Pharmacy Regulation Authority SA

PHARMACY SELF-ASSESSMENT FORM

Updated March 2018

Pharmacy Name and Address:	Phone:
Pharmacist completing assessment:	Date:

STANDARD OF PREMISES

Considerations	Y/N	Comments
Required references		The Pharmacy Board of Australia (PharmBA) publishes a list of references which must be readily accessible and should be accessed by pharmacists during the clinical assessment, reviewing, dispensing and counselling processes.
Cannot be accessed from a supermarket		Legislation prohibits a pharmacy premises from being accessed from a supermarket.
Safe, secure & hygienic storage of therapeutic goods & health care products		Stock must be stored in accordance with relevant scheduling legislation and in a manner which maintains the quality of the product.
Supervision from the dispensary for all scheduled medicines		The dispensary area should be located so as to allow the pharmacist(s) to observe scheduled medicines in the pharmacy.
Adequate signage displayed on non-PBS approved pharmacies		Pharmacies operating without Medicare approval must prominently display information advising the public. The wording for such a sign is included in PRASA's *Guidelines for the operation of pharmacy premises by pharmacy services providers March 2018.*

Temperature control		There must be a means of measuring the temperature within a fridge used for the storage of temperature sensitive scheduled items. All scheduled items must be stored in areas of the pharmacy which are able to be maintained within the required temperature range.

DISPENSING

Considerations	Y/N	Comments
Pseudoephedrine Recording		The use of an online system to record pseudoephedrine sales (including those supplied on prescription) is mandatory in South Australia.
CAL's		The use of label 1/1a is required by law (including on dose administration aids). If the dispensary software prints a warning on the dispense label, check that the wording is adequate to satisfy the requirements of the Poisons Standard (some printed warnings do not adequately cover all of the requirements).
Safe and secure storage of confidential and sensitive information		Patient privacy must be maintained at all times on the premises. Some areas where patient privacy may need extra vigilance include: - the storage of patient medication awaiting collection - the storage of patient duplicates and repeats - when handing out patient medication - when counselling a patient or providing information to their agent - when discarding empty, labelled packaging (eg. when packing DAA's) - when discarding surplus or incorrectly printed dispensary labels and repeats
Private counselling area		An area in the pharmacy must be available for conducting a private counselling session with a member of the public if required. Such an area cannot also be used for the storage of schedule 4 medications (ie. the dispensary).
Returned medication handling		Any returned medication must be handled and discarded appropriately with consideration for patient privacy, environmental impact and scheduling laws. Returned schedule 8 items must first be written into the DD register and their destruction must be witnessed and countersigned in the register by an authorised person.

BARCODE SCANNING

Barcode scanning		PRASA expects a scanning rate of 100% to be maintained to mitigate the potential for errors being made in product selection. However certain dispensing activities (such as work conducted on behalf of a health facility) may have an impact to lower the scanning rate. In such situations a scanning rate of at least 80% may be considered suitable.

WORKLOADS

Workloads		Staffing on the premises (both pharmacist and non-pharmacist staff) should be such that the workload when dispensing is at a reasonable and manageable level. The Pharmacy Board of Australia's *Guidelines for Dispensing of Medicines* Section 11 outlines the Board recommendations for staffing and the use of dispensary assistants/technicians.

DOSE ADMINISTRATION AIDS

DAA's		DAA's must be packed in an area away from the public. DAA's must be labelled correctly and with CAL's where appropriate. Patient medication packed in a DAA and the completed DAA's must be stored at the correct temperature and in a way that protects the privacy of the patient. A record of the packing/checking/handing out of each DAA must be signed, dated and kept for at least 6 months. Third party packing responsibilities are outlined in the Pharmacy Board of Australia's *'Guidelines on dose administration aids and staged supply of dispensed medicines'.*

SCHEDULED ITEM STORAGE AND HANDLING

Considerations	Y/N	Comments
Pharmacy Medicine (S2)		Schedule 2 items stored in public areas of the premises must be in blister or child proof packaging or stored at least 1.2 metres above the floor.
Pharmacist Medicine (S3)		Schedule 3 items must be labelled with the name and address of the pharmacy when sold. The pharmacist must personally (not through an assistant) give oral directions for the safe and proper use of the item.
Prescription Medicine (S4)		Must be stored in an area of the premises inaccessible to members of the public.
Controlled Drug (S8)		Schedule 8 (drugs of dependence) items have strict controls placed on their transport, storage and recording. Pharmacies are required to ensure that stock held on the premises does not exceed the capacity of the approved safe(s).
Schedule 8 Medicines Register		A Schedule 8 register must be kept in an approved format on the premises for at least 2 years. Register entries must include the patients full name, address, full date of supply, pharmacist initials and the balance of the item now in stock on the premises. Entries must be made on the same day as supply. Alterations or deletions in the register can only be made and initialled by a pharmacist. Returned schedule 8 items must be entered in the register. The destruction of schedule 8 items must be entered in the register and witnessed by an approved person (who must countersign the register entry).
Schedule 8 Medicines Safe		The safe used for Schedule 8 medicines storage must meet the requirements of the Department for Health and Ageing (SA) *Code of Practice for the Storage and Transport of Drugs of Dependence.* The safe must be fixed to an internal wall or the floor and be locked at all times. The key must be kept in the possession of the pharmacist.
Schedule 8 medicines Random Stock Check		The amount of each Schedule 8 item in the Schedule 8 register must match the actual amount in the Schedule 8 medicines safe. All incoming and outgoing stock must be entered in the register *immediately* after supplying or receiving the item(s).
Medication Assisted Treatment for Opioid Dependence Program (MATOD)		Pharmacists should have easy access to Drugs of Dependence Unit (DDU) resources (as outlined in the DDU MATOD Information sheet). Methadone/buprenorphine must be stored as for all other schedule 8 items (in a locked, approved safe).

		The script must be valid at the time of dispensing and the number of take away doses issued each week cannot exceed the number on the prescription OR the maximum number allowed by DDU. Daily signing sheets must include the daily dose, the initials of the client and the initials of the dispensing pharmacist. The incoming and outgoing supplies must be written up in the Schedule 8 register and the balance must be reconciled regularly.

IMMUNISATION SERVICES

Considerations	**Y/N**	**Comments**
Screened area or room		An area that does not allow members of the public to observe the immunisation. The room must be set up in a way that provides both *visual* and *auditory* privacy for the client undergoing immunisation.
Security		To ensure patient privacy & confidentiality measures must be taken to prevent unauthorised entry into the area during immunisation (eg. a door lock or a *'no entry'* sign). Patient records stored in *any* area of the pharmacy should be adequately secured (outside of the dispensary this should be in a lockable drawer/cupboard).
Seating		Appropriate seating should be available in the area for the patient undergoing immunisation, with consideration given to space for the patient's carer. Seating should also be made available in the pharmacy for the patient while being observed post-immunisation.
Hand basin		An area for hand washing (with hot and cold running water and drying facilities) should be readily accessible. If not immediately located in the immunisation area, additional cleaning techniques should be used within the immunisation area (eg. antibacterial hand sanitiser).
Storage		There should be adequate space to store immunisation consumables, as well as secure storage for patient records (see *security* above).
Vaccine storage		A reliable and stable refrigerator (with adequate capacity) and accurate and reliable temperature monitoring equipment should be available to store vaccines.
Sharps/medical waste disposal container		Disposal container(s) with adequate capacity must be available for immediate use post-immunisation.

Emergency response protocol on display		A suitable protocol is available in the current edition of the *Australian Immunisation Handbook.*
Emergency response kit		The requirements for such a kit are outlined in the current edition of the *Australian Immunisation Handbook.*
References		Current editions of *the Australian Immunisation Handbook* and the *National Vaccine Storage Guidelines* must be available (either in hard copy or a bookmarked link to the online version).
Contactable Medical Officer		Arrangements should be made with a Medical Officer or nurse practitioner who is prepared to be contactable in the event of an emergency. The contact details for this person should be readily available.
Appropriate pharmacist/nurse practitioner training		All pharmacists providing immunisation services on the premises must have successfully completed suitable training as approved by SA Health.

COMPOUNDING SERVICES

Considerations	**Y/N**	**Comments**
1. Supply		
Risk assessment		Pharmacists who compound products must have appropriate risk management processes in place to manage risks associated with the compounded product and the workplace. Refer to the *Extemporaneous dispensing* section of the current APF under *Risk assessment process for the preparation of extemporaneous preparations*.
Compounded medicines supplied directly to the patient/products prepared for specific patients		Pharmacists are exempt from being required to enter a compounded product on the Australian Register of Therapeutic Goods (ARTG) if the product is being compounded for a particular person. The exemption does not apply if a product is compounded for supply to another pharmacist.
Reasonable prepared quantities		As items can only be compounded for individual, named patients, the need for batch preparation is low. If a pharmacy is located near a prescriber who regularly prescribes a particular medicine (and the pharmacist has received multiple prescriptions for that medicine), it may be appropriate for batch preparation. Please note, batch preparation is not encouraged by PharmBA as it has greater risks (such as a compounding error or contamination having the

		potential to affect a larger number of patients).
Uninterrupted preparation		Interruptions during the compounding process increase the risk of an error being made, or contamination of the final compounded product. The compounding area should be located in a part of the pharmacy premises that discourages interruption.
Extemporaneous items for animals on vet prescription		Pharmacists who undertake the compounding of veterinary medicines (simple or complex) are expected to have completed sufficient training. Suitable resources on the compounding of animal medicines should be available. The PharmBA recommends that independent legal advice should be obtained to ensure that the compounding of veterinary medicines complies with the *Agricultural and Veterinary Chemicals Code* and any other state, territory and Commonwealth legislation.
Patient counselling		Pharmacists should ensure that every patient or their agent is offered counselling and relevant consumer medicines information on each occasion that a compounded medicine is supplied (ideally face to face). Written consumer medicine leaflets are not usually available for compounded medicines. Alternative written information should be supplied by the pharmacist and include: - how the compounded product differs from a commercially-available product - instructions for correct use - appropriate storage requirements and expiry date - side effect profile, any contraindications and specific counselling points - how to report adverse events
2. Records and labels		
Master formula book		All products compounded on the premises must be recorded in a master formula workbook. The records should be reviewed at regular intervals for suitability and accuracy.
Individual work sheets		Each time an item is compounded it must be recorded on an individual work sheet. The work sheet should show the name of the responsible pharmacist, and any weighing or measuring undertaken by a technician must be countersigned by a pharmacist. Work sheets must show the product expiry date and be kept for at least three years from the date of dispensing.
Countersigning of technician's work		Pharmacists may be assisted in the preparation, dispensing and supply of medicines by suitably trained dispensary assistants/technicians. The supervising pharmacist must countersign the

		individual work sheet for each product compounded by an assistant/technician under their supervision.
Product label		In addition to the same labelling requirements for proprietary dispensed products, every compounded product must be labelled with the appropriate storage conditions and the expiry date.
Incident/complaints record		The pharmacy premises should maintain a record of any incidents or complaints that occur as a result of compounding products.
Procedure manual		A procedure manual should be readily available to all compounding staff. The manual must include operator hygiene, cleaning procedures, waste disposal, operator exclusions and product recall.
Hazardous substances record		A record should be kept of the hazardous substances stored on the premises.
3. Equipment		
Facilities		The area used to compound products should be dedicated, clean and suitable. The area is ideally located away from routine dispensing, counselling and high-traffic areas.
Hazardous substances		If hazardous substances are compounded, a dedicated room must be used to minimise contamination and staff exposure. An approved powder containment hood should also be used. Equipment and ingredients used to compound hazardous materials should be stored separately from other equipment. A spill kit, showers and eyewash facilities may be appropriate.
Cleaning		All surfaces should be washable to prevent contamination and cross-contamination. Logs must be kept to record the cleaning of the compounding area and equipment. Logs must clearly show the date/time of cleaning and the initials of the person undertaking the task.
Hot and cold running water		To ensure compounding areas can be cleaned and hands can be frequently washed (to avoid cross contamination), hot and cold running water should be easily accessible.
Scales		The compounding area should include scales appropriate for the range of work undertaken. The scales should be calibrated according to the manufacturer's recommendation. Logs of the calibration and servicing of scales should be kept.
Protective clothing		Suitable protective clothing must be worn by staff during all compounding procedures. This includes items such as a laboratory coat, disposable gloves and hair covers. When handling hazardous substances, additional protective clothing such as eye

		protection, respiratory mask and shoe coverings may be required.
References		Relevant compounding references should be readily available.
Product storage		Compounded preparations must be packaged in appropriate containers in accordance with stability requirements (eg. light resistant, airtight, moisture-proof) and safety requirements (eg. child resistant).
4. Staffing		
Trained staff		All staff involved in the compounding of products must have, and maintain, adequate therapeutic knowledge and practice skills to complete their tasks. A training and education plan for all staff involved in compounding should be available for review on request.
Staff pathology		Staff who handle hazardous substances during the compounding process should be subject to base line and annual pathology monitoring.
5. Temperature control		
Compounding area temperature		The designated compounding area temperature must be maintained at less than 25^{o}C at all times.
Air filters		The air conditioning unit for the compounding area must have its air filters cleaned regularly to ensure effective temperature control and also to minimise cross contamination.
Fridge temperature		The fridge used to store raw materials and compounded items must be maintained at the appropriate temperature. A data logger or other suitable means of regularly measuring and recording the fridge temperature must be used.
Cold Chain		Cold chain management protocols must be in place when purchasing, transporting, storing and monitoring temperature consistency of raw ingredients and compounded preparations, in accordance with stability requirements. Contingency plans should be in place in the event of mechanical or power failure.
6. Quality assurance		
Raw materials		Raw materials used to compound products must be quality, dedicated ingredients from approved sources (ie. ingredients from suppliers granted a licence under the *Therapeutic Goods Act 1989*). Ingredients sourced from suppliers not licensed under the Act should be the subject of a risk assessment to ensure the material is safe and appropriate and meets

		applicable pharmacopoeial standards. The expiry date and batch number of each item must be easily identifiable and checked as part of the compounding process. Water used in the compounding process must be subject to regular endotoxin testing (including tap, proprietary and packaged supplies of water).
Quarantine		Quarantine procedures must be documented and areas set aside for quarantine purposes.
Stability data		Reliable stability data must be available for all compounded products prepared on the site.
Sterility		The sterility of ingredients used for aseptic compounding must be confirmed prior to use. Appropriate documented procedures must be used to compound sterile products.
Final product testing		Testing must be carried out on prepared products according to a documented process. Testing may utilise random samples at specified time intervals.