

20 September 2018

Ms Avril Diamante
Coroner's Registrar
65 Kavanagh Street
Southbank VIC 3006

By email: cpuresponses@coronerscourt.vic.gov.au

Dear Ms Diamante

Investigation into the death of Ian J Gilbert (COR 2015 000742)

I provide the following response to Coroner Rosemary Carlin's recommendations to the Pharmacy Board of Australia (the Board) arising from the investigation into the death of Mr Ian J Gilbert (Court Reference (COR 2015 000742)).

The Board is responsible for the regulation of pharmacists within the National Registration and Accreditation Scheme (the National Scheme), established under the Health Practitioner Regulation National Law, as in force in each state and territory (the National Law). The Board works collaboratively and in the public's interest with the National Boards of 14 other health professions and the Australian Health Practitioner Regulation Agency.

As outlined in the National Law, the functions of the Board include:

- registering pharmacists and students
- developing standards, codes and guidelines for the pharmacy profession
- handling notifications, complaints, investigations and disciplinary hearings
- assessing overseas trained practitioners who wish to practise in Australia
- approving accreditation standards and accredited courses of study.

The Coroner made the following recommendation to the Board and the Pharmaceutical Society of Australia (PSA):

Recommendation 4

That the Pharmacy Board of Australia and the Pharmaceutical Society of Australia consult with each other and any other professional body they deem relevant, as to what, if any, further guidance and support should be provided to pharmacists to enable and empower them to discharge their duty of care to patients in situations where they have a concern as to the safety and appropriateness of prescribed medication.

On 15 August 2018, Board nominees met with PSA via teleconference to discuss the existing resources including published guidance to pharmacists that is relevant to this case, and identified opportunities for further collaboration with a view to provide further information and guidance to pharmacists.

Stakeholder and interprofessional collaboration

On 21 August 2018, I represented the Board at a summit convened by PSA which also included representation from a range of pharmacist and medical practitioner associations.

Representatives from AHPRA, including the Board's Executive Officer also attended. Our combined attendance enabled contribution to the constructive discussion from a regulatory perspective with public protection at its core.

Acknowledging that PSA will respond to the Coroner about Recommendation 4 and will provide further details, in brief the summit focused on the development of collaboration principles for pharmacists and medical practitioners and strategies for their adoption by those professions.

Published guidance and other information to support pharmacists

Guidelines and other published information about pharmacy practice are an important source of information to guide pharmacists to achieve minimum standards during their practice.

In accordance with its functions under the National Law, the Board has published on its website (www.pharmacyboard.gov.au/Codes-Guidelines.aspx) a code of conduct and guidelines for pharmacists. These are detailed in Attachment A. Guideline 2 *Dispensing precaution – safety of prescriptions* of the Board's *Guidelines for dispensing of medicines* states:

"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."

Further details about the guidance provided to pharmacists by the Board about ensuring the safety of prescriptions is provided in the copy of the *Guidelines for dispensing of medicines* at Attachment B.

Professional bodies such as pharmacy member organisations have also published practice standards, guidelines and other information to guide pharmacists in their practice. Examples can be located on the following websites:

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

In each code and guideline for pharmacists published by the Board, it also advises:

"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 Board publishes communiqués and quarterly newsletters on its website (www.pharmacyboard.gov.au/News.aspx). Electronic copies of newsletters are sent to all registered pharmacists. The Board's newsletter updates pharmacists about a range of matters relevant to the National Scheme and routinely includes advice on a range of practice issues and case study summaries which outline lessons to be learnt.

These practice articles and case studies provide valuable information to pharmacists and act as a prompt to pharmacists to apply the information in practice. On several occasions since the commencement of the National Scheme, the Board has published articles about the supply of methotrexate, highlighting the vigilance required to manage the associated risks to patients.

Further action to support pharmacists in practice

The Board remains committed to ongoing consultation with PSA and other stakeholders about opportunities to further guide pharmacists to discharge their duty of care to patients in situations where they have a concern as to the safety and appropriateness of prescribed medication. This engagement will facilitate the progression of identified initiatives such as the development of

additional or revised guidance for pharmacists or education which can be completed as part of the continuing professional development required for pharmacists' annual re-registration to practise.

The Board and AHPRA have reviewed the current code of conduct for pharmacists as part of a wider review of codes of conduct for other health professions registered under the National Scheme and will seek feedback from the public and stakeholders as part of its wide-ranging consultation process. Subsequent to the review of the code of conduct for pharmacists, the Board will embark on its scheduled review of registration standards and guidelines for pharmacists.

The Board will continue to monitor areas of risk in practice identified through its consideration of complaints about the conduct and performance of pharmacists and where possible, publish details to support pharmacists to discharge their duty of care to patients.

If you wish to discuss this matter further, please do not hesitate to contact me on +61 417 484 350 or email on Bill.Kelly@ahpra.gov.au. Alternatively, you may contact the Board's Executive Officer, Mr Joe Brizzi on +61 3 8708 9020 or email on Joe.Brizzi@ahpra.gov.au.

Yours sincerely

A handwritten signature in blue ink, appearing to read 'William Kelly', with a stylized flourish at the end.

William Kelly

Chair

Attachments

- Att A Pharmacy Board of Australia code of conduct and guidelines
- Att B Guidelines for dispensing of medicines

Pharmacy Board of Australia code of conduct and guidelines

Under section 39 of the National Law, the Board may develop and approve codes and guidelines to provide guidance to pharmacists and about other matters relevant to the exercise of its functions.

In accordance with s40 of the National Law, the Board conducts wide-ranging consultation about the content of codes and guidelines before their publication. The Board invites feedback from the public, the profession, pharmacy stakeholders, government, partners in the National Scheme and other interested parties.

The code of conduct and guidelines for pharmacists were published upon commencement of the National Scheme and are reviewed and updated by the Board at least every five years.

Under section 41 of the National Law, the code and 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.

Summaries of the current code of conduct and other relevant guidelines are provided below.

The **Code of conduct for pharmacists** (March 2014) is based on a common code used by a number of National Boards. The code contains important standards for practitioner behaviour in relation to:

- providing good care, including shared decision-making
- working with patients or clients
- working with other practitioners
- working within the healthcare system
- minimising risk
- maintaining professional performance
- professional behaviour and ethical conduct
- ensuring practitioner health
- teaching, supervising and assessing, and
- undertaking research.

The **Guidelines for dispensing of medicines** (September 2015) focus on safe dispensing and labelling of medicines and on providing a good pharmacy service.

The **Guidelines for compounding of medicines** (March 2015) provide guidance and clarification on specific issues regarding compounding of medicines. They aim to minimise the associated risks for patients, pharmacists and other pharmacy staff, and improve patient outcomes and patient safety.

The **Guidelines on dose administration aids and staged supply of dispensed medicines** (September 2015) (previously titled *Guidelines on specialised supply arrangements, 2010*) were developed in recognition of the increased demand for dose administration aids (DAAs) 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.

The **Guidelines for proprietor pharmacists** (September 2015) focus on the professional responsibilities of proprietor pharmacists that impact on the safe, effective delivery of services to the public.

The **Guidelines on practice-specific issues** (September 2015) 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.

The Board's codes and guidelines outline that in addition to complying with its codes and guidelines, pharmacists are required to comply with all legislation relevant to the practice of pharmacy in the jurisdiction where the practice occurs, and must be aware of and comply with the profession's standards and guidelines as relevant to their scope of practice and type of registration.



GUIDELINES FOR DISPENSING OF MEDICINES

September 2015

GUIDELINES FOR DISPENSING OF MEDICINES

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GUIDELINES FOR DISPENSING OF MEDICINES

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*.

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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:
 - i. the patient to be properly identified so the medicine is dispensed to the person for whom it is intended, and
 - ii. the medicine to be dispensed safely
- d) determining the prescriber's intentions as to the patient's medicine, including the dosing instructions
- 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 such as complementary and alternative medicine, are taken into account
- f) entering the prescription details on the pharmacy computer and recording any other aspect of the dispensing according to the requirements of the law
- 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) 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)
- j) 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)**)*
- k) carefully checking and re-checking all dispensing for accuracy and completeness
- l) 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 (which may include provision of printed supplementary information when required), and to allow for a final check of the dispensed medicine, and
- m) 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.

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(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 'Guidelines on dose administration aids and staged supply of dispensed medicines', address the responsibilities of pharmacists when dose administration aids (DAAs) are supplied, including when they 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 judgement 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 patient or their agent should be consulted and if necessary, the prescriber 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. If the pharmacist decides not to dispense the prescribed medicine, the patient must be informed about the reasons for the decision and the alternative options available to the patient regarding their medication needs. 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.

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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 49 of the National Health (Pharmaceutical Benefits) Regulations 2017 (previously Regulation 24 of the National Health (Pharmaceutical Benefits) Regulations 1960).¹ 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-Pharmaceutical Benefits Scheme (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. An appropriate notation should be made to that effect on the prescription, in the dispensing record and where possible, in the patient's health record. Examples of exceptional circumstances may include a patient going away for an extended period of time, or a patient who cannot easily attend the pharmacy because of disability and/or a mobility issue. State and territory legislation must be complied with.

4 Hard-copy prescriptions that are copied and transmitted electronically

Hard-copy prescriptions and other written authorisations that are copied and transmitted electronically (e.g. scanned and transmitted by facsimile or email) may be a source of dispensing errors, and are a frequent source of forgeries and fraudulent behaviour to unlawfully obtain medicines.

Guideline

Before dispensing a medicine detailed on a hard-copy prescription which has been copied and transmitted electronically (e.g. scanned and transmitted by facsimile or email), a pharmacist must take reasonable steps to satisfy themselves that the order 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 order or receiving oral instruction from the prescriber before the supply is made, and obtaining and retaining the original prescription or other accepted written authorisation.

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.

¹ Amended on 2 June 2017 to reflect 2017 regulations.

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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. A risk management procedure including appropriate record keeping of events, assists pharmacists in managing such incidents.

Guideline

Pharmacists are to ensure that incident records are maintained 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, any outcomes and who recorded the incident. 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

The requirements for labelling dispensed medicines are specified in legislation in force in the jurisdiction in which a pharmacist is practising. Practice standards and guidelines (including these guidelines), address the labelling of dispensed medicines, with a view to:

- ensuring lawful possession by the patient
- maximising the benefits of the therapy
- improving the patient's understanding of the treatment
- enhancing adherence, and
- minimising adverse effects.

Guideline

7.1 Labels

Placement

The placement of the dispensing label on the medicine packaging is largely determined by the design of the packaging 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, insulin pen cartridges 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 plain English. Other languages that are accurate translations of the English may be used in addition to English. Pharmacists should ensure that the label is durable and legible for the expected duration of use of the medicine.

The special needs of patients with disabilities, such as 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 must include the particulars required under state and territory legislation, and include:

- 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, the name and strength of each active ingredient

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(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 product has been compounded by the pharmacist'.

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)

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- 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, cytotoxics or other medicines that are reported to pose a risk to patients and carers through inappropriate use or handling; 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,

including pharmacists.

Guideline

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 legislation and professional and quality assurance standards.

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.

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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 premises registering 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

- allowance of access to pharmacy computers by third party software providers
- allowance of third party software onto computers for data transference, 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 software programs used by pharmacies only access and transmit the data permitted by law
- ensure that appropriate backup and disaster recovery processes are in place and in accordance with any state or territory pharmacy premises registering 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

Various strategies can be employed to minimise the occurrence of dispensing errors.

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Guideline

Pharmacists should take all reasonable steps to minimise the occurrence of dispensing errors.

Good practice dictates 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 minimising selection errors but not a substitute for other checking procedures.

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 or 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 responsible for the dispensing of 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

Workload should be at a reasonable and manageable level to:

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

Guideline

Pharmacist owners and pharmacists in charge of a dispensary or pharmacy department are to have in place suitable quality-assurance systems and procedures for the management of pharmacist workload.

To support the delivery of an appropriate pharmacy service, pharmacists and their staff should give realistic waiting times to patients for dispensed medicines, and

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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. Arrangements should ensure adequate supervision by pharmacists of non-pharmacist staff.

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 dispensing 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 '[Managing Stress in Pharmacy: creating a healthier working environment in pharmacy by managing workplace stress](#)' published by the Pharmacists' Support Service, which contains useful guidance on workplace pressures, including workload.²

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 duties under pharmacist supervision, and ensure that the tasks correspond to and are limited to their level of education, training and experience. The responsible pharmacists should comply with the guidance outlined in this guideline and ensure that other pharmacists working with these individuals are also able to comply during their course of practice.

² Minor amendment made on 7 May 2018. Previously stated "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."

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12.1 Ensuring competence

Certificate qualifications, competencies and/or workplace training/practice experience can be used to ensure individuals are suitably prepared for their role as dispensary assistants/technicians. Pharmacists who employ dispensary assistants/technicians should carefully assess the most appropriate option(s) to achieve the level of skilled support required in practice and be able to demonstrate the evidence to support their decision. The following options (A, B and C) should be considered:

A. 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).

B. Competencies

The following essential competencies delivered by RTOs are recommended when pharmacists employ individuals as dispensary assistants/technicians in the relevant area of 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 (HLTPHA001)
- Pack pharmaceutical products (HLTPHA002)
- Assist with dispensing of prescriptions and medication orders (HLTPHA003)
- Order, maintain and distribute pharmaceutical stock (HLTPHA004)

(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).

The following additional competencies delivered by RTOs are recommended when pharmacists employ individuals as dispensary assistants/technicians in the relevant area of practice in order to deliver these additional services:

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):

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- Conduct small-scale compounding and labelling of pharmaceutical products (HLTPHA005)
- Provide assistance in dispensary administration (HLTPHA006)
- Conduct small-scale compounding and labelling of aseptic pharmaceutical products (HLTPHA007)
- Support pharmacist communication with clients and other health professionals (HLTPHA008)
- Support pharmacists in the collection and presentation of workplace data and information (HLTPHA009)

(Note: The competencies listed above, as available through the relevant training package, were correct at the time of publication of these guidelines. These competencies may be updated from time to time.)

C. Workplace training and practice experience

Pharmacists must determine whether an individual is appropriately educated, skilled and/or experienced to perform in the role of a dispensary assistant/technician. This should involve establishing whether, to perform in their role, the individual has:

- sufficient relevant 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 commence workplace training or 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, training and/or experience.

The scope of duties that may be assigned by a pharmacist to a dispensary assistant/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 essential 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 the dispensing process

A pharmacist must provide direct and personal supervision to a dispensary assistant/technician during the dispensing process (refer to Guideline 1 *The dispensing process*). 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 k in the dispensing process in Guideline 1), and
- counselling the patient or the patient's agent and performing the final check (step l in the dispensing process in Guideline 1).

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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 workload and responsibilities in their practice, and must be clearly justified (refer to Guideline 11 *Pharmacists' workloads*).

13 Patients' rights to choose where to access medicines

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

Providing good care includes:

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

Guideline

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

Unwanted medicines present a risk to the community and should be disposed of safely.

Guideline

Pharmacist owners and pharmacists in charge of a dispensary or pharmacy department should arrange to accept from the public unwanted medicines for safe disposal.

In hospital pharmacy practice, local policies and protocols should be followed.

In community pharmacy practice, participation in available programs such as the Return of Unwanted Medicines (RUM) project, is encouraged. 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 (for example, 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.

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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.

Dispensing is 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 (see Guideline 1 *The dispensing process*).

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 patient.

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**, for the purpose of these guidelines, 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* (Cth)

Pharmacy Board of Australia *Code of conduct for pharmacists*

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

Review

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These guidelines will be reviewed at least every five years.

From 7 December 2015, these guidelines replace the Pharmacy Board of Australia *Guidelines for dispensing of medicines* published 12 August 2010.