OVERVIEW OF LEGISLATIVE FRAMEWORK

The Health Practitioner Regulation National Law (South Australia) Act 2010 ("the Act") came into operation on 1 July 2010. Under the Council of Australian Governments agreement that led to the passing of the Act, pharmacy ownership and approval of premises were specifically excluded from it. The Parliament of South Australia therefore established the Pharmacy Regulation Authority SA (PRASA) under 'the Act' to assume these functions. PRASA is the successor in law to the Pharmacy Board of South Australia and carries out the latter's former functions relating to the registration of pharmacy premises and depots, and the registration of pharmacy services providers. Previous Pharmacy Board of South Australia functions relating to individual pharmacist registration, professional practice, complaint handling, discipline, competency, and approval of training of ancillary staff are now the responsibility of the Pharmacy Board of Australia. The Pharmacy Board of South Australia no longer exists.

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. Requirements under the regulations include the size and layout of the premises, hygiene, temperature control and lighting within the premises and safe and secure storage, amongst others.

Although matters relating to pharmacy practice are now the responsibility of the Pharmacy Board of Australia, some areas of practice combine both premises and practice elements. Therefore, this standard should be read in conjunction with any guidelines produced by the Pharmacy Board of Australia.

In these guidelines:

- '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

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 Pharmacy Board of Australia. These may be accessed via the Board's website: www.pharmacyboard.gov.au.

Standards and guidelines issued by professional organisations

GENERAL RESPONSIBILITIES

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

   1. in the case of a natural person
      1. 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
      2. he or she is a pharmacist who does not hold a current authorisation to practice and provides the service through the instrumentality of a natural person who is a qualified person;

   2. in the case of a body corporate
      1. the body corporate is a pharmacy services provider; and
      2. the body corporate provides the service through the instrumentality of a natural person who is a qualified person;

   3. in the case of a trust (however constituted)
      1. the trust is a trustee pharmacy services provider; and
      2. the trust provides the service through the instrumentality of a natural person who is a qualified person.

Responsibilities of pharmacy services providers (proprietors)

As above (in the extract from 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 business is 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 owners’ procedures and policies are being followed.

The policy of the Pharmacy Board of Australia is that a ‘pharmacist who owns a pharmacy is practicing pharmacy, given that ownership of a pharmacy business is a role that impacts on safe, effective delivery of services in the profession and involves use of professional skills’. The Board has prepared a set of guidelines entitled ‘Guidelines on responsibilities of pharmacists when practicing as proprietors’, which is available on the Board website www.pharmacyboard.gov.au under Codes & Guidelines. These should be read in conjunction with the relevant standards published by the following bodies:

- Pharmaceutical Society of Australia (PSA) www.psa.org.au
- The Society of Hospital Pharmacists of Australia (the SHPA) www.shpa.org.au
- The Pharmacy Guild of Australia (the PGA) www.guild.org.au

It is also the responsibility of the proprietor to ensure that a pharmacist is in attendance at the pharmacy and available for consultation by members of the public at all times while the pharmacy is open to the public.
PHARMACIES

REGISTRATION

Registration of Corporate/Trustee Pharmacy Services Provider

The Act describes the following in relation to a ‘corporate pharmacy services provider’:

26 – Interpretation

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

(a) A company that conforms with each of the following:

(i) it is a company limited by shares;

(ii) the sole object of the company is to provide pharmacy services;

(iii) all the directors of the company are pharmacists (or if there are only 2 directors, 1 director is a pharmacist and the other is a prescribed relative of that pharmacist);

(iv) no share issued by the company, and no right to participate in the distribution of the profits of the company, is owned beneficially otherwise than by a pharmacist who is a director or employee of the company, or by a prescribed relative of that pharmacist;

(v) the total voting rights exercisable at a meeting of the members of the company are held by pharmacists who are directors or employees of the company;

(vi) if the right of a pharmacist and of his or her prescribed relatives to hold shares in the company ceases by virtue of that person ceasing to be a director or employee of the company, his or her shares and those of his prescribed relatives will be redeemed by the company, distributed among the remaining members of the company, or transferred to a pharmacist who is to become a director or employee of the company, in accordance with the constitution of the company;

(vii) the shares of a person who is a shareholder by virtue of being the spouse or domestic partner of a pharmacist of the relevant class will-

(A) on dissolution or annulment of his or her marriage with that person; or

(B) in the case of a domestic partner on the cessation of that relationship,

be redeemed by the company, or distributed among the remaining members of the company, in accordance with the constitution of the company;

(b) a friendly society that conforms with each of the following:

(i) it is a company limited by guarantee or shares or by guarantee and shares;

(ii) it has at least 100 members;

(iii) its members have equal voting rights on a poll or a meeting or equal voting rights to elect a representative to vote on their behalf;

(iv) its objects include the provision of health or welfare facilities or services for its members or their dependents;

(v) it provides pharmacy services;

(vi) the undistributed surplus of the friendly society would, in the event of the company being wound up, be distributed among its members at the time of winding up or transferred to another person or body with a similar structure and objects;

(vii) it is not carrying on business for the dominant purpose of securing a profit or pecuniary gain for its members;
(viii) any object or intention of the friendly society to provide a dividend to its shareholders or members is a limited and not dominant purpose of the friendly society;

(ix) the property and income of the friendly society are applied towards the objects of the friendly society;

(c) a company other than-

(i) Friendly Society Medical Association Limited; or

(ii) The Mount Gambier United Friendly Societies Dispensary Limited,

That carried on a pharmacy business on 1 August 1942 and has continued to do so since that date.

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 Trustee/Corporate Pharmacy Services Provider

**Registration of premises**

The Act details 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 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

**PREMISES**

**Access to the premises**

The public is entitled to have reasonable access to registered pharmacy premises. The design and equipping of pharmacies and pharmacy departments are to ensure that the premises:

1. are secure and sanitary
2. are suitable for the safe dispensing and supply of therapeutic products;
3. provide an environment that ensures confidentiality in dealings with the public; and
4. are directly accessible from a public place

As mentioned above in Registration of Premises, access to a pharmacy cannot be from within the premises of a supermarket.

**Security**

It is strongly recommended that pharmacies 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. Particular attention therefore needs to be paid to the contents of, and accessibility to, storerooms and refrigerators. The requirements for the storage of schedule 8 medications are discussed in Equipment - Schedule 8 storage.
GENERAL DISPENSARY REQUIREMENTS

The dispensary is a private area dedicated to the dispensing of medicines. Lighting, ventilation and temperature control are essential to maintaining the integrity of the 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 approving alterations to existing pharmacy premises should provide a dispensary to be of an area not less than 9 square metres.

A dispensary in a pharmacy should include:

1. appropriate shelving or storage for Schedule 4 poisons that enables accurate selection of medicines and restricts access to dispensary staff only;
2. a safe for the storage of S8 poisons that meets or exceeds the requirements set out in the Code of Practice for the Storage and Transport of Drugs of Dependence (SA Government Department of Health, 31/7/2000; which can be accessed at www.dassa.sa.gov.au (see also Equipment - Schedule 8 storage);
3. a bench or bench area of suitable size for the unpacking and sorting of dispensary orders received;
4. at least one dispensing station;
5. a sink with hot and cold running water; and
6. 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 include pharmacotherapy (Subutex, Suboxone and methadone) and the filling of dose administration aids (DAA's), both 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.

The suggested requirements for a dispensing station are a dispensing bench of suitable size equipped with a;
- screen
- keyboard
- dedicated scanner
- dedicated printer for labels
- dedicated printer for repeat forms and
- adequate stationery

Each station must be convenient to a printer that prints Consumer Medicine Information (CMI). The CMI printer may be located at or away from the dispensing station and may service multiple dispensing stations.

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 while 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 on a private and confidential basis. 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 for extended services such as disease screening or prolonged consultations.

**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 an ‘unapproved’ 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 concessional, repatriation, general or safety net pharmaceutical prescriptions if subsequently presented at an ‘approved’ pharmacy and;
- being unable to obtain a refund from Medicare Australia for the amount paid over and above the gazetted PBS co-payment for the prescriptions dispensed.

As the public is entitled to know if a pharmacy is ‘unapproved’ to supply pharmaceutical benefits, a prominent sign should be located in the pharmacy stating the following:

- 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.

**WORKLOADS**

Pharmacist staffing levels should be adequate to cover the average workload in a pharmacy 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 scripts per day, consideration needs to be given to the use of trained dispensary assistants and/or intern pharmacists to assist the pharmacist. If the workload exceeds 200 scripts a day, additional pharmacists or dispensary assistants may be required to ensure adequate time is allowed to dispense properly every prescription in accordance with Board guidelines’

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 minimize the risk of dispensing errors. Additional pharmacist duties such as dose administration aid packing, the provision of pharmacotherapy (Subutex, Suboxone and methadone) 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 dispensing systems (such as locum pharmacists).
The use of dispensary assistants or technicians can reduce the load on a dispensing pharmacist, but it is recommended that an individual pharmacist does not supervise more than two dispensary assistants or dispensary technicians (engaged in the selection, processing and labelling of prescription medicines) at a time. Other trained dispensary assistants or dispensary technicians can be engaged in duties that do not require direct supervision outside of this ratio (e.g. in dispensary stock control or preparing dose administration containers).

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.

**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](http://www.qcpp.com) (search in the ‘Resources’ link, then ‘Cold Chain’).

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 at the same time each day, and then the thermometer should be reset for recording the next 24 hours. The pharmacist should be aware and take action if temperature readings are outside the range of 2 to 8 degrees Celsius. Of particular concern are temperatures below 2 degrees Celsius 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. Using ‘cold bags’ or ‘eskies’ or other means of maintaining the cold chain is considered appropriate.
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. 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 privacy is not compromised and in such a way that members of the public cannot view private 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.privacy.gov.au. This includes a fact sheet entitled ‘Some Privacy Issues for Pharmacists’.

Drug and Alcohol Services South Australia publishes an A4 poster suitable for display in pharmacies entitled ‘Privacy Policy Poster’ that may be printed from its website www.dassa.sa.gov.au (search under ‘Pharmaceuticals’ then ‘DASSA Publications’).
DISPOSAL OF WASTES

Sharps Disposal

Sharps must be disposed of in an approved yellow Sharps Container that 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).

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 register, rendered unusable and dispersed throughout the RUM Project Container. This process must be witnessed by another person, who may be an authorised officer, a police officer, a registered health practitioner or a veterinary surgeon. Further information about the RUM Project (including how to order and dispose of a full container) can be found at www.returnmed.com.au.

Confidential material

It is expected that the disposal of confidential material be 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 removed and shredded offsite) to render personal details on documents to be unreadable. The confidentiality of patients must be maintained at all times during the destruction process.

Cleanliness and 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 minimize 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).

Infection Control

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). At the same time due consideration should be paid to the ongoing processes for the disposal of contaminated dressings and supplies. Details may be obtained from the following government website: www.health.sa.gov.au/infectioncontrol.

The use of appropriate hand washing techniques should also be maintained when packing dose administration aids (DAAs). The use of gloves whilst packing to reduce cross-contamination of DAAs 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 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.
EQUIPMENT

References

The Pharmacy Board of Australia publishes a list of reference material that must be readily accessible and should be accessed by pharmacists during the dispensing, clinical assessment, reviewing and counseling processes. The references must be available in their current editions, and can be accessed in hard copy or via electronic means. The list can be found on the Pharmacy Board of Australia website www.pharmacyboard.gov.au under ‘Codes & Guidelines’.

Complementary Medicines

The sale of Complementary Medicines should be conducted with the provision of information to patients wherever possible. In many cases complementary medicines are seen as ‘always effective’ or ‘harmless’, therefore point of sale material explaining any possible drug interactions, allergic reactions or side effects, as well as scientific evidence about effectiveness is very important. This information should be displayed prominently to patients electing to self–select products. The use of an ‘evidence-based reference work on complementary and alternate medicines’ as required by the Pharmacy Board of Australia (see the section 3.4.1 References above) is useful when dealing with enquiries from patients. The promotion of complementary medicines by a pharmacist for conditions for which there is no evidence base is considered unprofessional and is discouraged.

Schedule 8 storage

Schedule 8 poisons (Drugs of Dependence) are to be stored in accordance with the Controlled Substances (Poisons) Regulations 2011 to prevent unauthorized access (generally in a securely locked drug safe or vault). The requirements of such a safe are listed in the ‘Code of Practice for the Storage and Transport of Drugs of Dependence’ published by the Department of Health (which can be accessed at www.dassa.sa.gov.au/goto/ddu). 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 or less monitoring require higher security.

The keys to such a safe should be retained by the pharmacist at all times when the keys are not in use. No other 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.

Bulk quantities of ‘in use’ substitution therapies that are administered to patients attending the pharmacy need to be located so that they are inaccessible to, and preferably out of sight of, the patient and the public.

Extemporaneous dispensing

Extemporaneous preparations may be prepared for individual patients by pharmacists in premises that fulfil professional standards and comply with relevant requirements. The Pharmacy Board of Australia has published ‘Guidelines for dispensing of medicines’ which is available at www.pharmacyboard.gov.au and contains a section (paragraph 5) on extemporaneous dispensing (compounding). The Australian Pharmaceutical Formulary (APF) also contains a section on extemporaneous dispensing, and both of the above 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.

Extemporaneous manufacturing (production of a batch of a particular product) may only be performed in premises that comply with the ‘Guide to Good Manufacturing Practice for Medicinal Products’ published by the Therapeutic Goods Administration (TGA), which is available at www.tga.gov.au.
Barcode Scanners

Barcode scanners are to be used as part of the dispensing process to minimize the risk of a selection error being made. The PBA includes this in their ‘Guidelines for dispensing of medicines’ (paragraph 10) which is available on their website www.pharmacyboard.gov.au. Further references to the use of scanners are included in guidelines issued by the following professional organizations:

PSA - ‘Professional Practice Standards’ at www.psa.org.au


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 medicines management system) has potential advantages for consumers that include:

1. Improving adherence and medication management;
2. decreasing the incidence of adverse events from medication mismanagement;
3. decreasing hospitalisation due to medicine misuse; and
4. possible cost savings through prevention of hoarding of medicines.

The packing of DAAs may be carried out by either a pharmacist or a suitably trained pharmacy student, intern or dispensary assistant (however the final pack must always be checked by a pharmacist). Packing should take place in an area of suitable size, which is tidy, well lit and free from distractions. 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 e.g. 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:

- name of patient
- name and address of the pharmacy
- strength and dose form of the medicine(s)
- directions for use
- description of the appearance of each medicine
- date of filling

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

- date of filling
• initials of the person filling
• initials of the person checking
• initials of the person handing out the pack

The PBA has available on their website (www.pharmacyboard.gov.au) a document entitled ‘Guidelines for specialised supply arrangements’ that outline the details of managing DAAs.

The PSA have extensive support materials relating to the provision of a DAA service on their website www.psa.org.au (search under ‘Practice Support’ then ‘Community Pharmacy Agreement Programs’).

MEDICATION DELIVERY

The delivery of pharmaceutical items to a patient at their home or workplace can be one of two types:

1. Delivery of items only (simple courier service)
2. Delivery of items and appropriate advice on their use (similar to an interaction in a pharmacy)

Prior to the delivery taking place, the pharmacist should determine which type of delivery will be provided, and convey that information to the patient before delivery (any costs associated with delivery should also be disclosed at this stage). 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.

A type 1 (a simple delivery service) is acceptable in certain situations, such as:

1. Delivery of unscheduled items
2. Delivery of an item previously used by the patient
3. Delivery of a specially procured item to a patient following their attendance in the pharmacy (and discussion with the pharmacist where necessary)

Delivery type 2 is preferred 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 (e.g. 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.

Regardless of the delivery type, the vehicle used to transport items should provide adequate security for any scheduled medicines being carried. The vehicle must remain locked when unattended, and all items should be stored out of view of the public wherever possible (such as in the boot of the car or in a suitably opaque storage container). Advertising the name of the pharmacy on the outside of a delivery vehicle is strongly discouraged.

Appropriate temperature requirements for medicines should also be maintained in the delivery vehicle at all times. The use of cold storage containers (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. Frequent visits back to the pharmacy to collect additional, individual deliveries is preferable.

If an item requires a signature on delivery (e.g. 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 (e.g. 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 are 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 (see Privacy and Confidentiality). 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.

PHARMACY DEPOTS

ESTABLISHING A PHARMACY DEPOT

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

1. prescriptions for drugs or medicines are left for dispensing by a pharmacist; or
2. 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.

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

1. have provision for temperature control of therapeutic goods and health care products; and
2. contain adequate provision for the safe, secure and hygienic storage of therapeutic goods and health care products; and
3. 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. The appropriate form is Pharmacy Depot Registration.