Note 1: If participating in opioid replacement therapy programs, copies of the “National Clinical Guidelines for the Use of Methadone in the Maintenance Treatment of Opioid Dependence 2003”, the “National Clinical Guidelines and Procedures for the Use of Buprenorphine in the Treatment of Heroin Dependence” and the Department of Health and Human Services’ most recent “Policy for maintenance pharmacotherapy for opioid dependence” are required. These may be accessed on www.health.vic.gov.au/dpcs/pharm.htm

Note 2: The *Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP)* is no longer required. Specific queries about scheduling should be directed to Drugs and Poisons Regulation of the Department of Health and Human Services (Tel: 1300 364 545). The SUSMP may be accessed on the Internet by typing: Comlaw poisons standard, in the search engine or via the TGA’s website on www.tga.gov.au.

4.4.2 Dispensing equipment

All community pharmacies are to be equipped with Class 1 or Class 2 approved scales and a range of accurately calibrated metric measures; blending equipment for powders, liquids and pastes; and suitable storage containers.

All pharmacy departments are to have access to certified and approved scales commensurate with the services provided within an institution.

Guidelines

Operating instructions, including the minimum weighable mass, are to be prominently displayed.

The scales should be stored in such a way that their accuracy is not compromised.

Pharmacists are responsible for the accuracy of the weighing equipment they use. Good practice suggests that weighing equipment should be tested at least every five years.

In the case of institutions, “access to approved scales” means the scales will be within and controlled by the institution.

Note: “Approved” means that the make and model of the scales has been approved by the National Measurement Institute.

4.5 SCHEDULE 8 POISONS

Schedule 8 poisons (Controlled Drugs) are to be stored and recorded in accordance with the Drugs, Poisons and Controlled Substances Regulations 2017. [see: <https://www2.health.vic.gov.au/public-health/drugs-and-poisons/documents-forms-print-or-download>] and scroll down to Pharmacists.

4.5.1 Storage

Guidelines

The increased use of Schedule 8 poisons (including substitution therapies) and bulkier packaging indicate the need for installing safes that are large enough to store all S8 poisons on hand (taking into account future needs) and to facilitate accurate selection of the medicines from the safe or locker. Unwanted or expired stocks of S8 poisons or identifiable returned stock from the public must be stored securely pending their destruction.

Specifications about drug safes are available from locksmiths and safe manufacturers. The safe or locker must meet at least the minimum standards prescribed under the Drugs, Poisons and Controlled Substances Regulations 2017 and installed in accordance with the Regulations to ensure that it cannot be removed easily.

Bulk quantities of “in use” substitution therapies that are administered to patients attending the pharmacy need to be located so that they are inaccessible to, and preferably out of sight of, the patient.

Keys to the Schedule 8 poisons safe must not be left on the premises overnight, unless they are stored in a safe of at least equivalent security to the Schedule 8 safe and to which pharmacists have exclusive access. In most cases, this will be a safe fitted with a combination lock or a keypad, the codes to which will be limited to pharmacists.

4.5.2 Records

Records of transactions and the remaining balance are required to be made contemporaneously to ensure that registers show the true and accurate balance of each S8 poison remaining after each transaction. In the case of methadone and buprenorphine for opioid replacement therapy, pharmacists are required to record in the register the total quantities used on a daily basis. The calculated balance of all S8 poisons must be reconciled regularly with actual stock on hand to ensure accuracy of the register.

4.6 COMPOUNDING PHARMACIES

4.6.1 Premises and equipment

The part of the pharmacy dedicated to extemporaneous dispensing of medicines must be suitable, sanitary and adequately equipped for the purpose.

Guidelines

Where the pharmacy operates as a compounding pharmacy or undertakes complex compounding, there is to be a dedicated area (a laboratory) separated from other parts of the pharmacy by floor to ceiling walls or partitions and one or more doors. The floor is to have an impervious covering. All surfaces such as walls, bench tops and shelves are to be washable. A sink and drainer with hot and

cold running water is required. The laboratory may be contiguous with other parts of the dispensary or separate from it. In the latter case, the door is to be fitted with a lock. The floor area of the laboratory is not counted as part of the floor area of the dispensary [see: General dispensary requirements, paragraph 4.3.2.4.2].

Equipment should be appropriate to the kinds of medicines and the quantities to be made up, having regard to possible complications arising from scaling up the quantity prepared for one patient.

In addition to the references prescribed by the Pharmacy Board of Australia, specialised references (hard copy or electronic) may be required.

4.6.2 Staffing and training

~~Adequate training for all staff, including pharmacists, is necessary to ensure the safety, quality and efficacy of the medicines.~~

Guidelines

~~Dispensary assistants (including those with a qualification in science) who take part in any aspect of extemporaneous dispensing are to have completed a certificated course in general dispensing and also a course in compounding that is accepted by the Authority.~~

4.6.3 Occupational health and safety

Statutory occupational health and safety laws are to be complied with and contamination of equipment, starting materials and final product minimised.

Guidelines

Protective clothing (laboratory coat, disposable gloves and hair covers) should be worn during all compounding procedures. Additional protective clothing and equipment are required when handling potent or hazardous substances e.g. hormones, antibiotics, cytostatics. These include non-shedding disposable laboratory coats or overalls with elasticised cuffs and closures up to the neck; particulate respirators (N95 rated) or HEPA filtered (P100) respirator masks; nitrile gloves; hair and beard coverings and shoe covering.

A powder containment cabinet with HEPA filtered exhaust air is required for operator and environment protection. All activities likely to release powder should be confined to the cabinet e.g. weighing powders, making capsules and compounding processes. The cabinet chosen should be suited to the materials and volumes handled. A pre-filter should be fitted and there should be a visual display of air velocity. A risk assessment should be undertaken and expert advice sought before purchase and installation. Appendix 6 has more information about powder containment cabinets.

Base line and periodic pathology monitoring is also required where high risk medicines, such as hormones, are prepared.

4.6.4 Quality and stability

Medicines that are extemporaneously prepared and supplied must be made from quality starting materials and the final product is to meet appropriate standards until its expiry date is exceeded.

Guidelines

Pharmacists should satisfy themselves that starting materials (including water) meet suitable quality standards. Pharmacists should refer to the Pharmacy Board of Australia's Guidelines on compounding of medicines and the section *Extemporaneous dispensing* in the current edition of the Australian Pharmaceutical Formulary and Handbook for guidance on standards for starting materials used for compounding.

The composition of the medicine is to be based on sound pharmacological, clinical and pharmaceutical principles. Ingredients and processing conditions that would result in potentially toxic or ineffective preparations must be avoided.

Expiry dates are determined from the date the medicine is prepared. Because the medicine is intended for immediate use or following short-term storage, the expiry dates are based on criteria different from those applied in commercial manufacture.

Pharmacists should consult and apply drug-specific and general stability documentation and literature when available, taking into account the properties of the drug, its degradation mechanism, the container in which it is packaged, the expected storage conditions, and the intended duration of therapy.

In the case of specialised or novel formulations that are frequently prepared, such as those that include high potency substances, at least one sample is to be submitted annually to a competent analytical laboratory for assay and, for tablets and capsules, disintegration and uniformity of content tests. The analytical report is to be filed and made available for inspection by the Authority's officers.

4.6.5 Sterile medicines

Sterile medicines may be made up only if:

1. The premises and equipment meet current Australian Standards;
2. Sterilisation equipment operates in accordance with the manufacturer's specification and the performance is validated;
3. Procedures are fully documented; and
4. Staff are suitably trained in the preparation of sterile products.

4.6.6 Disposal of unwanted chemicals

Unwanted chemicals are to be disposed of using the services of a company specialising in this work.

4.6.7 Regulatory framework

Extemporaneous dispensing in community pharmacies

The regulatory regime in Victoria results from the application of the *Therapeutic Goods Act 1989* (Cth) and the *Therapeutic Goods Regulations 1990* (Cth) as given effect by the *Therapeutic Goods (Victoria) Act 2010*. The general rules relating to the manufacture and supply of therapeutic goods are:

1. the goods must be entered in the Australian Register of Therapeutic Goods (ARTG) before they can be supplied, unless they are "exempt goods"; and
2. the premises where the medicines are manufactured must be licensed, unless the person carrying out the manufacturing is an "exempt person".

"Exempt goods" include "medicines that are dispensed, or extemporaneously compounded, for a particular person for therapeutic application to that person".

"Exempt persons" include "pharmacists in relation to the manufacture of therapeutic goods produced by the pharmacist" in a pharmacy where the pharmacist practises and is open to the public; or on the premises of a dispensary conducted by a Friendly Society; or on the premises of a private hospital for supply (other than by wholesale) on or from those premises.

The following table summarises the requirements.

CIRCUMSTANCES	ARE THE GOODS REQUIRED TO BE ENTERED ON THE ARTG?	ARE PREMISES REQUIRED TO BE LICENSED?	REFERENCES
Medicine made up for a named patient. Patient-specific label and records of supply kept. ¹	No	No	TG Reg Sch 5, Item 6 TG Reg Sch 8, Item 2

Medicine made up and supplied for general sale only from the pharmacy where it was made up. ²	Yes	No	TG Reg Sch 8, Item 2 TG(V) Act
Medicine made up and supplied to another person for on-supply. ³	Yes	Yes	TG Act and TG(V) Act TG Act and TG(V) Act

1. The first situation presents no difficulties and applies to medicines dispensed on prescription and to medicines that the pharmacist prescribes on his or her own motion. The usual recording and labelling requirements apply.
2. The second situation applies when a pharmacist decants from a bulk pack (of either a commercial product or something that he or she makes) into smaller containers with the pharmacy's own label for supply other than as in the previous paragraph.
3. In the third situation, the pharmacist is no different from any other manufacturer in that the premises would require licensing from the Therapeutic Goods Administration. The Code of Good Manufacturing Practice would have to be implemented.

Therapeutic goods that are prepared by pharmacists employed by a public hospital or public institution for supply in hospitals or public institutions within the State are exempt from having to be entered on the ARTG and the hospital or institution is not required to hold a manufacturing licence.

4.7 SATELLITES OF PHARMACY DEPARTMENTS

A hospital pharmacy department may include one or more satellites that are approved by the Authority. Each satellite is to be within the hospital and is part of the department but remote from it. The satellite and its staff are to be personally supervised by a pharmacist and may perform any function of the department, subject to it being suitable, sanitary and adequately equipped.

Guidelines

The satellite's area is to be not less than 20 m² (including the shelving and working areas), unless the Authority approves a smaller area in a particular case.

The satellite pharmacy is to be equipped with:

1. a sink made of stainless steel or similar with an impervious surrounding area and supplied with hot and cold running water;
2. an impervious dispensing bench of not less than 400 mm width and of sufficient length as to provide not less than 3 m² of free working space, in addition to the space occupied by computers and other equipment;
3. adequate lighting and ventilation;
4. a security intrusion detector alarm that is monitored in a control room to a central agency throughout the 24 hours;
5. a password-protected computer networked to the department computer;
6. direct access to a complete set of texts mandated by the Authority;
7. dispensing equipment appropriate to the intended function; and
8. a telephone.

The satellite is to be constructed to:

1. provide an area for patients to be counselled privately about their medicines;
2. maintain suitable conditions of temperature and humidity for the storage of all the drugs stored within; and
3. prevent unauthorised access by persons other than the staff of the pharmacy department.

4.8 WARD DISPENSING STATIONS

A hospital pharmacy department may, with specific Authority approval, establish, separate from the department, a ward dispensing station within the hospital to enable ward pharmacists to dispense

prescriptions for patients of up to two wards. A satellite that is approved by the Authority is required if the ward dispensing station is to service more than two wards.

Guidelines

The ward dispensing station is to be equipped with:

1. a password-protected computer networked to the department computer;
2. direct access to a complete set of texts mandated by the Authority;
3. dispensing equipment appropriate to the activities of the ward, including labels, ancillary cautionary and advisory labels, tablet counters;
4. a telephone; and
5. a lockable drug storage facility, if required.

The ward dispensing station is to:

1. be located in or adjacent to the ward drug storage area, preferably a lockable room;
2. be in a position that minimises distraction to the dispensing pharmacist; and have adequate lighting;
3. have ready access to hand washing facilities;
4. provide an impervious bench of sufficient size to accommodate dispensing equipment and provide 0.6 m² of clear working space; and
5. be dedicated to pharmacy use.

4.9 PHARMACY DEPOTS

4.9.1 Establishing a pharmacy depot

The Authority may register a pharmacy depot that is carried on by a person who is licensed to carry on a pharmacy business or a pharmacy department in accordance with sections 47 and 48 of the Act.

Guidelines

The depot is to be situated at least 15 km by the normal access route from the nearest pharmacy. If Schedule 2 poisons are to be stored at, or supplied from the depot, the depot must be connected to the pharmacy by an audio-visual link. A Schedule 2 poison may only be sold from the depot by a pharmacist following a consultation he or she has had with the client using the audio-visual equipment on every occasion of a sale.

In making application to the Authority for registering the depot, the applicant is to describe the depot and how it is to be conducted. The description is to include:

1. the means by which orders for medicines and prescriptions are to be received at the depot and their transmission to the pharmacy;
2. how prescriptions are to be collected from the depot and conveyed to the pharmacy;
3. the operation of a confidential audio-visual link between the depot and its clients with the pharmacy;
4. how a pharmacist intends to counsel the patient who obtains medicine from the depot;
5. how medicines supplied to the depot are to be packaged and transported to the depot;
6. how the medicines are to be stored at the depot, with reference to security, confidentiality and maintaining the integrity of the medicine;
7. the name of the person in charge of the depot and certification that the person has attained 18 years;
8. the kinds of medicines to be stocked at the depot and the maximum quantities of Schedule 2 poisons;
9. a copy of procedures that the person in charge is to follow with particular reference to confidentiality of any information about clients of the pharmacy and the need to refer all queries about the medicine to the pharmacist;

10. the business name of the depot (*note*: the words “pharmacy” or “chemist” must not be used to imply that the depot is, or operates as, a pharmacy); and
11. a statement that a pharmacist agrees to visit the depot at intervals of not less than two months to ensure that the procedures are adhered to.

4.9.2 Provision of a procedure manual for depot staff

The licensee should provide the person in charge of the depot with a procedure manual which covers all operational aspects including:

- security;
- ordering and storage of medicines;
- sale of scheduled medicines;
- transmission of prescriptions;
- supply of dispensed medicines;
- return of uncollected dispensed medicines;
- privacy and confidentiality; and
- the referral of queries to the pharmacist.

The licensee should ensure that the staff at the depot understands and follows the procedures set out in the procedure manual.

4.9.3 Schedule 2 poisons at depots

Schedule 2 poisons can be stored for sale at depots if:

1. the depot is a stand-alone business; and
2. the depot premises are owned or leased by the licensee of the related pharmacy. Schedule 2 poisons should not be stored at depots operated in other businesses such as supermarkets, post offices, general stores, petrol stations.

4.10 SUPPLYING etc. MEDICINES IN SPECIAL CIRCUMSTANCES

The Authority may approve in a particular case a pharmacist to supply, compound or dispense medicines in special circumstances under section 29(1)(b) of the Act.

4.10.1 Application process

Guidelines

The pharmacist seeking to practise under special circumstances is required to:

1. complete the appropriate application form obtained from the Authority’s office or website and;
2. forward the completed application to the Authority by the last working day of the month for it to be considered by the Authority at its meeting during the following month.

Application forms may be downloaded from www.pharmacy.vic.gov.au>Forms>Approvals.

Application to Practise in Special Circumstances, section 29(1)(b) – Form VP41

If the Authority approves the application, it will issue an approval letter valid for a maximum of three years. The Authority will also arrange for an inspection by an Authority officer.

4.10.2 Continuity of services in special circumstances

Guidelines

Where a person commences to carry on a pharmacy business or pharmacy department that provides a service the special circumstances of which are approved under section 29(1)(b) of the Act, then the special circumstances are deemed to be approved for a period of three months after commencing to

carry on the pharmacy business or department. This is intended to allow the service to continue to operate while the new owner applies for registration.

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MISCELLANEOUS

5.1 Commercial arrangements

Pharmacists who engage companies to provide management, marketing, franchising and other commercial services to a pharmacy business may do so provided:

1. the company does not enjoy any proprietary interest or in the pharmacy business or exert undue influence; and
2. there is a written agreement, contract, memorandum of understanding or other document between the parties setting out the details of the services and how they are paid for; and
3. any documentation is made available for inspection by the Authority at any reasonable time.

Notes

1. A "proprietary interest" means a legal or beneficial interest and includes a proprietary interest as a sole proprietor, as a partner, as a director, member or shareholder of a company and as the trustee or beneficiary of a trust.
2. Section 11 of the Act makes void a provision in any bill of sale, mortgage, lease or in any other commercial arrangement that gives a right to anyone (other than a person approved under the Act) the right to receive any consideration that varies according to the profits or takings of the business [see: Appendix 3].

Guidelines

The documentation and practice must not give any suggestion that the service company has any ownership rights or exerts any undue influence in connection with the pharmacy business.

If the service company maintains customer accounts on behalf of the pharmacy or provides computer services, the pharmacist must not supply the company with any information about a person's medication.

The purchase of any stock (especially scheduled poisons) for or on behalf of the pharmacy business is indicative of ownership in the assets of the pharmacy business. Subject to any licensing requirements imposed by law, a service company may carry on a *bona fide* business as a wholesaler but in such circumstances, it is a separate and distinct entity having its own premises and books of account.

Guidance on pharmacy business commercial arrangements is available in the *Resources* section of the Authority's website at www.pharmacy.vic.gov.au.

5.2 Pharmacy trusts

Some pharmacists have obtained advice about pharmacy trusts from persons who may not have fully understood the ownership provisions of the *Pharmacy Regulation Act 2010*. The Act defines proprietary interest as: "a legal or beneficial interest and includes a proprietary interest as a sole proprietor, as a partner, as a director, member or shareholder of a company and as *the trustee or beneficiary of a trust*" (italics added).

A pharmacy trust must not have as a trustee or beneficiary a person or company unless that person or company is:

- (a) a registered pharmacist; or
- (b) a company registered under the Corporations Act -
 - (i) whose directors are all registered pharmacists, and
 - (ii) in which all shares and beneficial and legal interest in those shares are held by registered pharmacists; or

- (c) a company registered under the Corporations Act that was registered or incorporated as a friendly society.

Additionally, a trustee or a beneficiary of a pharmacy trust must not own or have a proprietary interest in more than five separate pharmacy businesses in Victoria.

The Authority strongly recommends that pharmacy proprietors obtain advice from a lawyer to ensure that the deed to any pharmacy trust they operate does not contravene the ownership provisions of the *Pharmacy Regulation Act 2010*.

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APPENDIX 1

SECURITY

Electronic alarm systems

Any alarm system installed should conform to Australian Standard 2201: Intruder alarm systems. Some of the key items of this requirement are:

1. standby backup battery with a minimum capacity of 4 hours for a monitored alarm;
2. automatic rechargeable batteries;
3. concealed or protected wiring;
4. routine maintenance;
5. operating procedure instructions; and
6. weekly testing of the alarm system by the user.

The alarm system should be monitored offsite by a monitoring company as Category A – High Risk Premises. Consideration should also be given to CCTV-Remote Viewing to reduce false alarms and confirm offenders onsite. The monitoring company should be required to verify the alarm by multi-sector alarms (more than one sensor) / multi-breaks on one sensor or duress alarm or communication failure when the alarm fails to report to the monitoring station. The method of monitoring should provide for tamper proof monitoring ensuring an alarm response is received by the monitoring company if the alarm system is tampered with. Options to achieve this include but are not limited to:

1. direct line – dedicated line from premises to the security company;
2. mobile data – utilise a digital radio network;
3. cellular back up – cellular telephone technology providing a back-up facility should the telephone line be cut;
4. radio – wireless monitoring by the security company.

Some of these options are not available in all areas. Any reputable and licensed security firm registered with the Private Agents Register and which is a member of an organisation such as the Australian Security Industry Association Limited (ASIAL) should be consulted for further advice and assistance.

Responding to confirmed alarm activations should involve attendance by security personnel and police. Staff should not attend alarm responses until security and police have first attended and assessed the situation. Serious occupational health and safety issues could occur should staff attend before security or police. Staff attendance would be required to provide key access for further investigation by security or police.

In addition to offsite monitoring, the installation of satellite sirens (battery back-up audible alarms both internally and externally) assist in discouraging offenders from remaining on premises for extended periods. External sirens should be located to avoid tampering; likewise, internal sirens can be mounted in roof space out of view.

General advice on alarm systems include:

1. ensure adequate alarm detector coverage within the dispensing area and drug safe to ensure multi-break alarms and detect tampering with detectors;
2. alarm detectors should be positioned high to avoid tampering (consider tamper resistant alarms). PIR (passive infra-red) detectors to have movement indicating LED lights deactivated or covered to prevent walk-testing what areas are or are not covered by the alarm;
3. ensure any changes to the layout of premises do not obscure the view of alarm detectors. Examples include displays, blinds, posters etc;

4. consider incorporating or utilising existing duress capabilities within the alarm control keypad panel. This could involve a specific additional number utilised when staff are operating the alarm system under threat;
5. consider protecting a building's perimeter with early warning detectors such as reed switches (on doors), break glass or vibration sensors on or near windows; and
6. duress facilities (panic or hold-up buttons) should be considered at counters.

Alarm systems are an integral element of a number of security measures which when combined provide greater deterrence and protection.

Ram raids and smash grabs

Pharmacies are at risk of vehicle ram raids and smash grabs. Consideration should be given to reducing these risks. Options include, but are not limited to:

1. installing purpose-designed removable or fixed bollards internally or externally fitted, subject to municipal council approval. Dual purpose bollards include fixed bicycle racks and fixed seating;
2. reinforcing windows with security film or security grilles or shutters or trellises; and
3. ensuring that displays of targeted expensive items such as some perfumes and sunglasses are securely stored with a suitable locking system; and
4. cash is stored in a locked safe or drawer.

Bulk stocks of drugs that are subject to abuse

Consideration should be given to storing *bulk* stocks of drugs that are subject to abuse in a locked facility.

'Closed' dispensary storage systems such as 'Rhombic Units' should be locked after hours in a similar manner to a filing cabinet if drugs that are prone to abuse are stored in them.

The advice of the Victoria Police in the preparation of this appendix is acknowledged.

SCHEDULE to the PHARMACY REGULATION ACT 2010

Matters required for applications under Divisions 1 and 2 of Part 3 of the Act.

- 1 The premises are to be—
 - (a) laid out in a manner consistent with safe pharmacy practice;
 - (b) maintained in a clean and hygienic manner;
 - (c) maintained at a suitable temperature and humidity;
 - (d) equipped with the necessary equipment and reference material.
- 2 The different parts of the premises are properly situated and are secure and suitable for the purposes for which they are to be used.
- 3 The general physical security of the premises is assured and the control of keys or other entry devices is restricted to registered pharmacists authorised by the person carrying on the pharmacy business or pharmacy department.
- 4 There is no access to the dispensary of the pharmacy or pharmacy department except under the direct supervision of a registered pharmacist.
- 5 A registered pharmacist must be appointed to act as the pharmacist who is regularly and usually in charge of the pharmacy or pharmacy department when the pharmacy or pharmacy department is open for business.
- 6 When the pharmacist who is appointed as the pharmacist who is regularly and usually in charge of the pharmacy or pharmacy department is absent or not available, another registered pharmacist must be appointed to act as the pharmacist in charge of the pharmacy or pharmacy department when the pharmacy or pharmacy department is open for business.
- 7 A registered pharmacist must oversee the area of the pharmacy or pharmacy department where pharmacy services are provided.
- 8 A registered pharmacist appointed to act as the pharmacist in charge must oversee, supervise and monitor all registered pharmacists providing pharmacy services in the pharmacy or pharmacy department and any other staff who assist in the provision of pharmacy services.
- 9 Adequate arrangements are in place to ensure that—
 - (a) medicines are dispensed in accordance with an order or prescription as far as the dispensing is consistent with the safety of the person who is to use the medicines;
 - (b) medicines are not re-used after dispensing and after they have left the pharmacy or pharmacy department;
 - (c) written or electronic records are kept of all medicines supplied, compounded or dispensed and the records are kept confidential and secure;
 - (d) the sale of medicines particularly those known to be abused or misused are supervised and monitored;
 - (e) therapeutic goods are not removed from the premises except with the express permission of the registered pharmacist in charge of the pharmacy or pharmacy department;
 - (f) distance dispensing is carried out according to good pharmaceutical practice;
 - (g) confidential discussions can occur between pharmacists and their clients in privacy;

- (h) the identity of a medicine being supplied or dispensed to a client of the pharmacy or pharmacy department cannot be known by another person present in the pharmacy or pharmacy department who is not a person carrying on the pharmacy business or pharmacy department or a member of the staff of the business or department.
- 10 Adequate arrangements are in place to ensure that records of prescriptions are in English and include—
- (a) the name and address of the person to whom the medicine is dispensed;
 - (b) the date the medicine is dispensed;
 - (c) the name and dose form of the medicine dispensed;
 - (d) the strength or identifying formula;
 - (e) the quantity or number of doses ordered;
 - (f) the directions for the use of the medicine;
 - (g) any other ancillary written instructions supplied on the label;
 - (h) the name, address and telephone number of the prescriber;
 - (i) any alteration to the original prescription;
 - (j) any other information concerning the medicine and its use.
- 11 Adequate arrangements are in place to ensure that records of prescriptions are—
- (a) retained in a secure place at the pharmacy or pharmacy department for at least 3 years;
 - (b) made at the time of dispensing or, in the case of an emergency, within 24 hours after the dispensing;
 - (c) certified by the registered pharmacist who dispensed the prescription with his or her handwritten signature within 24 hours after the dispensing—
 - (i) in the prescription record; or
 - (ii) if the prescription record is made in a manner which precludes handwritten endorsement, in a separate record kept for that purpose, that he or she dispensed the prescription and the certified record must be kept as part of the prescription record;
 - (d) readily retrievable by reference to the name and address of the person to whom the medicine was dispensed, the date of dispensing and from information on the label on the container.

UNDUE INFLUENCE IN COMMERCIAL ARRANGEMENTS

Section 11 of the *Pharmacy Regulation Act 2010* states:

Undue influence

A provision in a bill of sale, mortgage, lease or in any other commercial arrangement in respect of a pharmacy or pharmacy business that gives to any person other than the person licensed under section 38 to carry on the pharmacy business –

- (a) the right to control the manner in which the pharmacy business is carried on; or
- (b) the right of access to books of accounts or records kept in respect of that business, otherwise than for the purpose of determining whether or not the conditions of the relevant document are being complied with; or
- (c) the right to receive any consideration that varies according to the profits or takings in respect of the business –

is void.

APPENDIX 4

LEVEL OF SERVICE TABLE ADAPTED FROM NEW SOUTH WALES HEALTH, GUIDE TO THE ROLE DELINEATION OF HEALTH SERVICES

Level	Description
1	Drugs supplied on individual prescription from community pharmacy, or drugs from a networked public hospital. No pharmacist employed but regular visits from pharmacists associated with provision of the service. Visiting pharmacist may participate in Drug and Therapeutics Committee or equivalent. Quality assurance activities.
2	As Level 1 plus pharmacist employed on part-time or sessional basis. Co-ordination of drug distribution from community pharmacy or networked source. Limited clinical service. May provide patient and staff education. May participate in ward meetings or rounds. Has an established and regularly updated formulary.
3	As Level 2 with at least one pharmacist employed full-time. May also have support staff. Pharmacy controlled drug distribution to inpatients. Clinical service includes drug information, drug monitoring, drug utilisation review, adverse drug reaction reporting. Has limited participation in ward meetings and rounds and provides patient and staff education programs. May have limited manufacturing services. Formal quality assurance program. May be involved in domiciliary/community care. May provide outpatient service.
4	As Level 3 plus more than one permanent full-time pharmacist employed plus support staff. Pharmacist on-call for emergency advice. Director of Pharmacy involved in Drug and Therapeutics Committee. Non-sterile manufacturing services with facilities provided to Standards Association of Australia (SAA) requirements. May have sterile manufacturing, which follows Good Manufacturing Practice (GMP) or equivalent Standards (see Note). May provide pre-registration training.
5	As Level 4 plus provides regular drug information service and bulletins. Participation in ward rounds or meetings. Must have outpatient service. Has staff development and training program for pharmacy staff. Sterile manufacturing and IV admixture service including cytotoxic drugs if clinical unit is present in hospital. Facilities to standard of SAA. Code of GMP or equivalent followed. May supply to other networked hospitals. Clinical trial support for research activities in hospital.
6	As Level 5 plus extensive involvement in research, clinical trials, clinical review. Provides pre-and post-graduate pharmacy training. Has pharmacist on call 24 hours.

Note : SHPA Guidelines for medicines prepared in Australian hospital pharmacy departments.
J Pharm Pract Res 2010; 40(2): 133-143.

TEMPERATURE DATA LOGGERS AND COLD CHAIN MANAGEMENT

What is a data logger?

A data logger is a small electronic device that records refrigerator temperature readings continuously at set intervals. Once programmed by a computer, a data logger is placed in the drug refrigerator where it operates independently on its own battery until the recording is downloaded to a computer. The data logger records the date, time and temperature of the refrigerator in increments. This allows the identification of temperature deviations, provides information as to when, and for how long deviations have occurred, and thus confirmation that the cold chain has been maintained.

A cold chain breach occurs if vaccine storage temperatures have been outside the recommended range of 2° to 8°. It excludes fluctuations up to 12°, lasting no longer than 15 minutes, as may occur during stock taking or restocking the refrigerator. Freezing of vaccines for any length of time is also a breach.

The practice of recording daily minimum/maximum refrigerator temperatures alone does not provide sufficient information to allow the effect of a refrigerator malfunction on the integrity of medicines to be adequately assessed. However, daily minimum/maximum temperatures still need to be recorded manually to alert staff to a potential breach in the cold chain at the earliest opportunity.

Data loggers should be used in the following way for all refrigerators used to store medicines:

1. Record and reset the current minimum and maximum refrigerator temperatures manually at the start of every working day.
2. Investigate any temperature readings outside 2° to 8° by downloading data from the data logger for at least the previous 24 hours.
3. Report any cold chain breaches (temperatures outside the range 2° to 8° over 15 minutes) promptly to the pharmacist in charge. Drugs and vaccines affected should be quarantined until further advice is sought from the manufacturer.

In addition, it is recommended that the following procedures be adopted to improve cold chain management:

- Develop a cold chain management protocol for the pharmacy and designate a responsible person for overseeing the protocol and maintaining the data logger(s).
- All dispensary staff should be trained in the use of the data logger(s) and procedure to be followed in the event of a data logger or refrigerator alarm.
- Check the data logger manufacturer's recommendations on ideal recording increment settings. They are usually 10-15 minutes duration.
- Ensure the data logger is placed in close proximity to the min/max thermometer probe in the refrigerator probe for routine use.
- Download data logger data weekly, and immediately after a potential cold chain breach is noted.
- Daily min/max temperature records and data logger printouts/records should be retained at the premises for 12 months.

It is recommended that data loggers are also used for "temperature mapping" of the refrigerator in order to identify areas in the refrigerator where medicines could freeze. Rotate the data logger on each shelf to map the temperature if different parts of the refrigerator. Freezing of vaccines is the most common reason for vaccine damage in Australia.

POWDER CONTAINMENT CABINETS

Non-sterile compounding pharmacies typically handle powders and should have containment facilities to protect operators and the environment. Where hazardous substances are handled, all product manipulation and compounding activities, including powder weighing, should take place inside a ventilated cabinet designed to prevent hazardous substances from being released into the work environment. Hazardous substances include hormones, antibiotics, cytostatics and immunosuppressants. Balances can be fitted with windshields to minimise interference caused by airflow in the cabinet.

A range of cabinets is available to compounding pharmacies for the purpose of powder containment in non-sterile compounding. The choice of cabinet will depend on the materials and volumes handled.

A risk assessment should be undertaken and expert advice sought prior to purchase and installation of a powder containment cabinet.

Training in the use of cabinets should be provided to compounding staff.

Cleaning of cabinets should take place between products according to the manufacturer's recommendations. Cleaning procedures should take into account the substances handled and prevent cross-contamination between products.

Cabinets should be serviced and certified at least annually and service records kept.

A continuous monitoring device should be included to monitor pressure drop due to loading on the filter and confirm adequate air flow before each use.

Powder containment cabinets are ventilated by an induced airflow through a working aperture. They rely on HEPA (high efficiency particulate air) filtration to remove airborne particles released in the cabinet. The HEPA filter should be preceded by a pre-filter to extend the working life of the HEPA filter by trapping the coarse dust, which could destroy its efficiency. There are two basic kinds of powder containment cabinets available.

A **recirculating fume cabinet (RFC)** is a partially enclosed workstation designed to prevent human exposure to fumes and particulates. HEPA filtration is required for powder handling.

Reverse laminar airflow workstations are horizontal laminar flow cabinets in which the airflow has been reversed. These cabinets usually provide large working apertures and stainless steel interiors.

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