VPA Standards

Frequently asked questions

21 December 2022

Introductory notes

The Victorian Pharmacy Authority (VPA) has developed these frequently asked questions (FAQs) to support licensees with the introduction of the VPA Standards which came into effect on 12 May 2022. The VPA Standards are mandatory requirements for licensees and premises registered by the VPA. The information provided is general in nature and by no means exhaustive. These FAQs should be read in conjunction with the *Pharmacy Regulation Act 2010* (Act), VPA Standards and the VPA Guidelines.

The current version of the Act can be accessed from the Victorian Law Today website (www.legislation.vic.gov.au) while the VPA Standards and VPA Guidelines are available on the VPA website (www.pharmacy.vic.gov.au).

The VPA Standards have 2 overarching principles, which are:

1. The licensee is responsible for the delivery of pharmacy services that, through appropriate governance and oversight, are consistent with the law and good pharmacy practice. Public safety is paramount and the risk of causing harm must always be considered as part of the delivery of pharmacy services.
2. The design, condition, facilities, and security of registered premises provide an appropriate environment for the safe custody of medicines and poisons and provision of pharmacy services.

Licensees can contact the VPA by phone on (03) 9653 1700 or email enquiries@pharmacy.vic.gov.au if there are further questions on the VPA Standards.

Frequently asked questions

1. **Who is responsible for complying with the VPA Standards?**
   The licensee holds responsibility for the registered premises and for the carrying on of a pharmacy business, pharmacy department or pharmacy depot. Accordingly, the licensee is responsible for complying with the Act, the VPA Standards and VPA Guidelines. Where there is a partnership, the responsibility is not held just by one single individual, but by each partner.

   Under the Act, licensees are required to appoint a registered pharmacist to act as the pharmacist who is regularly and usually in charge (PRUIC) of the pharmacy or pharmacy department when it is open for business. The PRUIC may be the licensee or another registered pharmacist or the director of a pharmacy department. The PRUIC have responsibilities under the Act to 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. However, the licensee is ultimately responsible for complying with the VPA Standards.

2. Why has the VPA issued standards?

The Act provides for the VPA to issue standards in relation to the operation of pharmacies, pharmacy businesses, pharmacy departments and pharmacy depots.

The VPA has issued standards in areas considered to be high risk that can have a significant impact on public safety. High-risk areas are drawn from existing legislation, guidelines, and good governance. For example, standard 2.4.1 has been elevated to a standard from a VPA guideline. It states that 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. This is a high-risk area because distraction can increase the risk of medication related errors while unrestricted access to the dispensary may impact the privacy of records and security of medicines.

Standards reflect existing minimum standard requirements expected of licensees and registered premises. The standards help to ensure that the facilities, equipment, security, management and operation of premises registered by the VPA comply with the Act and good pharmacy practice.

The standards provide clarity to licensees that these are mandatory requirements, and that they may be taken into consideration as part of VPA's regulatory activities. Compliance with the standards benefits licensees, their staff and the wider community. It is important that every staff member has read the standards, understands them, and knows where to access a copy.

3. What happens if the standards are not met?

The VPA may take action against licensees who do not comply with the VPA Standards.

The VPA may refuse to grant a licence or registration if the VPA is satisfied the applicant has contravened a standard on one or more occasions and the VPA believes that it is against the public interest for the person to be licensed to carry on the pharmacy business or pharmacy department.

The VPA may investigate a licensee's compliance with, or if the registered premises, meet the VPA Standards. A panel hearing may be convened to consider matters that have been the subject of an investigation.

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

The VPA does not regulate individual pharmacists. The registration of pharmacists and the handling of complaints about the conduct of a registered pharmacist is the responsibility of the Pharmacy Board of Australia which has its services administered by AHPRA. The VPA may notify the Pharmacy Board of Australia if it has concerns about a registered pharmacist's health, conduct or performance.

The VPA also routinely discloses information about registered pharmacists to the Victorian Department of Health, Medicines and Poisons Regulation Branch, when there is evidence of serious breaches of drugs and poisons legislation.

4. **How often are the VPA Standards reviewed?**
   The VPA plans to review the standards on an annual basis. However, before issuing new standards the VPA will need to go through a consultation process and approval by the Minister in accordance with the Act. The Act provides for the VPA to issue a standard without consultation where there is an immediate need to issue the standard to address a matter of public health or safety.

5. **What is the role of the VPA Guidelines?**
   The VPA Guidelines continue to represent the current policies of the VPA. Any departure from them must be justified on a case-by-case basis. The VPA Guidelines support the VPA Standards and requirements of the Act; as such they should be read together.

   An example of how guidelines supports the standards and requirements of the Act is highlighted in relation to security.
   - The Schedule to the Act requires the premises to be secure.
   - Standard 2.3.3 requires the premises to 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 VPA in special circumstances, and (b) covers all areas where medicines and poisons are kept.
   - The guideline supports this standard by specifying that the monitoring centre should be graded in accordance with the relevant Australian Standard to grade 1, 2 or 3 and should hold a security firm licence.

   The VPA Guidelines should also be read in conjunction with guidelines issued by the Pharmacy Board of Australia and standards and guidelines issued by pharmacy professional organisations.

6. **Are there guidelines for every standard?**
   For some standards, there are no corresponding guidelines and vice versa. The VPA may publish new guidelines or revise existing guidelines so that they better support the standards following review and stakeholder consultation in 2023.

7. **Will the VPA Standards affect the timeframe for processing applications?**
   It is not expected that the standards will affect the timeframe for processing applications since areas relating to the standards are already considered as part of VPA's current application process.

The following questions relate to specific standards.

8. **Standard 2.4.2 states that the dispensary shall be fitted with 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. Can a second S8 drug safe be located outside of the dispensary?**

At least one S8 drug safe must be in the dispensary. A second or additional S8 drug safes may be located outside of the dispensary provided:

- It is away from public access
- It complies with drugs and poisons legislation (in relation to construction, storage and access)
- It is covered by a functional, 24-hour monitored intrusion detector alarm in accordance with VPA standard 2.3.3

9. **Standard 2.5.6 states that registered premises (excluding pharmacy depots) shall be equipped with the minimum equipment required for simple compounding. What if the pharmacy or pharmacy department does not want to provide simple compounding services?**
   It is the VPA's expectation that the public can access simple compounding services from all pharmacies and pharmacy departments.

10. **Standard 2.1.1 states that registered premises shall comply with relevant requirements of the Schedule to the Act on an ongoing basis**. **What is the Schedule to the Act?**
    The Schedule to the *Pharmacy Regulation Act 2010* (Act) sets outs matters required for applications for a licence or premises registration. The Schedule to the Act sets out high-level requirements for registered premises, including layout, hygiene, temperature, privacy, security and access. For example:
    - The premises are to be maintained in a clean and hygienic manner
    - 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
    - A registered pharmacist must oversee the area of the pharmacy or pharmacy department where pharmacy services are provided
    - Adequate arrangements are in place to ensure that confidential discussions can occur between pharmacists and their clients in privacy

    This standard makes it clear that the requirements in the Schedule to the Act apply on an ongoing basis.

11. **Standard 2.1.2 states that registered premises shall be maintained in an organised, unclutter state. Why is this standard important?**
    Sustained clutter and disorganisation increases the risk of distraction and errors occurring, posing a clear risk to public safety. Further, untidiness may be associated with a lack of hygiene.

Images highlighting clutter and disorganisation in some pharmacies.

12. **VPA standard 1.2.6 states that 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. Where can licensees find the list of current reference texts?**
Current reference texts include any essential reference texts specified by the Pharmacy Board of Australia. The list can be found in the Pharmacy Board of Australia *Guidelines on practice-specific issues – Guideline 1 (List of reference texts for pharmacists)* here. Licensees are encouraged to set reminders to renew subscriptions or to purchase new editions and to schedule regular checks to ensure reference texts are up to date. Login details are to be readily available to all employed pharmacists to ensure there are no barriers to access.

13. **What are some of the cyber security considerations for licensees?**
VPA standard 1.3.2 states that the licensee is responsible for ensuring that records containing consumers' personal and health information are secure from theft, misuse, interference, loss, unauthorised access, modification or disclosure.

In the context of cyber security, licensees may wish to consider the following points:

- Does the pharmacy or pharmacy department foster a positive security culture?
- Are your staff adequately trained in cyber security basics, including phishing and ransomware?
- Do you have processes in place to ensure that software and hardware are patched and up-to-date on every computer?
- Is your data regularly and securely backed up? Do you test your backups regularly by attempting to restore data?
- How strong are your passwords, and do you have multi-factor authentication?
- Do you have a documented plan on how to respond to a security breach?

Licensees are encouraged to refer to the Australian Cyber Security Centre website here for more information.

Other points for consideration in relation to consumer records include:

- Are members of staff at the pharmacy informed of the need to observe confidentiality in all their dealings with the public?
- Are records stored in a way that they can be accessed/viewed by the public or a third party?
- Are there adequate arrangements in place to separate private information from general rubbish?
- How are records destroyed?
- Is access to the dispensary limited to dispensary staff?

14. **There are standards on management, for example, in relation to training and adequate staffing levels. What can licensees do to help meet these standards?**
The VPA Standards state that 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 (standard 1.2.2)
- ensuring that all staff are suitably qualified and trained (standard 1.2.3)
- ensuring that there are enough suitably qualified and trained staff to support service demands and the safe and effective provision of pharmacy services (standard 1.2.4)

It is paramount that the public receives medicines and services from staff that are suitably qualified and trained and that there is enough staff on duty to support the services provided to ensure public safety. When assessing workload, the VPA considers not only prescription numbers but also the range of pharmacy services provided (e.g. dose administration aids, vaccination, opioid replacement therapy) and staffing levels in the pharmacy.

In relation to hospital pharmacy departments, the VPA also takes into account the in-ward clinical activities, bed ratios for classes of patients (e.g. critical care, surgical, rehabilitation, hospice), drug information, clinical trial management and other pharmacy services to arrive at a comparable workload. The VPA notes that the Society of Hospital Pharmacists of Australia (SHPA) provides information on staffing levels and structure for the provision of clinical pharmacy services in its Standards of Practice for Clinical Pharmacy Services here.

Licensees are encouraged to implement a process including

- routine and regular checks to ensure that the qualifications and training of all staff are current
- alerts for when training may need to be updated or renewed, and
- keeping records of training and certificates and making them readily available in the premises for easy reference and inspection.

It is recommended that the registration status of pharmacists be checked prior to commencing employment and at least annually thereafter by licensees.

Licensees should regularly monitor the workload, staff level, staff skills and competencies. Where there are increasing demands or ongoing workforce challenges, licensees may need to hire more staff or reconsider the extent to which some services are offered to maintain safe dispensing and ensure the safe provision of those services.

Licensees may wish to refer to the Pharmacy Board of Australia *Guidelines for dispensing of medicines* here for information on the training of dispensary assistants and hospital pharmacy technicians.

15. There are standards on policies and procedures. What can licensees do to help meet these standards?

The VPA Standards state that 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 (standard 1.4.1)
- policies and procedures are clearly documented, easily accessible, regularly reviewed and updated as part of effective governance arrangements (standard 1.4.2)
- policies and procedures are readily available to all staff and are being followed (standard 1.4.3)

The lack or absence of policies and procedures can adversely affect the delivery of pharmacy services to consumers which may significantly impact public safety. Policies and procedures describe expected practices for day-to-day operations and help to ensure compliance with legislation and good pharmacy practice. This is especially important when there is a locum pharmacist who may be unfamiliar with the pharmacy or pharmacy department or when there is a new staff member.

Policies and procedures need to be clear and easy to follow. Staff should understand the policies and procedures and know where to access them for easy reference. Staff should be provided with the current policies and procedures at induction, where there is an update, following a prolonged absence from work and as part of scheduled reviews. The policies and procedures should be applied consistently in practice to support compliance.

VPA inspectors commonly find deficiencies in Schedule 8 management, cold chain management, vaccination and complex compounding. Non-compliance in these areas could have been minimised or avoided had there been documented, up-to-date policies and procedures understood and followed by all staff. Further, policies and procedures should be readily available, but this was not always evident during inspections.

Licensees may wish to use templated policies and procedures available through the Quality Care Pharmacy Program (QCPP) or other reputable resources. However, it is important to customise the templates so that the policies and procedures are specific to the registered premises. Licensees may also prefer to create their own policies and procedures based on legislation and good pharmacy practice.

16. There are standards on quality improvement and risk management. What can licensees do to help meet these standards?

The VPA Standards state that 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 (standard 1.5.1)
- identify, investigate and monitor incidents, adverse events and near misses (standard 1.5.2)
- identify and manage the risks associated with providing pharmacy services (standard 1.5.3)

Pharmacy services should be supported by ongoing, and cyclical improvement activities which support enhancement of patient safety. It is important to have good systems in place to identify and manage risks in registered premises and for licensees to develop a positive risk culture that involves staff in risk management processes.

These standards are consistent with the Code of Conduct approved by the Pharmacy Board of Australia for registered pharmacists here. Licensees are also encouraged to read the Pharmaceutical Society of Australia (PSA) *Clinical Governance Principles for Pharmacy Services 2018* which is freely available on the PSA website here. This document considers clinical governance concepts to provide pharmacists and organisations involved in the provision of pharmacy services with guiding principles for the design, implementation and ongoing evaluation of pharmacy services.