VICTORIAN PHARMACY AUTHORITY (VPA)

SELF AUDIT FORM

Introduction:

This document is designed to assist licensees and pharmacist employees to self-audit compliance with the key requirements of the *Pharmacy Regulation Act 2010* (**the Act**), Victorian Pharmacy Authority Guidelines (**VPA Guidelines**) and good pharmacy practice. In relation to good pharmacy practice, the VPA recognises the registration standards, guidelines, codes, and policies issued by the Pharmacy Board of Australia (**PBA**) and has regard to the standards, codes and guidelines issued by the Pharmaceutical Society of Australia, The Society of Hospital Pharmacists of Australia, Victorian Department of Health (**DH**) and Therapeutic Goods Administration.

It is not a requirement to send the completed form to the Victorian Pharmacy Authority.

When to use the self-audit form:

It is recommended that high risk areas or newly established services are audited at least twice a year. As systems become stable and well documented, the audit frequency can reduce to at least annually.

How to use the self-audit form:

1. **Check the Act**
   Before completing the self-audit, it is important to know the basics of the Act and VPA Guidelines and how they apply to your pharmacy. Table 1 outlines key sections of the Act, VPA Guidelines and other relevant references which relate to the audit topic to help you to refresh your knowledge of the requirements.

2. **Check your records and procedures**
   While the audit checklist typically calls for a Yes, No or N/A response, take the time to check that your records or procedures do in fact demonstrate compliance. As a guide, take an adequate sample of your records (at least 10%), and confirm that:
   - Records have been filled in with all the required information, checks and signatures;
   - Procedures do reflect good pharmacy practice and are being followed by all applicable employees. Have the procedures been recently reviewed and updated? Do the procedures reflect the specific conditions and circumstances that apply in your pharmacy?

   When answering a question, record 'No' if there is only partial compliance with the requirement as this will help you identify areas to focus your attention to improve the provision of pharmacy services.

3. **Review the findings**
   Typically, if the answer to a question is 'Yes', then the pharmacy is likely to comply with the requirements.

   If the self-audit is conducted by the pharmacist regularly and usually in charge (PRUIC) or by different pharmacist(s) reviewing each specialised service provided by the pharmacy, it is important that all the findings are reviewed by the licensee.

4. **Identify actions to address your compliance issues**
   Finally, if the checklist has identified deficiencies or areas for improvement, identify appropriate action(s) to rectify the issue(s) and prevent a reoccurrence in the future.

   If the licensee openly discusses the issue(s) identified by the self-audit with relevant employees, it is more likely that appropriate action(s) are identified to rectify the issues and introduce appropriate changes in culture, awareness, and a focus on continual improvement.

   Assigning who is responsible for implementing the action and a due date will allow the process to be monitored and addressed in a timely manner.

Table 1.		
Self-audit Checklist Section		Key references
1.	Licensee Responsibilities	
1.1	Compliance with *Pharmacy Regulation Act 2010* (**the Act**)	Sections 5, 11, 20, 24, 30, 31 of the Act VPA Guidelines, 3.1.3, 4.1.2, and Appendix 7 PBA *Guidelines for proprietor pharmacists*
1.2	Pharmacist(s) and Dispensing Assistants/ Technician(s)	Schedule to the Act PBA *Guidelines for proprietor pharmacists*
1.3	Workload	VPA Guidelines, 4.3.10
1.4	Staff training	VPA Guidelines, 4.3.14 and 4.6.2
1.5	Display of Names and Signs	VPA Guidelines, 4.3.5, 4.3.6 and 4.3.7
1.6	Dispensary Practice - General	Schedule to the Act PBA *Guidelines for dispensing of medicines*
1.7	Pharmacy Medicines and Pharmacist Only Medicines	VPA Guidelines, 4.3.9 Drugs, Poisons and Controlled Substances Regulations 2017
1.8	Privacy and Confidentiality	Schedule to the Act VPA Guidelines, 4.3.12
1.9	Returned Medicines	Schedule to the Act VPA Guidelines, 4.6.6
2.	Premises	
2.1	Essential and on-going requirements	Schedule to the Act
2.2	Alterations	VPA Guidelines, 4.2.2
2.3	Security	Schedule to the Act VPA Guidelines, 4.3.3.1, and Appendix 1
2.4	Design, Layout and Condition	VPA Guidelines, 4.3.3.2, 4.3.3.3, 4.3.3.4, 4.3.3.5, 4.3.4
3.	Equipment and References	
3.1	Equipment	VPA Guidelines, 4.3.11, 4.4.2, 4.4.3, Appendix 5 and 6
3.2	References	VPA Guidelines, 4.4.1 PBA *Guidelines on practice-specific issues Guideline 1 (List of reference texts for pharmacists)*
4.	Records	
4.1	Pharmacy Service Records	*Privacy Act 1988*
4.2	Medicine and Poison Records	VPA Guidelines, 4.5 Drugs, Poisons and Controlled Substances Regulations 2017
5.	Policies and Procedures	PBA *Guidelines for proprietor pharmacists*
6.	Specialised Services	
6.1	Complex Compounding	VPA Guidelines, 4.6 APF 25 PBA *Guidelines on compounding of medicines*
6.2	Dose Administration Aids (DAAs)	VPA Guidelines, 4.4.3 PBA *Guidelines on dose administration aids and staged supply of dispensed medicines*
6.3	Opioid Replacement Therapy (ORT)	Victorian Department of Health *Policy for maintenance pharmacotherapy for opioid dependence*
6.4	Injection Services (including vaccination)	VPA Guidelines, 4.3.13
7.	Quality Improvement and Risk Management	
7.1	Continual improvement	APF 25
7.2	Incident management	PBA *Code of conduct* PBA *Guidelines for dispensing of medicines*
7.3	Risk Management	PBA *Code of conduct* PBA *Guidelines for proprietor pharmacists*

Disclaimer: The Victorian Pharmacy Authority is committed to providing accurate information in relation to the Act and VPA Guidelines. The information contained in this self-audit checklist is general in nature and by no means exhaustive. If you are unsure about how the Act or the VPA Guidelines apply to your pharmacy, contact the Victorian Pharmacy Authority.

By email: enquiries@pharmacy.vic.gov.au By phone: (03) 9653 1700

VICTORIAN PHARMACY AUTHORITY (VPA)
SELF AUDIT FORM

Pharmacy Name and Address:

Postcode
Date of Audit:

Pharmacy Services:

☐ Dispensing and counselling	☐ Compounding (Simple)	☐ Injections (incl. vaccination)
☐ DAA (<15 patients/week)	☐ Compounding (Complex)	☐
☐ DAA (>15 patients/week)	☐ Opioid Replacement Therapy	☐

1.	**LICENSEE RESPONSIBILITIES**	**Requirement Met**		
		Yes	**No**	**N/A**
1.1	Compliance with Pharmacy Regulation Act 2010 (**the Act**)			
1.1.1	Is the licensee aware of and complies with all obligations and requirements in relation to holding a licence and registration of a pharmacy premise?	☐	☐	
1.1.2	Is the licensee aware of the ramifications of not meeting the requirements of the Act including the Schedule to the Act?	☐	☐	
1.1.3	Has the VPA been notified of any change(s) to commercial arrangement(s) affecting the operation of the pharmacy business?	☐	☐	
1.1.4	Does the licensee have effective oversight and management of all pharmacy services provided?	☐	☐	
1.1.5	Has the licensee sought approval from the VPA before authorising, causing, or permitting any other person to carry on a business within the registered pharmacy premises?	☐	☐	☐
1.1.6	Is the pharmacy personally supervised by a registered pharmacist, whenever it is open for business?	☐	☐	
1.1.7	When the pharmacy is NOT open for business, can the pharmacy only be accessed if a registered pharmacist is present?	☐	☐	
1.2	Pharmacist(s) and Dispensary Assistants/Technician(s)			
1.2.1	Do all employed pharmacists hold appropriate and current registration?	☐	☐	
1.2.2	Has the VPA been notified of the pharmacist regularly and usually in charge (PRUIC)?	☐	☐	
1.2.3	Do all employed dispensary technician(s)/assistant(s) have appropriate education, dispensary training and experience?	☐	☐	
1.2.4	Do pharmacist(s) uphold their professional responsibilities when delegating work to dispensary assistants/technicians under their supervision?	☐	☐	
1.2.5	Is a pharmacist directly supervising all staff who are carry out dispensing or compounding duties?	☐	☐	
1.2.6	Does the licensee manage any personal or organisational goals, incentives, or sales targets without compromising the professional judgement of staff to deliver safe and effective pharmacy services?	☐	☐	

1.	LICENSEE RESPONSIBILITIES	Requirement Met		
		Yes	No	N/A
1.3	Workload			
1.3.1	Is the dispensary staffed in accordance with the VPA Guidelines? *(One full-time equivalent pharmacist dispensing an average of 150 prescriptions over a 9.00am to 6.00pm day, and pro rata on weekends and public holidays, is regarded as the minimum staffing level. An individual pharmacist must not supervise more than two dispensary assistants or dispensary technicians engaged in the selection, processing and labelling of prescription medicines at a time. If dispensing levels are in the range of 150-200 prescriptions per day, a trained dispensary assistant and/or an intern pharmacist may assist the pharmacist. If the workload is in the range of 200 to 220 prescriptions daily, a second dispensary assistant may be used but above this workload, a second pharmacist will be necessary for at least part of the day.)*	☐	☐	
1.3.2	Is there sufficient suitably qualified staff on duty for the services provided, with clear lines of accountability?	☐	☐	
1.3.3	Is there a staffing plan which considers the specific services provided by the pharmacy?	☐	☐	
1.3.4	Is there staff contingency planning for short and long-term staff absence, whether planned or unplanned?	☐	☐	
1.4	Staff Training			
1.4.1	Do all staff have written position and duty descriptions which accurately reflect their role (Pharmacist, Pharmacist Immuniser, dispensary technician, compounding dispensary assistant, etc.)?	☐	☐	
1.4.2	Do all staff have training records which are regularly updated and accurately reflect the status of training undertaken? (e.g., recognised compounding, immuniser, current First aid and CPR certificates)	☐	☐	
1.4.3	Do pharmacists work within their level of competence?	☐	☐	
1.4.4	Do staff only perform roles for which they have been trained?	☐	☐	
1.4.5	Are there different sets of skills, knowledge and experience within the team which reflect the range of services provided?	☐	☐	
1.4.6	Is there on-going learning and development of the pharmacy team (i.e., staff keep their knowledge and skills up to date)?	☐	☐	
1.4.7	Do staff know when and how to raise a concern with the pharmacy owner(s)?	☐	☐	
1.4.8	Is there a culture of openness, honesty, and learning that promotes the raising of issues with the pharmacy owner(s)?	☐	☐	
1.5	Display of Names and Signs			
1.5.1	Is the proprietor's name or names clearly displayed at all public entrances to the pharmacy?	☐	☐	
1.5.2	Is the name of the pharmacist who is regularly and usually in charge of the pharmacy always clearly displayed in the professional services area of the pharmacy?	☐	☐	
1.5.3	Is the name of every pharmacist(s) on duty always clearly displayed in the professional services area of the pharmacy?	☐	☐	
1.5.4	Can the pharmacy clients easily identify who are staff and the role that they are performing?	☐	☐	
1.5.5	If a non-PBS pharmacy, is there a PBS disclaimer notice?	☐	☐	☐
1.6	Dispensary Practice - General			
1.6.1	Is good dispensing practice being followed?	☐	☐	
1.6.2	Is the patient history reviewed on all occasions of dispensing?	☐	☐	
1.6.3	Is the expiry date checked during the selection of the medicine?	☐	☐	

1.	LICENSEE RESPONSIBILITIES	Requirement Met		
		Yes	No	N/A
1.6.4	Is there an extensive range of CA labels available to each dispensing station?	☐	☐	
1.6.5	Are there additional dispensing checks performed for drugs with special dosing regimens (e.g., methotrexate)?	☐	☐	
1.6.6	Are CA labels routinely applied to dispensed medicines except if deemed inappropriate by the dispensing pharmacist in a particular case?	☐	☐	
1.6.7	Is there a system in place to monitor the expiry date of medicines to prevent expired medicines being supplied?	☐	☐	
1.6.8	Is barcode scanning being routinely undertaken during the dispensing process? [The Authority encourages pharmacists to aim for 100% and to actively monitor scanning rates]	☐	☐	
1.6.9	Is distance dispensing carried out according to good pharmacy practice?	☐	☐	☐
1.6.10	Is SafeScript checked prior to dispensing a prescription for a high-risk medicine monitored by the system?	☐	☐	
1.6.11	Is the dispensing of a high-risk medicine prescriptions routinely recorded in the SafeScript system?	☐	☐	
1.7	Pharmacy Medicines and Pharmacist Only Medicines			
1.7.1	Does the pharmacist on duty routinely monitor the sale of Pharmacy Medicines by non-pharmacist members of staff?	☐	☐	
1.7.2	Are S3 poisons displayed or stored for sale to prevent ready self-selection by the public, and in a way that does not promote or draw undue attention to them?	☐	☐	
1.7.3	For S3 poisons containing pseudoephedrine, is the quantity of stock for sale kept to no more than that sufficient for 1 week's sales from the pharmacy?	☐	☐	
1.7.4	For S3 poisons containing pseudoephedrine, is all stock kept out of public view?	☐	☐	
1.7.5	Is the pharmacist personally involved and takes all reasonable steps to ensure a therapeutic need exists before supplying an S3 poison?	☐	☐	
1.7.6	Does the pharmacist personally deliver/supervise the supply of and provide directions for use of S3 poisons?	☐	☐	
1.7.7	Is only one package of an S3 poison supplied at a time (unless there are exceptional circumstances, and the supply is documented)?	☐	☐	
1.7.8	Is the sale of medicines particularly those known to be abused or misused supervised and monitored?	☐	☐	
1.8	Privacy and Confidentiality			
1.8.1	When requesting customer information, is it undertaken in a manner which protects their privacy, dignity, and confidentiality?	☐	☐	
1.8.2	Is medicine counselling and other confidential discussion undertaken in a manner which protects the privacy of the patient?	☐	☐	
1.8.3	Are arrangements in place to ensure that client information cannot be obtained by others from discarded documents?	☐	☐	
1.8.4	Are 'cash and wrap' or 'checkout' counters arranged to ensure that the identity of a medicine being paid for by the client cannot be known by another client at the counter?	☐	☐	
1.8.5	Are arrangements in place to ensure the identity of dispensed medicine cannot be known by other clients in the pharmacy (e.g., being taken to the cash and wrap counter or a script awaiting collection)?	☐	☐	
1.9	Returned Medicines			
1.9.1	Is there a system in place to ensure that medicines are not re-used after dispensing and after they have left the pharmacy?	☐	☐	
1.9.2	Are returned medicines including those returned from nursing homes and those in dose administration aids stored in a secure manner and disposed of safely and regularly (e.g., use of RUM bins)?	☐	☐	
1.9.3	Are returned S8 medicines stored in a secure manner and disposed of safely and regularly?	☐	☐	

2.	**PREMISES**	**Requirement Met**		
		Yes	**No**	**N/A**
2.1	Essential and on-going requirements			
2.1.1	Do the registered premises comply with relevant requirements of the Schedule to the Act on an ongoing basis, including:			
	a) The different parts of the premises are properly situated and are secure and suitable for the purpose for which they are to be used.	☐	☐	
	b) 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.	☐	☐	
	c) A registered pharmacist must oversee the area of the pharmacy or pharmacy department where pharmacy services are provided.	☐	☐	
	d) The premises are maintained in a clean and hygienic manner.	☐	☐	
	e) There is no access to the dispensary of the pharmacy except under the direct supervision of a registered pharmacist.	☐	☐	
2.2	Alterations			
2.2.1	Has the Authority given prior approval to any significant alterations to the premises?	☐	☐	☐
2.3	Security			
2.3.1	Are the premises secure and safeguarded from unauthorised access?	☐	☐	
2.3.2	Is the pharmacy fitted with an electronic intruder alarm fitted that conforms to Australian Standard 2201: Intruder Alarm Systems?	☐	☐	
2.3.3	Does the electronic alarm cover the perimeter of the pharmacy as well as all areas where medicines are kept including the dispensary, Schedule 8 cabinet or safe, rooms used to store dispensed medicine for packing into dose administration aids, the professional service area and storerooms?	☐	☐	
2.3.4	Is the electronic alarm monitored by central agency on a 24-hour, 7 day a week basis?	☐	☐	
2.3.5	Does the central agency, monitoring the alarm system, hold a security firm licence?	☐	☐	
2.3.6	Does the central agency have facilities that conform to Australian Standard 2201.2 Intruder Alarm Systems – Monitoring Centres Grade 1, 2 or 3?	☐	☐	
2.3.7	If the building permit permits, is each perimeter door to the pharmacy fitted with: a) A lock that prevents the door from being opened by hand from the inside when the premises are not lawfully occupied, OR	☐	☐	☐
	b) Other measures in place to prevent entry through roofs or ceilings such as floor to roof walls or ceiling space alarm sensors?	☐	☐	☐
2.3.8	Are all perimeter doors that open to secluded or non-public areas either roller shutters or solid core doors reinforced with heavy gauge metal sheeting or protected by a substantial metal security grille door?	☐	☐	☐
2.3.9	Are perimeter windows to secluded or non-public areas fitted with bars or security grilles?	☐	☐	☐
2.3.10	Are skylights fitted with bars or security grilles?	☐	☐	☐
2.3.11	Is the dispensary equipped with safes or drug cabinets large enough to store all S8 poisons in a way that facilitates the accurate selection of medicines?	☐	☐	
2.3.12	Is each drug cabinet constructed and attached in accordance with the Drugs, Poisons & Controlled Substances Regulations 2017 and guidance issued by the Department of Health?	☐	☐	
2.3.13	Is the S8 safe key kept on the person of a pharmacist or otherwise secured e.g., in a key safe (may have combination lock) which provides security equivalent to that of the S8 safe?	☐	☐	

2.	PREMISES	Requirement Met		
		Yes	No	N/A
2.4	Design, Layout and Condition			
2.4.1	Does the pharmacy have at least one doorway opening from the premises to allow members of the public to enter the pharmacy from a public place such as a street, public walkway, mall, or public foyer?	☐	☐	
2.4.2	Does the design of the dispensary or the location of counters or other fixtures in the public area of the pharmacy prevent clients approaching and standing directly in front of the dispensary, except at designated service points, and distracting pharmacist or reading private documents that may be on the dispensary bench?	☐	☐	
2.4.3	Does the design of the dispensary prevent members of the public from entering the dispensary unnoticed by the pharmacist on duty?	☐	☐	
2.4.4	Is the pharmacy arranged so that the dispensary is not used as a thoroughfare to access “back of house” areas?	☐	☐	
2.4.5	Is the dispensary restricted to dispensary staff only?	☐	☐	
2.4.6	Are all S4 medicines stored outside the dispensary kept in a locked facility?	☐	☐	
2.4.7	Does the dispensary include: a) a specific bench or bench area of at least 0.6m^2 for the unpacking and sorting of dispensary orders received?	☐	☐	
	b) a sink with drainer and hot and cold running water?	☐	☐	
	c) a specific bench or bench area of at least 0.6m^2 located near to the sink for the simple compounding or preparation of medicines and that also provides storage for compounding equipment?	☐	☐	
	d) a specific bench or bench area of at least 0.6m^2 for dispensary clerical and research use?	☐	☐	
	e) one dispensing station for each 150 prescriptions or part thereof dispensed on a typical day between 9am and 6pm?	☐	☐	
	f) a refrigerator dedicated to the storage of medicines?	☐	☐	
2.4.8	Does each dispensing station include: a) a dispensing bench of at least 0.6 m^2?	☐	☐	
	b) a computer/network with access to dispensing software?	☐	☐	
	c) a keyboard?	☐	☐	
	d) a screen?	☐	☐	
	e) a dedicated scanner?	☐	☐	
	f) a dedicated printer for labels?	☐	☐	
	g) a dedicated printer for repeat forms	☐	☐	
	g) adequate stationary	☐	☐	
	h) being located near a printer that prints Consumer Medicine Information (CMI)? *(The CMI printer may serve multiple dispensing stations)*	☐	☐	
2.4.9	Are all non-dispensary tasks performed outside the dispensary (e.g., POS data entry, storage of non-dispensary stock, storage of display materials, promotional activities)?	☐	☐	
2.4.10	Do non-dispensary staff members store their personal belongings and take meal and tea breaks outside the dispensary?	☐	☐	
2.4.11	Is there a dedicated prescription reception and counselling point for each dispensing station used to dispense prescriptions?	☐	☐	

2.	PREMISES	Requirement Met Yes	No	N/A
2.4.12	Are the dedicated prescription reception and counselling points each fitted with opaque privacy screens rising not less than 600 mm above the bench to form a privacy booth or be otherwise arranged or situated to provide privacy?	☐	☐	
2.4.13	Is there a professional service area in the public part of the pharmacy that is situated and arranged to allow supervision by the pharmacist(s) on duty?	☐	☐	
2.4.14	Is the professional service area distinguished by décor and / or signs?	☐	☐	
2.4.15	Is the professional service area used solely for the display and storage of products for therapeutic use and information about them?	☐	☐	
2.4.16	Are all medicine storage areas serviced by a thermostatically controlled air-conditioner that maintains storage temperatures so that the temperature does not exceed 25ºC?	☐	☐	

3.	EQUIPMENT and REFERENCES	Requirement Met Yes	No	N/A
3.1	Equipment			
3.1.1	Is equipment obtained from reputable source(s)?	☐	☐	
3.1.2	Is the equipment safe to use and fit for purpose?	☐	☐	
3.1.3	Is equipment stored securely?	☐	☐	
3.1.4	Is equipment safeguarded from unauthorised access?	☐	☐	
3.1.5	Is equipment appropriately maintained (including calibration and testing at regular intervals and appropriate performance and maintenance logs kept)?	☐	☐	
3.1.6	Is the dispensary equipped with a set of approved Class 1 or Class 2 scales in good working order, the operating instructions for which, including minimum weighable mass, are prominently displayed?	☐	☐	
3.1.7	Is the dispensary equipped with an adequate range of accurately calibrated measures e.g., 10ml, 50ml & 200ml?	☐	☐	
3.1.8	Is the compounding area/laboratory equipped with approved scales which have the appropriate sensitivity for the range of work being undertaken?	☐	☐	
3.1.9	Is the compounding area/laboratory equipped with an adequate range of calibrated measures?	☐	☐	
3.1.10	Are all refrigerators dedicated to the storage of medicines fitted with a temperature data logger to allow the effect of any malfunction on the integrity of the medicines to be assessed?	☐	☐	
3.1.11	Is the vaccine refrigerator locked if not stored in the dispensary?	☐	☐	☐
3.1.12	Is the min/max temperature regularly monitored for all refrigerators dedicated to the storage of medicines?	☐	☐	
3.2	References			
3.2.1	Is the dispensary equipped with a current range of reference texts relevant to the pharmacy services provided?	☐	☐	
3.2.2	Do pharmacists (including locums) have ready access to all electronic references?	☐	☐	
3.2.3	Are relevant current compounding references readily available to compounding staff e.g., APF, Martindale, SDS (Safety data sheet) register?	☐	☐	☐
3.2.4	Are relevant current vaccination references readily available (e.g., Australian Immunisation Handbook, National Vaccine Storage Guidelines: Strive for 5)?	☐	☐	☐

4.	RECORDS	Requirement Met		
		Yes	No	N/A
4.1	Pharmacy Services Records			
4.1.1	Are all records relating to pharmacy services created, stored, and retained in accordance with relevant legislation (including *Privacy Act 1988*) and guidelines?	☐	☐	
4.1.2	Are all records containing customer's personal information secure from theft, misuse, interference, loss, unauthorised access, modification, or disclosure?	☐	☐	
4.13	Are electronic systems, and records adequately protected from cyber threats?	☐	☐	
4.2	Medicines and Schedule 8 Poison Records			
4.2.1	Are transactions involving Controlled Drugs (Schedule 8 poisons) recorded in the Controlled Drug Register as soon as practicable after completing the transaction?	☐	☐	
4.2.2	Is the true and accurate balance of a Controlled Drug recorded in the Register (e.g., negative balances are not recorded in the case of partial supply)?	☐	☐	
4.2.3	Is the Controlled Drug Register regularly (at least every 3 months) reconciled with the actual stock on hand of Controlled Drugs?	☐	☐	
4.2.4	Are returned Schedule 8 poisons awaiting destruction recorded in the Controlled Drug Register?	☐	☐	
4.2.5	Is SafeScript always checked before dispensing a medicine monitored by the system?	☐	☐	

5.	POLICIES AND PROCEDURES	Requirement Met		
		Yes	No	N/A
5.1.1	Are policies and procedures clearly documented, readily accessible, regularly reviewed and updated as part of effective governance arrangements?	☐	☐	
5.1.2	Are there standard operating procedures (SOPs) for all pharmacy services provided, such as: a) good dispensing practice?	☐	☐	
	b) counselling?	☐	☐	
	c) provision of S2 and S3 medication?	☐	☐	
	d) simple compounding?	☐	☐	
	e) complex compounding (including use of specialised equipment)?	☐	☐	☐
	f) dose administration aids (DAAs)?	☐	☐	☐
	g) opioid replacement therapy (ORT)?	☐	☐	☐
	h) injection services (including vaccination)?	☐	☐	☐

5.	POLICIES AND PROCEDURES	Requirement Met		
		Yes	No	N/A
5.1.3	Are there policies and procedures for systems that support the provision of safe pharmacy services, such as: a) complaint management process?	☐	☐	☐
	b) continual improvement?	☐	☐	☐
	c) incident management process (includes the handling of dispensing errors)?	☐	☐	☐
	d) risk management process?	☐	☐	☐
	e) conflict of interest?	☐	☐	☐
	f) record management (including digital and paper records)?	☐	☐	☐
	g) protecting information technology and communications (computers, phones, website) from cyber-security threats?	☐	☐	☐
	h) privacy and confidentiality and the disclosure of confidential information?	☐	☐	☐
	i) obtaining consent to provide pharmacy services?	☐	☐	☐
	j) workplace health and safety?	☐	☐	☐
	k) COVID-19 or other health related emergency plan(s)?	☐	☐	☐
	l) temperature monitoring (including actions to be taken if temperature monitoring is outside of specification)?	☐	☐	☐
	m) cold chain protocol – delivery and breach	☐	☐	☐
	n) scheduling of equipment calibration and/or testing?	☐	☐	☐
	o) product recall?	☐	☐	☐
	p) hygiene and infection control (including operator exclusions from performing compounding duties)?	☐	☐	☐
	q) cleaning (for facility – dispensary, compounding, DAA room etc. and equipment) and cleaning records?	☐	☐	☐
	r) waste disposal (including returned medicines)?	☐	☐	☐

6.	SPECIALISED SERVICES	Requirement Met		
		Yes	No	N/A
6.1	Complex Compounding			☐
6.1.1	Is complex compounding undertaken: a) in a dedicated room (laboratory) that is lockable or immediately next to the main dispensary?	☐	☐	
6.1.2	Is the laboratory fitted with hot and cold water and sink with drainer?	☐	☐	
6.1.3	Is the laboratory maintained and monitored at or below 25°C, at all times?	☐	☐	
6.1.4	Are all surfaces cleanable by washing?	☐	☐	
6.1.5	Is a suitable powder containment cabinet (for personal and environment protection) used for hazardous and potent substances?	☐	☐	
6.1.6	Is there a quarantine area and procedure for raw materials being held from use?	☐	☐	
6.1.7	Is protective clothing (laboratory coat, disposable gloves and hair covers) worn during compounding procedures?	☐	☐	
6.1.8	Is additional protective clothing worn for handling hazardous substances and potent substances such as hormones (e.g., eye protection, respirator mask, shoe coverings)?	☐	☐	
6.1.9	Are baseline and regular periodic pathology tests performed on all staff handling hazardous materials?	☐	☐	
6.1.10	Is compounding carried out without distraction and free of external interruption?	☐	☐	
6.1.11	Is a risk assessment to assess the potential risks to staff & consumers conducted before compounding a medicine as outlined in the current APF (*Compounding*)?	☐	☐	
6.1.12	Is the decision to prepare a compounded medicine(s) always justified as outlined in the current APF (*Compounding*)?	☐	☐	
6.1.13	Are animal medicines compounded only on the prescription or the instructions of a veterinary practitioner, irrespective of poison schedule?	☐	☐	
6.1.14	Do raw materials (including water) meet suitable quality standards and have validated expiry dates?	☐	☐	
6.1.15	Is batch preparation only undertaken in accordance with the Pharmacy Board of Australia Guidelines on compounding of medicines, e.g., for individual named patients for which multiple prescriptions have been received, and where a risk assessment has been undertaken?	☐	☐	
6.1.16	Is a dispensing worksheet completed for each prescription compounded e.g., APF compounding dispensing form template?	☐	☐	
6.1.17	Does the dispensing worksheet include the directions/steps for preparing the medicine?	☐	☐	
6.1.18	Is the expiry date of the finished product shown on the worksheet (may be included by means of a duplicate label attached placed on the worksheet)?	☐	☐	
6.1.19	Does a pharmacist initial or counter initial the compounding dispensing worksheet for each weighing/measuring and other significant step?	☐	☐	
6.1.20	Is each compounding dispensing worksheet signed-off and dated by the supervising or compounding pharmacist?	☐	☐	
6.1.21	Are compounding dispensing worksheets retained for three years from the date of dispensing?	☐	☐	
6.1.22	Are expiry dates consistent with APF recommendations except where reliable stability data exist (never > 6 months)?	☐	☐	
6.1.23	Are storage conditions and the expiry date shown on labels of dispensed compounded preparations?	☐	☐	
6.1.24	Are compounded medicines recorded and labelled for the use of a specific patient and supplied directly to that patient or bona fide agent OR recorded and labelled for the use of a doctor/veterinarian but not for the purpose of on-supply?	☐	☐	
6.1.25	Are testing protocols (as defined by APF 25) for compounding medicines in place?	☐	☐	
6.1.26	Are compounded medicines assayed by a competent analytical laboratory?	☐	☐	

6.	SPECIALISED SERVICES	Requirement Met		
		Yes	No	N/A
6.1.27	Are frequently compounded medicines assayed, at least annually, and including product(s) produced by each compounding staff member (as described in APF 25)?	☐	☐	
6.1.28	Is a risk-based selection criteria used to determine which compounded medicines are assayed?	☐	☐	
6.1.29	Are clients counselled on every occasion a compounded medicine is supplied including those delivered as part of a mail / online ordering system?	☐	☐	
6.1.30	Have equipment cleaning methods been shown to be effective to prevent cross-contamination?	☐	☐	
6.1.31	Are all raw materials sourced from a third-party supplier manufactured by an acceptable manufacturer?	☐	☐	
6.1.32	Are raw materials(s) which are subject to testing quarantined until the results are known?	☐	☐	
6.1.33	Is validation of complex compounding techniques performed? (e.g., activation of cannabis material, sterilisation methods)?	☐	☐	
6.2	Dose Administration Aids (DAAs)			☐
6.2.1	If the pharmacy regularly fills DAAs for 15 or more persons per week does: a) The dispensary include a specific bench or bench area of at least 1m^2 dedicated to the filling of DAAs; and secure storage for dispensed medicines?	☐	☐	
	b) The pharmacy include an area for the filling of DAAs located away from the dispensary that is air-conditioned; alarmed and that has access to hand washing facilities; a 'patient history look up' computer terminal, DAA printing equipment; and lockable storage for dispensed medicines?	☐	☐	
6.2.2	Are dispensed medicines stored in containers of sufficient size to ensure effective segregation of each client's medicine?	☐	☐	
6.2.3	Are storage containers for dispensed medicines labelled with client's name?	☐	☐	
6.2.4	Are dispensed S8 Medicines used for 'virtual pill count' DAA systems e.g., *Webstercare Meds Pro* stored in a S8 cabinet when not in use?	☐	☐	
6.2.5	Are clients' medicines stored: a) in the dispensary?	☐	☐	
	b) in a lockable room or cupboard which is kept locked when not in use?	☐	☐	
6.2.6	Are dose administration containers labelled with: a) the patient's name?	☐	☐	
	b) the pharmacy name, address, and telephone number?	☐	☐	
	c) the drug name, strength, and directions for use?	☐	☐	
	d) with APF cautionary and advisory labels OR is an alternative method of providing cautionary advisory information used e.g., providing clients with a medication profile?	☐	☐	
6.2.7	Is CAL 1 or 1a attached to the dose administration container where indicated by the APF? *(Note: This is a statutory requirement for the labelling of immediate containers. It is not satisfied by attaching a 1 or 1a CAL to a separate document such as a medication profile.)*	☐	☐	
6.2.8	Is client information e.g., age / weight / medical conditions / allergies / lifestyle (self-medicating, ambulatory etc) routinely collected and recorded for clients obtaining medicines in dose administration aids? (*Note: This is particularly relevant for clients who do not attend the pharmacy).*	☐	☐	
6.2.9	Are dose administration containers for patients requiring hazardous drugs (e.g., cytotoxic, warfarin) or drugs with special dose regimes (e.g., methotrexate, alendronate) identified or quarantined to ensure correct ongoing handling and filling?	☐	☐	
6.2.10	Are there additional dispensing procedures and checks performed for drugs with special dosing regimes (e.g., methotrexate)?	☐	☐	

6.	SPECIALISED SERVICES	Requirement Met		
		Yes	No	N/A
6.2.11	Are dose administration container filling and checking records (date, medication name, strength, dose, quantity, and initials of pharmacist) made and retained at pharmacy premises for at least 6 months?	☐	☐	

6.	SPECIALISED SERVICES	Requirement Met		
		Yes	No	N/A
6.3	Opioid Replacement Therapy (ORT)			☐
6.3.1	If the pharmacy provides pharmacotherapy to 20 or more persons per day, does: a) the dispensary include a bench or bench area of at least 0.6m2 dedicated to the pharmacotherapy program that is not accessible to the public and provides for the secure storage of "in-use" S8 medicines? or	☐	☐	☐
	b) the pharmacy include a pharmacotherapy area located away from the dispensary that is air-conditioned, alarmed, fitted with a hot and cold water sink with drainer, fitted with a safe or drug cabinet to store S8 poisons, fitted with lockable storage for client records, and arranged to protect the privacy of pharmacotherapy clients?	☐	☐	☐
6.3.2	Are current editions of the Pharmacotherapy Policy and Guidelines available and readily accessible in the pharmacy?	☐	☐	
6.3.3	Is there a comprehensive pharmacy pharmacotherapy procedure manual readily available?	☐	☐	
6.3.4	Have all participating pharmacists signed a Program Certification form (Pharmacotherapy Policy Appendix 7)?	☐	☐	
6.3.5	Are Methadone doses diluted prior to administration?	☐	☐	
6.3.6	Are Methadone take-away doses diluted to 200ml with water, fitted with a child resistant cap and labelled in accordance with the APF?	☐	☐	
6.3.7	Are Buprenorphine take-away doses labelled in accordance with the APF?	☐	☐	
6.3.8	Is client privacy maintained during daily dosing and handling and storage of administration books?	☐	☐	
6.3.9	Are all prescriptions current, and segregated from older ORT scripts?	☐	☐	
6.3.10	Are photos clear, certified, and suitable for the identification of clients?	☐	☐	
6.3.11	Are prescriptions and photos readily accessible when dosing?	☐	☐	
6.3.12	Is the date and time recorded for each dose administered or supplied?	☐	☐	
6.3.13	Is the attendance book signed by both the client and the pharmacist at the time each dose is administered or supplied?	☐	☐	
6.3.14	Is the total quantity of each S8 administered or supplied per day recorded in the S8 Register daily?	☐	☐	
6.3.15	Is S8 Register reconciled with the actual stock on hand on a regular basis?	☐	☐	
6.3.16	Is the working stock of methadone and buprenorphine kept secure and out of the sight and reach of clients?	☐	☐	
6.3.17	Is the working stock of methadone and buprenorphine returned to the S8 cabinet daily when dosing has been completed?	☐	☐	

6.	SPECIALISED SERVICES	Requirement Met		
		Yes	No	N/A
6.4	Injection Services (including Vaccination)			☐
6.4.1	Has VPA approval been obtained for a person who is *not* the owner or employee of the pharmacy business to provide vaccination services *(Refer to VP43 Application form*)?	☐	☐	☐
6.4.2	Is the pharmacy registered with the Department of Health (DH)?	☐	☐	
6.4.3	Is the pharmacy registered as a vaccination provider on Australian Immunisation Register (AIR)?	☐	☐	
6.4.4	Is another person trained in First Aid and CPR present in pharmacy during vaccinations?	☐	☐	
6.4.5	Is the vaccination room/area:			
	a) a suitable size?	☐	☐	
	b) visually private?	☐	☐	
	c) audibly private?	☐	☐	
	d) maintained at a comfortable temperature?	☐	☐	
6.4.6	Does the vaccination room/area have:			
	a) Bench, or suitable alternative, with an impervious surface?	☐	☐	
	b) Bed or suitable reclining chair?	☐	☐	
	c) Suitable hand washing facilities or alcohol sanitiser?	☐	☐	
	d) First aid equipment in a suitable and obvious location?	☐	☐	
	e) Anaphylaxis Kit in a suitable and obvious location?	☐	☐	
	f) Anaphylaxis Kit which is compliant with DH Victorian Pharmacist-Administered Vaccination program Guidelines?	☐	☐	
	g) Anaphylaxis response charts/guidelines on display?	☐	☐	
	h) Telephone within ready access in case of emergency?	☐	☐	
	i) Copy of Pharmacist's immuniser Certificate of Training on display?	☐	☐	
	j) Copy of Pharmacist's immunisers' First Aid Certificate on display?	☐	☐	
	k) Copy of Pharmacist's immunisers' CPR Certificate on display?	☐	☐	
	l) Emergency response protocol on display?	☐	☐	
	m) Sharps Kit?	☐	☐	
	n) Incident Record Book in a specific, suitable, and obvious location?	☐	☐	
	o) Patient observation area (for monitoring the patient for 15 min after vaccination or in accordance with professional guidelines)?	☐	☐	
6.4.7	Are the Certificates of Training, First Aid and CPR confirmed as being current?	☐	☐	
6.4.8	Is a Vaccination log/worksheet completed for each vaccination given? (e.g., Does it include all relevant information including name of administering pharmacist)?	☐	☐	
6.4.9	Is AIR checked prior to the administration of <u>every</u> vaccine?	☐	☐	
6.4.10	Are all vaccines administered recorded to the AIR (in a timely manner)?	☐	☐	

7.	QUALITY IMPROVEMENT AND RISK MANAGEMENT	Requirement Met		
		Yes	No	N/A
7.1	Continual Improvement			
7.1.1	Is the safety and quality of pharmacy services reviewed and monitored?	☐	☐	
7.1.2	Is the quality of pharmacy services improved by learning from feedback and taking appropriate actions to prevent the reoccurrence of incidents or concerns?	☐	☐	
7.1.3	Are poor practice and behaviours challenged?	☐	☐	
7.2.	Incident Management			
7.2.1	Are Incident Records made and retained for three years in a dedicated file?	☐	☐	
7.2.2	Is there a formal procedure in place to facilitate reliable inter-staff professional communications?	☐	☐	
7.2.3	Can feedback and concerns about the pharmacy, services and staff be raised by individuals and organisations, and are these concerns/complaints considered, and action taken where appropriate?	☐	☐	
7.3	Risk Management			
7.3.1	Are risks associated with the dispensing process managed to ensure a consistent and high-quality level of care to patients?	☐	☐	
7.3.2	Are risks associated with providing pharmacy services identified and managed?	☐	☐	
7.3.3	Is the safety and quality of pharmacy services reviewed and monitored?	☐	☐	
7.3.4	Are suitable insurance arrangements in place for the pharmacy services provided?	☐	☐	
7.3.5	Is a risk assessment to assess the potential risks to staff and consumers conducted before compounding a medicine as outlined in the current APF?	☐	☐	

Self-Audit Conducted By:		
Name	Position	Sections

Self-Audit Responses Reviewed by Licensee(s):		
Name	Position	Date:

Improvement Actions	Action to be completed by	Date action completed

Form last updated: 23 June 2021.