

PHARMACY REGULATION AUTHORITY SA



Guidelines for the operation of pharmacy premises by pharmacy services providers

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PART 1 – FOREWARD

1.1 Overview of legislative framework

The South Australian Parliament established the Pharmacy Regulation Authority SA (PRASA) under the *Health Practitioner Regulation National Law (South Australia) Act 2010* ('the Act') on 1 July 2010. PRASA carries out functions relating to the registration of pharmacy premises and depots, and the registration of pharmacy services providers in South Australia.

When registering premises as a pharmacy or a pharmacy depot, PRASA must be satisfied that the premises and their location comply with the requirements of the *Health Practitioner Regulation National Law (South Australia) Regulations 2010* ('the Regulations'), and any further requirements as determined by PRASA.

Although matters relating to pharmacy practice are the responsibility of the Pharmacy Board of Australia), some areas of practice combine both premises and practice elements. Therefore, these pharmacy premises focused guidelines should be read and considered in conjunction with all current Pharmacy Board of Australia guidelines.

In this document:

- 'the Regulations' means the *Health Practitioner Regulation National Law (South Australia) Regulations 2010* (which may be viewed on PRASA's website)
- 'the Authority' or PRASA means the Pharmacy Regulation Authority SA
- 'the Board' means the Pharmacy Board of Australia
- 'the Act' means the *Health Practitioner Regulation National Law (South Australia) Act 2010*

1.2 Standards, guidelines, codes and policies issued by the Pharmacy Board of Australia

The Authority recognises the registration standards, guidelines, codes and policies issued by the Board. These may be accessed via the Board's website: www.pharmacyboard.gov.au.

1.3 Standards and guidelines issued by professional organisations

The Pharmaceutical Society of Australia (PSA) and the Society of Hospital Pharmacists of Australia (SHPA) issue standards, codes and guidelines that are to be accessed via their respective websites: www.psa.org.au and www.shpa.org.au.

1.4 Making a notification/complaint

Consumers and pharmacists are able to make notifications/complaints regarding the operation of a pharmacy premises should they wish to do so. Notifications should be made in writing and forms and details on how to do so are available on the PRASA

website at www.pharmacyauthority.sa.gov.au Should a consumer or pharmacist have concerns about the health, performance or conduct of an individual who is a registered pharmacist or pharmacy student then this can be done at the Australian Health Practitioner Regulation Agency (AHPRA) website at www.ahpra.gov.au

PART 2 - GENERAL RESPONSIBILITIES

2.1 Restrictions relating to provision of pharmacy services

The Act describes the following in relation to a 'person' who may provide pharmacy services:

51 – Restrictions relating to provision of pharmacy services

- (1) A person must not provide a restricted pharmacy service unless –
- (a) in the case of a natural person –
 - (i) he or she is a qualified person and provides the service personally or through the instrumentality of a natural person who is a qualified person; or
 - (ii) he or she is a pharmacist who does not hold a current authorisation to practise and provides the service through the instrumentality of a natural person who is a qualified person;
 - (b) in the case of a body corporate –
 - (i) the body corporate is a recognised corporate pharmacy services provider; and
 - (ii) the body corporate provides the service through the instrumentality of a natural person who is a qualified person;
 - (c) in the case of a trust (however constituted) –
 - (i) the trust is a recognised trustee pharmacy services provider; and
 - (ii) the trust provides the service through the instrumentality of a natural person who is a qualified person.

2.2 Responsibilities of pharmacy services providers (proprietors)

In accordance with section 51(1)(a)(ii) of the Act, pharmacists who '*do not hold a current authorisation to practice*' are permitted to have a proprietary interest in a pharmacy. However, such a 'non-practising pharmacist' is still responsible for the restricted pharmacy service being provided in accordance with the Act. As such, they should make themselves regularly aware of the manner in which the pharmacy services are

being conducted, including maintaining a direction over the kinds of goods being sold (especially those known to be subject to abuse or misuse) and that the appropriate professional procedures and policies are being followed. Refer to the Board *Guidelines for proprietor pharmacists* for further information.

It is also the responsibility of the proprietor to ensure that a pharmacist is in attendance at the pharmacy to allow for the completion of all professional responsibilities (which includes being available for consultation by members of the public at all times while the pharmacy is open to the public).

PRASA expects the delivery of pharmacy services within hospital pharmacy settings to be provided in accordance with the Act and, except where hospital specific considerations provide an impediment, in line with appropriate professional standards and guidelines.

PART 3 – PHARMACY PREMISES AND DEPOTS

3.1 Registration of Corporate/Trustee Pharmacy Services Provider

The Act describes the following:

26 – Interpretation

(3) For the purposes of this Part, each of the following is a *recognised corporate pharmacy services provider*:

- (a) a pharmacist controlled company;
- (b) a friendly society;
- (c) a company that carried on a pharmacy business on 1 August 1942 and has continued to do so since that date other than:
 - (i) Friendly Society Medical Association Limited; or
 - (ii) The Mount Gambier United Friendly Societies Dispensary Limited.

(4) For the purposes of this Part, a *recognised trustee pharmacy services provider* is any pharmacist controlled trust.

For a new corporate pharmacy services provider or a new trustee pharmacy services provider to be registered, the provider is required to:

1. Complete the appropriate application form obtained from the Authority's office or website; and

2. Forward the completed application to the Authority (*prior* to the changes taking place) with payment of the appropriate fee. Please allow adequate time for the application to be considered by PRASA. Application forms may be downloaded from: www.pharmacyauthority.sa.gov.au

The required form is *Form B: Information to be provided by a Corporate/Trustee Pharmacy Services Provider*.

3.2 Registration of Premises

The Regulations detail the restrictions relating to the registration of premises as a pharmacy and are as follows:

6 - Registration of premises as a pharmacy

- (1) For the purposes of section 41(3)(a) of the Act, premises proposed to be registered as a pharmacy must –
 - (a) consist of an enclosed area with access to a public place; and
 - (b) contain an area set aside for the dispensing of items on prescription that is not less than 9 square metres; and
 - (c) be kept in a hygienic condition and be adequately ventilated; and
 - (d) have provision for adequate lighting; and
 - (e) have provision for temperature control of therapeutic goods and health care products; and
 - (f) contain adequate provision for the safe, secure and hygienic storage of therapeutic goods and health care products; and
 - (g) contain adequate provision for the safe and secure storage of confidential and sensitive information; and
 - (h) be constructed in such a manner as to allow a pharmacist to supervise effectively the whole of that part of the premises used in the provision of restricted pharmacy services and the activities of persons in that part of the premises.

In addition, the Act states that –

41 (5) The Authority must not register, or renew the registration of, premises as a pharmacy unless satisfied that members of the public cannot directly access the premises from within the premises of a supermarket.

For new premises to be registered or for existing premises to be altered, the pharmacist or recognised corporate/trustee services provider is required to:

1. Complete the appropriate application form obtained from the Authority's office or website; and
2. Forward the completed application to the Authority (*prior* to the changes taking place) with payment of the appropriate fee. Please allow adequate time for the application to be considered by PRASA. Application forms may be downloaded from:

www.pharmacyauthority.sa.gov.au

The required form is *Form A: Notification of Changes to the Pharmacy Premises Register*.

3.3 Pharmacy premises design and equipment

The design and equipping of pharmacies and pharmacy departments are to ensure that the premises:

- are secure and hygienic;
- are suitable for the safe dispensing and supply of therapeutic products;
- provide an environment that ensures confidentiality in dealings with the public; and
- are directly accessible from a public place

3.3.1 Security

It is strongly recommended that pharmacy premises are fitted with a security intrusion detector alarm which is control room monitored to a central agency on a 24 hour basis. Security patrols may be used in addition to physical security, but they are not a substitute for it. Intrusion detectors installed as part of a security system should at least cover any area where drugs are kept, including the dispensary, drug safe, professional service area and storerooms. Silent 'hold up' alarms (panic buttons) are also recommended.

Security systems should be periodically checked and physical security items such as locking systems and electronic devices should be tested to see that they are functioning. Advice from a security expert and/or a locksmith is recommended.

Schedule 4 poisons must be stored in a manner that they can be supervised by the pharmacist and cannot be accessed by members of the public. Particular attention therefore needs to be paid to the contents and accessibility of storerooms and refrigerators. Areas of the premises able to be accessed by members of the public (including areas used as a thoroughfare to other non-dispensary areas) cannot be used to store schedule 4 poisons.

3.3.2 Privacy and confidentiality

All staff members in a pharmacy must be made aware of the need to observe privacy and confidentiality in their dealings with the public. This can only be achieved through appropriate consideration and then implementation of measures to ensure auditory and visual privacy.

A pharmacy premises should maintain current privacy and confidentiality policies that all staff confirm they have read and understand and then sign to say they have done so. Updating of the policies should occur on a regular basis.

The policies should confirm that only pharmacy staff with work related responsibilities requiring access to dispensary computers should have the ability to log-on to dispensary

computers. The name and details of medicines and therapeutic products should not be disclosed to anyone other than the person for whom the item(s) are intended. Care should be taken when storing dispensed prescriptions awaiting collection and also the handling of patients' medicines at the service counter to prevent them being viewed by other members of the public. Inadvertent disclosure of medicine details can also occur when issuing patient accounts to other family members or third party organisations that process accounts, or to organisations collecting statistical data. Dispensary counters should be designed so that patient privacy is not compromised and in such a way that members of the public cannot view private information.

It is also the responsibility of pharmacy services providers to maintain the privacy of members of the public when destroying confidential information.

The *Controlled Substances Act 1984* states as follows:

60A - Confidentiality

- (1) A person must not divulge-
 - (a) information relating to trade processes; or
 - (b) medical records or details of medical treatment or a person, obtained (whether by that person or some other person) in the administration or enforcement of this Act except-
 - (c) in connection with the administration or enforcement of this Act; or
 - (d) as authorised or required by law; or
 - (e) with the consent of the person from whom the information was obtained or to whom the information relates; or
 - (f) for the purpose of any legal proceedings arising out of the administration or enforcement of this Act; or
 - (g) to a law enforcement, prosecution or health authority of another jurisdiction as may be reasonably required for the purpose of the administration or enforcement of a law of that jurisdiction.
- (2) Subsection (1)(b) does not prevent the disclosure of statistical or other information that could not reasonably be expected to lead to the identification of any person to whom it relates.

More information about privacy law in Australia can be found at www.oaic.gov.au.

3.3.3 General dispensary requirements

The dispensary is a private area dedicated to the dispensing of medicines. Lighting, ventilation and temperature control are essential to maintain the integrity of medicines and for personal comfort. The dispensary should be supplied with hot and cold running

water and have provision for the temperature control of therapeutic goods and health care products (such as refrigeration and air conditioning), and provide a sufficient area for equipment and free working space.

The public is not permitted access to the dispensary and therefore it should be designed to prevent persons from entering the dispensary or any part of it without being noticed by the pharmacist on duty. Ideally the pharmacy should be designed so that it is not used as a thoroughfare to access 'back of house' areas.

Therapeutic products are not to be removed from the dispensary without the express permission of a pharmacist unless by a student, intern or trained dispensary assistant under the supervision of a pharmacist.

Applications for registration of new pharmacy premises or for the approval of alterations to existing pharmacy premises should provide for a dispensary area of not less than 9m².

A dispensary in a pharmacy should include:

- a. appropriate shelving or storage for Schedule 4 poisons that enables accurate selection of medicines and restricts access to dispensary staff only;
- b. a safe for the storage of schedule 8 poisons that meets or exceeds the requirements set out in the Department for Health and Ageing *Code of Practice for the Storage and Transport of Drugs of Dependence November 2012*, which can be accessed at www.sahealth.sa.gov.au ;
- c. a bench or bench area of suitable size for the unpacking and sorting of dispensary orders received;
- d. at least one dispensing station (with a dedicated barcode scanner);
- e. a sink with hot and cold running water; and
- f. a bench or bench area of suitable size located near the sink for the compounding or preparation of medicines (with a nearby area to allow for storage of compounding equipment).

Many pharmacies provide additional services to members of the public that may impact on the amount of space required within a dispensary area. Such services may include a Medication Assisted Treatment for Opioid Dependence (MATOD) Program, the filling of dose administration aids (DAAs) and immunisation services all of which should be undertaken in an area of the dispensary where:

- the privacy of patient records and the security of scheduled medicines is ensured and
- the steps associated with the dispensing of medicines does not impact upon the ongoing professional activities.

The suggested requirements for a dispensing station are a dispensing bench of suitable size equipped with a;

- computer, screen and keyboard

- dedicated scanner
- dedicated printer for labels
- dedicated printer for repeat forms
- adequate stationery (including cautionary and advisory labels)

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.

A client waiting area may be included in a pharmacy to encourage members of the public to move away from the service areas while awaiting the preparation of their prescription(s). This helps to maintain a private area for other clients who are being attended by the pharmacist.

The general trading area is not an appropriate part of a pharmacy to store for sale any therapeutic products. There is no objection, however, to window displays or placing therapeutic devices in the general trading area provided the public is directed to obtain advice from a pharmacist about their use.

A professional service area is a distinct area within a pharmacy that is distinguished by signage (to differentiate from the general retail area) and is used to display and store products for therapeutic use and information about them. Such an area is ideally located near the dispensary to enable the pharmacist to assist members of the public with advice about the products displayed.

A counselling area is a distinct area (which may or may not be part of the professional service area) that permits the pharmacist to conduct discussions with a member of the public in a private and confidential manner. Such an area should be designed to allow conversations and the handling of prescription items to be conducted out of sight and earshot of other members of the public. A separate room or office may also be used as a private counselling area, and also for extended services such as disease screening or prolonged consultations.

When a pharmacist is not on the premises and the premises remains open to the public, all scheduled poisons must be unable to be accessed (by non-pharmacist staff or customers) or sold. Areas within the pharmacy containing these items must be locked. The days and times when a pharmacist is not in attendance should be prominently displayed with a sign to advise members of the public.

3.3.4 Immunisation

Immunisation programs provided from registered pharmacy premises are required to comply with the PSA *Practice Guidelines for the provision of immunisation services within pharmacy* and the *Australian Immunisation Handbook*. PRASA expects premises offering the administration of vaccinations by either a medical practitioner or an appropriately qualified and competent registered pharmacist or registered nurse to meet certain minimum standards:

- a suitably private area

- a cold chain management system for vaccines and vaccine products
- a disposal system for sharps and medical waste
- adrenaline for anaphylaxis treatment and anaphylaxis information (i.e. posters)
- a policy and procedures manual for the immunisation service

The immunisation area must provide suitable visual and auditory privacy for the patient. This may be obtained by the use of walls or barriers that PRASA deems to be of sufficient height. Entry to the area must be blocked or a roped off 'exclusion zone' be created and/or 'No Entry' signs must be used. Pharmacists/pharmacy service providers are encouraged to contact PRASA prior to commencing immunisation services to confirm the suitability of room arrangements within their specific premises.

3.3.5 Pharmacies without Medicare approval that do not supply pharmaceutical benefits

A pharmacy that is licensed under relevant State laws and regulations as a pharmacy but is not approved by Medicare Australia to supply pharmaceutical benefits, is known as a 'non-PBS approved' pharmacy. Prescriptions are able to be dispensed at such a pharmacy, but there are consequences for the public they must be made aware of before dispensing occurs. These consequences include;

- payments made for prescriptions do not contribute to PBS Safety Net Records
- any repeats issued are not valid as PBS concessional, repatriation, general or safety net prescriptions if subsequently presented at a 'PBS-approved' pharmacy and;
- the patient is unable to obtain a refund from Medicare Australia for the amount paid over and above the gazetted PBS copayment for the prescriptions dispensed.

As the public is entitled to know if a pharmacy is 'non-PBS approved' to supply pharmaceutical benefits, a prominent sign must be located in the pharmacy consisting of the following statements:

- Pharmaceutical Benefits (of all kinds) are not available from this pharmacy; and
- Patient Record Forms cannot be completed; and
- Repeat Authorisation forms for Pharmaceutical Benefits are not issued.

Patients presenting prescriptions at the pharmacy are to be directed to the sign above and have the financial consequences of not obtaining the medicine as a Pharmaceutical Benefit explained to them prior to dispensing taking place.

3.3.6 Workloads

Pharmacist staffing levels should be adequate to cover the average workload, including the provision of all professional services available from within the pharmacy premises, on a particular day. Attention needs to be paid to non-dispensing tasks that can take up

the pharmacists' time to ensure that these do not place additional pressure on the pharmacist.

The Board has published guidelines regarding pharmacists' workloads which state the following:

'The Board recommends that if dispensing levels are in the range of 150-200 items per day, consideration needs to be given to the use of trained dispensary assistants/technicians and/or intern pharmacists to assist the pharmacist. If the workload exceeds 200 items per day, additional pharmacists or dispensary assistants/technicians may be required to ensure adequate time is allowed to dispense properly every prescription in accordance with the practice standards and guidelines, and Board guidelines. Arrangements should include adequate supervision by pharmacists of non-pharmacist staff.'

Pharmacist workloads can vary due to a multitude of factors, but there may be predictable peaks in activity at specific times of the day, week or month. Staffing should be increased during these predictable peaks to reduce the pressure on the pharmacist and minimise the risk of dispensing errors. Additional pharmacist duties such as DAA packing, the provision of a MATOD program and the training of an intern pharmacist should also be allowed for when planning staffing levels. Attention must also be paid to the familiarity of individual staff members with specific dispensing systems (such as locum pharmacists).

The use of dispensary assistants/technicians can reduce the load on a dispensing pharmacist, however the Board recommends that an individual pharmacist does not supervise more than two dispensary assistants/technicians (engaged in the selection, processing and labelling of prescription medicines, and the compounding of medicines) at a time. Other trained dispensary assistants/technicians may be engaged in duties that do not require direct supervision outside of this ratio (e.g. in dispensary stock control or preparing DAAs).

The Authority acknowledges that a pharmacist may be required to dispense above this rate in unforeseen circumstances (such as staff shortage due to sudden illness). The Authority recognises that in such circumstances the pharmacist can take effective short-term measures to allow him or her to deal with the workload and meet his or her professional obligations.

3.3.7 Controlled temperature storage

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 25°C; to this end, thermostatically controlled air conditioning or cooling by other means is necessary unless the premises are so situated or constructed as not to allow this temperature to be exceeded. Air conditioners should be set to maintain temperatures not exceeding 25°C during periods when the pharmacy is not open for business.

Refrigerators used to store medicines should be dedicated to this purpose (other items such as staff food and beverages should be stored in a separate refrigerator). The

Pharmacy Guild of Australia has a list of approved vaccine refrigerators on their website www.qcpp.com (search under Resources > Cold Chain Testing > Resources > List of Compliant Dispensary/Vaccine Refrigerators).

The number of times the door is opened each day should be kept to a minimum by the use of a warning sign such as:

‘WARNING - DO YOU NEED TO OPEN THIS DOOR?’

The maximum and minimum temperature within the refrigerator should be measured and recorded using either a thermometer or a temperature logger. The pharmacist should be aware and take action if temperature readings are outside the range of 2 to 8°C. Of particular concern are temperatures below 2°C as freezing of vaccines can cause vaccine damage and the vaccine should be discarded.

To ensure that the refrigerator is not accidentally turned off, the power point should be taped over in the ‘on’ position. A warning sign should be positioned near the power point as a reminder not to disconnect the power supply.

The integrity of the ‘cold chain’ for items that require refrigeration should be maintained when receiving and supplying stock. When supplying an item to a client that requires refrigeration, instructions (verbal and via labelling) should be given to the client or agent at the time of collection. The use of cold bags, insulated coolers or other means of maintaining the cold chain is considered appropriate.

3.3.8 Disposal of wastes

3.3.8.1 Sharps Disposal

Sharps must be disposed of in an approved yellow Sharps Container which should be stored out of reach of the public. Appropriate Occupational Health and Safety precautions should be taken when handling sharps (if possible the person returning the item(s) should place them in the container).

3.3.8.2 Unwanted medicines

Unwanted medicine returned by patients should be disposed of via a RUM (Return Unwanted Medicines) Project Container which is then sent off for incineration. Schedule 8 medications should be recorded by the pharmacist in the drugs of dependence (DD) register in accordance with legislation, rendered unusable and dispersed throughout the RUM Project Container. This process must be witnessed by another person (who must be an authorised officer, police officer, registered health practitioner, veterinary surgeon or a person who has been authorised in writing by the Chief Executive of the SA Ambulance Service to administer drugs of dependence) who must countersign the destruction in the DD register. Further information about the RUM Project (including how to order and dispose of a full container) can be found at www.returnmed.com.au.

3.3.8.3 Confidential material

It is expected that the disposal of confidential material is handled appropriately to ensure that patient confidentiality is maintained. Such measures may include the use of in-

pharmacy shredders or a shredding service (where documents are securely stored, removed from the premises by a third party and shredded offsite) to render personal details on documents unreadable. The confidentiality of patients must be maintained at all times during the destruction process.

3.3.9 Cleanliness & access

The pharmacy must at all times be kept in a clean and tidy state which is conducive with a safe workplace environment. Aisles must be kept clear of items which may be a hazard to staff and customers. Unpacking of orders should be conducted in an area away from the flow of traffic wherever possible. At times when boxes and stock must be placed in aisles whilst unpacking, this should take place in a timely manner to minimise safety hazards and inconvenience. Access into and within the pharmacy should also be possible for people requiring mobility aids (such as wheelchairs, walking frames and crutches).

3.3.9.1 Infection Control

To reduce the transmission of disease to and from patients visiting the pharmacy, infection control techniques should be maintained. These include the use of an effective hand washing technique after contact with patients (especially those known to be carrying a readily transmitted disease such as influenza or gastroenteritis). Due consideration should be paid to the ongoing processes for disposal of contaminated dressings and supplies.

The use of appropriate hand washing techniques should also be maintained when packing DAAs. The use of gloves whilst packing to reduce cross-contamination is also advised.

When collecting sharps on behalf of a patient for disposal via a sharps container, care should be taken to avoid handling the item(s) to reduce the risk of a needle stick injury. As discussed in *3.3.8.1 Sharps Disposal*, if possible the person returning the item(s) should place them in the container.

All staff should be encouraged to maintain up to date immunisation to protect themselves from infection and to reduce the risk of transmission of disease. Information regarding current immunisation schedules can be found at www.immunise.health.gov.au.

3.3.10 Schedule 8 storage

In accordance with the *Controlled Substances (Poisons) Regulations 2011* schedule 8 medicines must be stored as follows:

27 – Storage of Poisons (section 25 of Act)

(d) a person must not store a drug of dependence except in accordance with the requirements of the *Code of Practice for the Storage and Transport of Drugs of Dependence*, published by the Department, as in force from time to time.

The above mentioned code of practice (published by the Department for Health and Ageing (www.sahealth.sa.gov.au > About Us > Legislation > Controlled Substances Legislation) details the requirements of a drug of dependence safe. The minimum specifications for a safe depend on the number of doses stored. A standard 10mm steel pharmacy safe is sufficient for storage of 500 doses or less or 1000 or less if there is 24 hour security monitoring. Larger quantities of DD's or less security monitoring on the premises requires a safe with higher security. Regardless of the size of the safe the code of practice requires it to be '*attached to a wall or floor of the pharmacy premises away from external walls where it is not visible from outside the room in which it is situated*'.

The safe must be locked at all times and the keys to the safe should be retained by the pharmacist at all times when the keys are not in use. No person other than a pharmacist should lock or unlock a drug safe; or remove, add to or in any way interfere with any drugs in the drug safe. Where the key is a combination, PIN or password, it must not be divulged to any unauthorised person.

An approved drug safe is to be used only for the storage of schedule 8 medication in accordance with the above code of practice. Money, computer software/hardware or non-scheduled items must be stored in a separate location on the premises.

It is the responsibility of the pharmacist to ensure all schedule 8 items on the premises are stored in an approved safe, including:

- dispensed schedule 8 items awaiting collection (including staged supply items)
- dispensed schedule 8 items awaiting packing in dose administration aids (DAAs)
- packed DAAs containing schedule 8 items
- schedule 8 items used in a MATOD program

3.4 Pharmacy Practice

3.4.1 References

The Board publishes a list of reference material that must be readily accessible and should be accessed by pharmacists during the dispensing, clinical assessment, reviewing and counselling processes. The references must be available in their current editions and can be accessed in hard copy or via electronic means. The '*Guidelines on practice-specific issues – Guideline 1 (list of reference texts for pharmacists)*' can be found on the Board website www.pharmacyboard.gov.au under '*Codes, Guidelines and Policies*'.

3.4.1.1 Complementary Medicines

The sale of Complementary Medicines should be conducted in line with the Pharmaceutical Society of Australia's Code of Ethics 2017 and with the provision of information to patients wherever possible. Any possible drug interactions, allergic reactions or side effects that may occur with complementary medicines, as well as scientific evidence about effectiveness should be communicated to patients electing to

self-select products via prominent point of sale material. The use of an *'evidence-based reference work on complementary and alternate medicines'* as required by the Board is useful when dealing with queries from patients. The promotion of complementary medicines by a pharmacist for conditions for which there is no evidence base is considered unprofessional.

3.4.2 Extemporaneous dispensing (including complex compounding of medicines)

Extemporaneous preparations may be prepared for individual patients by pharmacists in premises that fulfil professional standards and comply with relevant requirements. The current edition of the Australian Pharmaceutical Formulary (APF) contains a section on extemporaneous dispensing and should be read in conjunction with the guidelines below.

The equipment, premises and raw materials involved in the compounding process must be of an acceptable standard. Any formulation that is dispensed or compounded must be based on sound pharmacological, clinical and pharmaceutical principles. Appropriate storage instructions and expiry dates must be supplied when dispensing compounded products (expiry dates are calculated from the date of preparation, not the date of supply). Care must be taken when selecting the container for the prepared product, as this can influence its stability and shelf life. Instructions for the safe use of compounded products must be provided both verbally and in written form (most compounded products will not have an associated CMI in the same way that proprietary preparations do).

Extemporaneous manufacturing (production of a batch of a particular product) may only be performed in premises that comply with Therapeutic Goods Administration (TGA) requirements (www.tga.gov.au).

The Board has provided guidance to pharmacists in this rapidly evolving area of pharmacy practice through the release of their *'Guidelines on compounding of medicines'*. PRASA has adopted the Board guidelines and will use them as the basis for evaluating pharmacy premises undertaking compounding of medicines.

The Board has determined that the compounding of medicines of a more complex nature ('complex compounding') requires or involves specific competencies, equipment, processes and/or facilities to manage the higher risks associated with the preparation and dispensing of these medicines. Examples of complex compounded products are sterile preparations, preparations containing ingredients posing an occupational health and safety hazard (such as cytotoxics or hormones), micro-dose single unit dosage forms containing less than 25mg (or up to 25 per cent by weight or volume) of active ingredient, and sustained release or other modified-release preparations.

It is expected that all pharmacy premises undertaking complex compounding (as defined under the Board guidelines) will meet the Board, APF and PSA standards across the following areas:

3.4.2.1 Supply

It is expected that a risk assessment will be undertaken prior to complex compounding taking place. Products may only be prepared for direct supply to an individual, named patient or their agent (products may not be prepared for dispensing at another

pharmacy). The Board does not encourage batch preparation, which may only be undertaken at a pharmacy located near a prescriber who regularly prescribes a particular medicine (and that pharmacist has received multiple prescriptions for that medicine).

Care should be taken to minimise disruptions when undertaking complex compounding, to reduce the risk of errors being made.

The compounding of veterinary medicines (either simple or complex) should only be undertaken by a pharmacist who has completed sufficient training and has access to suitable resources. The Board recommends that prior legal advice be obtained to ensure compliance with the Agricultural and Veterinary Chemicals Code and any other state, territory and Commonwealth legislation.

3.4.2.2 Records and labels

Individual compounded items must be recorded on an individual work sheet for every dispensing. All compounds prepared on the premises must be recorded in a master formula workbook.

Suitably trained technicians may be used to assist the compounding pharmacist (who must countersign the individual work sheet for each product). The premises should maintain a record of any complaints or incidents that occur as a result of compounding products. A record should also be kept of any hazardous substances stored on the premises.

A procedure manual should be readily available to all compounding staff, and must include operator hygiene, cleaning procedures, waste disposal, operator exclusions and product recall.

3.4.2.3 Equipment

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. 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.

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. 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.

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. 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.

In addition to Board required references (see 3.4.1 References), relevant compounding references should be readily available.

Compounded preparations must be packaged in appropriate containers in accordance with stability requirements (for example light resistant, airtight, moisture-proof) and safety requirements (for example child resistant).

3.4.2.4 Staffing

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 who handle hazardous substances during the compounding process should be subject to base line and annual pathology monitoring.

3.4.2.5 Temperature control

The designated compounding area temperature must be maintained at less than 25°C at all times (see 3.3.7 Controlled temperature storage). 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.

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 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.

3.4.2.6 Quality assurance

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 (including tap, proprietary and packaged supplies of water) used in the compounding process must be subject to appropriate testing carried out on a regular basis (for example endotoxin testing).

Quarantine procedures must be documented and areas set aside for quarantine purposes.

Reliable stability data must be available for all compounded products prepared on the site. The sterility of ingredients used for aseptic compounding must be confirmed prior to use. Appropriate documented procedures must be used to compound sterile products. Testing must be carried out on prepared products according to a documented process. Testing may utilise random samples at specified time intervals.

3.4.3 Barcode Scanners

Barcode scanners are to be used as part of the dispensing process to minimise the risk of a selection error being made. The Board *'Guidelines for dispensing of medicines'* states that pharmacists should use barcode scanners when dispensing medicines in pharmacies and pharmacy departments. Further references to the use of scanners are included in guidelines issued by the following professional organisations: PSA - *Professional Practice Standard 3: Dispensing and other supply arrangements*, SHPA – *Standards of Practice for Hospital Pharmacy Outpatient Services* and PDL – *Guide to Good Dispensing*

Scanning of the product barcode towards the end of the dispensing process may be more effective in minimising selection errors. This is a separate step in the dispensing process to the scanning of a barcode on a prescription or repeat authorisation.

3.4.4 Dose Administration Aids (DAAs)

A DAA is a device designed to assist medication management for a patient by having medications divided into individual doses and arranged into a dose schedule throughout the day. A DAA can either be a unit dose pack or a multi-dose pack.

The supply of medicines in a DAA (as part of a medicine management system) has potential advantages for consumers that include:

- a) improving adherence and medication management;
- b) decreasing the incidence of adverse events from medication mismanagement;
- c) decreasing hospitalisation due to medicine misuse; and
- d) possible cost savings through prevention of hoarding of medicines.

The packing of DAAs may be carried out by either a pharmacist or delegated to a suitably trained pharmacy student, intern or dispensary assistant/technician (however the final pack must always be checked by a pharmacist). The activity should be undertaken in an area of the dispensary free from the impacts of activities associated with the dispensing of medicines. Patient confidentiality must be considered when selecting an area in a pharmacy for packing. Publicly accessible areas such as the front counter are not suitable. Packing should take place in an area of suitable size, which is tidy, well lit and free from distractions. The room used for the packing and storing of DAAs must be maintained at or below 25°C. The stability and storage requirements of medications should be considered before packing to ensure their suitability. The packing

process must be conducted in a hygienic manner to prevent contamination and to reduce health and safety risks to the person packing.

A current medication profile should be maintained for each DAA patient (including unpacked medications and documentation of any reasons for not packing specific medications eg. stability). Appropriate procedures should be in place in the event of a medication change for a DAA patient. These changes must be documented on the medication profile and the changes made to the DAA provided to the patient in a timely manner.

The final pack must be adequately labelled to maximise compliance, promote usability and minimise error. The following details must be included on the label:

- patient's name
- name and address of the supplying pharmacy
- name, strength and dose form of each medicine
- directions for use for each medicine (including frequency and dose)
- date of packing, applicable storage directions and expiry date of the DAA
- any cautionary and advisory labels required by law (1 or 1a) in addition to any considered appropriate by the dispensing pharmacist
- the words 'Keep out of reach of children'

Records should be kept relating to the packing of each DAA that include:

- each medicine's name, form, strength and dose
- the date of packing
- the initials of the person who packed it and those of the pharmacist who checked it, and if the packing is done by a third party the initials of the supply pharmacist
- the date of supply of the DAA to the patient or their agent, and
- the quantity of a patient's medication that remains after packing

Filling records must be retained for at least 6 months from the date of packing.

Prior to packing oral cytotoxic and other hazardous material into a DAA, a risk assessment should be undertaken by the pharmacist.

Automated and semi-automated dose packing systems may be used to prepare and pack medicines into DAAs. It is the responsibility of the pharmacist to ensure that appropriate cleaning, maintenance and testing of the equipment is carried out regularly. All staff operating the machine should receive initial and ongoing training.

DAAs may be packed by a third party packing facility as detailed in the Board *Guidelines on dose administration aids and staged supply of dispensed medicines*. The supply pharmacist (who supplies the DAA to the patient or their agent):

- must ensure the patient's right to privacy is understood, the patient or agent

has consented if a third party is to be involved in the packing of the DAA, and a record of the consent is kept

- is responsible for ensuring the packing pharmacist has accurate details of the medicines to be packed

- must make an assessment of the measures, techniques and technology used by the packing pharmacist at the third party packing facility to check packed DAAs for accuracy, to determine whether additional checking of a DAA is required prior to its supply to a patient or their agent, and

- is responsible for the quality use of medicines support for the patient, including provision of accompanying medicines information to the patient or their agent

The packing pharmacist at the third party packing facility is responsible for ensuring DAAs are prepared in a timely and accurate manner according to the patient's current medication regimen.

The packing of schedule 8 items in DAAs must comply at all times with the storage requirements outlined above in paragraph 3.3.10 - Schedule 8 storage.

The above mentioned Board guideline detailing the management of DAAs is available on the Board website. PSA have a Professional Practice Standard relating to the provision of a DAA service on their website at www.psa.org.au. It is Standard 15 - Dose Administration Aid Service).

3.4.5 Delivery of medication to patients

For the delivery of pharmaceutical items to a patient at their home or workplace the patient needs to be aware that the person delivering the medication to them is unable to answer medication related questions, and that all queries must be directed to the pharmacist.

When the supply of an item requires the intervention of the pharmacist such advice may be given by the pharmacist in person (at the point of delivery), via phone, email or video conferencing facilities (eg. Skype) or in writing (such as brochures, CMI, etc.).

The staff member conducting the delivery must be appropriately trained to liaise between the patient and the pharmacist (by phone or other appropriate means) when necessary and should not provide advice for which they are not qualified.

The patient should always be offered the opportunity to discuss their medication with a pharmacist, therefore the contact details for the pharmacy should be provided with all deliveries.

Vehicles used to transport items should provide adequate security for any scheduled medicines being carried. The vehicles must remain locked when unattended, and all items should be stored out of view of the public.

Appropriate temperature requirements for medicines should also be maintained in the

delivery vehicle at all times. The use of insulated coolers (with cold packs) or small refrigerators to maintain medicines within their temperature range is recommended. If possible, large numbers of individual deliveries should not be stored in the delivery vehicle awaiting delivery.

If an item requires a signature on delivery (eg. schedule 8 medications) or is temperature sensitive, it should not be left if the patient or their agent is not present. The items should be returned to the pharmacy and contact made with the patient to advise that the delivery was unsuccessful (eg. a note in the letterbox or a subsequent phone call).

A heightened level of attention to detail and process is required when delivery services are provided to sites and locations where the persons for whom the medicines have been prescribed are known to, or suspected to suffer from, dementia or confusion.

If a pharmacy service is provided via the internet, the pharmacist must ensure the privacy and confidentiality of the patient is protected at all times in the same manner as for interactions within the pharmacy. The handling of prescriptions must comply with all appropriate legislation in relation to recording, labelling, and validity of the prescription. The courier service contracted to provide the delivery service must comply with all the requirements listed above for deliveries by pharmacy staff including security, appropriate packaging and temperature requirements.

3.4.6 Schedule 3 handling

The *Controlled Substances (Poisons) Regulations 2011* Regulation 13 details the procedure required by the pharmacist when supplying a schedule 3 item. The schedule reads a pharmacist 'must personally (not through an assistant) give oral directions, supplemented wherever practicable with written directions, for the safe and proper use of the poison to the person purchasing or being supplied with the poison'

3.4.7 Ancillary labels

The use of ancillary labels is outlined in the *Australian Pharmaceutical Formulary and Handbook*. Some ancillary labels are mandatory in accordance with the *Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP)*. Pharmacists are reminded that mandatory ancillary labels must be used on all packaged forms of the medication (including DAAs and ODSP take away doses).

3.5 Schedule 8 Recording

The scheduling of poisons in South Australia is listed in the *Poisons Standard 2014*, which also includes legislation regarding the labelling of poisons. The handling and storage requirements for scheduled poisons in South Australia are dealt with by the *Controlled Substances (Poisons) Regulations 2011*.

3.5.1 Schedule 8

Regulation 40 of the *Controlled Substances (Poisons) Regulations 2011* details the recording requirements for schedule 8 poisons in a drug of dependence (DD) register. Part 40 of the regulations states:

(1) A supplier who sells or supplies a drug of dependence must comply with the following provisions:

(a) the supplier must, immediately after selling or supplying the drug –

(i) make a record in electronic form

Entries must include the full name and address of the person to whom the drug was supplied, the date of supply, the name, strength and quantity of the drug and the balance of the drug now in stock on the premises. All register entries and modifications must be initialled by the pharmacist and stock checks should be performed at least once a month to confirm the accuracy of register balances. When reconciling the DD register balance with the actual balance in the DD safe, a 'stock check' entry should be made by the pharmacist in the register to reflect this.

Balance adjustment entries may not be made in the register without explanation. Alterations and/or deletions in the register must not be made using any means that will obliterate the original entry (eg. Liquid paper, stickers). A line should be made through the entry and the alteration should be signed by the pharmacist.

When two or more brands of the same strength generic schedule 8 item are stored and dispensed on the premises, the brand used in each transaction must be identified by either:

- recording each brand on a unique register page with a separate ongoing balance OR
- identifying the brand used in each transaction (when recording two or more brands on the same register page)

Records made in a DD register must be retained on the premises for at least two years from the date of the entry being made. DD records must be kept using a form approved by the Minister (computer software must have the ability to require a unique personal identification code for entries and alterations to identify the pharmacist making each entry).

All incoming and outgoing stock must be entered in the DD register (including stock returned from patients awaiting destruction). The requirements that must be met when destroying a DD (including the categories of authorised persons who can witness the destruction) are listed in Part 45 of the Regulations.

South Australian Controlled Substances legislation does not allow for supply of schedule 8 poisons without a valid prescription (including to nursing homes).

3.5.2 Medication Assisted Treatment for Opioid Dependence (MATOD) Program

Pharmacies supplying methadone and buprenorphine via the MATOD must observe all of the storage, handling and recording requirements for schedule 8 poisons outlined previously. Further information can be obtained from the Drug and Alcohol Services South Australia *Guidelines for South Australian Pharmacists Dispensing Medication Assisted Treatment for Opioid Dependence (MATOD) 2016*.

MATOD incoming and outgoing stock must be recorded in the DD register and reconciled regularly with the true balance in the same manner as all other schedule 8 items. The daily dosing record must include the date and time of dosing and be signed by both the client and the dispensing pharmacist. Take away doses must be diluted and labelled in accordance with legislation (including cautionary label 1). The maximum number of take away doses that can be dispensed each week cannot exceed the number authorised on the prescription or the number permitted in the Guidelines.

Large numbers of daily MATOD clients should be taken into consideration when determining safe pharmacist workloads.

3.5.3 Pseudoephedrine

Regulation 14 of the *Controlled Substances (Poisons) Regulations 2011* describes the requirement to check identification and record the sale of pseudoephedrine:

14 – Special provisions relating to sale or supply of pseudoephedrine

(1) A person must not sell or supply pseudoephedrine unless a prescribed identification document or a birth certificate is produced by the person to whom the pseudoephedrine is to be sold or supplied.

(2) A person who sells or supplies pseudoephedrine must make and keep a record of the following information:

(a) the name and address of the person to whom the pseudoephedrine is being sold or supplied;

(b) the form of prescribed identification document produced by the person to whom the pseudoephedrine is being sold or supplied;

(c) the unique identification number (if any) on the prescribed identification document provided;

(d) the date of the sale or supply;

(e) the directions given for the safe and proper use of the pseudoephedrine;

(f) the trade name or the approved name of the pseudoephedrine being sold or supplied, or, if it does not have either a trade or approved name, its ingredients and the form, strength and quantity sold or supplied;

(g) a unique identifier enabling those records to be linked with the pseudoephedrine sold or supplied.

(4) A person who makes a record under subregulation (2) must keep it in an electronic form that is accessible via the internet by the Chief Executive and the Commissioner of Police.

3.6 Pharmacy Depots

3.6.1 Establishing a pharmacy depot

A pharmacy depot is considered to be premises (other than a pharmacy) at which –

- (a) prescriptions for drugs or medicines are left for dispensing by a pharmacist;
or
- (b) drugs or medicines dispensed by a pharmacist on prescription are left for collection by or on behalf of the person for whom the drugs or medicines are prescribed.

Scheduled items are not permitted to be stocked on the premises of a depot to be sold on request to members of the public. Schedule 2 and 3 items may be ordered by a patient via a depot, 'dispensed' by the pharmacist at the supplying pharmacy and then delivered to the depot for collection by the patient.

Premises must be located outside of Metropolitan Adelaide and comply with the regulations to be registered as a depot. For the purposes of section 45(2)(a) of the Act, premises proposed to be registered as a pharmacy depot must –

- (a) have provision for temperature control of therapeutic goods and health care products; and
- (b) contain adequate provision for the safe, secure and hygienic storage of therapeutic goods and health care products; and
- (c) contain adequate provision for the safe and secure storage of confidential and sensitive information.

The process to establish a pharmacy depot is as follows:

1. Complete the appropriate application form obtained from the Authority's office or website; and
2. Forward the completed application to the Authority with payment of the appropriate fee. The application will then be considered by PRASA.

Application forms may be downloaded from: www.pharmacyauthority.sa.gov.au