Victorian Pharmacy Authority Guidelines

Effective from 5 September 2024

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

- represent the current policies of the VPA (any departure from them should 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 formatted to align with the numbering system introduced with the Victorian Pharmacy Authority Standards (published in Victorian Government Gazette Number 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 right-hand margin to the respective guideline.

Some guidelines do not correspond to specific standards.

The guidelines contain information predominately relating to licensee responsibilities and premises requirements. 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 registered premises is available on the VPA website: www.pharmacy.vic.gov.au.

Public register

The VPA public register includes details of all licensees and registered premises and any conditions on a licence or registration.

See: www.pharmacy.vic.gov.au/register-search/.

Registered business names

Under these guidelines, licensees are to notify the VPA within 14 days of any change to the registered business name of the pharmacy.

ii **Key terms**

Act	*Pharmacy Regulation Act 2010*
AHPRA	Australian Health Practitioner Regulation Agency
APF	Australian Pharmaceutical Formulary and Handbook
Board	Pharmacy Board of Australia
Complex compounding	As defined in the current edition of the APF
DAA	Dose administration aid
Drugs and Poisons legislation	refers to the *Drugs, Poisons and Controlled Substances Act 1981* and any regulations made under this Act
National Law	*Health Practitioner Regulation National Law (Victoria) Act 2009*
PSA	Pharmaceutical Society of Australia
SHPA	The Society of Hospital Pharmacists of Australia [Advanced Pharmacy Australia (AdPha) from 28 August 2024]
TGA	Therapeutic Goods Administration
VPA	Victorian Pharmacy Authority

G1. Licensee responsibilities

G1.1 Compliance

G1.1.1	*The Act, VPA Standards and conditions* The licensee holds responsibility for the carrying on of a pharmacy business, pharmacy department or pharmacy depot in accordance with the Act and the VPA Standards. Where there is a partnership, the responsibility is not held just by one single individual, but by each of the partners.	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 (including the Australian Pharmaceutical Formulary and Handbook), The Society of Hospital Pharmacists of Australia, the Victorian Department of Health and the Australian Government 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* All scheduled medicines must be stored and/or displayed in accordance with Drugs and Poisons legislation. Schedule 4 (S4) poisons must be stored in a lockable storage facility or in the dispensing area of the registered premises in accordance with Drugs and Poisons legislation, and in a manner that they can be supervised by a pharmacist. Particular attention needs to be paid to the receipt of S4 poisons, and the contents of, and accessibility to, storerooms, packing and dispatch areas and refrigerators containing S4 poisons. Schedule 8 (S8) poisons (Controlled Drugs) and Schedule 9 (S9) poisons (Prohibited Substances) are to be stored in a lockable storage facility which meets the requirements of Drugs and Poisons legislation. S8 and S9 poisons which are received at the registered premises should be handed directly to the pharmacist, and records made in accordance with the legislation. Refer also to G2.4.2. Guidance documents are available at www.health.vic.gov.au/drugs-and-poisons/documents-and-forms-to-print-or-download-medicines-and-poisons-regulation 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. Further information on the destruction of S8 poisons is available in the Department of Health document “Managing Schedule 8 Poisons” which can be found via the link above.	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 (PRUIC) 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;	Standard 1.2.1 The licensee shall provide for the appropriate management of the

- 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.

Licensees and PRUICs are required under the Act to ensure that the pharmacy or pharmacy department is personally supervised by a registered pharmacist at all times it is open for business and must not allow a person to have access to a registered premises unless a registered pharmacist is present (sections 30 and 31 of the Act).

Under the Schedule to the Act (see Appendix 1), "*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."*

It is the VPA's expectation that PRUICs need to be working for a majority of the standard business hours of the pharmacy or pharmacy department on a regular ongoing basis. It is ultimately the responsibility of licensees to determine what hours PRUICs need to be present in order to fulfil their respective responsibilities and obligations and to ensure that the pharmacy business or pharmacy department is conducted properly.

Each pharmacy or pharmacy department must have a designated PRUIC (refer to the Schedule to the Act). The PRUIC of a pharmacy or pharmacy department may not practise as such in more than one pharmacy or pharmacy department at a time.

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 <u>Display of names</u>

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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 licensee(s) of a pharmacy, natural or corporate as the case may be, should be displayed 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. In the case of company licensee, the names of the company director(s) should also be displayed.

The full name of the pharmacist who is regularly and usually in charge of the pharmacy or pharmacy department is 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.

The full name(s) of other pharmacists on duty should also be displayed in a way that they can be identified by the public. The wearing of name badges is deemed sufficient to comply with this guideline.

All pharmacist names displayed should be consistent with the registered name of that pharmacist.

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.

Licensees 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 Register of practitioners maintained by AHPRA.

To check the register, go to www.ahpra.gov.au.
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*

Licensees 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 specify that pharmacists may be assisted in the preparation, dispensing and supply of medicines, and other tasks in a pharmacy business or pharmacy department, by suitably trained dispensary assistants, dispensary technicians or hospital pharmacy technicians. For the purposes of these guidelines, 'dispensary assistant/technician' will be used. The Board's guidelines set out detailed requirements for the training, activities, and competencies of dispensary assistants/technicians. For the purposes of inspection of pharmacies and pharmacy departments, the licensee should ensure that copies of the dispensary assistants'/technicians' certificates or other evidence of training are kept at the registered premises.

Dispensary assistants/technicians (including those with a qualification in science) who take part in any aspect of compounding medicines are to have completed training in accordance with relevant Board guidelines.

Pharmacists may 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.
www.health.vic.gov.au/immunisation/pharmacist-immunisers
www.health.vic.gov.au/immunisation/victorian-pharmacist-administered-vaccination-program-guidelines

Any training program undertaken, known as an "immuniser program of study" must be one of those recognised by the Chief Health Officer of Victoria. Further details can be found at:
www.health.vic.gov.au/immunisation/programs-of-study

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.

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 typical day (standard business hours) 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

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

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.

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

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.

qualified and trained staff to support service demands and the safe and effective provision of pharmacy services

G1.2.4.2 Hospital pharmacy departments

The workload guidelines referred to above apply 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, clinical activities, bed ratios for classes of patients (e.g., critical care, surgical, rehabilitation, palliative care), medicines 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 defined in the SHPA Clinical Pharmacy Services Standard of Practice: www.shpa.org.au/publications-resources/standards-of-practice/standards-of-practice-for-clinical-pharmacy-services.

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 themself 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 pharmacy practice. If the licensee finds that it is not, they must intervene to ensure that the pharmacy is properly conducted.

Ensuring the pharmacy business is properly conducted includes but is not limited to:

- ensuring compliance with relevant legislation and good pharmacy practice
- ensuring appropriate risk management procedures are in place
- maintaining a direction over the kinds of goods being sold - particularly those known to be subject to abuse or misuse
- ensuring that procedures and policies are being maintained and followed (refer also to G1.4).

Licensees should refer to the Board Guidelines for proprietor pharmacists for further information about responsibilities of proprietor pharmacists.

In a partnership or other business structure, a member cannot abdicate his or her professional obligations even if that partner is not regularly present at the pharmacy. [Refer: *David Loewy and Sandra Loewy* v *The Pharmacy Board of Victoria*, [1991] VSC 11301].

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. There should be a procedure in place to ensure that all staff, including locum pharmacists, are aware of login details for online reference texts. Refer also to 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. Electronic patient records are to be stored securely on-site or in the cloud. Refer also to *Cyber Security* guidelines below.	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* Licensees are expected to have arrangements in place that ensure the integrity of customer's personal and health information. This includes both physical and digital information. Information should not be given to other than the person for whom it was intended unless the person waives that right. The inadvertent disclosure of the identities of patients' medicines (and therefore the patients' medical conditions) to third parties is to be avoided. 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. 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. Refer also to G2.4.1 and G2.4.10.	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
G1.3.2.1	<u>Cyber security</u> Licensees should consider taking the following steps to ensure that all computers, applications (in house and externally hosted), and the sensitive data they contain are secure: • Staff adequately trained in cyber security basics, including being able to identify phishing attempts through email and SMS. • Control access to consumers' personal and health information via individual and strong user passwords and the use of Multifactor Authentication (MFA) to authorised persons only. • Automatic software updates on every computer (desktops, laptops, servers, smartphones and other handheld devices), including ensuring using the most up to date operating systems versions. • Regular and secure backups on an encrypted and physically secure and separated portable device or on a secure and encrypted cloud. • Testing backup recovery regularly (e.g. quarterly) to ensure data is accessible and can be restored if required. • Use of up-to-date anti-virus scanner and firewall software. • Ensuring wireless internet networks are password protected (including passwords changed from the default) and secure (physically unable to be accessed by the public).	

- Use of multi-factor authentication for initial daily login and on all applications (in house and cloud) that contain sensitive information. Types of MFA include Authenticator app on a smartphone, six-digit SMS codes, hardware tokens/keys, facial recognition, fingerprint recognition
- Not downloading free or non-work applications from the internet onto devices used for work.

Licensees are reminded that dispensary computers may only be used for activities related to the dispensing of medicines. Non-dispensary and clerical activities (e.g. invoicing, customer accounts) should occur on computers outside the dispensary.

Licensees should ensure they have cyber security policies and procedures in place which include how to implement and maintain high level digital security, how to respond to a cyber incident (incident guide - what to do, action plans etc.), and a cyber incident report form to record any incidents which may occur.

For specific guidance see:
www.business.vic.gov.au/business-information/protect-your-business/manage-cyber-security-in-your-business#how-to-improve-cybersecurity-in-your-business

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 and S9 poison remaining after each transaction. A true and accurate balance should be determined by counting the actual stock on hand, rather than simply calculating what should be on hand.

In addition, the calculated balance of all S8 and S9 poisons should be reconciled regularly with the actual stock on hand to ensure the accuracy of the entire register. If any reconciliation finds that there is a discrepancy in S8 or S9 records that cannot be resolved, pharmacists must report this to the Victorian Department of Health.

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.

Guidance documents are available at
www.health.vic.gov.au/drugs-and-poisons/documents-and-forms-to-print-or-download-medicines-and-poisons-regulation

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*

A policy provides the framework which governs a specific process; a procedure contains the steps which are required to achieve a consistent outcome.

Policies and procedures should be written in a concise, step-by-step, easy to read format by individuals who know and understand the activity or process and the overall operation of the pharmacy or pharmacy department. They should be consistent with legislation and relevant guidelines.

The overall list of policies and procedures will vary depending on the pharmacy services provided and must cover at a minimum: pharmacy operations, governance arrangements and the relevant professional services. They should also be tailored and appropriate to the setting in which pharmacy services are being delivered.

Examples of commonly used policies and procedures are listed in Appendix 2. This list is not exhaustive.

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

Appendix 3 shows an example template which can be utilised for both policy and procedure documents.

G1.4.2 *Maintenance of policies and procedures*

Policies and procedures should be maintained as part of effective governance arrangements and to ensure that they remain current and useful. All current versions of the policies and procedures are required to be easily accessible.

Policies and procedures should be systematically reviewed on a periodic basis, for example, every one to two years and may need to be reviewed and updated following a change, incident, complaint or near miss. Where the delivery of pharmacy services and associated activities have changed, the relevant policy and procedure should be updated and re-approved as soon as practicable.

Updated policies and procedures should be communicated and available to staff once approved by the licensee or their delegate.

A master list of all policies and procedures should be maintained and should include superseded versions of the policies and procedures. The master list should also identify how and where superseded versions are archived. Superseded policies and procedures must be clearly annotated as a non-current version and stored in a format that prevents their continued use but are available for historical review. A clear and logical numbering system for documentation of policies and procedures should be used (as shown in the example, Appendix 3).

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*

It is the responsibility of the licensee to:

- ensure staff know where and how to access current versions of the policies and procedures relevant to their role
- ensure the policies and procedures are being followed, and
- maintain a record of the orientation of staff to policies and procedures.

Only current versions of policies and procedures (either electronic versions or hard-copy documents) are to be readily accessible by all staff. Electronic access should be limited to read-only format to avoid unauthorised changes being made to the documents.

Staff should be provided with appropriate induction and orientation, supervision and ongoing training that is documented to ensure they have a thorough understanding of policies and procedures and their responsibilities. The licensee should have processes in place to then observe, monitor and document staff compliance with policies and procedures. Non-compliance with policies and procedures should be addressed promptly.

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*

A quality improvement (QI) system is a core component of a clinical governance framework that supports the provision of consistent, safe and high-quality pharmacy services, by actively identifying and implementing measures to improve the quality and safety of pharmacy services.

Continuous quality improvement (CQI) is a process of ongoing and cyclical QI activities to drive improvements. Pharmacies and pharmacy departments should have a policy to support CQI.

QI activities are not specifically defined and can include any activity that the pharmacy undertakes. QI activities should be informed by data or identified opportunities to improve, such as consumer feedback, incident reviews, clinical data or performance measures, periodic reviews or audits of services and processes. Each of these activities can inform a QI activity. Examples of QI activities can be found in Appendix 4.

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

There are several tools, methods and approaches that can be used for QI. Appendix 4 contains one example, 'Plan Do Study Act' (PDSA) is a common approach used to implement QI.

QI activities should be clearly documented with details on data collection, evaluation or analysis, proposed actions, responsibilities, evidence of implementation and any follow-up actions that are required.

QI should include monitoring compliance with policies and procedures. Measures to monitor compliance can include audits, spot checks, observation or reviews of documentation or reports. Steps should be taken to understand the reason for any non-compliance identified and a pathway for improvement should be established and agreed.

G1.5.2 *Incident monitoring and investigation*

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

Incident management involves the identification, investigation and monitoring of incidents, adverse events and near misses, to support the delivery of consistent, safe and high-quality pharmacy services. The licensee is responsible for ensuring there are appropriate systems in place to support consistent incident management processes.

The key steps to follow when an incident, adverse event or near miss has occurred include:

Action	**Example(s)**
1. Identify the event or incident and assess to determine its severity i.e., can it be resolved within the pharmacy, or does it require escalation? (e.g. referral for medical assessment or management).	a) A patient has received the wrong medicine b) A cytotoxic product has been spilled
2. Take any immediate action to reduce further harm or risks.	a) Ensure the patient receives the appropriate medicine and any intervention b) Ensure cytotoxic spills are cleaned quickly and appropriately (according to set procedures).
3. Document the event or incident as soon as possible after it has occurred, preferably documented by a pharmacist and the pharmacist directly involved in the incident. Describe what has happened, who was affected, where and how the event occurred.	Use an Incident Report Template such as the example given in Appendix 5
4. Apply principles of open disclosure.	Open disclosure is the open discussion with the patient, their family or carer, of adverse events that result in harm to a consumer whilst they are receiving healthcare, including in the delivery of pharmacy services
5. Inform the owner or manager of the pharmacy or pharmacy department.	
6. Investigate the incident and develop an appropriate intervention, where needed. All investigations should identify what happened, how and why it	Contacting the prescriber where an incorrect medicine has been dispensed, or providing further training and education to staff to re-enforce best practice and/or policy

	happened, and any actions required to prevent it happening again. However, the method of investigation may vary based on the severity of the event. Interventions may target the patient, other health professionals, pharmacy staff, systems or policies or procedures.	

Comprehensive records of all incidents, adverse events and near misses must be kept (e.g. Incident Report). This may be in hard copy or electronic format. These records should contain detailed information about the incident including when it occurred, who was involved, nature of the incident or event, contributing factors, evidence and outcomes from an investigation, follow up actions and who recorded the incident. An example of an incident report template can be found in Appendix 5.

An appropriate policy and procedure should be in place for the investigation of incidents and adverse events. This should include guidance on the method of investigation based on the nature and severity of the incident. For example:

- minor incidents, adverse events and near misses may be managed with appropriate documentation and a local investigation to determine what happened and why, and if any intervention or further actions need to be taken.
- moderate incidents and adverse events where the patient experienced harm may be appropriately managed by in-depth case reviews (IDCR) which provide a more thorough investigation. They are usually overseen by a senior manager and may involve additional staff. An IDCR closely looks to identify what happened, why it happened and what can be done to prevent it from happening again.
- serious incidents (high risk, high impact) which have resulted in significant patient harm require a root cause analysis (RCA) to be undertaken. The RCA is a defined process of analysis that looks to identify the critical factors that have contributed to the incident. It usually focuses on significant system and process failures. An RCA is often overseen by a team, commences as soon as possible after the incident and delivers recommendations and system wide learning.

There should also be policies and procedures in place to support regular review and monitoring of incidents, adverse events and near misses to identify any trends, similar contributing factors and areas for improvement. This also applies to investigations and any interventions or recommendations. This will facilitate a robust and appropriate approach to incident management, and feed into CQI activities.

G1.5.3 *Risk management*

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

Pharmacies and pharmacy departments should have a risk management plan appropriate for the pharmacy services being delivered and the level of risk. The licensee is responsible for ensuring that there is a risk management plan in place and for fostering a strong risk culture.

Risk management also includes establishing a business continuity plan, ensuring the pharmacy or pharmacy department complies with legislation, confirming that each health practitioner employed or contracted has appropriate qualifications, registration, and professional indemnity insurance, and ensuring the pharmacy or pharmacy department has appropriate insurances and public liability insurance cover, and that current reference materials are available.

A risk management plan involves identifying and assessing risks through informal and formal pathways and adopting strategies that reduce the likelihood

or incidence of the risk from occurring. Risks and strategies to prevent risks should be documented on a risk register. Appendix 6 provides guidance on the steps which should be considered in a risk management process.

The risk management system should also capture professional, legal, reputational or financial risks. Strategies to mitigate these types of risks may include:

- maintaining a procedure to manage internal and external emergencies and disasters
- maintaining a business continuity plan that provides that there will be appropriate systems and processes to maintain quality care and patient safety and comply with applicable laws at all times
- documenting current qualifications and registration for each pharmacist, and
- ensuring there is appropriate professional indemnity, public liability and other relevant insurance policies.

Pharmacists can minimise risks and contribute to a strong risk culture by maintaining and developing professional capability and understanding and applying the principles of clinical governance, risk minimisation and management in practice. Structured performance reviews, peer review and CPD opportunities are strategies which can reduce professional risks by assuring professional competence.

Appendix 7 provides examples of templates to manage and assess risks.

Additional resources and tools are available through:

- International Council For Harmonisation Of Technical Requirements For Pharmaceuticals For Human Use (ICH) Quality Guidelines, Q9
- Pharmacy Guild of Australia's Quality Care Pharmacy Program (QCPP)
- Pharmaceutical Society of Australia (PSA) Clinical Governance Principles
- National Safety and Quality Health Service (NSQHS) Standards Risk Management Approach
- Society of Hospital Pharmacists (SHPA) Standards of Practice for Clinical Pharmacy Services - Chapter 14: Improving the Quality of Clinical Pharmacy Services
- AHPRA & National Boards *Code of Conduct*
- Pharmaceutical Defence Limited (PDL) Guide to Incident Management
- SHPA Standard of practice in dispensing and distribution for pharmacy services
- Australian Standard 85000:2017 Quality Care Community Pharmacy Standard

or current editions as updated where applicable.

G2. Premises

G2.1 Essential and ongoing requirements

G2.1.1	*Compliance with the Schedule to the Act* The *Pharmacy Regulation Act 2010* is available at: www.legislation.vic.gov.au/in-force/acts/pharmacy-regulation-act-2010 A copy of the Schedule to the Act is included at Appendix 1 of these guidelines.	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* Maintaining registered premises in an organised, uncluttered state is crucial for: • Cleanliness and hygiene • Safe pharmacy practice and prevention of dispensing errors • Provision of quality and safe use of medicines • The safety of staff and the public. Maintaining registered premises in a clean and hygienic manner is a legislated requirement (refer to the Schedule to the Act, clause 1).	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 licensee 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 or significant alteration to 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 licensees introduce and maintain a key register to ensure that all keys are accounted for. Swipe card access systems, for example in pharmacy departments, must be restricted to pharmacists only, noting that access to any override keys is also to be restricted.

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.

The VPA recognises that perimeter doors must be fitted with a locking system that meet the requirements of the building code and any other relevant requirements. Expert advice should be obtained. Measures are needed to prevent entry through ceilings or roofs when the premises are not lawfully occupied. For example, floor-to-floor walls, steel mesh welded or mechanically fixed to the underside of roofing purlins or structural roof beams, throughout the whole roof space, before a suspended ceiling system is installed, or ceiling space alarm sensors are installed.

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.

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

Standard 2.3.1

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

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 in relation to this and other security requirements.

Subject to expert advice, additional security considerations may include:

- Protecting door release buttons from outside manipulation
- Shortening alarm delay time upon entry and locating alarm keypads closer to entry
- Security film on glass doors and windows
- Duress alarms.

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.

Appendix 8 includes further guidance on security including electronic alarm systems and monitoring.

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. For example, 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, key code or swipe card.

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.

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

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.

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.

A dispensary area in a pharmacy or hospital pharmacy department must be fit for purpose, have sufficient workspaces and suitable areas for a range of pharmacy services and activities.

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/technician 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 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 simple 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.

In regard to the dispensary sink, a hand basin without an integrated drainer is not deemed sufficient for compliance with the standard.

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;

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
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

- 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 G2.4.13.

The increased use of S8 poisons (including substitution therapies and medicinal cannabis) and bulkier packaging indicate the need for installing safes/lockable storage facilities that are large enough to store all S8 and S9 poisons on hand (taking into account future needs) and to facilitate accurate selection of the medicines from the safe/lockable storage facility. Unwanted or expired stocks of S8 and S9 poisons or identifiable returned stock from the public must be stored securely pending their destruction.

The safe/lockable storage facility, whether constructed using modular panels or as a free-standing six-sided vault, must meet the minimum standards prescribed under Drugs and Poisons legislation.

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 safe/lockable storage facility must not be left on the premises overnight unless they are stored in a separate safe of at least equivalent security to the safe/lockable storage facility 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.

G2.4.2.1 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 areas in hospital pharmacy departments and general design guidance for hospital pharmacy dispensary areas

In addition to the requirements stipulated in standard 2.4.2 of the VPA Standards and the general dispensary requirements above, the VPA has regard to:

- The Society of Hospital Pharmacists of Australia (SHPA) Standard of practice in dispensing and distribution for pharmacy services (J Pharm Prac Res 2021; 51, 511–535) which describe current best practice for the provision of dispensing and distribution pharmacy services in hospitals by pharmacists, intern pharmacists, pharmacy technicians and pharmacy assistants. It describes the fundamental features of the dispensary design including dispensary location, security and layout, equipment in the dispensary and occupational health and safety factors (see Appendix 9: Features for a dispensary).
- The Australasian Health Facility Guidelines (AHFG) Part B Health Facility Briefing and Planning B.0560 – Pharmacy Unit, which provides recommendation for the floor space which should be allocated to the functional areas typically required in a pharmacy department. The Schedule of Accommodation contained in the AHFG which provides guidance as to minimum floor space requirements is based on the NSW Health Guide to the Role Delineation of Clinical Services, Section One: Core Services 8. Pharmacy for levels 1 to 6 hospitals. Appendix 10 provides an adaptation of this to Victorian hospitals.
- the SHPA Factors to consider for the implementation of automated pharmacy distribution systems in hospitals and health services (see: www.shpa.org.au/publicassets/db7618a0-de53-ec11-80dd-005056be03d0/automation_practice_update_0.pdf).
- the VPA's experience; and
- relevant parallels with community pharmacies.

The licensee must allocate appropriate space to all functional areas such as the dispensing area, offices, staff amenities, bulk storage, clinical trials, medicines information, and aseptic/sterile and/or cytotoxic preparation areas.

The minimum dispensary area (i.e. the area allocated for assembly/dispensing, preparation and collection of items to be dispensed only) as appropriate to pharmacy departments fitting the levels described in Appendix 10 are:

- Level 3: 45 m^2
- Level 4: 60 m^2
- Level 5: 135 m^2
- Level 6: 155 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 pharmacy services required.

Automated pharmacy distribution systems such as pharmacy robotic systems, and unit dose packaging equipment are being increasingly implemented in hospital pharmacy departments. A licensee should have regard to the guidance contained the SHPA Factors to consider for the implementation of automated pharmacy distribution systems in hospitals and health services.

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

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

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 (recording at a maximum of 5 minute intervals) 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.

Refer to the National Vaccine Storage Guidelines 'Strive for 5' for further guidance on data loggers and cold chain management: www.health.gov.au/resources/publications/national-vaccine-storage-guidelines-strive-for-5.

Refer to the Victorian Cold Chain Management protocols for vaccine temperature monitoring requirements for automated temperature monitoring and back-to-base alarm systems. www.health.vic.gov.au/immunisation/automated-temperature-monitoring-and-back-to-base-alarm-systems

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.

G2.4.4 *Hygiene and infection prevention*

Good hygiene and effective infection prevention measures reduce the risk of transmission of infections between patients/consumers and staff, and prevent contamination of equipment, surfaces and products. They are essential for delivering high quality and safe pharmacy services and to provide a safe working environment.

The minimum requirements for hygiene and infection prevention include:

1. Hand hygiene: Hand hygiene is a simple and important measure in preventing the spread of infections in the pharmacy. All pharmacy staff should perform hand hygiene before and after direct patient contact, after handling hazardous medicines, and after any activity that may contaminate their hands.
2. Cleaning and disinfection: It is imperative that the work environment is clean and uncluttered, and all equipment and surfaces are cleaned and disinfected regularly to prevent the buildup of dirt and microbes. This includes cleaning of air conditioners and dusting of shelves and regularly disinfecting surfaces and equipment which come into contact with medicines. A cleaning schedule should be maintained, and procedures may specify products and techniques.
3. Personal Protective Equipment (PPE): Pharmacy staff should wear appropriate PPE for the pharmacy services being delivered. For example, gloves when filling DAA's or gloves, gowns, and face masks, when handling hazardous materials. Protective clothing (laboratory coat, disposable gloves, hair covers, shoe covers and beard covers (if necessary)) should be worn during all compounding procedures.

Standard 2.4.4

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

4. Proper storage of medicines and equipment: Medicines should be stored properly to prevent contamination and ensure their efficacy. Medicines should be stored in clean and dry areas, away from direct sunlight and sources of heat. Equipment used for compounding or specialised services should be stored clean, dry and covered in a clean, dry designated area, separate from regular pharmacy activities.
5. Waste management: Proper waste management is essential to prevent the spread of infections. All waste generated in the pharmacy should be properly collected and disposed of according to regulations and guidelines. For example, sharps should be disposed of in an appropriate sharps' container.
6. Education and training: All pharmacy staff should receive appropriate training on hygiene and infection prevention procedures relevant for their role and should be updated on any changes.

A pharmacy or pharmacy department should be able to identify pharmacy activities that require additional hygiene and infection prevention measures and have a clear process to follow where infection precautions have failed, or there has been an incident / risk of exposure to infection.

Licensees should also be familiar with and ensure staff are familiar with the relevant guidelines and references. Key guidelines and resources include:

- The Australian Guidelines for the Prevention and Control of Infection in Healthcare which provide recommendations, statutory requirements and practice statements on key hygiene and infection control measures.
- The International Council For Harmonisation Of Technical Requirements For Pharmaceuticals For Human Use (ICH) Q7 Good Manufacturing Practice for Active Pharmaceutical Ingredients which provides further information on the standards required for Personal hygiene (3.2) and Equipment maintenance and cleaning (5.2).
- The USP Chapter <797> Pharmaceutical Compounding: Sterile Preparations provides the standards for hygiene and infection prevention when compounding sterile preparations.
- PSA, Practical Guideline for pharmacists providing immunisation services.
- Hand Hygiene Australia: www.hha.org.au.

The Pharmacy Guild of Australia's Quality Care Pharmacy Program, PSA and Board provide further recommendations and standards for specific pharmacy activities.

In the event of infectious disease outbreaks, guidance on infection control measures should be taken from the federal and state health departments.

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.

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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 should 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.

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	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	*Privacy Requirements under the Schedule to the Act* The Act obliges licensees 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. 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).	-

Refer also to 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.

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.

The Pharmacy services self-audit tool: immunisation site readiness codesigned by the VPA and Department of Health aims to support pharmacies and pharmacist immunisers.
www.health.vic.gov.au/immunisation/pharmacy-services-self-audit-tool-immunisation-site-readiness.

Refer to the National Vaccine Storage Guidelines 'Strive for 5' for further guidance on vaccine storage management:
www.health.gov.au/resources/publications/national-vaccine-storage-guidelines-strive-for-5.

Note: twice daily manual minimum and maximum temperature checks are required as a timely alert to cold chain breaches. Automated central monitoring systems, also known as data loggers, can fail to alarm.

G2.4.12 *Complex compounding*

For information about the regulatory framework for compounding, pharmacists should refer to the APF, Board guidelines and guidance issued by the TGA.

Complex compounding (non-sterile)

Where the pharmacy undertakes complex compounding there is to be a dedicated area (i.e. a compounding laboratory) separated from other parts of the pharmacy by floor-to-ceiling walls 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. All equipment used should be specifically designed and suitable for pharmaceutical compounding. (Refer to G2.5).

The compounding laboratory may be contiguous with other parts of the dispensary or separate from it. In the latter case, the door(s) must be lockable.

The size of the compounding laboratory should be commensurate with the level of service provided by the pharmacy but not less than 9 m^2.

The floor area of the compounding laboratory is not counted as part of the floor area of the dispensary (Refer to G2.4.2.1).

In the case of formulations that are frequently prepared, a risk-based program is to be developed for quality control, as defined in the APF, which includes both in-house tests and regular submission of samples to an appropriately accredited analytical laboratory for assay. The number and frequency of samples submitted should be commensurate with the compounding workload and profile and include formulations with high-potency substances. Samples prepared by each compounding staff member should be tested to demonstrate reproducible practices between individuals. 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.

Compounded medicines are also required to meet the relevant TGA quality standards. For example, Therapeutic Good Order (TGO) 93 Standard for Medicinal Cannabis or TGO 100 Microbial Standards for Medicines. Further information can be found at: www.tga.gov.au/resources

Complex compounding (sterile)

Sterile medicines may be compounded only if:

1) Compounding takes place in a dedicated, purpose-designed clean room (or equivalent)
2) The type of clean room (or equivalent) used
    a. is designed and operated based on a documented risk assessment that is readily accessible for audit purposes
    b. is controlled to minimise the risk of microbial, particulate, or other contamination of the sterile medicines
3) The clean room (or equivalent) and equipment used for compounding sterile medicines
    a. comply with relevant current Australian Standards and guidelines*
    b. are suitable for the sterile medicines compounded and for the expiry dates assigned
4) The operation of the clean room (or equivalent) otherwise meets relevant requirements specified in the current edition of the APF.

In accordance with Board guidelines and the APF, sterile compounding must be undertaken in accordance with the principles contained in a relevant

guide/standard (*refer to the current edition of the APF and the Pharmacy Board of Australia Guidelines on compounding of medicines for information about standards and guidelines pharmacists must comply with when compounding sterile medicines).

Applicants and licensees will be required to nominate the relevant guide/standard they have chosen to follow and VPA inspections will focus on compliance with the relevant guide/standard.

The VPA may impose conditions on the registration of pharmacy premises where sterile compounding is undertaken due to the significant risks to public safety associated with sterile compounding.

G2.4.13 *Dose administration aids* -

Also refer to G2.4.2

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.

G2.4.14 *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.

G2.4.15 *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 equipment used in a pharmacy or pharmacy department should be:

- appropriate for the activities being undertaken, for example, equipment should be size appropriate to the quantities being used when preparing a product and be installed and operated in accordance with manufacturers recommendations
- comply with any regulatory / legislative requirements
- inspected regularly to ensure the equipment is in good working order and does not show signs of damage, excessive wear and tear or malfunction
- regularly and appropriately cleaned and maintained, and
- stored in a clean and appropriate location to prevent damage or contamination.

Defective equipment should be removed from the work area as soon as practically possible and clearly labelled as defective.

Dedicated equipment must be used for the handling and compounding of cytotoxic materials, which must be distinguishable from routine equipment and stored in a separate, designated location. Control measures for equipment used for compounding or handling hazardous materials, other than cytotoxics, should address the potential risk of cross contamination of equipment and whether separate distinguishable equipment is used and stored for each class of hazardous material if a validated cleaning/decontamination protocol is not used after each use.
Refer also to G2.5.7

Procedures on equipment use may also need to provide alternatives in the event of emergency situations such as a power outage or equipment malfunction.

General resources include:

- Australian Standard 85000:2017 Quality Care Community Pharmacy Standard

Standard 2.5.1

Equipment shall be safe to use and fit for purpose

- The Pharmacy Guild of Australia's Quality Care Pharmacy Program
- USP-NF <797> and USP-NF <795> (refer to G.2.6.1)

G2.5.2 *Maintenance, calibration, and servicing*

The maintenance, calibration and servicing of all equipment used in pharmacies and pharmacy departments is essential to ensure the equipment performs as intended and accurately.

All equipment should undergo routine maintenance, calibration and servicing in accordance with manufacturers' instructions and depending on the frequency and type of activity for which the equipment is being used.

A maintenance schedule should be developed and followed, including the frequency and type of maintenance required. A maintenance log should be kept which includes the date, type of maintenance and staff member who performed the maintenance activity. These records should be readily accessible.

Regular calibrations and/or servicing may be required for certain equipment, for example, scales, and may need to be undertaken externally. A log of calibration and/or servicing should be maintained and able to be produced upon request.

Staff should have appropriate training on the maintenance, calibration and servicing of equipment.

Procedures should be readily accessible to all staff and reflect the maintenance schedule and intervals for routine calibration and servicing (see also G2.5.5).

Standard 2.5.2

Equipment shall undergo regular maintenance, including routine calibration or servicing

G2.5.3 *Operation*

Pharmacies and pharmacy departments use a range of equipment in preparation, storage and dispensing of medicines and delivery of specific pharmacy services. This includes, for example, compounding equipment, data loggers, scanners, DAA machines, medication/dispensing automation/robots.

The correct use and operation of equipment will ensure the safety and quality of pharmacy services, follows good pharmacy practice and will prevent equipment damage.

Standard operating procedures (SOP) for equipment must be accessible for all staff involved in using the equipment, read prior to operating an unfamiliar piece of equipment and reviewed regularly. Written instructions should be available for all equipment at the point of use. This could be an abbreviated form of the relevant SOP. Where appropriate, equipment should be inspected before use to ensure it is in good working order.

Certain equipment may require training. Staff should be trained and assessed on the proper operation of the equipment prior to use and a log of training kept.

Equipment used in compounding must be accurate. Licensees are responsible for the accuracy of weighing equipment. Automated, mechanical, electronic or other sensitive equipment, such as scales, require routine calibration and servicing. This equipment should be used and stored in such a way as to not compromise accuracy. The minimum weighable mass for scales must be prominently displayed. The APF provides guidance on how to calculate the minimum weight, with an acceptable margin of error of 2%.

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*

Routine cleaning of equipment is essential to keep equipment in good working order and prevent contamination.

Standard 2.5.4

Equipment shall be routinely cleaned

All equipment should undergo regular, scheduled cleaning as part of basic hygiene and infection prevention measures, taking into account to any manufacturer specifications. This includes equipment used to count and handle tablets and capsules, for example, counting trays and triangles and reusable components of a DAA. After cleaning, all equipment should be stored in a clean and hygienic location.

At a minimum, equipment having direct patient contact or if used in compounding activities should be thoroughly cleaned before and after use using appropriate, recognised processes.

Procedures should contain routine cleaning and disinfection requirements, including information about cleaning products, especially for equipment used for compounding.

A log of routine cleaning of equipment should be maintained and easily accessible and licensees should be able to produce a copy of any manufacturer's specifications.

Cleaning procedures should also include other equipment used in the pharmacy for example, air conditioners.

G2.5.5 *Maintenance records and operating procedures*

Records of maintenance, calibration and servicing of equipment should be kept, in either hard or electronic formats. Records should be kept for 5 years.

Current standard operating procedures must be readily available to all staff involved in operating the equipment.

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*

Pharmacists are responsible for the quality, safety and efficacy of compounded medicines and should have regard to the standards set out in the APF, the Pharmacy Board's guidelines for compounding and relevant legislation.

The equipment used in simple compounding must be safe for use and fit for purpose. This means that it must be in good working order, clean and appropriate (appropriate range and precision) for the compounding activities performed at the pharmacy.

Compounding of medicines should only be undertaken with equipment that is appropriate for the dosage forms and quantities being compounded. At a minimum, all pharmacies and pharmacy departments must have the following equipment available for simple compounding:

- Class I or Class II approved scales (i.e., the make and model of the scales have been approved by the National Measurement Institute technical requirements for non-automatic weighing instruments)
- a range of accurately calibrated metric measures
- mixing equipment for powders, liquids, and semi-solids preparations (creams, ointments, pastes), and
- suitable storage containers.

Scales

The accuracy of the ingredients used in compounding is critical to ensure the safety and efficacy of the compounded medicine. Prior to purchasing a scale, an assessment of the type of compounding activities that are likely to take place should be undertaken to determine the appropriate scale to meet the identified requirement.

Factors to consider when selecting scales include:

1. Accuracy: The scales should be able to accurately weigh the smallest amount of ingredients used in compounding. For example, a Class I scale may be accurate to increments of 10 to 100mg, whereas a Class II scale may be accurate to increments of 100mg.

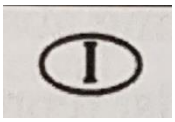
Standard 2.5.6

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

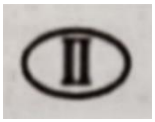
2. Capacity: Scales should be selected which are appropriate for the weights being measured. For example, a scale with a 320 mg weight capacity would be inappropriate for measuring 1000mg. A scale with a 3200mg weight capacity would be more suited to weigh heavier quantities.
3. Calibration: Routine calibration of scales is essential. Calibration will vary according to manufacturer's instruction. Scales which are easy to calibrate and/ or have easily sourced calibration weights can be readily maintained.
4. Size: The size of the scales should be appropriate for the workspace.

For the avoidance of doubt, Class I and Class II is a reference of the scales accuracy via a measure of their readability, i.e., to 0.1g, and the number of divisions the scale can read. Both Class I and II scales support the measurement of small weights, with Class I (microbalances) having a higher accuracy than Class II. Scales will vary based on the weight capacity, (e.g., 320mg weight capacity versus 3,200g weight capacity) and the increment, (e.g., increments of 10mg versus increments of 100mg).

A certificate of National Measurement Institute (NMI) approval should be provided upon purchase and maintained on file. Certified scales should have a specification plate with either of the following symbols:



Class I



Class II

Scales should be externally validated and calibrated at least annually.

Measures
Pharmacies and pharmacy departments should have a range of Class A measures available to accurately measure liquids of different volumes and densities. Class A measures will be stamped accordingly with an A and have ring marks at major graduations.

The measures must be suitable for the volumes and precision of measurements required in compounding activities. For example, if using a cylindrical measure, the measure used should have a volume capacity close to the volume to be measured or if measuring viscous liquids, a syringe provides the best accuracy.

Measures are usually calibrated during the production process and classified as either 'To Contain' or 'To Deliver' the capacity indicated on the measure. As with all compounding equipment they should be cleaned and dried before and after use, with consideration to the liquids used in compounding and appropriate cleaning product and method. They should be stored in a clean, hygienic location to prevent damage or contamination.

G2.5.7 *Hazardous materials*

Additional protective clothing and equipment commensurate with the processes and the materials handled, are required when handling hazardous substances (e.g., hormones, antibiotics, cytotoxics). These may include (but are not limited to) 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.

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

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

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.

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 of personnel 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: www.safeworkaustralia.gov.au/safety-topic/hazards/chemicals

G2.6 Reference texts

G2.6.1 *Current editions*

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.
See: www.pharmacyboard.gov.au/Codes-Guidelines.aspx

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

- National Guidelines for Medication-Assisted Treatment of Opioid Dependence April 2014; www.health.gov.au/resources/publications/national-guidelines-for-medication-assisted-treatment-of-opioid-dependence
- Department of Health Policy for maintenance pharmacotherapy for opioid dependence. www.health.vic.gov.au/publications/policy-for-maintenance-pharmacotherapy-for-opioid-dependence

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:

- The USP-NF <795> *Pharmaceutical compounding – Nonsterile Preparations*
- The USP-NF <797> *Pharmaceutical compounding – Sterile Preparations*
- PIC/S *Guide to Good Manufacturing Practice for Medicinal Products* (PE 009)
- PIC/S *Guide to Good Practices for the Preparation of Medicinal Products in Healthcare Establishments* (PE010)
- Australasian Health Facilities Guidelines – Part B: Health Facility Briefing and Planning, B.0560 – Pharmacy Unit.

When providing vaccination services, the following are required:

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

www.health.vic.gov.au/immunisation/cold-chain-management

Standard 2.6.1

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

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.

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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.

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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

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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 licensee(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 S4, S8 and S9 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 licensee 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 licensee 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 licensee.

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.

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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

www.legislation.vic.gov.au/in-force/acts/pharmacy-regulation-act-2010

Schedule - 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.

Note: Standard 2.1.1 of the VPA Standards clarifies that the requirements of the Schedule to the Act apply on an ongoing basis.

APPENDIX 2 COMMONLY USED POLICIES AND PROCEDURES

This list is not exhaustive and individual licensees should ensure that policies and procedures are relevant to the services provided and the activities being undertaken at the registered premises. The overall list of policies and procedures will vary depending on the pharmacy and should also be tailored and appropriate to the setting in which pharmacy services are being delivered.

Topic	Policy	Procedure	Records
Management and Governance			
Business Strategies	Business and operational objectives and strategies for the pharmacy	Management Review and Report	
	Roles, Responsibilities, Accountabilities and Authorities		Role Descriptions
Risk Management	Risk Management Plan	Risk Assessment	Risk Register
	Business Continuity and Disaster Recovery	Disaster Recovery Plan	
Quality Management (QM)	Quality Management System		Documentation of responsibilities to implement, maintain, participate in, and comply with QM system.
Operations Manual (OM) (containing all Policy and Procedure documents)	Records Management	Maintenance and Review of OM	Policy and Procedure Register
	Document Control/Review		Policy and Procedure Templates (see Appendix 3).
Continuous Quality Improvement and Evaluation	Continuous Quality Improvement	Recording consumer feedback and experience	Records of complaints and actions
	Incident/Complaint Reporting /Investigation	Addressing and resolution of complaints	
		Incident Management	Incident/near miss Register
	Performance Evaluation	Identifying and promoting opportunities for improvement (i.e. Corrective and Preventative Actions)	
		Recall	
	Internal Audit External Audit		Internal Audit plan Audit Schedule
Human Resources			
Staff Recruitment, Induction and Management	Position Descriptions for all employees and roles (including required competencies e.g. qualifications, registration).	Recruitment (advertising and interviews)	Position Descriptions Certificates/Qualifications
	Induction, Training and Awareness	Employee Induction/Training	Induction and Training Records
	Performance monitoring and review (includes, ongoing professional development & self-assessment)	Performance review, regular and incident based	Professional development and self-assessment records

Topic	Policy	Procedure	Records
Operations			
Premises/Equipment	Premises and Equipment Cleanliness	Cleaning of premises and equipment	Cleaning records
	Equipment Use and maintenance	Equipment Use, Calibration and Maintenance	Equipment and Calibration Register
	Maintenance of appropriate storage conditions (Pharmacy and Dispensary Refrigerators)	Whole pharmacy temperature control	
		Maximum temperature breach protocol	
		Cold Chain management	Refrigerator certification
		Cold Chain Breach Protocol	Twice daily min and max drug refrigerator temperature records
	Stock Management	Storing, handling, and disposing of hazardous materials	Training records of staff involved in handling, repacking, and disposing of hazardous materials.
		Ordering, storing, and tracking pharmacy stock	
		Storage of stock according to regulatory requirements	
		Identification and management of expired stock	
		Disposal of returned unwanted or expired stock	
		Return of Schedule 8 stock	Schedule 8 Register
	Physical Security and Safety	Identification of safety risks	Records of emergency, safety and security systems testing
		Measures to prevent potential risks	CPR/First Aid Qualification records
			Employee emergency training records
		Security and Emergency Procedures	
	Digital records and information technology (IT) security and confidentiality	Information Security Management	
		Data Backup	
		IT Hardware and Data Recovery Plan	

Topic	Policy	Procedure	Records
Delivery of Pharmacy Services and Outsourced Services	General Pharmacy Services	Dispensing	Prescription records
		Pharmacy/Pharmacist Only medicines	S2/S3 employee training records
		Schedule 8 management	Schedule 8 register
		Simple Compounding	Equipment cleaning and calibration records
			Worksheet templates
	Additional Pharmacy Services - Complex Compounding	Complex Compounding - Procedure for each type of compounding activity to be undertaken	Employee training records and qualifications/certification
			Master formula database and/or worksheets
			Raw ingredient Safety Data Sheets and Certificates of Analysis
		Maintenance and cleaning of equipment and separate area	Maintenance and cleaning records
		Risk management assessment for each dispensing/supply	Risk assessment template
		Final product testing	Test results
		Product Recall	
		Third Party Supply arrangements	Documentation of third-party supply
	Additional Pharmacy Services - Medication Management (HMR/RMMR/In-pharmacy reviews) - Dose Administration Aids Packing - Pharmacotherapy - Vaccination Services - Infection Prevention and Hygiene - Clinical Trials - Medicinal Cannabis - Indirect Supply (including Internet supply services and/or third-party services and delivery services) - Staged Supply	Medication Management (HMR/RMMR/In-pharmacy reviews)	Relevant training and accreditation qualifications of pharmacists
		Dose Administration Aids Packing	Training records for staff
			Medication packing records
		Pharmacotherapy	Individual patient records
			Schedule 8 register
		Vaccination Services	Pharmacist vaccination certificate/qualifications
			Pharmacist CPR and anaphylaxis training/certification
		Infection Prevention and Hygiene	
		Clinical Trials	
		Medicinal Cannabis	
		Indirect Supply (including Internet supply services and/or third-party services and delivery services)	Third party agreements/contracts
		Staged Supply	

APPENDIX 3: EXAMPLE POLICY AND PROCEDURE TEMPLATE

The structure and format for policies and procedures will vary and should be tailored to the pharmacy and its specific requirements. The following is an example template. There are many other templates available online. Licensees should ensure that any template used captures all the information specifically relevant to the services provided and activities being undertaken at the registered premises.

Pharmacy Name	Document No[a].:	xx-xx
	Version No[b].:	01
	Effective Date:	
	Review Date[c]:	

Title – *clearly states the name of policy or procedure*

Prepared By:	Reviewed By:	Approved By:
Title/Position[d]:	Title/Position[d]:	Title/Position[e]:

1. PURPOSE - *provides a clear and concise explanation of the intent and objective of the policy or procedure.*

"The purpose of this document is to…"

2. SCOPE - *defines the parameters of the policy or procedure. This may include to whom the policy or procedure applies (who), the relevant services (what) or the area (where)*

3. POLICY/PROCEDURE - *forms the bulk of the document and provides all the required detail of the policy or procedure. This may include a breakdown of the steps or tasks in a procedure, quality and safety considerations, documentation and record keeping, training and assessment requirements, compliance or rules relevant to the policy or procedure.*

4. RESPONSIBILITIES - *provides a list of people and their responsibilities relevant to the policy or procedure.*

ROLE//EMPLOYEE POSITION	RESPONSIBILITY
	•
	•

5. DEFINITIONS - *defines key terms throughout the policy or procedure.*

6. REFERENCES - *lists the documents of information used to inform the policy or procedure*

Doc. No.	Rev. No.	Title:
xx-01	01	
xx-02	01	

7. RELATED DOCUMENTS - *provides a list of any other policies or procedures that may be related to or impacted by this policy or procedure*

Doc. No.	Rev. No.	Title:
xx-01	01	
xx-02	01	

8. REVISION HISTORY - stipulates when the policy or procedure was last reviewed and a description of any changes

Rev. No.	Date	Description of Change:
01	-	New document

[a.] Document (policy or procedure) number: this should be a unique number which allows the policy or procedure to be identified and easily referenced.

[b.] Document version number: represents the policy and procedure development and revision history

c. Next review date: stipulates when the policy or procedure is due for the next review.
d. Document owner: identifies which team or position title is responsible for maintaining the policy or procedure.
e. Approval: stipulates the person designated to approve the policy or procedure

APPENDIX 4: QUALITY IMPROVEMENT: EXAMPLE ACTIVITIES AND APPROACH

Example QI Activities (in different settings):

- In the community setting, a review of compliance with barcode scanning after a dispensing error could inform a QI activity.
- In the hospital setting, data from routine monitoring of adherence of the health service to medication-related National Safety and Quality Health Service Standards or high-risk medicine audits can inform a QI activity.

Example of QI Approach/Tool:

The 'Plan Do Study Act' (PDSA) is a common approach that uses simple measurements to monitor a change, or changes, over time. Successful changes can then be implemented to deliver improvement.

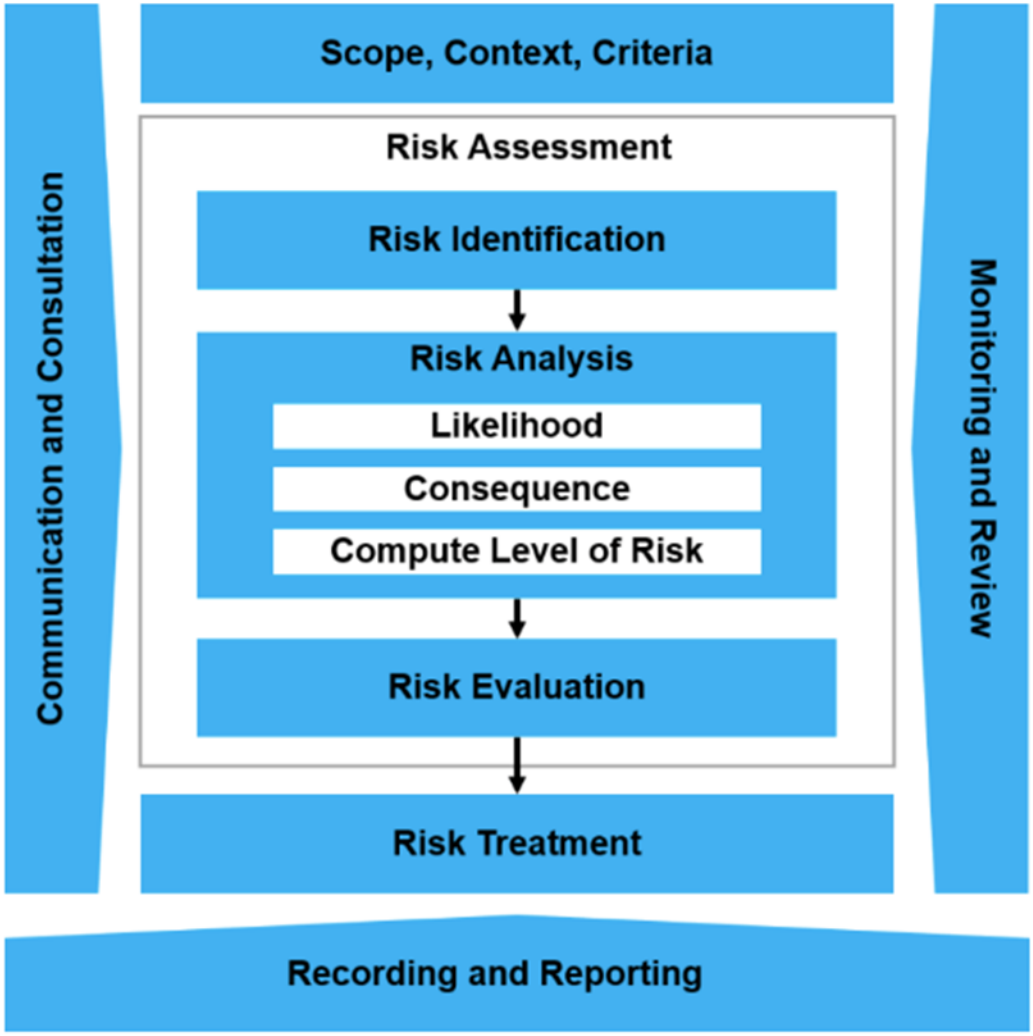
The PDSA cycle involves:

- Plan: i.e., identify the QI activity and plan the idea. Make sure the goal is SMART i.e., specific, measurable, achievable, relevant, and time-based. Make predictions and define the data or measure to be collected. Measures can be quantitative or qualitative, or process or outcome based.
- Do: i.e., carry out the plan, and collect and record the data. Data can be collected through a variety of methods including surveys, audits, worksheets, or feedback.
- Study: i.e., analyse the data, compare these to predictions and reflect on any key lessons that can be taken from the analysis.
- Act: i.e., implement the change or consider a new approach.

APPENDIX 5: INCIDENT REPORT TEMPLATE

Incident details				
Name of person involved in the incident:		Date of incident:		
Location of incident:				
Incident investigation team:				
What task was being performed at the time of the incident?				
What happened? (e.g. 'dispensing error – perindopril 2mg dispensed instead of 5mg')				
Establish the facts of the incident, including: - *What happened?* - *When and where did it happen?* - *What task was being undertaken?* - *Who was involved?* *Include relevant background information, (e.g. training records, related policies)*				
What factors contributed to the incident?				
Consider all factors that may have contributed, (e.g. poor communication, being tired or rushed, high workload)				
Environment:		**Equipment:**		
☐ Noise	☐ Distraction	☐ Wrong equipment for the job	☐ Equipment failure	
☐ Layout / design	☐ Other	☐ Inadequate maintenance / cleaning	☐ Inadequate training	
☐ Hazard		☐ Incorrect use of equipment	☐ Other	
Work conditions:		**People:**		
☐ High workload	☐ Inadequate training / supervision	☐ Procedure not followed / no procedure exists	☐ New / inexperienced staff	
☐ Insufficient staff	☐ Other	☐ Fatigue	☐ Distraction / personal issues / stress	
		☐ Lack of communication	☐ Other	
Determine the primary cause				
Determine the primary cause/s of the incident, asking 'Would the incident have happened if….?' and 'Why did this happen?'				
Corrective actions:				
Contributing factor (from above list)	**What are we going to do to fix the problem?**	**Who**	**When**	**Completion date**

APPENDIX 6: RISK MANAGEMENT PROCESS



[Source: ISO 31000:2018 Risk management process]

The key steps in risk management are:

1. **Communication and Consultation**
   - communicate risks to staff to promote awareness and understanding of risks
2. undertake a **Risk Assessment** which involves identifying, analysing and evaluating risk as follows.
   - **Identify** the source of the risk, events, causes and potential consequences and consider:
     i) Who is at risk?
     ii) What is involved?
     iii) What is the likelihood (probability) it will go wrong?
     iv) Why can it happen?
     v) What are the consequences?
   - **Analyse** the risk to determine the nature of the risk and level of the risk. Use a risk matrix based on likelihood and consequence ratings to assist in determining a risk level (see Diagram 1: Risk matrix to determine the risk level) and consider:
     i) What is the likelihood (probability) it will go wrong or why can it happen?
     ii) What controls are already in place?
     iii) Review any relevant workflows for weaknesses.
     iv) Use a risk matrix tool (see Diagram 1) to determine the risk level.
   - **Evaluate** the risk analysis with the risk level to determine the appropriate actions to reduce the risk and consider:
     i) doing nothing further, or
     ii) implementing risk treatments / actions where the hierarchy of control principles can be applied (see Diagram 2). For example, the least effective intervention may be reducing exposure by wearing appropriate PPE or staff training. A

moderate intervention may be an alert on the dispensing program with override function. Eliminating the risk is the most effective intervention. For example, a hard stop on a dispensing function or completely eliminating a trip hazard near a dispensing station.

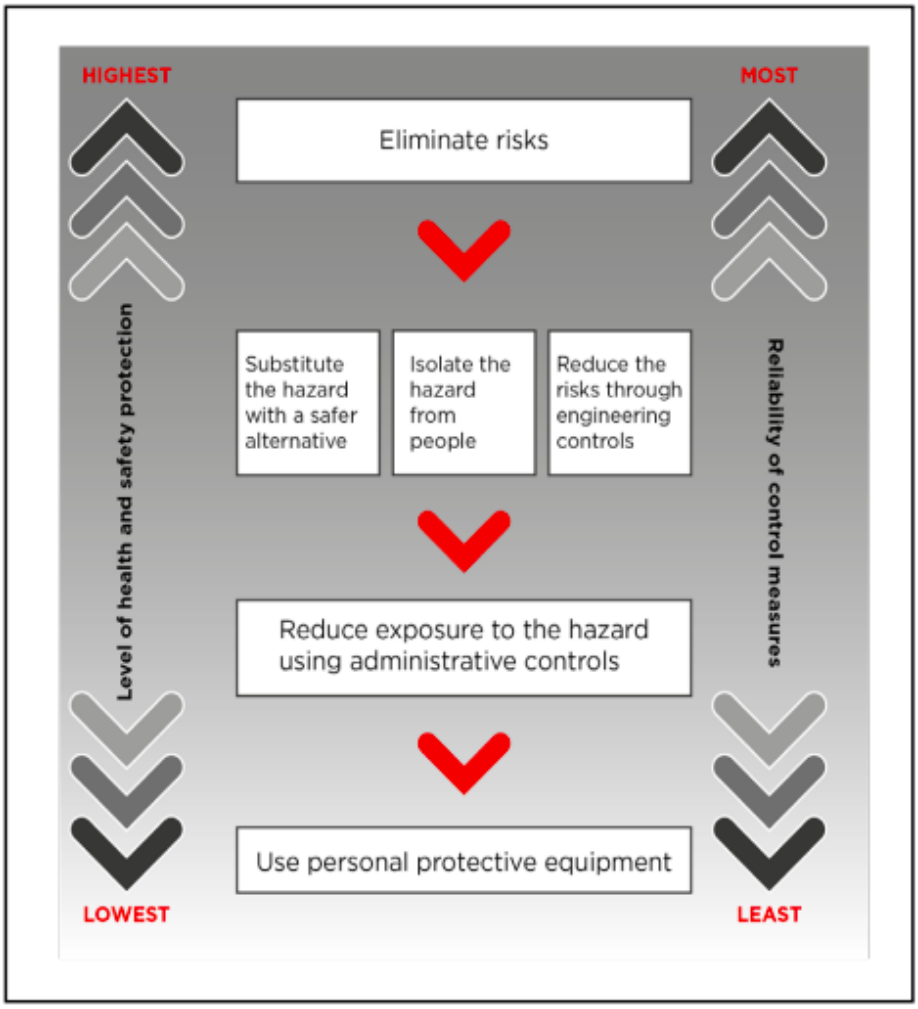
iii) maintaining the existing controls: at any stage in the risk assessment consider collaborating with stakeholders or staff to obtain feedback and information to support the risk assessment and actions or risk treatments.

3. **Risk Treatment**
   - implement any risk treatments or actions.
4. **Monitoring and Review**
   - regularly review actions and risk treatments implemented, to ensure they are appropriate and that the risk management system is robust. This could be via informal (staff feedback) or formal (audit) pathways. Determine whether new risks have emerged, and
5. **Recording and Reporting**
   - maintain a record of risks and actions to prevent risks (i.e. a risk register). Records should be kept and maintained on a risk register in a hard or electronic format.

Diagram 1: Risk matrix tool to determine the risk level

	Consequence				
Likelihood	**Insignificant**	**Minor**	**Moderate**	**Major**	**Severe**
Almost Certain	Medium	High	High	Extreme	Extreme
Likely	Medium	Medium	High	Extreme	Extreme
Possible	Medium	Medium	High	High	Extreme
Unlikely	Low	Medium	Medium	High	High
Rare	Low	Low	Medium	High	High

Diagram 2: Hierarchy of control



Source: Safe Work Australia

APPENDIX 7: EXAMPLES OF TEMPLATES FOR A RISK ASSESSMENT

Identify the risk	**Assess the risk**	**Control the risk**					
What is the risk?	What might go wrong? Who might be harmed and how?	What are you already doing to control the risk?	Risk level	What else do you need to do to control the risk?	Action by whom?	Action by when?	Date completed
		.					

Risk *[What is the risk? What could this risk result in?]*	**Likelihood** *[How likely is this to happen?]*	**Consequence** *[What is the severity of the risk? Would it cause a lot of damage?]*	**Risk level** *[This number indicates the level of risk.]*	**Planning and control** *[What will you do to prevent or minimise the risk? What actions will you take?]*
[Example: The prolonged use of computer screens could result in headaches, eye strain, blurred vision and neck and back pain.]	Select likelihood	Select level	*[Likelihood number x consequence number = risk level]*	*[Example: We'll use software that tells staff to take a computer break every hour and stretch.]*

APPENDIX 8: 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 9: FEATURES FOR A DISPENSARY

(Hospital pharmacy departments)

The following is from Table 1 (Features for a dispensary) from: *SHPA. Standard of practice in dispensing and distribution for pharmacy services J Pharm Prac Res 2021; 51, 511–535.*

Location

- ease of access for patients (including considerations for accessibility), pharmacy staff, hospital staff and for delivery of medicines from suppliers
- signage to direct patients to the pharmacy
- proximity to outpatient clinics

Security

- maintaining staff safety while allowing effective patient counselling to occur
- ease of access to a designated alert/duress system in the event of a perceived threat or breach of security
- restricted visibility of medication storage areas to the public
- restricted access to unauthorised persons including staff and the public
- mechanisms to record access to the dispensary (e.g., swipe card, biometric devices)
- installation and operation of a 24-h monitoring intrusion alarm system
- closed-circuit television (CCTV) monitoring

Layout

- workflow movements including review of prescriptions and direct supervision of non-pharmacist members of the dispensing and distribution team
- dispensing and checking areas should be suitably situated to minimise interruptions
- provision of a suitable area for the preparation of extemporaneous products if required
- designated counselling areas should maintain patient privacy and allow counselling to be undertaken with minimal distraction

Equipment

- adequate bench space for safe dispensing
- barcode scanners must be available on every dispensing terminal
- ancillary equipment such as measuring cylinders, counting trays
- equipment must be accurate, and cleanliness maintained to prevent contamination; separate equipment must be available for the dispensing of oral cytotoxic medicines
- an accurate record should be kept of the location of equipment
- equipment should be maintained according to manufacturers' specifications
- appropriate storage conditions for all medicines must be maintained (e.g. temperature, humidity and light)
- an appropriate library should be maintained to include hard copy or online texts as required by law
- other medicines information, including online resources, should be readily accessible
- telephones should be situated for ease of access; the number of telephones should be limited to avoid excessive diversion of staff from the dispensing process
- appropriate computer and printer equipment

Occupational health and safety factors

- storage space must be adequate and readily accessible, particularly for high usage medicines
- availability and accessibility of spill kits
- ergonomics
- general noise levels that are acceptable and non-distracting
- the environment must be conducive to the comfort and safety of both the patient and the dispensing and distribution team, respecting appropriate cultural beliefs and practices including those of Aboriginal and Torres Strait Islander people

APPENDIX 10: NSW HEALTH GUIDE TO THE ROLE DELINEATION OF CLINICAL SERVICES, SECTION ONE: CORE SERVICES 8. PHARMACY FOR LEVELS 1 TO 6 HOSPITALS - *ADAPTED FOR VICTORIAN HOSPITALS*

Level	Service scope	Service requirements	Workforce
1	Service provided by health service or external pharmacy. Drugs supplied to patients/clients on individual prescription and/or through an imprest system.	Access to medicines procurement and distribution service. Access to patient and staff medicines education. Access to therapeutic guidelines. Access to drug and therapeutics committee or equivalent. Referral pathways to relevant Aboriginal programs and services. Quality and risk management programs in line with current *National* Safety and Quality Health Service (NSQHS) Standards as appropriate.	Pharmacist available for consultation, advice and support (may include virtual care). Aboriginal hospital liaison roles available, preferably both male and female.
2	*As for Level 1.* In addition, provide on-site clinical pharmacy service (e.g. patient medicines information, medication chart review, staff education).	As for *Level 1.* In addition, access to information technology to support integrated pharmacy management system. May have dedicated pharmacy space.	Allocated pharmacist resource (may be via health service network).
3	As for Level 2. In addition, provide administration and pharmacy management support. May provide medicines procurement, dispensing and distribution services.	As for *Level 2.* In addition, dedicated pharmacy space. May have processes to provide medications that require compounding (may be networked or external arrangement).	Pharmacist on-site. May have pharmacy support staff (e.g. pharmacy technician, stores person).
4	*As for Level 3.* In addition, provide medicines procurement, dispensing and distribution services. Drug and therapeutics committee or equivalent. May support specialised services (e.g., renal dialysis).	*As for Level 3*. In addition, the pharmacy department: • provides service during business hours with access out of hours. • has processes to provide medications that require compounding (may be networked or external arrangement). • provides clinical trial and research support. May provide administration and pharmacy management support to other health facilities or services. May supply to other health facilities or services not on-site.	*As for Level 3.* In addition, the Director of Pharmacy has Pharmacy support staff (e.g., pharmacy technician, pharmacy assistant, stores person).
5	*As for Level 4.* In addition, provide support for clinical specialty services (e.g., oncology, haematology), quality improvement, and medication	As for *Level 4.* In addition, processes for sterile manufacturing and cytotoxic drugs where clinically necessary (may be networked or external arrangement).	*As for Level 4.* In addition, a pharmacist appointed as clinical pharmacy educator. Senior pharmacy technician/s.

	safety and stewardship services. Provide support for clinical trial and research activities.	May provide support for electronic medication management and distribution systems. May provide networked support to lower-level pharmacy services within the health service (e.g., advice, purchasing assistance).	May have clinical specialist pharmacist roles (e.g., oncology, haematology). May have pharmacist management roles (e.g. distribution service, mental health, cytotoxic production unit, aseptic production unit). May have pharmacist medication safety quality improvement role. May have pharmacist stewardship role such as antimicrobial stewardship (AMS). May have pharmacist health informatics role.
6	*As for Level 5.* In addition, provide advanced level support for a wide range of highly specialised services (e.g., cystic fibrosis), cancer services, and transplantation including bone marrow transplant, neonatology). Active involvement in clinical trials and research activities (e.g., contribute to Human Research Ethics Committee, extensive numbers of clinical trials). Active involvement in supporting electronic medication management and medication safety quality improvement activities. May provide specialist medicines information services. May have pharmacy automation.	*As for Level 5.* In addition, 24 hour on call access to pharmacy service. Provide networked support to lower-level pharmacy services within the LHD/SHN.	*As for Level 5.* In addition, clinical specialist pharmacist roles. Senior pharmacists. May have chief pharmacist information officer role.

APPENDIX 11: 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 or obliterate 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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