Victorian Pharmacy Authority Guidelines

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i Introduction

The Victorian Pharmacy Authority Guidelines ("VPA Guidelines", this document)

- represent the current policies of the VPA (any departure from them must be justified on a case-by-case basis);
- support the VPA Standards and the requirements of the *Pharmacy Regulation Act 2010*; and
- should be read in conjunction with
  - the VPA Standards
  - guidelines issued by the Pharmacy Board of Australia
  - standards and guidelines issued by pharmacy professional organisations

These guidelines have been reformatted to align with the numbering system introduced with the Victorian Pharmacy Authority Standards (published in Victorian Government G19 dated 12 May 2022 at pages 2435-2440) ("VPA Standards") and to remove those guidelines which have been elevated to a standard.

For ease of reference, the relevant standard has been included in the righthand margin to the respective guideline.

For some standards, there are no corresponding guidelines and vice versa. During 2023, the VPA plans to consult with stakeholders about revised guidelines to assist licensees and pharmacists to comply with the VPA Standards.

The guidelines now predominately contain information relating to licensee responsibilities and premises requirements. Information on establishing a pharmacy depot, other businesses or activities in a pharmacy and supplying, compounding or dispensing medicines in special circumstances is included. General information relating to the role of the VPA, applications for a licence and/or registration of premises, notification processes and the public register of licensees and premises has been removed; this information is available on the VPA website www.pharmacy.vic.gov.au.

ii Key terms

Act	*Pharmacy Regulation Act 2010*
AHPRA	Australian Health Practitioner Regulation Agency
Board	Pharmacy Board of Australia
Complex compounding	refers to compounding, which is the extemporaneous preparation and supply of a single 'unit of issue' of a therapeutic product intended for supply for a specific patient in response to an identified need, and which requires or involves special competencies, equipment, processes and/or facilities [or as defined in the current edition of the Australian Pharmaceutical Formulary and Handbook (APF)]. Examples of complex compounded products include: • sterile products • products containing ingredients that pose a work health and safety hazard (e.g., cytotoxics, hormones, gene therapy) • monoclonal antibodies • single-unit dosage forms containing less than 25 mg (or up to 25% by weight or volume) of active ingredient • sustained-release or other modified-release products • capsules that contain more than one ingredient • tablets • troches, suppositories or pessaries.

DAAs	Dose administration aids
National Law	*Health Practitioner Regulation National Law (Victoria) Act 2009*
PSA	Pharmaceutical Society of Australia
SHPA	The Society of Hospital Pharmacists of Australia
TGA	Therapeutic Goods Administration
VPA	Victorian Pharmacy Authority

G1. Licensee responsibilities

G1.1 Compliance

G1.1.1	*The Act, VPA Standards and conditions* Licensees are to notify the VPA within 14 days of any changes to the registered business name of the pharmacy.	Standard 1.1.1 The licensee is responsible for compliance with the requirements of the Act, the Standards and any conditions imposed by the Authority
G1.1.2	*Legislation and good pharmacy practice* In relation to good pharmacy practice, the VPA recognises the standards, codes, guidelines and policies issued by the Pharmacy Board of Australia and has regard to standards, codes and guidelines issued by the Pharmaceutical Society of Australia, The Society of Hospital Pharmacists of Australia, Victorian Department of Health and Therapeutic Goods Administration.	Standard 1.1.2 The licensee is responsible for ensuring that the delivery of pharmacy services complies with relevant legislation, and follows good pharmacy practice
G1.1.3	*Management of medicines and poisons* Schedule 4 poisons must be stored in a manner that they can be supervised by a pharmacist. Particular attention needs to be paid to the contents of, and accessibility to, storerooms and refrigerators. Schedule 8 poisons (Controlled Drugs) and Schedule 9 poisons (Prohibited Substances) are to be stored and recorded in accordance with the Drugs, Poisons and Controlled Substances Regulations 2017. Refer to section G2.4.2. All stocks of medicines containing pseudoephedrine should be kept out of view of the public. Returned and unwanted medicines or chemicals are to be disposed of using the services of a company specialising in this work.	Standard 1.1.3 The licensee is responsible for ensuring that all medicines and poisons are managed in accordance with legislation and good pharmacy practice

G1.2 Management

G.1.2.1	*Pharmacist regularly and usually in charge* The pharmacist who is regularly and usually in charge of a pharmacy or pharmacy department is either: • the owner or in the case of a partnership, one (or more) of the owners of that pharmacy; • 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); • 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 • 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 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 *Act*, must inform the VPA as soon as practicable of the circumstances of the appointment.	Standard 1.2.1 The licensee shall provide for the appropriate management of the pharmacy business, pharmacy department or pharmacy depot by: a) acting as the pharmacist regularly and usually in charge, or b) appointing a pharmacist to be regularly and usually in charge, and c) notifying the Authority in each case

G1.2.1.1 Display of names

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

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 guideline 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.

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G1.2.2 *Registration status of employed pharmacists*

Employers of registered health practitioners have an important obligation under the National Law to ensure that practitioners hold current registration.

Proprietors should routinely and regularly check the registration status of their pharmacists - prior to commencing employment and at least annually thereafter to stay up to date with any changes to the registration status of employee pharmacists.

Registration details can be checked using the National Register of practitioners maintained by AHPRA.

To check the register go to www.ahpra.gov.au/Register-of-Practitioners For clarification or advice contact AHPRA.

Standard 1.2.2

The licensee shall provide for the appropriate management of the pharmacy business, pharmacy department or pharmacy depot by ensuring that employed pharmacists hold appropriate and current registration

G1.2.3 *Qualifications and training of staff*

Proprietors should ensure that all pharmacists providing pharmacy services are suitably trained in accordance with Board guidelines and good pharmacy practice.

The Board's Guidelines for dispensing of medicines sets out detailed requirements for the training, activities, and competencies of dispensary assistants. 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.

Dispensary assistants (including those with a qualification in science) who take part in any aspect of extemporaneous dispensing are to have completed training in accordance with the Board's Guidelines for dispensing of medicines and Guidelines on compounding of medicines.

Pharmacists must only administer vaccines in accordance with the Secretary Approval(s), and the corresponding program guidelines specified within the Secretary Approval(s), current at the time of vaccine administration and as issued by the Victorian Department of Health.

A copy of the training certificate showing completion of an immuniser program of study that has been recognised by the Chief Health Officer of Victoria should be available in the administration area.

Standard 1.2.3

The licensee shall provide for the appropriate management of the pharmacy business, pharmacy department or pharmacy depot by ensuring that all staff are suitably qualified and trained

G1.2.4 *Workforce*

A pharmacy or pharmacy department should be staffed to meet the expected workload and support the range of services provided.

Standard 1.2.4

The licensee shall provide for the appropriate management of the pharmacy business, pharmacy department or pharmacy depot by ensuring that there are enough suitably qualified and trained staff to support service demands and the safe and effective provision of pharmacy services

G1.2.4.1 Community pharmacies

As a benchmark, not less than one full-time equivalent pharmacist dispensing an average of 150 prescriptions over a 9.00 am to 6.00 pm 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.

Consideration should also be given to the time taken to undertake non-dispensing tasks, for example checking dose administration aids and immunisation.

The VPA acknowledges that a pharmacist may be required to dispense above this rate in unforeseen circumstances such as staff shortage due to sudden illness. The VPA 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.

Extra pressures can affect the performance of locums who are working in new surroundings. Locums should be given a full induction before commencing, with particular attention being paid to policies and procedures, computer software, providing access to current reference texts, opening, and closing procedures, and dispensary layout. Contact telephone numbers should be made available.

G1.2.4.2 Hospital pharmacy departments

The workload principle in section G1.2.4.1 applies to hospital pharmacy departments modified in recognition of the more varied functions and complexity of the work. To this end, the VPA 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 SHPA) 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.

G1.2.5	*Professional and legal obligations* 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 regularly 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. 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. [Refer: *David Loewy and Sandra Lowey* v *The Pharmacy Board of Victoria*, [1991] VSC 11301]. A business or activity carried on within the pharmacy business (by a person other than the owner of the pharmacy business), must be compatible with the pharmacy business. Also refer to section G4.	Standard 1.2.5 The licensee shall provide for the appropriate management of the pharmacy business, pharmacy department or pharmacy depot by ensuring that staff comply with professional and legal obligations
G1.2.6	*Reference texts* 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. Also refer to section G2.6.1.	Standard 1.2.6 The licensee shall provide for the appropriate management of the pharmacy business, pharmacy department or pharmacy depot by ensuring that staff have access to current reference texts
G1.3	**Records**	
G1.3.1	*Records relating to pharmacy services* Patient records are to be securely stored in the dispensary or in a locked facility.	Standard 1.3.1 The licensee is responsible for ensuring that records relating to pharmacy services are created, stored and retained in accordance with relevant legislation and good pharmacy practice
G1.3.2	*Privacy of records* The Act obliges proprietors 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. 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.	Standard 1.3.2 The licensee is responsible for ensuring that records containing customers' personal and health information are secure from theft, misuse, interference, loss, unauthorised access, modification or disclosure

	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 for 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 Act makes specific mention of these matters; see Appendix 1, paragraphs 9(g) and 9(h). Also refer to section G2.4.1. 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.	
G1.3.3.	*Records for Schedule 8 and Schedule 9 poisons* 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 the actual stock on hand to ensure the accuracy of the register.	Standard 1.3.3 The licensee is responsible for ensuring that records for Schedule 8 and 9 poisons are in accordance with Drugs and Poisons legislation
G1.4	**Policies and procedures**	
G1.4.1	*Relevant policies and procedures* The VPA has not issued any guidelines in relation to this standard.	Standard 1.4.1 The licensee is responsible for ensuring that there are policies and procedures in place which are relevant to the services provided and activities being undertaken at the registered premises
G1.4.2	*Maintenance of policies and procedures* The VPA has not issued any guidelines in relation to this standard.	Standard 1.4.2 The licensee is responsible for ensuring that policies and procedures are clearly documented, easily accessible, regularly reviewed and updated as part of effective governance arrangements
G1.4.3	*Policies and procedures available and followed* The VPA has not issued any guidelines in relation to this standard.	Standard 1.4.3 The licensee is responsible for ensuring that policies and procedures are readily available to all staff and are being followed

G1.5	Quality improvement and risk management	
G1.5.1	*Monitoring and review of pharmacy services* The VPA has not issued any guidelines in relation to this standard.	Standard 1.5.1 The licensee is responsible for ensuring that there are appropriate systems in place to monitor and review the safety and quality of pharmacy services as part of ongoing improvement activities
G1.5.2	*Incident monitoring and investigation* The VPA has not issued any guidelines in relation to this standard.	Standard 1.5.2 The licensee is responsible for ensuring that there are appropriate systems in place to identify, investigate and monitor incidents, adverse events and near misses
G1.5.3	*Risk management* The VPA has not issued any guidelines in relation to this standard.	Standard 1.5.2 The licensee is responsible for ensuring that there are appropriate systems in place to identify and manage risks associated with providing pharmacy services

G2. Premises

G2.1 Essential and ongoing requirements

G2.1.1	*Compliance with the Schedule to the Act* The VPA has not issued any guidelines in relation to this standard.	Standard 2.1.1 Registered premises shall comply with relevant requirements of the Schedule to the Act on an ongoing basis
G2.1.2	*State of the premises* The VPA has not issued any guidelines in relation to this standard.	Standard 2.1.2 Registered premises shall be maintained in an organised, uncluttered state
G2.1.3	*Access to premises* The public is entitled to have reasonable access to registered pharmacy premises. 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 VPA 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 VPA immediately. A proprietor of a pharmacy business who wishes to have the VPA approve access to pharmacy premises from other premises should apply to the VPA 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 VPA website.	-
G2.1.4	*Local government planning permits* The VPA 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.	-

G2.2 Alterations

G2.2.1 *Alterations to registered premises*

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 a VPA officer for advice.

Standard 2.2.1

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

G2.3 Security

G2.3.1 *Doors, windows, skylights and ceilings*

Pharmacies and pharmacy departments are required to be constructed to prevent, as far as is reasonable, unauthorised access through doors, windows, walls, and ceilings.

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.

Restricted keying systems are highly recommended as they provide the ability to control the quantity and issue of keys. Additional keys cannot be copied by hardware stores or key cutters. It is recommended that proprietors introduce and maintain a key register to ensure that all keys are accounted for.

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 the wall thickness. Bolts are to be welded to bars.

Roller shutters are recommended for large or recessed entry areas.

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.

Standard 2.3.1

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

G2.3.2	*Perimeter security* Deterrence is enhanced by a secure perimeter that includes security lighting (particularly of rear entrances) and signs, such as “this property has security alarms”, and “all narcotics and cash stored in a substantial safe”. Patrols are supplementary to physical security and are not a substitute for it.	Standard 2.3.2 There shall be adequate perimeter security measures in place to prevent and deter unauthorised access
G2.3.3	*Alarms* Premises are to be fitted with a functional 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 2201.2:2022 (Alarm and electronic security systems, Part 2: Monitoring centres) to grade 1, 2 or 3 and should hold a security firm licence. The intrusion detector must at least cover any area where medicines and poisons are kept, including the dispensary, drug safe, professional service area and storerooms. Silent “hold up” alarms (duress alarms or panic buttons) are recommended.	Standard 2.3.3 The registered premises shall be fitted with a functional, 24-hour monitored intrusion detector alarm which: a) is monitored by an appropriately graded monitoring centre or an onsite security service approved by the Authority in special circumstances, and b) covers all areas where medicines and poisons are kept
G2.4	**Design, layout and condition**	
G2.4.1	*Dispensary activities* 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.	Standard 2.4.1 The dispensary shall be a private area dedicated to tasks associated with the dispensing, supply and compounding of medicines and secure storage of medicines and patient records
G2.4.2	*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 VPA officers during all inspections. The area of the dispensary should be in keeping with the level of service provided by the pharmacy.	Standard 2.4.2 The dispensary shall be fitted with: a) a sink with integrated drainer, that is supplied with hot and cold running water and connected to an appropriate waste outlet

G2.4.2.1 Dispensary area in pharmacies

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 m^2 but not less than 20 m^2.

Examples:

A pharmacy of up to 200 m^2, the dispensary area will be not less than 20 m^2.
A pharmacy of 260 m^2, the dispensary area will be not less than 26 m^2.
A pharmacy of 300 m^2, the dispensary area will be not less than 30 m^2.
A pharmacy of 400 m^2, the dispensary area will be not less than 30 m^2.

In calculating the area of the dispensary;

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

G2.4.2.2 Dispensary area in hospital pharmacy departments

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

- the level classifications described in Appendix 3 to these Guidelines, as adapted from the New South Wales Department of Health's Guide to the Role Delineation of Health Services;
- 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];
- the VPA's experience; and
- the relevant parallels with community pharmacies.

The VPA 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.

The minimum dispensary area (i.e. the area allocated for dispensing only) as appropriate to departments fitting the levels described in Appendix 4 are:

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

The VPA at its discretion may approve a smaller dispensary area provided the hospital can demonstrate to the VPA's satisfaction that it is appropriate for the needs of the hospital and in the public interest. Conversely, the VPA 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.

The dispensary should also include:

- a bench or bench area of at least 0.6 m^2 for the unpacking and sorting of dispensary orders received
- one dispensing station for each 150 prescriptions or part thereof dispensed on a typical day between 9 am and 6 pm
- a bench or bench area of at least 0.6 m^2 located near the sink for the compounding or preparation of medicines that provides storage for measuring and weighing equipment
- a bench or bench area of at least 0.6 m^2 for dispensary or clerical and research use

b) refrigeration which is dedicated to and appropriate for the storage of medicines with adequate temperature monitoring
c) an appropriate number of suitably equipped dispensing stations
d) sufficient free working space and area/s for equipment storage and use
e) a storage system which provides for the safe custody and accurate selection of medicines
f) a dedicated storage facility for Schedule 8 and 9 poisons which complies with legislation, provides adequate storage for poisons on hand at all times and facilitates their accurate selection

If the pharmacy provides pharmacotherapy to 20 or more persons per day, the dispensary should include:

- a bench or bench area dedicated to the pharmacotherapy program of at least 0.6 m^2 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 it is:

- air-conditioned;
- alarmed;
- fitted with a hot and cold water sink with drainer;
- fitted with a safe or drug cabinet to store S8 poisons;
- fitted with lockable storage for client records; and
- suitable arrangements are in place in the pharmacy to protect the privacy of pharmacotherapy clients

If the pharmacy regularly fills DAAs for 15 or more persons per week, the dispensary should include:

- a bench or bench area of a least 1m^2 dedicated to the filling of DAAs, and
- secure storage of dispensed medicines.

An area for the filling of DAA may be located away from the dispensary if it meets the requirements specified in section G2.4.12.

A dispensing station is to include a dispensing bench of at least 0.6 m^2 (e.g., 1000 mm x 600 mm) equipped with a screen, a keyboard, a dedicated barcode 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 m^2, 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.

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 must meet at least the minimum standards prescribed under the Drugs, Poisons and Controlled Substances Regulations 2017 and be 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.

G2.4.3	*Lighting and temperature control* Pharmacies and pharmacy departments are required to provide facilities in which medicines are stored at temperatures within their recommended temperature range. Temperatures in a pharmacy or pharmacy department should not exceed 25ºC; 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 25ºC during periods when the pharmacy is not open for business. Refrigerators used to store medicines should be dedicated to this purpose. Purpose-built vaccine refrigerators are specifically designed to store vaccines and should be used for all vaccine storage. This vaccine refrigerator may also be used to store other medicines. If the vaccine refrigerator is not in the dispensary, it must be kept locked when not in use. Pharmacists should consult and follow relevant guidelines and product information for the storage of vaccines that have additional storage requirements (e.g., the use of an ultra-low temperature freezer). 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 4 provides further information on data loggers and cold chain management. 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.	Standard 2.4.3 The dispensary shall be well lit, adequately ventilated and temperature controlled to maintain the integrity of medicines and provide for personal comfort
G2.4.4	*Hygiene and infection prevention* The VPA has not issued any guidelines in relation to this standard.	Standard 2.4.4 There shall be hygiene and infection prevention measures in place which are appropriate for the pharmacy services being provided
G2.4.5	*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.	-
G2.4.6	*Counselling areas* 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.	
G2.4.7	*Consultation rooms* The VPA encourages the incorporation of consultation rooms in premises to facilitate in-depth counselling and professional services. Such consultation rooms would be separate and additional to the counselling areas required under G2.4.6. Where consultation rooms are available, their availability should be highlighted to members of the public (e.g., through the use of signs and verbal communication by the pharmacist) as some consumers may not be aware of their existence. Consultation rooms should be designed and set up to accommodate people with disability.	-
G2.4.8	*Client waiting area* 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. A client waiting area may also apply to hospital pharmacy departments in cases where patients may be required to collect dispensed medicines.	-
G2.4.9	*Activities not to be included in the dispensary* Point of sale data entry stations, non-dispensary clerical work areas and staff areas are to be located outside of the dispensary.	-
G2.4.10	*Complex compounding* Where the pharmacy 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 (Refer to Section G2.4.2). Also refer to Appendices 5, 6 and 7.	-
G2.4.11	*Vaccination or injection facilities* Vaccines are to be administered in a room or consulting area suitable for the purpose and in which privacy, confidentiality and hygiene standards are maintained (“administration area”). The dispensary is not to be used for the administration of vaccines.	-

There is to be a dedicated preparation area if vaccines are being prepared from multi-dose vials. The preparation area may be in the dispensary or the administration area and must:

1. be away from direct patient contact, distraction and separate from areas that provide other pharmacy services at the same time so that vaccines from multi-dose vials may be drawn up, labelled, and prepared for administration;
2. be clean, hygienic and uncluttered;
3. have a cleaning and disinfection schedule in place;
4. be equipped with hand sanitisation facilities and sharps disposal container;
5. have a bench with an impervious surface of an adequate area; and
6. be maintained at a suitable temperature and with adequate lighting.

The use of a preparation area near or adjacent to a sink should be avoided.

The administration area must:

1. be clean, hygienic and uncluttered;
2. be maintained at a suitable temperature and with adequate lighting;
3. be designed such that the procedure is not visible or audible to other persons in the pharmacy;
4. have sufficient floor area, clear of equipment and furniture, to accommodate the client and an accompanying person, and to allow the practitioner room to safely manoeuvre;
5. be equipped with hand sanitisation facilities and sharps disposal container;
6. have a bench with an impervious surface of an adequate area;
7. have a chair, a first aid couch or similar* that is ready for use, of a suitable height and fit for purpose; and
8. have an emergency response protocol (preferably laminated) on display, an anaphylaxis response kit, and ready access to the Australian Immunisation Register

*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.

The administration area should be designed and set up to accommodate people with disability.

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

G2.4.12 *Dose administration aids*

Also refer to Section G2.4.2

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The area for the filling of DAAs may be located away from the dispensary provided it is/has:

- Air-conditioned
- Alarmed
- Access to hand-washing facilities
- A patient history look-up computer terminal and DAA printing equipment
- Provides lockable storage for dispensed medicines, and
- Free from interruption and distraction.

Staff who pack DAAs should follow appropriate hand hygiene processes.

G2.4.13 *Satellites of pharmacy departments*

A hospital pharmacy department may include one or more satellites that are approved by the VPA. 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.

The satellite's area is to be not less than 20 m^2 (including the shelving and working areas) unless the VPA 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 m^2 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 reference texts mandated by the VPA;
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.

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G2.4.14 *Ward dispensing stations*

A hospital pharmacy department may, with specific VPA 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 VPA is required if the ward dispensing station is to service more than two wards.

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 reference texts mandated by the Board;
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 m^2 of clear working space; and
5. Be dedicated to pharmacy use.

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G2.5	Equipment	
G2.5.1	*Safety and fit for purpose* The VPA has not issued any guidelines in relation to this standard.	Standard 2.5.1 Equipment shall be safe to use and fit for purpose
G2.5.2	*Maintenance, calibration, and servicing* The VPA has not issued any guidelines in relation to this standard.	Standard 2.5.2 Equipment shall undergo regular maintenance, including routine calibration or servicing
G2.5.3	*Operation* Pharmacists are responsible for the accuracy of the weighing equipment they use. Scales should be stored in such a way that their accuracy is not compromised. The minimum weighable mass for scales is to be prominently displayed.	Standard 2.5.3 Equipment shall be operated safely, in accordance with standard operating procedures and within the manufacturer's specified operating range
G2.5.4	*Routine cleaning* Equipment used to count and handle tablets and capsules in preparation for packing dose administration aids such as counting trays and triangles should be routinely cleaned, maintained in a hygienic condition, and stored in a clean and hygienic location. Reusable components of a DAA should be maintained in a clean condition, suitable for use with medicines.	Standard 2.5.4 Equipment shall be routinely cleaned
G2.5.5	*Maintenance records and operating procedures* The VPA has not issued any guidelines in relation to this standard.	Standard 2.5.5 Maintenance records shall be kept and standard operating procedures shall be current and readily available
G2.5.6	*Simple compounding 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. 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 have been approved by the National Measurement Institute.	Standard 2.5.6 Registered premises shall be equipped with the minimum equipment required for simple compounding
G2.5.7	*Hazardous materials* 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, cytotoxics, and 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 coverings.	Standard 2.5.7 Appropriate equipment shall be used for the handling and compounding of hazardous materials to ensure that staff and the public are not put at risk and the integrity of the product is maintained

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.

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

Baseline and periodic pathology monitoring are also required where high-risk or hazardous medicines, or hormones and immunosuppressants, are prepared.

Note: Safe Work Australia defines hazardous chemicals as substances, mixtures and articles that pose a significant risk to health and safety if not managed correctly.
[See: https://www.safeworkaustralia.gov.au/chemicals#hazardous-chemicals]

G2.6 Reference texts

G2.6.1 *Current editions*

Standard 2.6.1

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

Current editions, together with any supplements, addenda or amendments to the references specified in the Board's Guidelines on practice-specific issues – Guideline 1 (List of reference texts for pharmacists) must be maintained.

If participating in opioid replacement therapy programs the following documents are required:

- National Clinical Guidelines for the Use of Methadone in the Maintenance Treatment of Opioid Dependence 2003;
- National Clinical Guidelines and Procedures for the Use of Buprenorphine in the Treatment of Heroin Dependence;
- Department of Health Policy for maintenance pharmacotherapy for opioid dependence.

These may be accessed at www.health.vic.gov.au

Specialised references (hard copy or electronic) are required when providing complex compounding services.

The VPA has regard to the following references in relation to compounding services and facilities:

- United States Pharmacopeia <795> Pharmaceutical Compounding – Non-sterile Preparations;
- United States Pharmacopeia <797> Pharmaceutical Compounding – Sterile Preparations;
- Pharmaceutical Inspection Convention, Pharmaceutical Inspection Co-operation Scheme – PIC/S Guide to Good Practices for the Preparation of Medicinal Products in Healthcare Establishments PE010-4 Mar 2014;
- Australasian Health Facilities Guidelines, – Health Facility Briefing and Planning B.0560 – Pharmacy Unit.
  [Refer: https://healthfacilityguidelines.com.au >Health Planning Units>B.0560 - Pharmacy]

When providing vaccination services, the following are required:

- Current online version of the Australian Immunisation Handbook; and
- National Vaccine Storage Guidelines: Strive for 5.

G3. Pharmacy depot

G3.1 *Registration of depot*

The VPA 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. -

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 an application to the VPA 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 the 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.

G3.2 *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.

G3.3 *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, and petrol stations.

G4 Business or activity carried on by another person in a pharmacy

G4.1 *Approval of another business in a pharmacy*

Section 24 of the Act provides that: -

> "a licensee must not authorise, cause or permit any other person to carry on in the registered premises of the licensee any business or activity unless the business or activity is permitted by the licence or approved by the Authority."

The VPA will require a licensee to obtain approval under section 24 for any business or activity that:

- Is carried on:
  - at or from the registered premises;
  - by anyone **other than the licensee**;

  and which
- Can be construed as separate from the pharmacy business.

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

If the VPA 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 VPA approve the carrying on of another business in the pharmacy premises should apply to the VPA 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.

While each situation will need to be assessed on its own individual facts, a business or activity carried on at registered premises will generally be considered to be separate from the pharmacy business in the following circumstances:

1. The business or activity is performed by a third party who receives a fee directly from a customer or member of the public, whether or not the customer or member of the public is also a customer of the pharmacy business.
2. The sale and patient records of any transaction arising from the activity or business are held by a third party and do not form part of the pharmacy business records.
3. The income or profit received as a direct result of the activity is not retained in full by the pharmacy business.

While each situation will need to be assessed on its own individual facts, a business or activity carried on at registered premises will generally not be considered to be separate from the pharmacy business (and will therefore not need approval under s 24) in the following circumstances:

1. The business or activity is carried on by the licensee as part of, or ancillary to, the pharmacy business.
2. The business or activity is the sale, or offer of sale, of goods by the licensee (see definition of 'pharmacy' and 'pharmacy business' under s 3 of the Act).
3. The business or activity is provided by a third party for and on behalf of the licensee. A business or activity is likely to be for and on behalf of the licensee if:
    - the pharmacy business retains all income or profit directly associated with the activity. A fee that is not calculated with reference to any profit or income, may be paid by the licensee to the third party; and
    - the pharmacy business retains the records, being patient files or sale records, related to the activity.
    - the third-party business or activity complies at all times with all relevant pharmacy legislation.

If a licensee has any doubt as to whether an authority or permission given or proposed to be given to another person might contravene the Act, the VPA should be consulted for guidance.

G5 Supply, compound or dispense medicines in special circumstances

G5.1 *Approval of special circumstances*

The VPA 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. -

The pharmacist seeking to practice under special circumstances should complete and submit a VP41 application form available from the VPA website.

If the VPA approves the application, it will issue an approval letter for a maximum of three years.

G5.2 *Continuity of services in special circumstances*

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 approval. -

APPENDIX 1 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.

APPENDIX 2 SECURITY

1. *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 backup 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 backup 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.

2. *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.

3. *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.

APPENDIX 3 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.

APPENDIX 4 TEMPERATURE DATA LOGGERS AND COLD CHAIN MANAGEMENT

1. *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 confirming that the cold chain has been maintained.

For vaccines, a cold chain breach occurs if storage temperatures have been outside the recommended range of 2° to 8°, excluding fluctuations up to 12°C lasting less than 15 minutes. Exposure of a vaccine to freezing for any period constitutes a breach. In the event of a cold-chain breach, pharmacists should contact the manufacturer(s) for advice.

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.

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

2. *Cold chain management*

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 the procedure to be followed in the event of a data logger or refrigerator alarm.
- Data loggers should be set to record temperatures at 5-minute intervals.
- 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.

APPENDIX 5 COMPLEX COMPOUNDING IN COMMUNITY PHARMACIES

1. *Regulatory framework*

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.

APPENDIX 6 POWDER CONTAINMENT CABINETS

1. *Why powder containment cabinets are required*

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.

2. *Types of powder containment 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 the purchase and installation of a powder containment cabinet.

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.

3. *Usage considerations*

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

Balances can be fitted with windshields to minimise interference caused by airflow in the cabinet.

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 airflow before each use.

APPENDIX 7 EXTEMPORANEOUSLY PREPARED MEDICINES

1. *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.

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, 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 formulations that are frequently prepared, a risk-based program is to be developed for regular submission of samples to a competent analytical laboratory for assay and, for tablets and capsules, disintegration, and uniformity of content tests. The number and frequency of samples submitted should be commensurate with the compounding workload and profile and include formulations with high-potency substances. Any instances of out-of-specification results are to be investigated and appropriate actions documented and implemented. Analytical reports are to be filed and made available for inspection by the VPA's officers.

2. *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

APPENDIX 8 SIGNAGE

1. *Cessation of operation*

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.

2 *Pharmacies that do not supply pharmaceutical benefits*

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

There should be a 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 above sign and have the financial consequences of not obtaining the medicine as a Pharmaceutical Benefit explained to them.

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