



Public consultation

6 March 2015

You are invited to provide feedback on this public consultation

Review of Board guidelines:

Guidelines for dispensing of medicines

Guidelines on practice-specific issues

Guidelines on specialised supply arrangements

Guidelines on responsibilities of pharmacists when practising as proprietors

Please provide your feedback in a Word document (or equivalent)¹ by email to pharmacyconsultation@ahpra.gov.au by close of business Friday 1 May 2015.

A template document for your response has been provided for your convenience.

Public consultation

The Pharmacy Board of Australia (the Board) is releasing the attached consultation paper on the review of its Board guidelines (*Guidelines for dispensing of medicines*, *Guidelines on practice-specific issues*, *Guidelines on specialised supply arrangements* and *Guidelines for proprietor pharmacists*).

You are invited to provide your comments on the consultation paper, including the questions in the paper, by close of business on Friday 1 May 2015. A template document for your response has been provided for your convenience. The Board will consider the consultation feedback on the draft Board guidelines before finalising them for publication on its website.

¹ You are welcome to supply a PDF file of your feedback in addition to the word (or equivalent) file, however we request that you do supply a text or word file. As part of an effort to meet international website accessibility guidelines, AHPRA and National Boards are striving to publish documents in accessible formats (such as word), in addition to PDFs. More information about this is available at www.ahpra.gov.au/About-AHPRA/Accessibility.aspx.

How your submission will be treated

Submissions will generally be published unless you request otherwise. The National Boards publish submissions on their websites to encourage discussion and inform the community and stakeholders. However, the National Boards retain the right not to publish submissions at their discretion, and will not place on their website, or make available to the public, submissions that contain offensive or defamatory comments or which are outside the scope of the consultation.

Before publication, the National Boards will remove personally-identifying information from submissions, including contact details. The views expressed in the submissions are those of the individuals or organisations who submit them and their publication does not imply any acceptance of, or agreement with, these views by the National Boards.

The National Boards also accept submissions made in confidence. These submissions will not be published on the website or elsewhere. Submissions may be confidential because they include personal experiences or other sensitive information. Any request for access to a confidential submission will be determined in accordance with the *Freedom of Information Act 1982* (Cth), which has provisions designed to protect personal information and information given in confidence.

Please let the Board know if you do not want your submission published, or want all or part of it treated as confidential.

Contents

Introduction	1
Overview of consultation	4
Overview <i>Review of the Guidelines for dispensing of medicines</i>	6
Consultation <i>Guidelines for dispensing of medicines</i>	9
Overview <i>Review of the Guidelines on practice-specific issues</i>	24
Consultation <i>Guidelines on practice-specific issues</i>	27
Overview <i>Review of the Guidelines on specialised supply arrangements</i>	35
Consultation <i>Guidelines on dose administration aids and staged supply of dispensed medicines²</i>	37
Overview <i>Review of the Guidelines on responsibilities of pharmacists when practising as proprietors</i>	43
Consultation <i>Guidelines for proprietor pharmacists³</i>	46
<i>Statement of assessment against AHPRA's Procedures for development of registration standards and COAG principles for best practice regulation</i>	50

² Previously titled *Guidelines on specialised supply arrangements*

³ Previously titled *Guidelines on responsibilities of pharmacists when practising as proprietors*

Overview of consultation

6 March 2015

Consultation on guidelines:

Guidelines for dispensing of medicines

Guidelines on practice-specific issues

Guidelines on specialised supply arrangements

Guidelines on responsibilities of pharmacists when practising as proprietors

Summary

Purpose of the proposal

The Health Practitioner Regulation National Law, as in force in each state and territory (the National Law), empowers a National Board to develop and approve codes and guidelines to provide guidance to the profession.

The Board entered the National Registration and Accreditation Scheme (the National Scheme) on 1 July 2010 and developed guidelines and codes at its commencement. The following sets of guidelines were published by the Board in 2010:

- Guidelines for dispensing of medicines
- Guidelines on practice-specific issues
- Guidelines on specialised supply arrangements
- Guidelines for proprietor pharmacists

In keeping with good regulatory practice, these guidelines were scheduled for review at least every three years. The review of these guidelines was scheduled as part of the review of all Board registrations standards and guidelines and is the final component of the review.

Section 40 of the National Law requires National Boards to conduct wide-ranging consultation when developing a registration standard, code and guideline. As part of the scheduled review of its guidelines, the Board has developed draft revised guidelines and is inviting general comments on these. There is an overview before each proposed draft that explains the proposed changes. There are also specific questions about the guidelines which you may wish to address in your response.

The Board will consider the consultation feedback on the draft Board guidelines before finalising them for publication on its website.

Please provide feedback in a Word document by email to pharmacyconsultation@ahpra.gov.au by close of business on Friday 1 May 2015. A template document for your response has been provided for your convenience.

Background

The Board has developed guidelines to provide guidance to the profession not set out in the legislation or a registration standard. They provide interpretation for pharmacists, and help to clarify the Board's views and expectations on a range of issues in the public's interest.

The draft revised guidelines acknowledge the relevance in practice of:

- state, territory and Commonwealth legislation
- professional practice standards and guidelines, and

- where relevant, the codes, guidelines and/or requirements of other authorities.

The Board deliberately avoided providing summaries of the relevant legislation and/or practice standards and guidelines in the draft revised guidelines, as it holds the view that pharmacists are expected to be familiar with and comply with such legal and professional obligations relevant to their practice. Where appropriate, the draft revised guidelines refer pharmacists to the primary sources of information outlining pharmacist's obligations which the Board, the profession and the public would expect pharmacists to comply with.

As outlined in section 41 of the National Law, guidelines published by the Board may be used as evidence of what constitutes appropriate professional conduct or practice for pharmacists in proceedings under the National Law or a law of a co-regulatory jurisdiction⁴ against a pharmacist. Failure to comply with the existing professional practice standards and guidelines and Board guidelines may result in a number of outcomes, including disciplinary action by the Board.

Next steps

The Board will consider the consultation feedback on the draft Board guidelines before finalising them for publication on its website.

⁴ **co-regulatory jurisdiction** means a participating jurisdiction in which the Act applying this Law declares that the jurisdiction is not participating in the health, performance and conduct process provided by Divisions 3 to 12 of Part 8.

Note - Queensland and New South Wales are co-regulatory jurisdictions.

Overview

6 March 2015

Review of the *Guidelines for dispensing of medicines*

Summary of issue

The National Law outlines that a Board may develop guidelines to provide guidance to the health practitioners it registers, or about any other matters relevant to the exercise of its functions.

The Board's current *Guidelines for dispensing of medicines* were developed to outline its expectations of pharmacists in relation to the safe dispensing and labelling of medicines, and on the provision of a good pharmaceutical service, in the public's interest.

The Board has reviewed the current guidelines to ensure they meet the objectives of the National Law and the National Registration and Accreditation Scheme, and are worded as simply and clearly as possible. Much of the content of the revised guidelines is consistent with the current published guidelines with additional guidance included where appropriate. Two proposed changes to the guidelines to note are outlined below.

i. *Extemporaneous dispensing (compounding)*

The Board proposed that *Guideline 5 Extemporaneous dispensing (compounding)* be removed from the current guidelines, and published as a separate set of guidelines retitled *Guidelines on compounding of medicines*. The Board has completed public consultation on these revised guidelines which will be finalised and published on its website prior to the completion of the consultation process for the revised *Guidelines for dispensing of medicines*.

ii. *Dispensary assistants/dispensary technicians and hospital pharmacy technicians*

The Board proposed a number of changes to the guideline on *Dispensary assistants/dispensary technicians and hospital pharmacy technicians*. These revisions include further guidance for pharmacists about education and training of dispensary assistants / technicians that it believes will benefit pharmacists to effectively and safely deliver services to the public.

As the Board does not regulate dispensary assistants or dispensary technicians, and the decision to regulate a group of individuals who provide a service in a health field by inclusion in the National Scheme rests with the Australian Workforce Ministerial Council, this is not included in the scope of this review.

Options statement

The Board has considered a number of options in developing this proposal.

Option 1 – Status quo

Option 1 would continue with the existing guidelines. These guidelines outline the Board's expectations of pharmacists in relation to the dispensing of medicines. The Board has identified a range of minor issues with the current guidelines, including the need to:

- provide further guidance for pharmacists about education and training of dispensary assistants / technicians that it believes will benefit pharmacists to effectively and safely deliver services to the public
- define dispensing
- remove *Guideline 5 Extemporaneous dispensing (compounding)*, a new and separate set of guidelines, the *Guidelines on compounding of medicines*
- address specific risks to pharmacists' electronically stored data
- provide further guidance on the use of scanners, and

- update *Guideline 8 Privacy and confidentiality* to ensure the guidance is aligned with the new Australian Privacy Principles.

The Board has also identified the ability to clarify the language and structure of the guidelines to make them easier to understand.

Option 2 – Proposed revised guidelines

Option 2 would involve the Board publishing revised *Guidelines for dispensing of medicines*. The revised guidelines would continue to outline the Board's expectations in relation to the dispensing of medicines, but without specifically addressing the compounding of medicines by removing *Guideline 5 Extemporaneous dispensing (compounding)* and publishing separate *Guidelines on compounding of medicines*.

The revised guidelines include changes to *Guideline 12 Dispensary assistants/dispensary technicians and hospital pharmacy technicians*. Additional guidance has been included to address the education and training of dispensary assistants / technicians that the Board believes will benefit pharmacists to effectively and safely deliver services to the public.

The revised guidelines define a step-by-step process for dispensing. They address additional issues including the protection of pharmacists' electronically stored data, and patients' rights to choose where to access their medicines. They also provide further guidance on the Board's expectations regarding the use of scanners while dispensing.

In line with the new Australian Privacy Principles, the revised guidelines state that a pharmacist must ensure that patients are made fully aware of the risks if a patient chooses that their information is not disclosed to their treating health practitioner. This differs from the current guidelines which state that a pharmacist may divulge this information without patient consent if, in the pharmacist's opinion, it is in the patient's best interest for this information to be disclosed.

The revised guidelines also have clearer wording and structure to make them easier to understand.

Preferred option

The Board prefers Option 2.

Issues for discussion

Potential benefits and costs of the proposal

The benefits of the preferred option are that the draft revised guidelines:

- provide additional guidance on the training of dispensary assistants/dispensary technicians, the dispensing process, the protection of electronic data and the use of scanners
- contain information on privacy and confidentiality which is consistent with the new Australian Privacy Principles
- support the publication of a revised separate set of guidelines, the *Guidelines on compounding of medicines*, which address additional issues regarding the compounding of medicines
- are user-friendly
- strike a balance between protecting the public and impact on pharmacists
- have been reworded to be simpler and clearer.

The costs of the preferred option are:

- pharmacists, other stakeholders, AHPRA and National Boards will need to become familiar with two new sets of guidelines, the revised *Guidelines for dispensing of medicines* and the *Guidelines on compounding of medicines*

- there will likely need to be a period of transition to the revised *Guidelines for dispensing of medicines* and the separate *Guidelines on compounding of medicines*.

Estimated impacts of the draft revised guidelines

The changes proposed in the revised *Guidelines for dispensing of medicines* are relatively minor, although more significant changes may be proposed through consultation. There is little impact anticipated on practitioners, business and other stakeholders arising from the changes proposed.

The revised guidelines address education and training of dispensary assistants / technicians that the Board believes will benefit pharmacists and assist them to effectively and safely deliver services to the public.

The draft revised guidelines will also require pharmacists to become familiar with two new sets of guidelines.

Relevant sections of the National Law

Relevant sections of the National Law relating to the guidelines (and summarised above) are:

- Section 35, and
- Section 39.

Questions for consideration

The Board is inviting feedback on the following questions:

- From your perspective, how are the current *Guidelines for dispensing of medicines* working?
- Is the content and structure of the draft revised guidelines helpful, clear, relevant and more workable than the current guidelines?
- Is there any content that needs to be changed or deleted in the draft revised guidelines?
- Is there anything missing that needs to be added to the draft revised guidelines?
- Do you have any other comments on the draft revised guidelines?
- Do you think that the proposed review period of five years, with the option to review earlier if the need arises, is appropriate?

The Board has also noted the potential for advancements in technology to change the way that pharmacists deliver particular pharmacy services. It has decided to explore through this consultation, the views of its stakeholders and the public about the possible inclusion of further guidance for pharmacists on the use of technology in the delivery of pharmacy services. The Board is also seeking feedback on the following questions:

- Is guidance for pharmacists required to address the use of information and communication technology, including, but not restricted to videoconferencing, internet and telephone, as an alternative to face-to-face delivery of pharmacy services?
- If guidance is required, what should it specifically address?
- Is the provision of explanatory information for pharmacists instead of a guideline a suitable alternative approach to address the use of information and communication technology in the delivery of pharmacy services?

The proposed revised *Guidelines for dispensing of medicines* is included on page 10 of this consultation paper.

The current *Guidelines for dispensing of medicines* is published on the Board's website, accessible from www.pharmacyboard.gov.au/Codes-Guidelines.aspx.

Attachments

The *Statement of assessment against AHPRA's Procedures for development of registration standards and COAG principles for best practice regulation* is at [Attachment 1](#).

Draft revised Guidelines for dispensing of medicines

Effective from: <<date>>

Review date: <<date>>

Contents

Introduction

Who needs to use these guidelines?

What happens if I do not comply with these guidelines?

Summary of guidelines

Guidelines

1. The dispensing process
2. Dispensing precaution – safety of prescriptions
3. Dispensing multiple repeat prescriptions at one time
4. Facsimile and scanned prescriptions
5. Internet, mail-order dispensing and other indirect supply of medicines
6. Incident records
7. Labelling of dispensed medicines
8. Counselling patients about prescription medicines
9. Privacy and confidentiality
10. Dispensing errors and near misses
11. Pharmacists' workloads
12. Dispensary assistants/dispensary technicians and hospital pharmacy technicians
13. Patients' rights to choose where to access medicines
14. Return of unwanted medicines

Definitions

References

Review

Introduction

These guidelines have been developed by the Pharmacy Board of Australia (the Board) under section 39 of the Health Practitioner Regulation National Law, as in force in each state and territory (the National Law). They provide guidance to pharmacists in relation to the dispensing of medicines, not set out in the legislation or a registration standard.

Note: As part of the agreement by the Council of Australian Governments to provide for the National Law, pharmacy ownership, regulation of premises, inspections and related matters do not form part of the National Law. Each jurisdiction will have separate legislation and guidelines for these purposes.

Who needs to use these guidelines?

These guidelines were developed to provide guidance to registered pharmacists or those seeking to become registered pharmacists. They apply to all pharmacists holding the following types of registration:

- general
- provisional, or
- limited.

These guidelines do not apply to pharmacists holding non-practising registration or to students. However, students should become familiar with these guidelines prior to undertaking supervised practice placements.

What happens if I do not comply with these guidelines?

Pharmacists must comply with all legislation relevant to the practice of pharmacy in the jurisdiction where the practice occurs. Additionally, pharmacists are expected to be aware of and comply with the profession's standards and guidelines (including any other standards or guidelines referred to in those documents), as relevant to their scope of practice and type of registration. The pharmacy practice standards and guidelines can be accessed on the websites of the relevant professional bodies:

- Pharmaceutical Society of Australia (PSA) (www.psa.org.au), and
- The Society of Hospital Pharmacists of Australia (The SHPA) (www.shpa.org.au).

Non-compliance with these guidelines and the practice standards and guidelines relevant to dispensing may be notified to the Board for appropriate action under the National Law. Under section 41 of the National Law, these guidelines can be used in disciplinary proceedings under the National Law or law of a co-regulatory jurisdiction as evidence of what constitutes appropriate professional conduct or practice for pharmacists. When considering notifications (complaints) against pharmacists, including those which might relate to a dispensing error, the Board will give consideration to whether a breach of these guidelines has taken place. The Board will also have regard to the legislation and practice standards and guidelines relevant to pharmacy practice.

Further information for pharmacists regarding the possible outcomes of notifications is available on the website of the Australian Health Practitioner Regulation Agency (AHPRA) (www.ahpra.gov.au).

Summary of guidelines

These guidelines focus on safe dispensing and labelling of medicines, including compounded (or extemporaneously prepared) medicines, and on providing a good pharmacy service. They also address the role of dispensary assistants / technicians in assisting pharmacists. Pharmacists who dispense compounded medicines should also refer to the Board's *Guidelines on compounding of medicines*.

(Note: At the time of this consultation, the 'Guidelines on compounding of medicines' are being finalised for publication)

Guidelines

1 The dispensing process

For the purpose of these guidelines, the Board defines dispensing as:

The review of a prescription and the preparation, packaging, labelling, record keeping and transfer of the prescribed medicine including counselling, to a patient, their agent, or another person who is responsible for the administration of the medicine to that patient.

Guideline

The pharmacist should ensure that the prescription is valid, that the medicine is clinically appropriate for the patient, and that information is provided to ensure safe and appropriate use of the medicine.

The process of dispensing includes:

- a. receiving a prescription
- b. ascertaining the authority of the prescriber to prescribe
- c. obtaining any supplementary information to enable the patient to be properly identified and the medication to be dispensed safely
- d. determining the prescriber's intentions as to the patient's medicines
- e. reviewing the medication history and other relevant patient information, to ensure that the medicine is safe and proper for the patient to use and that where possible, all other relevant considerations

of the patient's health including the use of any other prescription and non-prescription medicine including complementary and alternative medicine, are taken into account

- f. entering the prescription details on the pharmacy computer
- g. generating a label for the dispensed medicine and a repeat authorisation where required
- h. selecting or preparing the product intended by the prescriber
- i. making full records of all aspects of the dispensing according to the requirements of the law
- j. clearly labelling the container of the medicine with the directions for its use as intended by the prescriber along with any other information that facilitates its proper, safe and effective use
(Note: Cautionary/advisory labels and instructions of the 'Australian pharmaceutical formulary and handbook' should always be used unless in a particular case there is good reason not to. Where a cautionary/advisory label is required by law for a particular medicine, this must always be used)
- k. using a barcode scanner (where packaging includes a barcode) to verify the selection of the correct product for the patient
(Note:
 1. *Scanning of the product barcode towards the end of the dispensing process may be more effective in minimising selection errors*
 2. *The scanning of the product barcode is a separate step in the dispensing process to the scanning of a barcode on a prescription or repeat authorisation)**)*
- l. carefully checking and re-checking all dispensing for accuracy and completeness
- m. counselling the patient, or the patient's agent, sufficiently to allow a proper understanding of all the information required by the patient to use the medicine safely and effectively and to motivate the patient to comply with that advice, and to allow for a final check of the dispensed medicine, and
- n. ensuring that the entire dispensing process has been carried out according to good pharmacy practice, and accepting that responsibility by placing his or her initials or signature in the prescription records of the pharmacy and any other place according to relevant legislation.

(Note:

1. *If more than one pharmacist is involved in the dispensing and counselling process, suitable processes should be in place to ensure that the involvement of each pharmacist is identifiable through a suitable record.*
2. *The Pharmacy Board of Australia (draft revised) Guidelines on dose administration aids and staged supply of dispensed medicines address the responsibilities of pharmacists when dose administration aids (DAAs) are packed by a third party.*
3. *A dispensary assistant / technician may assist the pharmacist in the dispensing process by carrying out the functions of data entry and assembling medicines. However, the pharmacist is responsible for:*
 - *assessing the appropriateness of the medicines in relation to the medication history and other relevant patient information (step e above)*
 - *confirming the required formulation for medicines that have been compounded*
 - *checking the dispensed medicine (step k above), and*
 - *counselling the patient or the patient's agent and performing the final check (step l above).*
4. *Pharmacists should refer to the 'Pharmaceutical Defence Limited (PDL) and Australian Journal of Pharmacy's (AJP) Guide to good dispensing'*
5. *Pharmacists are expected to comply with Standard 5 – Dispensing of the Pharmaceutical Society of Australia's Professional Practice Standards. This standard refers to the SHPA standards of practice for the provision of oral chemotherapy for the treatment of cancer, whose principles are applicable to the treatment of conditions other than cancer, and must be complied with given the significant risks associated with dispensing these medicines.)*

2 Dispensing precaution – safety of prescriptions

A pharmacist must take reasonable steps during the dispensing process (detailed in Guideline 1 *The dispensing process*) to ensure that the dispensing of a medicine in accordance with a prescription or order is consistent with the safety of the person named in that prescription or order.

Guideline

In dispensing a prescription, a pharmacist has to exercise an independent judgment to ensure the medicine is safe and appropriate for the patient, as well as that it conforms to the prescriber's intentions. Where clarification is required, the prescriber is to be contacted. Good practice involves seeking consent from patients before disclosing information, where practicable (refer to Guideline 9.1 *Disclosure of information*). If the prescriber cannot be contacted, or if on consultation with the prescriber there is a difference in opinion regarding the safety of the prescription, professional judgement must be exercised by the pharmacist in deciding appropriate action to take. At all times the dispensing of a prescription or any other action taken by the pharmacist, must be consistent with the safety of the patient. Appropriate documentation should be kept to support the action taken.

In conforming to the above principle, dose, frequency and route of administration, duration of treatment, the presence or absence of other medicines, the patient's illness, medication history, allergies, and other relevant circumstances need to be taken into account. When this information is collected by the pharmacist, relevant details should be recorded in the dispensing record, and where possible in the patient's health record, so that the safety of any future medicines that are prescribed and/or dispensed for that patient can also be assured.

3 Dispensing multiple repeat prescriptions at one time

Dispensing multiple quantities of particular medicines (whether or not directed by the prescriber) may not be consistent with the safety of the patient (refer to Guideline 2 *Dispensing precaution – safety of prescriptions*).

The supply of multiple repeats at the one time is permitted under Regulation 24 of the National Health (Pharmaceutical Benefits) Regulations 1960. An authorised prescriber must endorse each prescription for multiple supplies if satisfied that the patient's circumstances meet the criteria outlined in the regulations. In the case of non-PBS medicines, prescribers may specify quantities that suit the patient's circumstances.

When not directed by the prescriber, the simultaneous supply of multiple quantities of a particular medicine (i.e. the supply of multiple repeats at once) may be contrary to the Quality Use of Medicines principles outlined in the National Medicines Policy. It does not promote regular review of therapy and effective provision of medicine information by pharmacists, which may assist in minimising medication misadventure. It may also be contrary to state or territory legislation.

Guideline

Dispensing multiple quantities of any prescription should only occur at the specific direction of the prescriber on each occasion, unless exceptional circumstances exist to the satisfaction of the pharmacist (in which case the prescriber should be informed), and an appropriate notation is made to that effect on the prescription, in the dispensing record and where possible, in the patient's health record. State and territory legislation must be complied with.

4 Facsimile and scanned prescriptions

Scanned prescriptions and prescriptions transmitted by facsimile may be a source of dispensing errors, and are a frequent source of forgeries and fraudulent behaviour to unlawfully obtain medicines seen by pharmacists.

Guideline

Before dispensing a prescription received as a scanned copy or via facsimile, a pharmacist must take reasonable steps to satisfy themselves that the prescription is bona fide and in accordance with relevant state or territory legislation. Pharmacists must be familiar with any jurisdictional requirements regarding the supply in these circumstances, which may include sighting the original prescription or receiving oral instruction from the prescriber before the supply is made, and obtaining and retaining the original prescription.

5 Internet, mail-order dispensing and other indirect supply of medicines

The Board views the indirect supply of medicines, such as internet and mail-order dispensing, as less than the optimal way of delivering a pharmacy service because communication including opportunities for counselling, may be compromised. However, the Board recognises that particular patient circumstances may exist where these forms of communication are necessary or appropriate (e.g. in remote areas). The Board also recognises that some consumers may prefer to access particular pharmacy services in this way.

Guideline

A pharmacist should encourage face-to-face contact with patients as the preferred option for supplying medicines. If medicines are supplied indirectly to a patient, the pharmacist must comply with all relevant state or territory and Commonwealth legislation, these guidelines, and established practice standards including Standard 2 *Managing Pharmacy Practice* and Standard 6 *Indirect Pharmacy Services* of the Pharmaceutical Society of Australia's *Professional Practice Standards*.

As with the direct supply of medicines, where face-to-face contact is not possible a pharmacist should communicate with the patient to obtain any required information, and to offer counselling. Written information and other suitable materials should be provided to reinforce the oral counselling provided (refer to Guideline 8 *Counselling patients about prescribed medicines*).

6 Incident records

Dispensing errors, significant other errors, omissions and other non-compliances, including complaints of a non-commercial nature arising both within and external to the pharmacy, may be the subject of investigation. Pharmacists should therefore follow a risk management procedure, including appropriate record keeping of such incidents.

Guideline

Pharmacists are to maintain incident records that show when the incident was recorded, when it occurred, who was involved (both actual and alleged), the nature of the incident or complaint, what actions were taken and any conclusions. If contact was made with third parties, such as government departments, prescribers, lawyers or professional indemnity insurance companies, details of the conversation should be recorded.

Regardless of how serious the incident may appear, comprehensive detailed records need to be kept.

7 Labelling of dispensed medicines

Dispensed medicines are to be labelled in accordance with legislation in force in the jurisdiction in which the pharmacist is practising, applicable practice standards and guidelines, and these guidelines, with a view to:

- maximising the benefits of the therapy
- improving the patient's understanding of the treatment
- enhancing compliance, and
- minimising adverse effects.

Guideline

7.1 Labels

Placement

The placement of the dispensing label on the product is largely determined by the design of the medicine package and the manufacturer's label.

The dispensing label is to be firmly attached to the immediate container (including each component of multiple-therapy packs) unless the immediate container is so small or is so constructed that the label would

compromise the patient's ability to use the medicine (e.g. metered aerosols and some eye drops). In such instances, the label should be attached to the primary packaging or alternatively, purpose-designed labelling tags or 'winged' labels may be used.

Legibility

The label should be clearly and legibly printed in unambiguous and understandable English. Other languages that are accurate translations of the English may be used in addition to English.

The special needs of patients with disabilities, such those with poor eyesight, should be accommodated and the patient adequately informed.

The label should be placed to leave visible any of the manufacturer's statements that may be important to the patient, including the expiry date, storage conditions and where possible, the name and strength of the medicine.

7.2 Label content

The label of each medicine dispensed is to include the following:

- in the case of proprietary medicines, the brand and generic names of the medicine, the strength, the dose form and the quantity supplied
- in the case of compounded medicines and medicines not dispensed by count, the name and strength of each active ingredient (especially if a formulation other than a standard pharmacopoeial formulation is used), the name and strength of any added preservatives, the name of the formula as described in a standard pharmacopoeial reference book (where applicable), the dose form and the quantity supplied
- specific directions for use, including frequency and dose
- the patient's name or, in the case of an animal, the owner's name and the kind of animal
- the date of dispensing or supply
- the initials of the dispensing pharmacist (and if different, the initials of the pharmacist checking and issuing the medicine)
- a unique identifying code for the dispensed medicine
- the name, address and telephone number of the pharmacy or pharmacy department at which the medicine was dispensed
- the applicable storage directions and expiry date of the medicine which are required to facilitate the safe and effective use of the medicine by the patient
- the words 'Keep out of reach of children', and
- for compounded medicines, the words 'This medicine has been compounded by the pharmacist for you'.

7.3 Ancillary labels

Some ancillary labels are mandatory - these are listed in the *Standard for the uniform scheduling of medicines and poisons* (SUSMP). State and territory legislation may also mandate additional labelling requirements of medicines, which must also be complied with. The routine use of other ancillary labels in the current edition of the *Australian pharmaceutical formulary and handbook* is recommended, taking into consideration the individual patient circumstances.

8 Counselling patients about prescribed medicines

Patient counselling is part of the process of dispensing medicines and provides an opportunity to elicit the necessary information from a patient, and to provide the required information to enable safe and effective use of medicines. Patients have the right to expect that the pharmacist will counsel them privately about their medicines.

Counselling is also the final checking process to ensure the correct medicine is supplied to the correct patient. Lack of counselling can be a significant contributor in failing to detect dispensing errors. In this regard, the Board endorses the current patient counselling guidelines produced by the Pharmaceutical

Society of Australia and The Society of Hospital Pharmacists of Australia, including the use of 'Consumer medicines information' (CMI) leaflets.

Guideline

The pharmacist should make every effort to counsel, or to offer to counsel the patient whenever a medicine is supplied, but the patient reserves the right not to be counselled.

More detailed advice is especially important when certain medicines are supplied and in certain circumstances. Examples include:

- the supply of medicines that can cause drowsiness or sedation
- the supply of medicines that have a narrow therapeutic index (e.g. cytotoxics and other immunosuppressants, warfarin, digoxin, insulins)
- the taking of medicines that require therapeutic monitoring or specific biochemistry or haematology monitoring (e.g. warfarin and other anticoagulants, antithrombotics, digoxin, clozapine)
- unusual dose forms (e.g. fentanyl patches)
- unusual frequency of use (e.g. alendronate, methotrexate)
- when a new medicine is prescribed
- when there is a change in the dose or frequency of administration
- when the brand of medicine has changed
- when the medicine is a controlled drug
- with each supply of medicine for which there are valid reasons for regular reinforcement of information (e.g. teratogenics or cytotoxics; anticonvulsants; major contraindications; special patient needs, such as language preference, vision, hearing or cognitive impairment, or cultural issues)
- at regular intervals (e.g. six monthly) for medicines used for long-term therapy
- when the medicine is for a child
- if the patient is taking many medicines, and
- when there is an acute illness or event (e.g. hospital admission).

In the case of patients taking repeat prescriptions, counselling provides the opportunity to inquire if the patient is taking the medicine correctly, if the medicine is having the desired outcome or if there are unwanted effects. It offers a further opportunity to detect any errors.

The contents of a CMI, such as mention of certain diseases or side effects, may cause confusion or even alarm among some patients. Therefore, the pharmacist may need to work through the CMI with the patient in order to relate its contents to the individual circumstances.

Face-to-face counselling is the best way of communicating information about medicines, but where that is not possible or practicable, written information and/or a telephone call are recommended while making sure that the information is provided directly to the patient.

9 Privacy and confidentiality

Commonwealth, state and territory privacy laws set out the privacy principles applicable to health providers. Pharmacists should ensure that all pharmacy services are provided in a manner that respects the patient's privacy requirements, and is in accordance with relevant professional and quality assurance standards.

Guideline

9.1 Disclosure of information

Information about a person that a pharmacist obtains in the course of their professional practice is confidential and may be disclosed only:

1. with that person's permission
2. to other persons authorised to the extent of the latter person's lawful jurisdiction, or
3. on a court order.

If, in the pharmacist's opinion, it is in the patient's best interest to divulge pertinent information to another health practitioner who is treating the patient, the pharmacist should seek consent from the patient to disclose that information. If the patient refuses, the pharmacist should ensure that the patient has been made fully aware of the risks of this information not being disclosed and ensure that any action is consistent with the safety of the patient (refer to *Guideline 2 Dispensing precaution – safety of prescriptions*).

In accordance with the relevant Australian Privacy Principles, if a patient is unable to consent to the disclosure of information (e.g. they are unconscious), the pharmacist may disclose the information to another health practitioner who is treating the patient provided that:

- the pharmacist is satisfied that the disclosure is necessary to provide appropriate care or treatment of the patient, and
- the disclosure is not contrary to any wish of the patient.

Appropriate documentation should be kept to support any action taken.

Authorised persons to which information may be disclosed include:

- an investigator or an inspector appointed under the National Law
- an officer of the state or territory pharmacy authority
- a person authorised under the state or territory poisons law (including a member of the police force to the extent authorised)
- a member of an enforcement agency in accordance with the Privacy Act 1988 (Cth), or state or territory privacy laws
- an authorised officer of Medicare Australia for the purposes of examining prescriptions supplied as pharmaceutical benefits under the National Health Act 1953 (Cth), or
- an authorised officer of state or territory statutory authorities that administer laws of work or road traffic related insurance.

It may be an offence for a pharmacist to refuse to disclose requested information to an authorised person.

Particular care should be exercised if other official bodies seek information. State or territory privacy authorities should be contacted in cases of uncertainty.

The inadvertent disclosure of the identities of patients' medicines (and therefore the patients' medical conditions) to third parties must be avoided.

Examples of situations where information may be inadvertently disclosed could include:

- payment of a family account
- provision of information to third party organisations (including service companies) that process accounts
- provision of information to organisations collecting statistical data for marketing purposes
- provision of information on clinical functions to software providers
- provision of information on points earned in a customer loyalty program, and
- use of overseas cloud data storage.

9.2 Protection of electronic data

Data collection and electronic storage by pharmacists poses significant risks to patient privacy. Pharmacy proprietors and pharmacists in charge of a dispensary or pharmacy department must:

- ensure that appropriate measures are in place to ensure electronic data is stored securely
- ensure that appropriate backup and disaster recovery processes are in place and in accordance with any jurisdictional pharmacy premises regulatory authority requirements, to ensure the integrity of data is maintained
- refer to and comply with Section 8.4 *Health records* of the Board's *Code of conduct for pharmacists*, which describes good practice in maintaining health records, including that

pharmacists should ensure that records are held securely and are not subject to unauthorised access

- ensure that pharmacists are aware of threats to maintaining secure electronic data, such as malicious software, which can be used to block access to a computer system and encrypt data such as patient records
- ensure that pharmacists take reasonable steps to ensure that electronic data is protected, and
- consult with their computer software and hardware providers to ensure that appropriate protection measures are in place.

10 Dispensing errors and near misses

All reasonable steps need to be taken to minimise the occurrence of errors.

Guideline

Good practice dictates that there should be a systematic approach in dealing with errors and near misses so that lessons can be learned from them and corrective action taken.

Pharmacists should refer to Section 6.2 *Risk management* of the Board's *Code of conduct for pharmacists*, which describes good practice in relation to risk management.

10.1 Scanners

Pharmacists should use barcode scanners when dispensing medicines in pharmacies and pharmacy departments. Barcode scanners are an aid to, but not a substitute for, minimising selection errors.

When dispensing medicines, pharmacists should refer to and follow the guidance regarding use of scanners contained in:

- the Pharmaceutical Society of Australia's *Professional Practice Standard 5: Dispensing*
- The Society of Hospital Pharmacists of Australia's *Standards of Practice for Hospital Pharmacy Outpatient Services*, and
- the Pharmaceutical Defence Limited (PDL) and Australian Journal of Pharmacy's (AJP) *Guide to good dispensing*.

Barcodes should be scanned:

- on prescriptions and repeat authorisation forms where available for eHealth processing
- on products where barcodes exist, and
- on the dispensing label in circumstances where a barcode is printed.

10.2 Checking dispensed medicines

Routine checking throughout the dispensing process is necessary, with particular emphasis being attached to the final check at the time of actual supply and at the time of dispatch of the medicine from the pharmacy. Counselling of the patient or carer about the dispensed medicines prior to supply provides an additional check.

Where automated dispensing systems are utilised, vigilance must be maintained by pharmacists and their dispensary staff when managing such systems to ensure that the occurrence of errors is minimised. This needs to occur when stocking the system as well as at the point of checking the dispensed medicine.

10.3 Workload and workflow

Adequate time must be allowed to safely and accurately dispense every prescription (see also Guideline 11 *Pharmacists' workloads*).

Arrangements should be in place to minimise distractions during the dispensing process, which can lead to dispensing errors. Pharmacists dispensing medicines need to ensure that the operation of the pharmacy dispensary is such that the risk of errors is minimised to their professional satisfaction.

11 Pharmacists' workloads

Pharmacists should ensure that the individual workloads under which they operate are at reasonable and manageable levels to:

- ensure the safety of the patient
- provide an appropriate pharmacy service in an accurate, professional and timely manner, and
- cope with fluctuations in workflow.

Pharmacist owners and managers are to have in place suitable quality-assurance systems and procedures for the management of pharmacist workload.

Guideline

To support the delivery of an appropriate pharmacy service, pharmacists and their staff should give realistic waiting times to patients for dispensed medicines, and should not impose maximum prescription waiting times.

The Board recommends that if dispensing levels for a pharmacist 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 dispensing 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.

Additional pharmacists or dispensary assistants / technicians may be required:

- to coincide with spikes in activity during specific times, days or months
- depending on the workload created by the types of prescriptions received (e.g. harm-minimisation therapy, cytotoxics, compounded medicines, repeat prescriptions, prescriptions for dose administration aids)
- depending on whether advanced dispensing technologies are available to assist the pharmacist(s)
- to ensure the pharmacy-dispensing model utilised in the pharmacy is successful (e.g. 'forward pharmacy')
- to ensure sufficient staff with suitable experience and familiarity with systems are rostered to work
- to ensure that all dispensing-related responsibilities are met (e.g. counselling, review of the patient's medication history, medication reviews, adherence programs)
- to ensure that other non-dispensing responsibilities are met (e.g. Schedule 3 poisons (Pharmacist Only Medicines), preceptor responsibilities and patients' expectations), or
- to accommodate new initiatives in practice (e.g. pharmacists gathering or verifying information before it is placed in the patient's health record).

The Board acknowledges that pharmacists may be required to dispense above this rate in unforeseen circumstances, such as staff shortage due to sudden illness or unpredicted demand. The Board recognises that in such circumstances pharmacists can take effective short-term measures to deal with the workload while continuing to meet their professional obligations.

The Board refers pharmacists to a resource titled "[Workplace Pressures in Pharmacy: Practical advice for New Zealand pharmacists, pharmacy staff and employers](#)" by the Pharmacy Council of New Zealand, which contains useful guidance on workplace pressures, including workload, that is also relevant to the Australian pharmacy context.

12 Dispensary assistants/dispensary technicians and hospital pharmacy technicians

Pharmacists may be assisted in the preparation, dispensing and supply of medicines, and other tasks in a pharmacy business or pharmacy department, by suitably trained dispensary assistants, dispensary technicians or hospital pharmacy technicians.

For the purposes of these guidelines, 'dispensary assistant / technician' will be used. In different industrial relations circumstances, various terms are used in different awards.

The descriptions, 'dispensary assistant', 'dispensary technician' or 'hospital pharmacy technician' do not apply to a pharmacist, a provisionally registered intern pharmacist or a registered pharmacy student.

Guideline

Pharmacists who are responsible for employing a dispensary assistant / technician in practice must employ or engage suitably trained and experienced individuals to perform under pharmacist supervision, and ensure that the tasks correspond to and are limited to their level of education and training. These responsible pharmacists must comply with the requirements outlined in this guideline and ensure that other pharmacists working with these individuals are also able to comply with the guidance during their course of practice.

12.1 Education and training

When employing dispensary assistants / technicians, pharmacists must ensure that these individuals are able to achieve the certificate qualifications or minimum competencies or other education and training specified in this guideline.

Certificate qualifications

The Australian Qualifications Framework (AQF) provides the standards for nationally recognised qualifications. The following certificate qualifications under the AQF are the current recognised qualifications for dispensary assistants / technicians:

- a. Certificates III and IV in Community Pharmacy from SIR07 the *Retail Services Training Package* (<http://training.gov.au/Training/Details/SIR07>), and
- b. Certificates III and IV in Hospital/Health Services Pharmacy Support from HLT07 the *Health Training Package* (<http://training.gov.au/Training/Details/HLT07>).

(Note: The qualifications from these training packages are updated from time to time).

Where Certificates III and IV are undertaken, these should incorporate the minimum competencies outlined below. As an alternative to requiring dispensary assistants / technicians to complete one of the above full certificate qualifications, pharmacists may also accept the minimum competencies outlined below. Successful completion of the required competencies should be evidenced by a certificate of the qualification, or a statement of attainment of the minimum competencies, which has been issued by the Registered Training Organisation (RTO).

Minimum competencies

When employing dispensary assistants / technicians, pharmacists must ensure that the following essential competencies delivered by RTOs have been achieved or are being achieved by a dispensary assistant / technician in the relevant area of practice (community or hospital practice):

Community practice - Essential competencies (from SIR07 the Retail Services Training Package):

- Support the supply of Pharmacy Medicines and Pharmacist Only Medicines (SIRCHCS201)
- Accept prescriptions and return dispensed medicines to customers (SIRCDIS301)
- Assist in dispensing prescriptions (SIRCDIS303)
- Assist in dispensary stock control (SIRCDIS404)
- Assist in dispensary administration (SIRCDIS405)

Hospital Practice - Essential competencies (from HLT07 the Health Training Package):

- Maintain pharmaceutical imprest stock (HLTPH305A)
- Pack pharmaceutical products (HLTPH307A)
- Procure, store, maintain and distribute pharmaceutical stock (HLTPH315A)
- Assist with dispensing of prescriptions and medication orders (HLTPH316A)

(Note: Essential competencies may be completed as a skill set where identified as such in the relevant Training Package and offered by a training provider).

Additional competencies which may be undertaken

When employing dispensary assistants / technicians, pharmacists must ensure that the following additional competencies have been achieved or are being achieved by a dispensary assistant / technician in the relevant area of practice (community or hospital practice) if involved in supporting pharmacists in these aspects of practice:

Community practice - Additional competencies (from SIR07 the Retail Services Training Package):

- Deliver medicines to customers outside the pharmacy (SIRCDIS302)
- Assist in preparing dose administration aids (SIRCDIS406)
- Assist in preparing extemporaneous prescriptions (SIRCDIS407)
- Coordinate service to patients in residential care settings (SIRCDIS408)

Hospital Practice - Additional competencies (from HLT07 the Health Training Package):

- Conduct small-scale compounding and labelling of pharmaceutical products (HLTPH408A)
- Conduct small-scale compounding and labelling of aseptic pharmaceutical products (HLTPH409A)
- Provide assistance in dispensary administration (HLTPH411A)
- Support pharmacists in the collection and presentation of workplace data and information (HLTPH418A)
- Support pharmacists by collecting information for clients and other health professionals (HLTPH419A)

Recency of education, training and practice

When employing dispensary assistants / technicians, pharmacists must determine whether an individual is appropriately educated, skilled and experienced to perform in the role. This should involve establishing whether, to perform in their role, the individual has:

- sufficient practice experience, and / or
- completed relevant education and workplace training.

The employing pharmacist may determine that to perform in their role, the individual would:

- need to undertake further workplace training, and / or
- need to undertake education (e.g. any of the relevant competencies outlined in this guideline), and / or
- benefit from undertaking part or all of an updated qualification if the individual previously completed education or attained a qualification from a superseded training package under the AQF.

When assessing an individual's completed education (which may include overseas qualifications), training and /or experience, an employing pharmacist may benefit from obtaining information to determine whether previously achieved competencies are equivalent to the competencies in the current certificate qualifications in this guideline. Further advice and expertise may be sought from the RTOs. The assessment of competency should be documented and form part of the individual's training record.

12.2 Assignment of duties

A pharmacist must assign to a dispensary assistant / technician, duties commensurate with the individual's education and training.

The scope of duties that may be assigned by a pharmacist to a dispensary assistant or dispensary technician and articulated in his/her job description is limited by:

- a. the competencies achieved by completion of one of the above listed current or equivalent full qualifications; and
- b. the specific combination of competencies achieved which have been selected from any of the above listed qualifications or equivalent qualifications (achievement of the minimum competencies and if applicable, additional competencies), and/ or
- c. the competencies achieved through completion of an equivalent qualification or through appropriate workplace training and experience.

12.3 Pharmacists' responsibilities during dispensing and supply of medicines and other tasks

A pharmacist must provide direct and personal supervision to a dispensary assistant / technician during the preparation, dispensing and supply of a medicine. As stated in the dispensing process in Guideline 1, the supervising pharmacist is responsible for:

- assessing the appropriateness of the medicines in relation to the medication history (step c in the dispensing process in Guideline 1)
- confirming the required formulation for medicines that have been compounded
- checking the dispensed medicine (step i in the dispensing process in Guideline 1), and
- counselling the patient or the patient's agent and performing the final check (step j in the dispensing process in Guideline 1).

Pharmacists should refer to Standard 5 *Dispensing* of the Pharmaceutical Society of Australia's *Professional Practice Standards* and The Society of Hospital Pharmacists of Australia's *Standards of Practice for Hospital Pharmacy Outpatient Services*.

A pharmacist must not devolve his/her professional responsibilities to a dispensary assistant / technician undertaking a task under his/her supervision.

All relevant State or Territory, and Commonwealth legislation, Pharmacy Board of Australia guidelines and established practice and quality assurance standards are to be met by pharmacists who are supervising dispensary assistants / technicians.

12.4 Supervision ratios

The Board suggests that an individual pharmacist 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. Any alternative supervision ratio must be carefully considered in light of the pharmacist's responsibilities in their practice and must be clearly justified.

13 Patients' rights to choose where to access medicines

Pharmacists must comply with the Board's *Code of conduct for pharmacists*, which applies to the supply of commercially prepared and compounded medicines. The Code states:

Providing good care includes:

- e) *recognising and respecting the rights of patients or clients to make their own decisions.*

Pharmacists must not enter into arrangements for exclusive supply of prescriptions from a health practitioner/prescriber or other third party. Pharmacists may offer to retain prescriptions for subsequent dispensing with the patient's or client's consent.

14 Return of unwanted medicines

Pharmacist owners or managers are encouraged to arrange to accept for safe disposal, unwanted medicines from the public through their pharmacy's participation in available programs, such as the Return of Unwanted Medicines (RUM) project.

Guideline

Pharmacists are referred to the detailed procedures relating to the return and disposal of unwanted medicines, including Schedule 8 poisons (Controlled Drugs), needles, other sharps and cytotoxic products available at www.returnmed.com.au.

Any unwanted medicines are preferably placed immediately in an approved disposal bin that is stored to prevent unauthorised access. Pharmacists must take reasonable steps to ensure that any returned Controlled Drugs are recorded, stored and destroyed in accordance with state or territory legislation.

When a pharmacist collects unwanted medicines from a person's residence (e.g. in the course of a home medication review), the unwanted medicines are to be placed in a suitable interim container (as supplied by the RUM project), before being transferred to a pharmacy for disposal.

Definitions

A **co-regulatory jurisdiction** means a participating jurisdiction in which the National Law declares that the jurisdiction is not participating in the health, performance and conduct process provided by Divisions 3 to 12 of Part 8. Queensland and New South Wales are co-regulatory jurisdictions.

A **compounded medicine** for the purpose of these guidelines, is a therapeutic product that has been extemporaneously prepared and supplied by a pharmacist. For further information, refer to the Board's *Guidelines on compounding of medicines*.

A **dispensary assistant / dispensary technician / hospital pharmacy technician** (referred to as 'dispensary assistant / technician' in these guidelines), is a suitably trained individual who assists a pharmacist in the preparation, dispensing and supply of medicines, and other tasks in a pharmacy business or pharmacy department.

Dose administration aids (DAAs) are defined in a number of documents. For the purposes of these guidelines, a DAA is defined as a device or packaging system for organising doses of medicines according to the time of administration, which assists medication management for a consumer.

Dispensing is the review of a prescription and the preparation, packaging, labelling, record keeping and transfer of the prescribed medicine including counseling, to a patient, their agent, or another person who is responsible for the administration of the medicine to that patient (see Guideline 1 *The dispensing process*).

Health record is a record of information relevant to a patient's health, including clinical history, clinical findings, investigations, information given to the patient, their medication and other management. The record may be held electronically and/or in hard copy.

Practice means any role, whether remunerated or not, in which the individual uses their skills and knowledge as a pharmacist in their profession. For the purposes of these guidelines, practice is not restricted to the provision of direct clinical care. It also includes working in a direct non-clinical relationship with clients; working in management, administration, education, research, advisory, regulatory or policy development roles; and any other roles that impact on safe, effective delivery of services in the profession.

Registered training organisation means an educational organisation in Australia that provides students with training that results in qualifications and statements of attainment that are recognised and accepted by industry and other educational institutions throughout Australia.

Scope of practice means the professional role and services that an individual health practitioner is educated and competent to perform.

A **supervising pharmacist** is a pharmacist holding general registration who is responsible for the direct and personal supervision of a dispensary assistant or dispensary technician in their allocated tasks in this role.

References

Australian Privacy Principles (APPs) contained in schedule 1 of the *Privacy Act 1988*
Pharmacy Board of Australia *Guidelines on compounding of medicines*

Pharmacy Board of Australia *Guidelines on dose administration aids and staged supply of dispensed medicines*

Pharmacy Board of Australia *Code of conduct for pharmacists*

Pharmacy Council of New Zealand *Workplace Pressures in Pharmacy: Practical advice for New Zealand pharmacists, pharmacy staff and employers*

Review

These guidelines will be reviewed at least every five years.

Last reviewed: XXXX

These guidelines replace the previously published guidelines from XXXX

Overview

6 March 2015

Review of the *Guidelines on practice-specific issues*

Summary of issue

The National Law outlines that a Board may develop guidelines to provide guidance to the health practitioners it registers, or about any other matters relevant to the exercise of its functions.

The Board's current *Guidelines on practice-specific issues* were developed to outline the Board's expectations of pharmacists in relation to a range of practice-specific issues not set out in legislation or a registration standard, with particular reference to drugs of abuse, which is in the public's interest.

Guideline 1 Reference texts for pharmacists requires pharmacists to have access to contemporary works of professional reference. It refers to a list of essential references to be readily accessed by pharmacists, which is published on the Board's website separate to the guidelines. The Board is reviewing this list of references to ensure it is up-to-date and appropriate to support pharmacists in their practice. The publication of the list separate from the *Guidelines on practice-specific issues* enables the Board to review the list of references and undertake further and timely consultation as required.

The Board is reviewing the current guidelines to ensure they meet the objectives of the National Law and are worded as simply and clearly as possible.

Options statement

The Board has considered a number of options in developing this proposal.

Option 1 – Status quo

Option 1 would continue with the existing guidelines. These guidelines outline the Board's expectations in relation to a range of practice-specific issues. The Board has identified a range of opportunities to improve the current guidelines, including the ability to clarify the language and structure to make them easier to understand, and to update the list of reference texts for pharmacists.

Option 2 – Proposed revised guidelines

Option 2 would involve the Board publishing revised *Guidelines on practice-specific issues*. The revised guidelines would continue to outline the Board's expectations in relation to a range of practice-specific issues, with no substantive changes.

The revised guidelines include an updated list of reference texts for pharmacists. The following changes are proposed:

- inclusion of the *AMH Children's dosing companion* in place of 'a current paediatric reference available from an Australian source (including a teaching hospital)', because the primary reference previously utilised by pharmacists in this category, the *Royal Children's Hospital (RCH) Pharmacopoea*, is no longer published
- addition of the *SHPA Australian don't rush to crush handbook*
- addition of MIMS Online as an alternative source of current Australian product information and consumer medicine information
- a revised list of 'an evidence-based reference work on complementary and alternative medicines', with removal of e-MIMS and AusDI from this list, and inclusion of a larger range of options, based on results of the National Prescribing Service *Review of the Quality of Complementary Medicines Information Resources* published in March 2009

http://www.nps.org.au/_data/assets/pdf_file/0005/69656/CMsInfoSummary.pdf). One of the proposed options is available free online.

The revised guidelines provide the following guidance, which differs from the guidance provided in the current guidelines:

- Guideline 3 *Pseudoephedrine* – the revised guidelines state that stock levels of pseudoephedrine should be minimal. The current guidelines specifically state that no more than one week's supply should be kept.
- Guideline 4 *Supply of Schedule 2 poisons (pharmacy medicines) and Schedule 3 poisons (pharmacist only medicines)* - the revised guidelines state that caution should be exercised when considering requests for supply of multiple packages. The current guidelines specifically state that only one package is to be supplied at a time, except in exceptional circumstances.

The revised guidelines provide additional guidance on the provision of complementary and alternative medicine and accompanying advice in a pharmacy. They also have clearer wording and structure to make them easier to understand.

Preferred option

The Board prefers Option 2.

Issues for discussion

Potential benefits and costs of the proposal

The benefits of the preferred option are that the draft revised guidelines:

- provide additional guidance on the provision of complementary and alternative medicine and accompanying advice in a pharmacy
- provide an updated list of reference texts for pharmacists
- are user-friendly
- strike a balance between protecting the public and impact on pharmacists
- have been reworded to be simpler and clearer.

The costs of the preferred option are:

- pharmacists will need to become familiar with a new list of reference texts, and pharmacy owners will need to ensure that any new references are provided
- pharmacists, other stakeholders, AHPRA and National Boards will need to become familiar with a new set of guidelines
- there will likely need to be a period of transition to the two new sets of guidelines, however the nature of the changes are anticipated not to give rise to difficulty in meeting the proposed requirements.

Estimated impacts of the draft revised guidelines

The changes proposed in the draft revised guidelines are relatively minor, although more significant changes may be proposed through consultation. There is little impact anticipated on practitioners, business and other stakeholders arising from the changes proposed.

Relevant sections of the National Law

Relevant sections of the National Law relating to the guidelines (and summarised above) are:

- Section 35, and
- Section 39.

Questions for consideration

The Board is inviting feedback on the following questions.

- From your perspective, how are the current *Guidelines on practice specific issues* working?
- Is the content and structure of the draft revised guidelines helpful, clear, relevant and more workable than the current guidelines?
- Is there any content that needs to be changed or deleted in the draft revised guidelines?
- Is there anything missing that needs to be added to the draft revised guidelines?
- Do you have any other comments on the draft revised guidelines?
- Do you think that the proposed review period of five years, with the option to review earlier if the need arises, is appropriate?

The proposed revised *Guidelines on practice specific issues* are included on page 27 of this consultation paper.

The current *Guidelines on practice specific issues* is published on the Board's website, accessible from www.pharmacyboard.gov.au/Codes-Guidelines.aspx.

Attachments

The *Statement of assessment against AHPRA's Procedures for development of registration standards and COAG principles for best practice regulation* is at [Attachment 1](#).

Draft revised Guidelines on practice-specific issues

Effective from: <<date>>

Review date: <<date>>

Contents

Introduction

Who needs to use these guidelines?

What happens if I do not comply with these guidelines?

Summary of guidelines

Guidelines

1. Reference texts for pharmacists
2. Drugs of abuse
3. Pseudoephedrine
4. Supply of Schedule 2 poisons (Pharmacy Medicines) and Schedule 3 poisons (Pharmacist Only Medicines)
5. Complementary and alternative therapy when practised by pharmacists
6. Allied health, and complementary and alternative therapy when practised by other persons in the pharmacy
7. Screening and risk assessment
8. Raw materials not approved for human use in medicines
9. Supply of tobacco and alcohol products

Definitions

References

Review

Introduction

These guidelines have been developed by the Pharmacy Board of Australia (the Board) under section 39 of the Health Practitioner Regulation National Law, as in force in each state and territory (the National Law). They provide guidance to pharmacists in relation to a range of practice-specific issues not set out in legislation or a registration standard.

Note: As part of the agreement by the Council of Australian Governments to provide for the National Law, pharmacy ownership, regulation of premises, inspections and related matters do not form part of the National Law. Each jurisdiction will have separate legislation and guidelines for these purposes.

Who needs to use these guidelines?

These guidelines were developed to provide guidance to registered pharmacists or those seeking to become registered pharmacists. They apply to all pharmacists holding the following types of registration:

- general
- provisional, or
- limited.

These guidelines do not apply to pharmacists holding non-practising registration or to students. However, students should become familiar with these guidelines prior to undertaking supervised practice placements.

What happens if I do not comply with these guidelines?

Pharmacists must comply with all legislation relevant to the practice of pharmacy in the jurisdiction where the practice occurs. Additionally, pharmacists are expected to be aware of and comply with the profession's standards and guidelines (including any other standards or guidelines referred to in those documents), as relevant to their scope of practice and type of registration. The pharmacy practice standards and guidelines can be accessed on the website of the relevant professional bodies:

- Pharmaceutical Society of Australia (PSA) (www.psa.org.au), and
- The Society of Hospital Pharmacists of Australia (The SHPA) (www.shpa.org.au).

Non-compliance with these guidelines and the relevant practice standards and guidelines may be notified to the Board for appropriate action under the National Law. Under section 41 of the National Law, these guidelines can be used in disciplinary proceedings under the National Law or law of a co-regulatory jurisdiction as evidence of what constitutes appropriate professional conduct or practice for pharmacists. When considering notifications (complaints) against pharmacists, the Board will give consideration to whether a breach of these guidelines has taken place. The Board will also have regard to the legislation and practice standards and guidelines relevant to pharmacy practice.

Further information for pharmacists regarding the possible outcomes of notifications is available on the website of the Australian Health Practitioner Regulation Agency (AHPRA) (www.ahpra.gov.au).

Summary of guidelines

These guidelines address various pharmacy practice matters, including those which relate to specific services provided by some pharmacists or at some pharmacies. Particular reference is made to drugs of abuse. As patterns of drug abuse change over time, the content of these guidelines is expected to be revised as needed.

Guidelines

1 Reference texts for pharmacists

Access to contemporary references is essential to the practice of pharmacy.

On its website the Board provides an up-to-date list of essential references for pharmacists (document titled: *Guidelines on practice-specific issues – Guideline 1 (List of Reference texts for pharmacists)*). This list includes the primary reference the *Australian Pharmaceutical Formulary and Handbook* which contains Internet addresses on a wide variety of subjects. The list also includes Australian Commonwealth, state and territory acts and regulations, and a number of additional references, which are accessible free of charge on the Internet.

Guideline

Pharmacists must be able to readily access contemporary works of professional reference in either conventional or electronic forms. The information is to be immediately available to the pharmacist during the clinical assessment, reviewing, dispensing and counselling processes.

In addition to accessing the references listed in these guidelines during the clinical assessment, reviewing, dispensing and counselling processes, pharmacists should use additional references specific and relevant to their scope of practice (refer to the Board's *Guidelines on compounding of medicines* for examples of additional reference texts for compounding pharmacists). Consideration should also be given to accessing reference material which provides information in the Australian context. At any one time, pharmacists may need to use more than one reference to ensure that all current and relevant information is accessed.

While it is the pharmacy owner's responsibility to provide the resources, it is the responsibility of the pharmacist to ensure prescribed references are readily available and accessed when required. As part of the premises approval process, the state or territory pharmacy premises authority or responsible body may prescribe particular references in addition to those shown on the Board's website.

2 Drugs of abuse

As part of their continuing professional development, pharmacists are expected to have a contemporary knowledge of the drugs that are subject to abuse or misuse, both generally and in their own localities.

Guideline

Keeping abreast of the Australian professional literature and the public media relating to drugs of abuse, and engagement with colleagues, is strongly recommended.

Requests for drugs to which this guideline relates are to be treated circumspectly because of manipulative behaviour on the part of drug seekers. A genuine therapeutic need is to be established by careful questioning. A pharmacist supplying potential drugs of abuse to a patient must comply with all relevant state or territory, and Commonwealth legislation, Pharmacy Board of Australia *Guidelines for dispensing of medicines*, and established practice standards and guidelines.

Evidence of any developing trend in the use of drugs of abuse should be communicated to the authorities, such as the state or territory health authority, and to colleagues and professional bodies, for example a notable increase in the presentation of prescriptions for a particular medicine subject to abuse.

3 Pseudoephedrine

Pseudoephedrine is used as a precursor in the illicit manufacture of amphetamines. It is extracted from products in which pseudoephedrine is the sole active ingredient or is one of several active ingredients. Additional obligations, which vary between states and territories, apply to pharmacists when responding to requests for pseudoephedrine-containing products.

Guideline

Requests for pseudoephedrine are to be treated cautiously to limit the risk of the product being diverted for illicit use / manufacture. A genuine therapeutic need is to be established by careful questioning, including when requested on prescription.

Only one proprietary pack is to be supplied at a time unless there are exceptional circumstances clearly demonstrated by the customer or communicated by the prescriber, additional documentation of which should be kept. The sale of multiple packs of pseudoephedrine-containing products (other than in exceptional circumstances and when appropriately prescribed by an authorised prescriber) and failure to comply with the local regulations applying to Schedule 3 poisons (Pharmacist Only Medicines) and these guidelines may be considered as unprofessional conduct.

Stock levels should be minimal in accordance with the sales history of the pharmacy and any relevant security issues. Bulk supplies should be avoided and any reserve stock kept out of public view.

The Board endorses the use of a real-time online monitoring system (e.g. Project STOP), as a means of assisting the pharmacist in determining whether pseudoephedrine should be supplied when a person requests it, noting that this may also involve communicating suspicious requests to the section of the police that deals with drug crimes. All purchases, including those on prescription, should be entered on this system.

4 Supply of Schedule 2 poisons (Pharmacy Medicines) and Schedule 3 poisons (Pharmacist Only Medicines)

In addition to any statutory requirements, the Board has regard to the *Standards for the Provision of Pharmacy Medicines and Pharmacist Only Medicines in Community Pharmacy* (produced by the Pharmaceutical Society of Australia) and any substance-specific protocols and quality-assurance standards.

Guideline

Staff members need to be trained to ask specific questions of intending purchasers of Pharmacy Medicines and Pharmacist Only Medicines. This should include (but is not limited to) questioning the purchaser about other medication they are taking, including complementary and alternative medicine. Any queries relating to

Pharmacy Medicines or unscheduled medicines that arise from the person's response should be referred to a pharmacist. All requests relating to Pharmacist Only Medicines must be referred to a pharmacist.

Pharmacists are reminded that particular statutory obligations relating to the supply of Pharmacist Only Medicines must be observed. The pharmacist must be satisfied that there is a therapeutic need. This means more than agreeing to supply the medicine on request, or merely asking patients if they have used the medicine previously and know how to use it.

Only one proprietary pack is to be supplied at a time of Pharmacy Medicines and Pharmacist Only Medicines, unless there are exceptional circumstances clearly demonstrable by the customer, additional documentation of which should be kept. Caution should be exercised when considering requests for supply of multiple packages, particularly for drugs subject to abuse or misuse, for example codeine-containing products and products containing pseudoephedrine (also refer to Guideline 3 Pseudoephedrine). Failure to comply with local jurisdiction regulations applying to Pharmacy Medicines and Pharmacist Only Medicines and these guidelines may be considered as unprofessional conduct.

5 Complementary and alternative medicines

Pharmacists and their staff may supply complementary and alternative medicine and accompanying advice in the ordinary course of pharmacy practice, which does not imply that the pharmacist is practising as a complementary or alternative medicine practitioner. A pharmacist may also hold an additional qualification to practise as a complementary or alternative medicine practitioner, as separate and distinct from their practice as a pharmacist.

Guideline

When complementary or alternative medicine is provided at a pharmacy, pharmacists should provide products of proven safety and quality. Relevant accompanying advice should be offered to assist patients in making a well informed choice regarding treatment with a complementary or alternative medicine, which should include available information on the potential benefits and harms, and whether there is sufficient evidence to support its proposed use. Where appropriate, pharmacists should incorporate details of the supply of complementary or alternative medicines in the dispensing record and where possible, in the patient's health record.

A pharmacist who is also a complementary or alternative medicine practitioner may provide these services in a pharmacy. When consulting clients privately in this capacity, this should be done:

- in a room that is separate from the dispensary, general trading and professional services areas, and where required by law, approved by the state or territory pharmacy premises authority
- in accordance with state and territory regulatory requirements, and
- while another pharmacist is in charge of the pharmacy.

6 Allied health, and complementary and alternative therapy when practised by other persons in the pharmacy

An allied health practitioner or complementary or alternative medicine therapist may practise in a pharmacy premises as either an employee of the pharmacy business, or as a practitioner working independently under a leasing arrangement with the pharmacy business subject to state or territory pharmacy authority approval.

Guideline

If an allied health practitioner or complementary or alternative medicine therapist practises in a pharmacy as an employee of the pharmacy business, the activities and services provided must complement the role of the pharmacist and should be provided by suitably qualified practitioners. Proprietors and individual pharmacists supervising pharmacy employees are responsible for the dispensing of complementary or alternative medicine and any accompanying advice provided by the employees of the pharmacy business.

Pharmacists must ensure that allied health practitioners and complementary or alternative medicine therapists who are employees of a pharmacy business do not:

- compound or otherwise dispense any medicines at the pharmacy, or
- use any dispensing labels relating to the pharmacy.

Where appropriate, pharmacists should incorporate details of the supply of complementary or alternative medicines in the dispensing record and where possible, in the patient's health record. Separate records of the supply must not be kept by employees of the pharmacy.

In the case where a pharmacist rents or leases consulting rooms in a pharmacy to an allied health practitioner or complementary or alternative medicine therapist subject to any state or territory pharmacy authority approval, that person may not be an employee of the pharmacy business and must use labels unrelated to those of the pharmacy.

7 Screening and risk assessment

This guideline relates to pharmacists providing in-pharmacy health screening.

Guideline

Pharmacists who conduct screening and risk assessment tests are expected to follow established practice and quality-assurance standards, including the relevant guidelines issued by professional associations and state or territory pharmacy premises authorities.

8 Raw materials not approved for human use in medicines

Manufacturers of analytical reagents (ARs) do not usually sanction the use of their products for therapeutic use, despite the implicitly high level of purity.

Guideline

Pharmacists should only supply or use after careful consideration, chemicals and other substances for therapeutic purposes that have not been approved by Australian health authorities for use in humans. When pharmacists use such substances in a medicine, it is prudent to keep records of the supply to and from the pharmacy (also refer to the Board's *Guidelines on compounding of medicines*).

Pharmacists are reminded of their obligation to comply with any state and territory requirements in relation to raw materials.

9 Supply of tobacco and alcohol products

Guideline

The sale or supply of tobacco products, alcoholic beverages, home brewing or alcohol distilling kits by a pharmacist is inconsistent with the practice of pharmacy and is considered as unprofessional conduct within the meaning of the National Law.

Definitions

A **co-regulatory jurisdiction** means a participating jurisdiction in which the National Law declares that the jurisdiction is not participating in the health, performance and conduct process provided by Divisions 3 to 12 of Part 8. Queensland and New South Wales are co-regulatory jurisdictions.

Practice means any role, whether remunerated or not, in which the individual uses their skills and knowledge as a pharmacist in their profession. For the purposes of these guidelines, practice is not restricted to the provision of direct clinical care. It also includes working in a direct non-clinical relationship with clients; working in management, administration, education, research, advisory, regulatory or policy development roles; and any other roles that impact on safe, effective delivery of services in the profession.

Scope of practice means the professional role and services that an individual health practitioner is educated and competent to perform.

Unprofessional conduct, as defined in the National Law, means professional conduct that is of a lesser standard than that which might reasonably be expected of a health practitioner by the public or a practitioner's professional peers.

References

Pharmacy Board of Australia *Guidelines for dispensing of medicines*

Review

These guidelines will be reviewed at least every five years.

Last reviewed: XXXX

These guidelines replace the previously published guidelines from XXXX

Draft revised Guidelines on practice-specific issues – Guideline 1 (List of Reference texts for pharmacists)

Effective from: <<date>>

Review date: <<date>>

1 Reference texts for pharmacists

The following is the list of reference texts for pharmacists referred to in Guideline 1 of the Board's *Guidelines on practice-specific issues*.

Current editions of the following references in the form of a published document (hard copy) or via electronic means, such as computer, must be readily accessible and should be accessed by pharmacists during the clinical assessment, reviewing, dispensing and counselling processes:

- a) **the Australian Pharmaceutical Formulary and Handbook (APF)**
- b) **the Australian Medicines Handbook (AMH)**
- c) **Therapeutic Guidelines series (the complete set in hardcopy) or eTG**
- d) **a source of current Australian product information and consumer medicine information**
 - MIMS Annual with MIMS Abbreviated
 - e-MIMS
 - MIMS Online, or
 - AusDI Advanced/AusDI.
- e) **a Drug interactions reference (updated at least quarterly)**
 - AusDI Advanced/AusDI
 - Drug Interaction Facts – Facts and Comparisons
 - Drug interactions Analysis and Management, Hansten and Horn
 - eMIMS
 - MIMS Online
 - Micromedex
 - Stockley's Drug Interactions Online, or
 - Lexicomp Interactions.
- f) **the AMH Children's Dosing Companion**
- g) **the Australian Don't Rush to Crush Handbook**
- h) **an evidence-based reference work on complementary and alternative medicines**
 - Herbs and Natural Supplements: An evidence-based guide. Braun and Cohen
 - Herbal Medicines. Barnes, Anderson and Phillipson
 - Herbal Medicines and Dietary Supplements package (each resource can be independently accessed through MedicinesComplete)

- MedlinePlus: Drugs, Supplements, and Herbal Information (available free online)
- Natural & Alternative Treatments: EBSCO
- Natural Medicines Comprehensive Database (Health professional edition)
- Natural Standard Professional Database (bottom line monographs)
- Natural Standard Professional Database (professional monographs), or
- Natural Standard Professional Database package (includes access to all levels of monographs).

The following can be accessed electronically via websites:

i) copies of the legislation controlling the practice of pharmacy (can be accessed at www.comlaw.gov.au):

- the Health Practitioner Regulation National Law, as in force in each state and territory (the National Law)
- Drugs, medicines and poisons legislation
- Standards, codes and guidelines relevant to pharmacy practice for each jurisdiction (including information published by relevant government departments and jurisdictional pharmacy premises regulatory authorities)
- Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP)

j) the Australian Immunisation Handbook

k) the professional practice standards and guidelines published by the Pharmaceutical Society of Australia (PSA) and The Society of Hospital Pharmacists of Australia (SHPA)

l) the Pharmacy Board of Australia guidelines

m) the Merck Manual of Diagnosis and Therapy

(Merck Sharp and Dohme)

Review

These guidelines will be reviewed at least every five years.

Last reviewed: XXXX

These guidelines replace the previously published guidelines from 1 July 2010 (or XXXX)

Overview

6 March 2015

Review of the *Guidelines on specialised supply arrangements*

Summary of issue

The National Law outlines that a Board may develop guidelines to provide guidance to the health practitioners it registers, or about any other matters relevant to the exercise of its functions.

The Board's current *Guidelines on specialised supply arrangements* were developed to outline the Board's expectations in relation to arrangements for the specialised supply of medicines to patients.

The Board is reviewing the current guidelines to ensure they meet the objectives of the National Law and are worded as simply and clearly as possible.

Options statement

The Board has considered a number of options in developing this proposal.

Option 1 – Status quo

Option 1 would continue with the existing guidelines. These guidelines outline the Board's expectations in relation to arrangements for the specialised supply of medicines to patients. The Board has identified a range of opportunities to improve the current guidelines, including the ability to clarify the language and structure to make them easier to understand.

Option 2 – Proposed revised guidelines

Option 2 would involve the Board publishing revised *Guidelines on dose administration aids and staged supply of dispensed medicines*. The revised guidelines would continue to outline the Board's expectations in relation to arrangements for the supply of medicines to patients in these circumstances, with minor changes.

The revised guidelines include a change of title of the guidelines from *Guidelines on specialised supply arrangements* to *Guidelines on dose administration aids and staged supply of dispensed medicines* as this reflects the content of the guidelines. They provide additional guidance on the labelling of dose administration aids (DAAs). The revised guidelines propose that, in the case where both the active ingredient name and brand name do not fit on the DAA label due to space limitations, one name can be included on the DAA label. The revised guidelines propose that in these circumstances, additional information should be provided by the pharmacist, for example a current medication chart, which ensures that patients and their carer(s) have access to both the active ingredient name and brand name of all medicines packed into a DAA. The revised guidelines also propose that a pharmacist may initiate periodic administration of a dispensed medicine without instruction from a prescriber, and include a new guideline which provides guidance about the supply of cytotoxic medications in DAAs.

The revised guidelines have clearer wording and structure to make them easier to understand.

Preferred option

The Board prefers Option 2.

Issues for discussion

Potential benefits and costs of the proposal

The benefits of the preferred option are that the draft revised guidelines:

- have a new title which better reflects the content of the guidelines

- provide additional guidance on the labelling of DAAs, the initiation of periodic administration of a dispensed medicine, and a new guideline on the supply of cytotoxic medications in DAAs
- are user-friendly
- strike a balance between protecting the public and impact on pharmacists
- have been reworded to be simpler and clearer.

The costs of the preferred option are:

- pharmacists, other stakeholders, AHPRA and National Boards will need to become familiar with a new sets of guidelines
- there will likely need to be a period of transition to the two new sets of guidelines.

Estimated impacts of the draft revised guidelines

The changes proposed in the draft revised guidelines are relatively minor, although more significant changes may be proposed through consultation. There is little impact anticipated on pharmacists, pharmacy business and other stakeholders arising from the changes proposed.

Relevant sections of the National Law

Relevant sections of the National Law relating to the guidelines (and summarised above) are:

- Section 35, and
- Section 39.

Questions for consideration

The Board is inviting feedback on the following questions.

- From your perspective, how are the current *Guidelines on specialised supply arrangements* working?
- Is the content and structure of the draft revised guidelines helpful, clear, relevant and more workable than the current guidelines?
- Is there any content that needs to be changed or deleted in the draft revised guidelines?
- Is there anything missing that needs to be added to the draft revised guidelines?
- Do you have any other comments on the draft revised guidelines?
- Do you think that the proposed review period of five years, with the option to review earlier if the need arises, is appropriate?

The current *Guidelines on specialised supply arrangements* is published on the Board's website, accessible from <http://www.pharmacyboard.gov.au/Codes-Guidelines.aspx>.

The proposed revised *Guidelines on dose administration aids and staged supply of dispensed medicines* and are included on page 37 of this consultation paper.

Attachments

The *Statement of assessment against AHPRA's Procedures for development of registration standards and COAG principles for best practice regulation* is at [Attachment 1](#).

Draft revised Guidelines on dose administration aids and staged supply of dispensed medicines⁵

Effective from: <<date>>

Review date: <<date>>

Contents

Introduction

Who needs to use these guidelines?

What happens if I do not comply with these guidelines?

Summary of guidelines

Guidelines

1. Dose administration aids
2. Staged supply

Definitions

References

Review

Introduction

These guidelines have been developed by the Pharmacy Board of Australia (the Board) under section 39 of the Health Practitioner Regulation National Law, as in force in each state and territory (the National Law). They provide guidance to pharmacists in relation to the supply of medicines to patients using dose administration aids and the staged supply of dispensed medicines.

Note: As part of the agreement by the Council of Australian Governments to provide for the National Law, pharmacy ownership, regulation of premises, inspections and related matters do not form part of the National Law. Each jurisdiction will have separate legislation and guidelines for these purposes

Who needs to use these guidelines?

These guidelines were developed to provide guidance to registered pharmacists or those seeking to become registered pharmacists. They apply to all pharmacists holding the following types of registration:

- general
- provisional, or
- limited.

These guidelines do not apply to pharmacists holding non-practising registration or to students. However, students should become familiar with these guidelines prior to undertaking supervised practice placements.

What happens if I do not comply with these guidelines?

Pharmacists must comply with all legislation relevant to the practice of pharmacy in the jurisdiction where the practice occurs. Additionally, pharmacists are expected to be aware of and comply with the profession's standards and guidelines (including any other standards and guidelines referred to in those

⁵ Currently titled *Guidelines on specialised supply arrangements*

documents), as relevant to their scope of practice and type of registration. The pharmacy practice standards and guidelines can be accessed on the website of the relevant professional bodies:

- Pharmaceutical Society of Australia (PSA) (www.psa.org.au), and
- The Society of Hospital Pharmacists of Australia (The SHPA) (www.shpa.org.au).

Non-compliance with these guidelines and the relevant practice standards and guidelines may be notified to the Board for appropriate action under the National Law. Under section 41 of the National Law, these guidelines can be used in disciplinary proceedings under the National Law or law of a co-regulatory jurisdiction as evidence of what constitutes appropriate professional conduct or practice for pharmacists. When considering notifications (complaints) against pharmacists, the Board will give consideration to whether a breach of these guidelines has taken place. The Board will also have regard to the legislation and practice standards and guidelines relevant to pharmacy practice.

Further information for pharmacists regarding the possible outcomes of notifications is available on the website of the Australian Health Practitioner Regulation Agency (AHPRA) (www.ahpra.gov.au).

Summary of guidelines

These guidelines were developed in recognition of the increased demand for dose administration containers and, where used in association with them, automated dose packaging systems. Also addressed is advice on dealing with the supply of medicines to be issued periodically.

Guidelines

1 Dose administration aids

Pharmacists may provide dose administration aids (DAAs) for selected patients to assist in the safe and effective administration of a patient's medicines and to enhance compliance. In addition to the Board's *Guidelines for dispensing of medicines*, the Board has regard to established practice and quality assurance standards, including the DAA service standards and guidelines issued by the Pharmaceutical Society of Australia, and The Society of Hospital Pharmacists of Australia *SHPA Standards of Practice for the Provision of Oral Chemotherapy for the Treatment of Cancer*. These standards should be considered as part of the process of determining whether the provision of a DAA to a patient is appropriate.

Guideline

Medicines which are requested to be packed into a DAA must, prior to packing, be dispensed in accordance with any statutory provisions and in accordance with these guidelines.

1.1 Packing of DAAs

The packing of DAAs is repetitive, yet it requires close and systematic concentration to minimise the risk of error. The role may be delegated to suitably trained pharmacy students, interns and dispensary assistants / technicians, and the work subjected to checking by a pharmacist.

Sufficient space and time, freedom from interruption and good lighting are necessary for safe performance of the task. The area where the work is carried out must be clean, tidy and orderly. Adequate breaks are necessary owing to the mechanistic nature of the task.

The ability to review the patient's current medication regimen and medication history is essential, and pharmacists need to consider the stability and safety of medicines being packed in a DAA and identify those not suitable for packing in a DAA.

Tablets and capsules should be distributed into the compartments in such a way as to prevent physical incompatibilities between medicines, and contamination of the medicines being packed, as well as that of the local environment, so as not to pose any health or safety risks to the person doing the packing, other staff, patients and their carers (also refer to Guideline 1.4 *Packing oral cytotoxic medicines into DAAs*). Appropriate hygiene procedures need to be followed prior to, during and following the packing process.

Components of a DAA that are reusable should be maintained in a clean condition, suitable for use with medicines.

When Schedule 8 poisons (Controlled Drugs) are included in a DAA, pharmacists must ensure that the storage of such medicines is in accordance with any state or territory requirements.

1.2 Labelling of DAAs

The label on the DAA should maximise compliance, promote usability and minimise error associated with administration of the patient's medicines. It should also support the patient or carer's understanding of the dosing regimen and include suitable information to minimise adverse effects.

The label should include:

- the name of the patient
- the name, address and telephone number of the pharmacy
- the name, strength and dose form of each of the medicines
- the directions for use for each of the medicines
- any required cautionary and advisory labels for the medicines as outlined in the current edition of the *Australian pharmaceutical formulary and handbook*
- the date of packing and the expiry date of the DAA
- the words 'Keep out of reach of children', and
- any other requirement as outlined in state or territory legislation.

Best practice is to include both the active ingredient and brand name on the label. When circumstances necessitate, such as space limitations, the active ingredient/Australian approved name should be included, and where there is insufficient space for this, the brand name only can be used.

In the case where only one name is included on the label, additional information should be provided to the patient and/or their carer(s) to ensure access to the active ingredient and brand name of all medicines packed into the DAA, for example through provision of a current medication list at every change of medication or brand of medication.

The DAA label and medication list, if provided, should be clearly and legibly printed in unambiguous and understandable English. Where space permits, other languages that are accurate translations of the English may be used in addition to English.

In appropriate circumstances, a photograph of the patient may be attached to the DAA. Where cautionary and advisory labels are needed, these can be attached directly to the DAA or provided on a separate sheet such as the medication list (where provided). Pharmacists should give consideration to whether additional information such as patient allergies or medications taken by the patient that are not included in the DAA, should be included on the DAA label or provided as ancillary information. A product identification option to assist nurses and carers is recommended, such as a coloured picture or description of each medicine in the DAA.

1.3 Checking of DAAs

A packed DAA must be checked by a pharmacist before it is supplied to a patient, to ensure that it has been packed accurately and is in accordance with the patient's current medication regimen. Pharmacists should exercise vigilance when undertaking this important task, which is as important as the check of any individually dispensed medicine. Sufficient time without interruption should be dedicated to undertaking this important task.

1.4 Records of DAA packing

A record of each packing should be generated under the patient's name showing:

- the date of packing
- the initials of the person who packed it, those of the pharmacist who checked it (if not packed by a pharmacist), those of the person who handed out the pack
- each medicine's name, form, strength, dose, expiry date and batch number, and

- the quantity of a patient's medication that remains after packing.

The packing record should be retained for at least six months.

Procedures should be established to indicate how changes of medication, dose or frequency are recorded.

1.5 Packing oral cytotoxic medicines into DAAs

An oral cytotoxic medicine should only be packed into a DAA if there is evidence that the benefit of improved patient compliance from using a DAA outweighs the risk of exposure to the cytotoxic medicine when taking or administering the medicine from a DAA or when packing the DAA. This risk assessment should include discussion with the patient and/or their carer to assess their ability to administer the medication correctly and safely from the chosen container, in accordance with the prescriber's instructions.

Given the narrow therapeutic index of cytotoxic medicines and the risk of death from incorrect dosing, extra vigilance must be exercised when dispensing and packing these medicines into DAAs. For these reasons, the Board advises pharmacists that:

- other non-cytotoxic medicines for a patient must not be placed in the same DAA, and
- the DAA containing the cytotoxic medicine must be labelled with a cytotoxic warning label in addition to all other information required when labelling a DAA.

The packing of cytotoxic medicines into DAAs should be undertaken by a pharmacist, or if circumstances require, by a suitably trained pharmacy student, intern or dispensary assistant after which the DAA must be checked by a pharmacist. This should be undertaken in a suitable environment using suitable equipment, systems and techniques to minimise direct exposure to these medicines, as outlined in the practice standards.

1.6 Automated dose packaging systems

Automated dose packaging systems may be used to prepare and pack medicines into single and multi-dose packaging for use by patients.

Pharmacists who use automated dose packaging machines must ensure:

- there is a cleaning and maintenance protocol that is adhered to
- testing is carried out at the start of each day and at any other time, as may be operationally required
- any person using the machine has received initial and ongoing training in its use
- the machine is operated in a clean environment away from the dispensing bench and the dispensing computer, and where the temperature is controlled by an air conditioner to ensure the temperature is below 25 degrees Celsius
- the patient's right to privacy is understood and the patient or agent must consent if a third party is involved in the packing of the dose administration container
- the labelling of the container in which any strip packs are placed meets any statutory requirements and the Board's guidelines
- the records maintained at the pharmacy include the batch number, the expiry date, the packing date and the initials of the pharmacist, pharmacy student, intern or dispensary assistant who is responsible (*note: if someone other than a pharmacist packs the container, the pharmacist must also initial the packing after checking*)
- there is a written procedure describing the use of the machines, including maintenance and error records, and
- there is a written quality assurance program that includes the refilling of bulk canisters.

1.7 Packing by a third-party

A pharmacist may engage the services provided by another pharmacy or a packing facility licensed by the Therapeutic Goods Administration (TGA) to pack a DAA on their behalf.

The supply pharmacist (who supplies the DAA to the patient or their agent) is responsible for ensuring the packing pharmacist has accurate details of the medicines to be packed, as well as being responsible for

the quality use of medicines support for the patient. The supply pharmacist should also maintain a record of the date of supply of the DAA to the patient. The packing pharmacist is responsible for ensuring packs are prepared in a timely and accurate manner according to the current medication regimen.

If a DAA is prepared at a third-party packing facility, the supply pharmacist cannot delegate their professional responsibilities to individuals at that facility. It is the supply pharmacist who is ultimately responsible for all aspects of the supply of DAAs, including accuracy of the DAA, and provision of the DAA and accompanying medicines' information to the patient or their agent. The direct supply of the DAA to the patient or their agent from the third-party packing facility should not take place, as it precludes the supply pharmacist from being able to fulfill these professional responsibilities.

A packing pharmacist who uses an automated dose packaging system to pack sachets or similar packs on behalf of a supply pharmacist may need licensing by the Therapeutic Goods Administration in jurisdictions that have laws to complement the *Therapeutic Goods Act 1989* (Cth).

2 Staged supply

Staged supply is the process by which pharmacists supply medicine to a patient in periodic instalments of less than the originally prescribed quantity, at agreed time intervals. The balance of the medicine is held by the pharmacy to fulfil subsequent instalments. This service can be initiated by the pharmacist, the prescriber, the patient or their agent, or another health professional involved in the care of the patient⁶.

Staged supply should be in accordance with any state and territory regulations.

Guideline

The staged supply of medicines, including methadone and buprenorphine, should be provided in accordance with the prescriber's request (when initiated by a prescriber), state or territory regulations and guidelines issued by relevant authorities.

For the staged supply of Schedule 8 poisons (Controlled Drugs), the storage of the medicines and the recording of the staged supply must be in accordance with any state or territory requirements.

Consideration of the individual patient circumstances and needs is required to achieve an effective staged supply arrangement. The patient's consent should be obtained, including a written agreement between the pharmacist and the patient. The dispensed medicine should be stored and administered periodically with consideration of the patient's privacy. Appropriate records of the periodic supply should be maintained and reviewed to ensure that the arrangement remains effective and in accordance with the agreement. Where necessary, further contact with the patient, their agent, the prescriber and/or another health professional involved in the care of the patient, may be required to achieve compliance.

The patient and the prescriber should be informed of the proposed staged supply arrangement, including pricing for the service, so that an informed decision about the service can be made.

Definitions

A **co-regulatory jurisdiction** means a participating jurisdiction in which the National Law declares that the jurisdiction is not participating in the health, performance and conduct process provided by Divisions 3 to 12 of Part 8. Queensland and New South Wales are co-regulatory jurisdictions.

Dose administration aids (DAAs) are defined in a number of documents. For the purposes of these guidelines, a DAA is defined as a device or packaging system for organising doses of medicines according to the time of administration, which assists medication management for a consumer.

⁶ Derived from Pharmaceutical Society of Australia 2015, *Staged supply*, Pharmaceutical Society of Australia, viewed 16 January 2015, <<http://www.psa.org.au/supporting-practice/5cpa/ppi-staged-supply>>

Practice means any role, whether remunerated or not, in which the individual uses their skills and knowledge as a pharmacist in their profession. For the purposes of these guidelines, practice is not restricted to the provision of direct clinical care. It also includes working in a direct non-clinical relationship with clients; working in management, administration, education, research, advisory, regulatory or policy development roles; and any other roles that impact on safe, effective delivery of services in the profession.

Scope of practice means the professional role and services that an individual health practitioner is educated and competent to perform.

References

Pharmacy Board of Australia *Guidelines for dispensing of medicines*

Review

These guidelines will be reviewed at least every five years.

Last reviewed: XXXX

These guidelines replace the previously published guidelines XXXX

Overview

6 March 2015

Review of the *Guidelines on responsibilities of pharmacists when practising as proprietors*

Summary of issue

The National Law outlines that a Board may develop guidelines to provide guidance to the health practitioners it registers, or about any other matters relevant to the exercise of its functions.

The Board's current *Guidelines on responsibilities of pharmacists when practising as proprietors* were developed to provide guidance on the professional responsibilities of proprietor pharmacists that impact on the safe, effective delivery of services to the public.

The current guidelines outline a policy previously agreed by the Board, that a pharmacist who owns a pharmacy is practising pharmacy. Given that state or territory law in some jurisdictions permits non-practising pharmacists to own pharmacies, the Board also published a statement *Clarification on registration type required by proprietors of pharmacies*, to provide clarification on the type of registration required by proprietor pharmacists in each jurisdiction. The Board is reviewing the current guidelines to ensure they clearly outline the obligations of proprietor pharmacists, in the public interest and to ensure that the information regarding ownership of pharmacies is consistent with the state and territory legislation regulating pharmacy premises in each jurisdiction.

The Board is reviewing the current guidelines to ensure they meet the objectives of the National Law and are worded as simply and clearly as possible.

Options statement

The Board has considered a number of options in developing this proposal.

Option 1 – Status quo

Option 1 would continue with the existing guidelines. These guidelines provide guidance on the professional responsibilities of proprietor pharmacists. The Board has identified a range of opportunities to improve the current guidelines, including the ability to clarify the language and structure to make them easier to understand, and to ensure the guidance is consistent with the state and territory legislation regulating pharmacy premises in each jurisdiction.

Option 2 – Proposed revised guidelines

Option 2 would involve the Board publishing revised *Guidelines for proprietor pharmacists*. The revised guidelines would continue to provide guidance on the professional responsibilities of proprietor pharmacists.

The revised guidelines include a change of title of the guidelines from *Guidelines on responsibilities of pharmacists when practising as proprietors* to *Guidelines for proprietor pharmacists* as this reflects the content of the guidelines. They outline that the type of registration required by a proprietor depends on the legislation regulating pharmacy premises in their particular jurisdiction. It is proposed that a revised statement *Registration type required by proprietor pharmacists* outlining the current registration options for proprietor pharmacists in the individual jurisdictions, will replace the currently published statement *Clarification on registration type required by proprietors of pharmacies*. It is proposed that this revised statement be published in the registration section on the Board's website.

The revised guidelines provide additional guidance on the responsibilities of proprietor pharmacists relating to the advertising of services and/or products sold at a pharmacy, and facilitating employee pharmacists to meet the Board's registration standards.

The title of the revised guidelines has been simplified to *Guidelines for proprietor pharmacists*. The guidance has been separated into three guidelines to make the guidelines easier to read, and they have clearer wording to make them easier to understand.

Preferred option

The Board prefers Option 2.

Issues for discussion

Potential benefits and costs of the proposal

The benefits of the preferred option are that the draft revised guidelines:

- provide clarity on the registration options for proprietor pharmacists
- provide additional guidance on the responsibilities of proprietor pharmacists relating to the advertising of services and/or products sold at a pharmacy, and enabling employee pharmacists to meet the Board's registration standards
- have a simplified title which better reflects the content of the guidelines
- are user-friendly
- strike a balance between protecting the public and impact on pharmacists
- have been reworded to be simpler and clearer.

The costs of the preferred option are:

- pharmacists, other stakeholders, AHPRA and National Boards will need to become familiar with a new sets of guidelines, and a new statement titled *Registration type required by proprietor pharmacists*
- there will likely need to be a period of transition to the two new sets of guidelines.

Estimated impacts of the draft revised guidelines

The changes proposed in the draft revised guidelines are relatively minor, although more significant changes may be proposed through consultation. There is little impact anticipated on pharmacists, pharmacy business and other stakeholders arising from the changes proposed.

Relevant sections of the National Law

Relevant sections of the National Law relating to the guidelines (and summarised above) are:

- Section 35, and
- Section 39.

Questions for consideration

The Board is inviting feedback on the following questions.

- From your perspective, how are the current *Guidelines on responsibilities of pharmacists when practising as proprietors* working?
- Is the content and structure of the draft revised *Guidelines for proprietor pharmacists* helpful, clear, relevant and more workable than the current guidelines?
- Is there any content that needs to be changed or deleted in the draft revised guidelines?
- Is there anything missing that needs to be added to the draft revised guidelines?
- Do you have any other comments on the draft revised guidelines?
- Do you think that that the proposed review period of five years, with the option to review earlier if the need arises, is appropriate?

The proposed revised *Guidelines for proprietor pharmacists* are included on page 46 of this consultation paper.

The current *Guidelines on responsibilities of pharmacists when practising as proprietors* are published on the Board's website, accessible from www.pharmacyboard.gov.au/Codes-Guidelines.aspx.

Attachments

The *Statement of assessment against AHPRA's Procedures for development of registration standards and COAG principles for best practice regulation* is at Attachment 1.

Draft revised Guidelines for proprietor pharmacists

Effective from: <<date>>

Review date: <<date>>

Contents

Introduction

Who needs to use these guidelines?

What happens if I do not comply with these guidelines?

Summary of guidelines

Guidelines

1. Proprietors to maintain an active interest of how the pharmacy business is conducted
2. Proprietor pharmacists cannot delegate their professional obligations
3. Responsibilities of proprietor pharmacists

Definitions

References

Review

Introduction

These guidelines have been developed by the Pharmacy Board of Australia (the Board) under section 39 of the Health Practitioner Regulation National Law, as in force in each state and territory (the National Law). They provide guidance to pharmacists in relation to the professional responsibilities of pharmacy proprietors, not set out in the legislation or a registration standard.

Note:

1. *As part of the agreement by the Council of Australian Governments to provide for the National Law, pharmacy ownership, regulation of premises, inspections and related matters do not form part of the National Law. Each jurisdiction has separate legislation, guidelines and/or requirements for these purposes.*
2. *In each jurisdiction, the type of registration required by pharmacist proprietors is specified in the legislation regulating pharmacy premises. The Board maintains a list outlining each jurisdiction's requirement on its website.*

Who needs to use these guidelines?

These guidelines were developed to provide guidance to registered pharmacists or those seeking to become registered pharmacists. They apply to all registered pharmacists who own or hold a proprietary or pecuniary interest in a pharmacy business. They also apply to a pharmacist who holds a position of authority in a corporate structure or who acts as a trustee of a trust in a corporate structure.

What happens if I do not comply with these guidelines?

Pharmacists (including proprietors) must comply with all legislation relevant to the practice of pharmacy and requirements for pharmacy premises in their jurisdiction. Additionally, all pharmacists are expected to be aware of and comply with the profession's standards and guidelines (including any other standards or guidelines referred to in those documents), as relevant to their scope of practice and type of registration. The pharmacy practice standards and guidelines can be accessed on the websites of the relevant professional bodies:

- Pharmaceutical Society of Australia (PSA) (www.psa.org.au), and
- The Society of Hospital Pharmacists of Australia (The SHPA) (www.shpa.org.au).

Non-compliance with these guidelines and the practice standards and guidelines may be notified to the Board for appropriate action under the National Law. Under section 41 of the National Law, these guidelines can be used in disciplinary proceedings under the National Law or law of a co-regulatory jurisdiction as evidence of what constitutes appropriate professional conduct or practice for pharmacists. When considering notifications (complaints) against proprietors, the Board will give consideration to whether a breach of these guidelines has taken place. The Board will also have regard to the relevant legislation and requirements for pharmacy premises, and the practice standards and guidelines relevant to pharmacy practice.

Further information for pharmacists regarding the possible outcomes of notifications is available on the website of the Australian Health Practitioner Regulation Agency (AHPRA) (www.ahpra.gov.au).

Summary of guidelines

These guidelines focus on the professional responsibilities of proprietor pharmacists that impact on the safe, effective delivery of services to the public.

A registered pharmacist who is a proprietor of, or who has a pecuniary interest in, a pharmacy business, must:

- maintain, and be able to demonstrate an awareness of, the manner in which that pharmacy business is being conducted, and
- where necessary, intervene to ensure that the practice of pharmacy is conducted in accordance with applicable laws, standards and guidelines.

Guidelines

1. Proprietors to maintain an active interest in how the pharmacy business is conducted

If the proprietor/owner or partner-in-ownership pharmacist is not the pharmacist usually in charge of that pharmacy, he or she must vigilantly maintain an active interest in how the practice of pharmacy is being conducted. This is to ensure that the pharmacy operation is in accordance with:

- any applicable state, territory or Commonwealth law
- relevant Pharmacy Board of Australia policies, codes and guidelines
- applicable professional practice and quality-assurance standards and guidelines, and
- good pharmacy practice.

If the proprietor finds that the practice of pharmacy does not operate in accordance with these, he or she must intervene to ensure that the pharmacy business is conducted properly.

2. Proprietor pharmacists cannot delegate their professional obligations

A proprietor/owner or partner-in-ownership of a pharmacy cannot delegate his or her professional obligations, even if that partner is not regularly present at the pharmacy. This applies to pharmacists who own a pharmacy, or pharmacies, in all forms of business structures.

3. Responsibilities of proprietor pharmacists

For the purposes of these guidelines, ensuring the pharmacy business is conducted properly includes:

- assuring themselves that the pharmacists they employ are complying with and adhering to the Board's registration standards and guidelines, and where applicable, make any necessary arrangements that facilitate the pharmacists meeting these requirements, for example:
 - proprietors who arrange professional indemnity insurance (PII) cover for an employed pharmacist should ensure that sufficient evidence of currency of PII cover is available to the employed pharmacist

- ensuring that their employed pharmacists have ready access to the list of essential references specified by the Board in Guideline 1 of its *Guidelines on practice specific issues*
- ensuring compliance with any state or territory legislation regarding facilities and equipment required for the types of services delivered at the pharmacy
- ensuring appropriate risk management procedures are in place for the operation of the pharmacy, including all types of services delivered at that pharmacy
- ensuring that confidential patient information is appropriately stored and accessed
- having an awareness and understanding of the range of goods sold and services provided at the pharmacy, including non-traditional and novel goods and services, and their associated liabilities
- ensuring that the pharmacy is suitably resourced, and that staff members are suitably trained and appropriately supervised to provide services in accordance with their position descriptions
- maintaining an awareness of and responsibility for the services being provided including unregulated services, and goods being sold, particularly those known to be subject to abuse or misuse and those not regulated through the Therapeutic Goods Administration (TGA) or the pharmacy premises regulatory authorities
- ensuring that business procedures, policies and protocols are developed, implemented and routinely followed for all services delivered at the pharmacy, and
- ensuring that advertising of services and/or products sold at the pharmacy is carried out in accordance with applicable legislation and guidelines.

The vigilance of the practice described in these guidelines includes on-site visits and attendance at staff meetings at a frequency that ensures that the proprietor is able to fulfill the above responsibilities at all times.

The proprietor/owner or partner-in-ownership pharmacist must ensure that procedures and policies for all services provided by the pharmacy, as well as those relating to occupational health and safety, are documented and available within the pharmacy for all staff to access and follow.

Proprietors of pharmacies that are not approved to supply pharmaceutical benefits must ensure that:

- consumers are made fully aware that the pharmacy cannot supply pharmaceutical benefits
- the pharmacy staff do not engage in unprofessional practices such as purporting to be able to supply pharmaceutical benefits when the pharmacy is unapproved to do so, and
- no claims for pharmaceutical benefits are made from the pharmacy.

Definitions

A **co-regulatory jurisdiction** means a participating jurisdiction in which the National Law declares that the jurisdiction is not participating in the health, performance and conduct process provided by Divisions 3 to 12 of Part 8. Queensland and New South Wales are co-regulatory jurisdictions.

Practice means any role, whether remunerated or not, in which the individual uses their skills and knowledge as a pharmacist in their profession. For the purposes of these guidelines, practice is not restricted to the provision of direct clinical care. It also includes working in a direct non-clinical relationship with clients; working in management, administration, education, research, advisory, regulatory or policy development roles; and any other roles that impact on safe, effective delivery of services in the profession.

Proprietary or pecuniary interest means a legal or beneficial interest and includes a proprietary interest as a sole proprietor, as a partner, as a director, member or shareholder of a company and as the trustee or beneficiary of a trust.

Scope of practice means the professional role and services that an individual health practitioner is educated and competent to perform.

References

A recognition of the principle of proprietor responsibilities is acknowledged in the decision of the Supreme Court Judge in the case of David Loewy and Sandra Loewy v The Pharmacy Board of Victoria, [1991] VSC 113 01.

Review

These guidelines will be reviewed at least every five years.

Last reviewed: XXXX

These guidelines replace the previously published guidelines from XXXX

Board's statement of assessment against AHPRA's *Procedures for development of registration standards* and *COAG principles for best practice regulation*

Guidelines for dispensing of medicines

Guidelines on practice-specific issues

Guidelines on specialised supply arrangements

Guidelines on responsibilities of pharmacists when practising as proprietors

The Australian Health Practitioner Regulation Agency (AHPRA) has *Procedures for the Development of Registration Standards* which are available at: www.ahpra.gov.au

These procedures have been developed by AHPRA in accordance with section 25 of the *Health Practitioner Regulation National Law* as in force in each state and territory (the National Law) which requires AHPRA to establish procedures for the purpose of ensuring that the National Registration and Accreditation Scheme operates in accordance with good regulatory practice.

Below is the National Boards' assessment of their proposal for its draft revised guidelines against the three elements outlined in the AHPRA procedures.

1. The proposal takes into account the National Scheme's objectives and guiding principles set out in section 3 of the National Law

Board assessment

The Board considers that the draft revised guidelines meet the objectives and guiding principles of the National Law.

The draft revised *Guidelines for dispensing of medicines* will provide for the protection of the public by providing clear guidance to pharmacists on the dispensing and labelling of medicines, and on providing a good pharmaceutical service.

The draft revised *Guidelines on practice-specific issues* will provide for the protection of the public by providing clear guidance to pharmacists on various pharmacy practice matters, including in relation to the supply of drugs of abuse.

The draft revised *Guidelines on dose administration aids and staged supply of dispensed medicines (currently titled Guidelines on specialised supply arrangements)* will provide for the protection of the public by providing clear guidance to pharmacists on the supply of dose administration aids and the periodic supply of medicines to patients to facilitate and improve patient compliance with their medication.

The draft revised *Guidelines for proprietor pharmacists* (currently titled *Guidelines on responsibilities of pharmacists when practising as proprietors*) will provide for protection of the public by providing clear guidance to proprietor pharmacists on their professional responsibilities to ensure that pharmacists practising in their pharmacies are able to safely, effectively deliver services to the public.

The draft revised guidelines support the National Scheme to operate in a transparent, accountable, efficient, effective and fair way.

2. The consultation requirements of the National Law are met

Board assessment

The National Law requires wide-ranging consultation on proposed guidelines. The National Law also requires the Board to consult other boards on matters of shared interest.

The Board will ensure that there is public exposure of its proposals and there is the opportunity for public comment by undertaking an eight week public consultation process. This process includes the publication of the consultation paper (and attachments) on its website.

The Board has drawn this paper to the attention of key stakeholders.

The Board will take into account the feedback it receives when finalising its proposals for publication on its website.

3. The proposal takes into account the COAG Principles for Best Practice Regulation

Board assessment

In developing the draft revised guidelines for consultation, the Board has taken into account the Council of Australian Governments (COAG) Principles for Best Practice Regulation.

As an overall statement, the Board has taken care not to propose unnecessary regulatory burdens that would create unjustified costs for the profession or the community. The Board outlines in its guidelines, that pharmacists have obligations under relevant legislation and that they are also expected to be guided by the information in the practice standards developed by the profession for the profession as well as the Board's guidelines.

The Board makes the following assessment specific to each of the COAG principles expressed in the AHPRA procedures.

COAG Principles

A. Whether the proposal is the best option for achieving the proposal's stated purpose and protection of the public

Board assessment

The Board considers that its proposals are the best options for achieving the stated purposes. As only minor changes to the existing guidelines are proposed, the impact of the proposals is similar to the existing guidelines.

The Board considers that the draft revised guidelines would have a low impact on the profession. These low impacts are significantly outweighed by the benefits of protecting the public and providing clearer guidance, in the public interest.

B. Whether the proposal results in an unnecessary restriction of competition among health practitioners

Board assessment

The Board considered whether its proposals could result in an unnecessary restriction of competition among health practitioners. The proposals are not expected to impact on the current levels of competition among health practitioners.

C. Whether the proposal results in an unnecessary restriction of consumer choice

Board assessment

The Board considers that the draft revised *Guidelines for dispensing of medicines* will support consumer choice by providing clear guidance to pharmacists on the dispensing and labelling of medicines, and on providing a good pharmaceutical service.

The Board considers that the draft revised *Guidelines on practice-specific issues* will support consumer choice by providing clear guidance to pharmacists on various pharmacy practice matters, including in relation to drugs of abuse.

The Board considers that the draft revised *Guidelines on dose administration aids and staged supply of dispensed medicines* will support consumer choice by providing clear guidance to pharmacists on the

supply of dose administration aids and the periodic supply of medicines to patients to facilitate and improve patient compliance with their medication.

The Board considers that the draft revised *Guidelines for proprietor pharmacists* will support consumer choice by providing clear guidance to proprietor pharmacists on their professional responsibilities to ensure that pharmacists practising in their pharmacies are able to safely, effectively deliver services to the public.

D. Whether the overall costs of the proposal to members of the public and/or registrants and/or governments are reasonable in relation to the benefits to be achieved

Board assessment

The changes proposed in the draft revised guidelines are minor. The Board has improved the current guidelines by revising the language and structure to make them clearer and easier to understand.

The Board considered the overall costs of the draft revised guidelines to members of the public, registrants and governments, and concluded that subject to stakeholder feedback on the proposed revisions, the likely costs are appropriate when offset against the benefits that the draft revised guidelines contribute to the National Scheme.

E. Whether the requirements are clearly stated using 'plain language' to reduce uncertainty, enable the public to understand the requirements, and enable understanding and compliance by registrants

Board assessment

The Board considers that the draft revised guidelines have been written in plain English that will help practitioners to understand their requirements. The Board has changed the structure of the guidelines and reviewed the wording to make them clearer and easier to understand.

F. Whether the Board has procedures in place to ensure that the proposed registration standard, code or guideline remains relevant and effective over time

Board assessment

The Board will review the revised guidelines at least every five years, including an assessment against the objectives and guiding principles in the National Law and the COAG principles for best practice regulation.

However, the Board may choose to review the guidelines earlier, if it is necessary to ensure their continued relevance and workability.