Public consultation paper

18 August 2025

Public consultation on the draft *Guidelines for pharmacists on the safe provision of pharmacy services including medicines and advice*.

Summary

The Pharmacy Board of Australia (the Board) has drafted the *Guidelines for pharmacists on the safe provision of pharmacy services including medicines and advice,* which comprises a review and consolidation of the following guidelines, published in 2015:

1. *Guidelines for dispensing of medicines.*
2. *Guidelines on practice-specific issues.*
3. *Guidelines for proprietor pharmacists.*
4. *Guidelines on dose administration aids and staged supply of dispensed medicines.*

Under the Health Practitioner Regulation National Law, regulatory guidelines can be used as evidence of what constitutes appropriate conduct or practice for the pharmacy profession. Before publishing guidelines, the Board is required to undertake wide ranging consultation.

The Board has proposed to:

- consolidate the four sets of guidelines into one set with a new title – *Guidelines for pharmacists on the safe provision of pharmacy services including medicines and advice*
- retire a range of guidelines that are no longer necessary for the Board to publish
- update and revise remaining guidelines so that they are more contemporary, relevant and outcomes focused.

More information about the draft guidelines is included in this consultation paper. The consultation is open until close of business on **13 October 2025**.

Contents

Providing feedback during public consultation

The Board is releasing this public consultation paper for feedback on its draft *Guidelines for pharmacists on the safe provision of pharmacy services including medicines and advice* (the draft guidelines). Specific questions have been provided, which you may wish to address in your response.

You are invited to give feedback on the draft guidelines at Attachment A.

The Board will publish a consultation report after the public consultation phase has been completed to provide a summary of feedback received and how the Board has responded.

Feedback can be provided as a Word document (not PDF) by email to PharmBAFeedback@ahpra.gov.au or by completing the online survey by close of business on **13 October 2025.**

Publication of submissions

Submissions are published at the discretion of the Board and the Australian Health Practitioner Regulation Agency (Ahpra). Generally, submissions are published on our websites to encourage discussion and inform the community and stakeholders. Please advise us if you do not want your submission published.

We will not place on our websites, or make available to the public, submissions that contain offensive or defamatory comments or are outside the scope of the subject of the consultation. Before publication, we may remove personally identifying information from submissions, including contact details.

The Board and Ahpra can 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 us know if you do not want us to publish your submission or want us to treat all or part of it as confidential.

Published submissions will include the names of the individuals and/or the organisations that made the submission unless confidentiality is requested.

Next steps

After the public consultation closes, the Board will review and consider all feedback before making decisions about the content of its draft guidelines, their publication and implementation and any supporting documents that it intends to publish.

Ahpra together with the National Boards, through its implementation of the National Scheme, would like to acknowledge the Traditional Custodians of the land in which we regulate registered health practitioners in Australia.

We acknowledge Aboriginal and Torres Strait Islander culture as the oldest continuing culture in the world. Aboriginal and Torres Strait Islander Peoples never ceded sovereignty and we recognise the impact colonisation continues to have on the health of Aboriginal and Torres Strait Islander Peoples to date.

We acknowledge Aboriginal and Torres Strait Islander Peoples for their continuing connection to culture, language and country; along with Elders past and present, and the ancestors who walk with Aboriginal and Torres Strait Islander Peoples every day.

Background

The Pharmacy Board of Australia works with Ahpra and other National Boards to achieve the objectives of the National Registration and Accreditation Scheme (the National Scheme), which has public safety at its core.

The Board develops registration standards, codes and guidelines under the Health Practitioner Regulation National Law, as in force in each state and territory (the National Law). These documents:

- set out the requirements for registration
- establish obligations for professional practice
- can be used as evidence in disciplinary proceedings of what constitutes appropriate professional conduct or practice for the profession.

The Board does not monitor registered pharmacists' compliance with Board guidelines. The guidelines are intended to be used by pharmacists to inform their practice through self-assessment.

Under section 41 of the National Law, the Board may use these guidelines to assess the conduct and practice of a pharmacist, such as in the case of receiving a notification about a pharmacists' practice.

The Board regularly reviews its standards, codes and guidelines to make sure they remain relevant, contemporary and effective.

Guidelines

The Board's guidelines inform registered pharmacists and the community about the Board's expectations of pharmacists in relation to a range of issues relevant to pharmacists' practice. Board guidelines are developed in the public's interest.

All Board guidelines for pharmacists acknowledge the relevance in practice of:

- state, territory and Commonwealth legislation
- professional practice standards and guidelines
- codes, guidelines and/or other resources published by relevant authorities that provide advice to pharmacists about their requirements
- other relevant resources and documents.

Overview

The Pharmacy Board of Australia (the Board) publishes guidelines for pharmacists on its website (www.pharmacyboard.gov.au).

The Board originally published guidelines for pharmacists about the practice of pharmacy at the beginning of the National Scheme in 2010. These were informed by state and territory board guidelines for pharmacists that predated the National Scheme. The Board completed a review of its guidelines in 2015 and published the following revised guidelines, which are now being reviewed:

1. *Guidelines for dispensing of medicines*
2. *Guidelines on practice-specific issues*
3. *Guidelines for proprietor pharmacists*
4. *Guidelines on dose administration aids and staged supply of dispensed medicines.*

While the Board had proposed to review these guidelines within five years of publication, the review was delayed due to the COVID-19 pandemic which required the Board to focus its efforts on emerging priorities.

The Board commenced its preliminary work to review these guidelines in 2019. This included applying its principles for reviewing guidelines (see **Principles that informed the review/changes** section below), mapping the guidelines to other published documents, reviewing guidelines published by pharmacy regulators in other countries and identifying potential improvements.

The Board also engaged with key stakeholders, including key consumer bodies, to obtain feedback on the usefulness of the published guidelines and to discuss its ideas to improve the guidelines, such as:

- removing information that is published in other documents to reduce unnecessary duplication
- simplifying the guidelines to improve their usability and application in practice
- highlighting the importance and relevance of applying the Board's Code of conduct in practice and how the Board's guidelines further support good conduct and practice.

Other guidelines published by the Board are not part of this review.

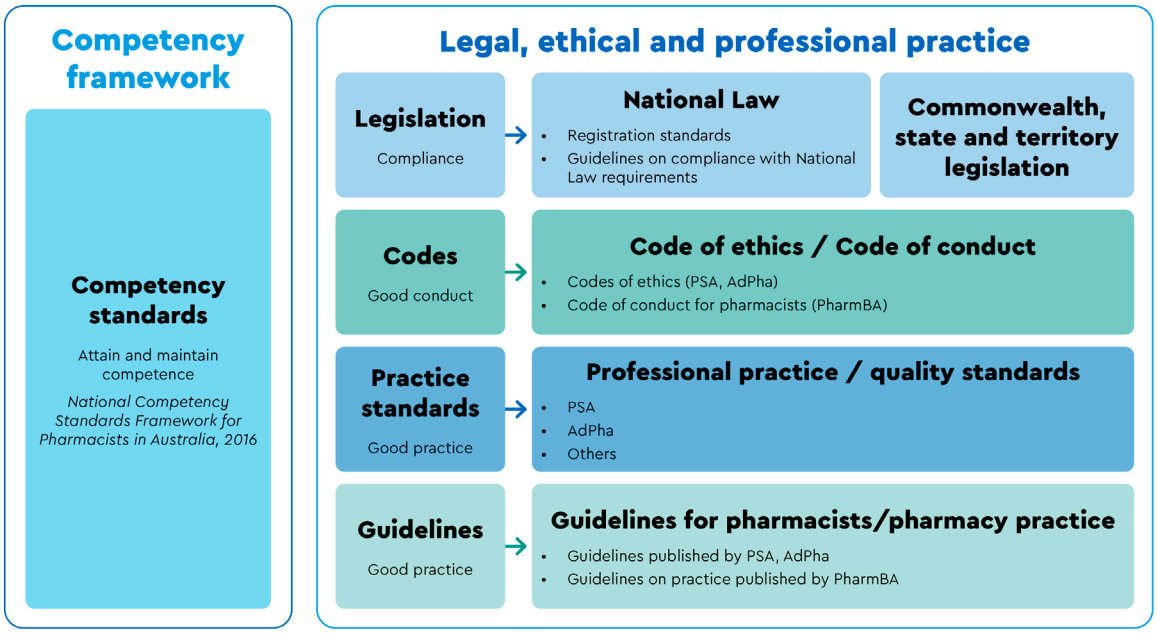
What are guidelines?

When we refer to guidelines in this paper, we mean guidelines developed under the National Law in the context of practitioner regulation. The National Law says that guidelines have two purposes. They can be used:

- to guide the profession
- as evidence of appropriate professional conduct or practice in a disciplinary proceeding against a practitioner.

The Board typically uses guidelines to explain its registration standards, the way it regulates pharmacists under the National Law and to provide guidance about the practice of the profession that is in the public's interest.

Guidelines developed by the Board under the National Law are distinct from practice guidelines developed by professional associations or other entities that provide detailed advice on a specific area of clinical practice. The Board's guidelines should be considered in the context of the broad range of information that supports professional practice, illustrated in the following diagram:



Note:

1. *In the above diagram:*
   - *PharmBA means the Pharmacy Board of Australia*
   - *PSA means the Pharmaceutical Society of Australia*
   - *AdPhA means Advanced Pharmacy Australia.*
2. *There may be other standards and guidelines that support good practice.*
3. *The National Competency Standards Framework for Pharmacists in Australia 2016 applies at the time of consultation. The framework is currently under review which may change how this diagram appears in other places, such as on the Board's website.*

Consultation on changes to the guidelines

The proposed changes to the guidelines are reflected in the draft guidelines at Attachment A. A diagrammatic overview of the changes is provided at Attachment B. A table mapping the changes is provided at Attachment C.

For information, the current published guidelines are available on the Board's website on its Codes, Guidelines and Policies webpage.

Principles that informed the review/changes

When reviewing the guidelines, the Board considered the following:

- The objectives and guiding principles of the National Scheme set out in section 3 of the National Law.
- The regulatory principles for the National Scheme.
- Policy Direction 2019-02 issued by the Ministerial Council.
- The National Scheme's Aboriginal and Torres Strait Islander Health and Cultural Safety Strategy 2020-2025.
- Ahpra's Procedures for the development of registration standards, codes and guidelines.

The Board also assessed its published guidelines against the following principles to consider whether each guideline is:

a. **within our remit**: is within the functions of the Board under the National Law
b. **risk-based**: is proportionate to the risk and evidence based
c. **outcome-focused**: leads to outcomes that protects the public
d. **achievable**: is relevant and achievable in practice
e. **streamlined:** acknowledges original sources of information relevant to pharmacists and reduces unnecessary duplication
f. **transparent:** is developed in a fair, transparent and consultative manner.

Guidelines that duplicate information available in other reputable sources place an unnecessary regulatory burden on pharmacists, who must navigate a broad range of practice and quality standards, codes, guidelines, and legislation. The Board prefers that its guidelines do not re-articulate existing information from reputable sources unless it is considered necessary (such as for providing context). This aligns with the Board's aim of regulating efficiently and effectively.

In applying the above principles, the Board identified some issues that may be resolved by a number of changes, as outlined in Table 1 below, and further detailed in the Summary of proposed changes to current guidelines at Attachment C.

Table 1: Issues identified and how we proposed to address them

Issue	Proposed change
The Board published four sets of guidelines with a total of 28 individual guidelines. Navigating four separate documents in practice may create unnecessary challenges for practitioners.	Consolidate the four sets of guidelines into a single document under a new guideline title - *Guidelines for pharmacists on the safe provision of pharmacy services including medicines and advice*
The Board's guidance duplicates some of the guidance that supports good practice which has also been published by professional organisations which might create confusion for practitioners. For example, guidelines about dose administration aids and staged supply arrangements.	Remove unnecessary duplication and direct practitioners to the guidelines published by professional organisations, such as PSA's *Guidelines for pharmacists providing dose administration aid services* and *Guidelines for pharmacists providing staged supply services*.
Some guidelines were largely contextual in nature, providing factual information to pharmacists without specifying Board guidance (such as Guideline 1 of *Guidelines for dispensing of medicines: The dispensing process*).	Remove the guideline and reposition contextual information under other relevant guidelines or new documents such as fact sheets which can be reviewed and updated separately to guidelines as required.

Issue	Proposed change
Some guidelines were developed to address emerging areas of risk where there was a lack of published guidance from other entities at the time (such as dose administration aids and staged supply).	Remove the guideline where other information has since been published to address the issue. Address any new emerging areas of risk in a more responsive manner by utilising other avenues of communication such as newsletters or statements (for example, Joint statement on professional responsibilities for prescribing and dispensing medicines). Advice on applying the Code of conduct to the issue would also be provided in the statement.
Some guidelines addressed areas that are not within the remit of the Board, such as setting training requirements for pharmacy technicians and assistants.	Remove the guideline and ensure that guidance provided is within the remit of the Board (for example, highlighting in the guidelines the responsibilities of a pharmacist in leadership/management role to ensure the pharmacy is suitably staffed).
Some guidelines addressed issues more suitably addressed by pharmacy premises regulators such as guidelines that address leasing arrangements in a pharmacy when working with an allied health practitioner and guidelines about equipment.	Remove the guideline and ensure that guidance provided addresses issues related to a pharmacists' practice and not related to premises requirements.
Some guidelines were unnecessarily prescriptive and focused on inputs rather than outcomes.	Revise the guidance and include any relevant guiding principles, ensuring that guidance is evidence-based and focuses on outcomes that contribute to protection of the public. This recognises that practice has evolved and assessment of resource needs in practice should be flexible and responsive to the individual practice environment.
Some guidelines were creating unnecessary burdens in an era where practice has evolved. For example, mandating a list of reference texts for all pharmacists which may not be relevant or necessary in their specific role.	Remove the guideline and include any relevant guiding principles in the contextual information for the guidelines, ensuring that guidance enables innovation in service delivery by pharmacists and provides for the protection of the public.

Before proposing to retire a specific guideline, the Board undertook an assessment of the regulatory landscape including guiding information published for pharmacists as well as the current range of information published by pharmacy member organisations to ensure the issue was adequately addressed.

In addition, the review of the guidelines included:

- removal of duplicated information that can be accessed in the Board's Code of conduct, practice standards and/or suitable reference sources such as the Australian Pharmaceutical Formulary and Handbook
- where possible, separating board guidance from the contextual information that addressed applicable legal requirements and the standards of practice published by professional organisations
- re-organising content to make the sequence of information more logical
- minor changes to refine and clarify wording and expression.

The changes proposed were informed by:

- research of international approaches to guidelines for pharmacists
- the Board's insights through its regulatory work, such as management of notifications and externally made decisions about the conduct of pharmacists
- input and feedback from stakeholders
- emerging issues that affect public safety
- feedback from members of the profession
- feedback from the Board's Committees
- input from National Boards.

The Board's proposal to remove information from its guidelines does not indicate that the issue is no longer relevant to pharmacy practice, but rather, it has identified alternative ways that pharmacists can access suitable information that supports good practice. Also, the Board does not publish guidance to inform all aspects of pharmacy practice and therefore, pharmacists need to access any other relevant published information to support good practice.

New title for consolidated guidelines

The Board reviewed the four sets of guidelines listed above and redrafted and restructured guidance as a single set of guidelines titled *Guidelines for pharmacists on the safe provision of pharmacy services including medicines and advice.* The draft guidelines provide updated guidance to pharmacists about the Board's expectations of pharmacists in relation to a range of important issues, which in the public's interest, must be routinely considered by pharmacists.

Good practice starts with good leadership and management, and places patients at the centre of all decisions about their health and their health service needs. Patients must be supported to make informed choices about their health and expect that confidentiality will be assured and their privacy will be respected. Good communication is essential to enable patients to understand the choices they need to make about their health, and patients rely on pharmacists communicating well and when required with other health professionals to help deliver good health outcomes. The draft guidelines address these issues under the four guidelines described in the section titled 'Draft guidelines content' below.

Reference to the Code of conduct

The draft guidelines follow a format where contextual information for pharmacists from sources such as legislation and the Code of conduct published by the Board precede the guidance. The Code of conduct is the overarching document for pharmacists that describes the Board's expectations of professional behaviour and conduct. The introductory information for each draft guideline references parts of the Code of conduct that are relevant to the issue being addressed.

Draft guidelines content

1. Leadership/management in practice

This draft guideline addresses principles of leadership and management which apply when pharmacists work in any of a range of leadership and management roles in various practice settings. It is not limited to the role of a proprietor of a community pharmacy, which is the focus of the Board's current *Guidelines for proprietor pharmacists*.

This new guideline also expands on the important principle of risk management, which must be applied to all areas of pharmacy practice to ensure patient safety as well as safety of staff delivering pharmacy services. Adequate resourcing is also addressed in this guideline, including ensuring adequate staffing and reference material to support good practice.

Effective leadership and management support good practice, however this guideline also reminds pharmacists of their individual responsibilities to monitor their own practice and performance as an element of self-leadership. Guidance and principles from the current *Guidelines for proprietor pharmacists, Guidelines for dispensing of medicines* and *Guidelines on practice-specific issues* have been incorporated into this guideline.

2. Supporting informed patient choice

This draft guideline addresses the principle that patients must be free to choose where they access pharmacy services and is an update of Guideline 13 (Patients' rights to choose where to access medicines) included in the current *Guidelines for dispensing of medicines*. It contains additional contextual information and has been broadened to acknowledge that patients must be free to choose where they access all types of pharmacy services, not just where they get their prescriptions dispensed.

3. Confidentiality and privacy

This draft guideline addresses confidentiality and privacy in the context of providing pharmacy services. It is an update of Guideline 9 (Privacy and confidentiality) of *Guidelines for dispensing of medicines*. The title has been changed to align with and complement the related section in the Board's Code of conduct. Some duplicated information has been removed and some additional contextual information has been added, including references to the important resources published by the Office of the Australian Information Commissioner (OAIC).

4. Communication in practice

This draft guideline addresses communication by pharmacists with both patients and members of the patient's healthcare team. It combines important guidance published in Guideline 2 (Dispensing precaution – safety of prescriptions) and Guideline 8 (Counselling patients about prescribed medicines) of *Guidelines for dispensing of medicines*. This guideline contains strengthened guidance to avoid breakdowns in communication which can compromise patient safety.

Other changes to the guidelines

We have made some other changes to guideline structure and content.

Workload

The Board's current guidelines addressing workload are input focused, in that they:

- recommend reassessment of staffing levels based on a number of prescriptions being dispensed per pharmacist per day
- suggest supervision ratios to guide the number of support staff a single pharmacist can safely supervise.

The Board's agreed principles include that its guidelines should be outcome focused and evidence-based. This has led to revised guidance which supports greater flexibility in applying the guidance in certain circumstances. The Board recognises that advances in technology have allowed changes in dispensary workflow, and changes to service provision that necessitate a more flexible approach to determining staffing levels.

The Board is committed to ensuring that pharmacy services are safe and that risks to the public are minimised and recognises that the 'inputs' required to achieve this will differ with each practice setting and, in some cases, individual pharmacists according to their role and scope of practice.

The Board's view is that the responsibility of determining relevant parameters that support good practice rests with the leaders and managers of the services being delivered. Development and management of these parameters should be informed by a risk assessment. This should include input from impacted staff about their experiences, such as the inability to meet minimum practice standards which gives rise to risks to the public and employees. The draft guidelines also draw attention to work health and safety legislation, in which there is a duty for leaders and managers to eliminate risks to health and safety of workers. This includes managing the risk of fatigue which can result from inadequately resourcing a workplace.

Reference texts that support good practice

As with current guidelines on workload (see above), the Board's current guidelines around reference texts are prescriptive and input focused. The Board currently publishes *Guidelines on practice-specific issues – Guideline 1 (List of reference texts for pharmacists)* which guides pharmacists about having access to and using relevant information during the clinical assessment, reviewing, dispensing and counselling processes. The Pharmacy Board of Australia is the only Board in the National Scheme that publishes a list of reference material for their practitioners.

In keeping with being focused on the outcome of protecting the public and providing guidelines that are relevant and do not create unnecessary barriers, the Board is proposing to retire the list of essential references. The Board, the public and stakeholders expect pharmacists to access and use evidence based, relevant, high-quality sources of information when they are practising. Competency Standard 3.1[1] *Develop a patient-centred, culturally responsive approach to medication management* addresses the use of best available evidence when assessing medication management practices and needs.

It is the Board's view that the specific resources used by pharmacists should be provided by the leaders and managers of the service, according to a risk assessment informed by staff who need those resources. The draft guidelines also remind pharmacists in leadership and management positions about work health and safety legislation and the obligation to provide adequate support to employees. Poor support is a psychosocial hazard and may include 'not having the things needed to do the work well, safely or on time'.

State and territory pharmacy premises regulators may have a list of mandatory references that must be kept at a pharmacy as part of licensing requirements. Currently there are a number of these entities that

[1] National Competency Standards Framework for Pharmacists in Australia 2016

refer to the Board's *Guidelines on practice-specific issues – Guideline 1 (List of reference texts for pharmacists)*. To acknowledge the potential impact on these entities, the Board consulted with them separately, prior to consultation.

Dose administration aids

The Board first published guidelines on dose administration aids (DAAs) in recognition of the increased demand for DAAs and the risks involved, in an era where there was limited other sources of guidance or information for pharmacists. As significant time has passed, other organisations have published comprehensive guidelines and other information that support pharmacists in this area of practice. In alignment with the review principle of streamlining guidance and avoiding any unnecessary duplication, the Board believes that there is no longer a need to publish a guideline on DAAs. However, the overarching principle of risk management, which underpins the provision of DAA services, is addressed in the draft guidelines under Guideline 1, Leadership/management in practice.

Technicians and pharmacy assistants

The Board's current guidelines specify units of study for pharmacy technicians and assistants. The Board does not regulate pharmacy technicians or assistants and it acknowledges that pharmacists in leadership/management positions are responsible for ensuring that pharmacists and other staff under their management are capable of performing their roles which can change in response to rapidly evolving practice and service delivery. Participation in the planning and delivery of educational programs is described in the National Competency Standards for pharmacists, and professional practice standards describe that pharmacists in senior roles develop procedures that describe the education and training required of the team delivering the service.

Notifications to the Board in the absence of a Board Guideline

The removal of an existing Board guideline does not necessarily mean that a notification cannot be made to the Board about the issue. If the notifier believes a pharmacist is practising unsafely or behaving in a way that might place the public at risk, then a notification should be made. When dealing with notifications against pharmacists, the Board considers whether the pharmacist's conduct is consistent with legislation, the Board's Code of conduct, professional practice standards and guidelines published by professional organisations, as well as any relevant Board guidelines. More information can be found about notifications at https://www.ahpra.gov.au/Notifications.aspx.

Supporting professional practice

Guidelines are not always the most suitable way of advising the profession about the Board's expectations of pharmacists in practice, as they take time to develop including undergoing a lengthy consultation process. When risks emerge in practice, the Board may respond using channels such as releasing a statement or update, or using a newsletter, to explain how existing documents such as the Code of conduct and other guidance should inform good practice in such circumstances. Examples of recent communications about emerging issues are available at https://www.pharmacyboard.gov.au/News.aspx.

Consumer fact sheet

The Board has developed a consumer fact sheet to assist patients and consumers to understand some of the obligations pharmacists have when providing pharmacy services. This includes areas such as privacy and confidentiality, or steps pharmacists must take when dispensing or supplying medicines. The Board intends to make the fact sheet available to members of the public and pharmacists by publishing it on its website. A draft consumer fact sheet is available at Attachment D and feedback on its content is invited.

Applying the draft guidelines and other relevant information in practice

Managing issues that emerge in practice legally, safely and professionally requires correct application of relevant legislation as well as pharmacy practice standards and guidelines.

The Board's guidelines should be considered in the context of the broad range of information that supports professional practice, illustrated in the following diagram:

The Board does not publish guidelines on all aspects of pharmacy practice and after reviewing guidelines, it may retire particular guidelines if other published information about pharmacy practice adequately supports pharmacists in their practice.

To demonstrate how the Board's draft guidelines and other information such as the references listed in the above diagram can be applied to manage emerging issues in practice legally, professionally, safely and in the public interest, the Board has developed case studies. The Board is planning to publish these or similar case studies along with its finalised guidelines.

Case study 1 – Meeting legal and professional obligations

An employee pharmacist working in a community pharmacy identifies that requests for Rikodeine cough syrup have dramatically increased in recent weeks. Rikodeine contains dihydrocodeine tartrate, an opioid medicine, which carries various risks, including the development of drug dependence. The pharmacist has observed that the same 3-4 patients are coming in every few days and asking to speak directly to the pharmacist manager, who appears to have been supplying Rikodeine to these patients without any meaningful discussion. The pharmacist attempts to raise this with the pharmacist manager but their concerns are dismissed.

The employee pharmacist considers all the relevant information, such as:

- state and territory medicines and poisons legislation, which sets out obligations around supplying drugs of dependence which includes Schedule 3 medicines
- professional practice standards and guidelines published by professional organisations (such as Standards 4, 5 and 6 of the PSA *Professional Practice Standards*)
- the Board's *Code of conduct*, which describes the Board's expectation of professional behaviour and conduct (refer to sections 1.1 and 1.2 of the Code of conduct around providing good care)
- the Board's *Guidelines for pharmacists on the safe provision of pharmacy services including medicines and advice*, which obliges all pharmacists to raise concerns around identified deficiencies or unsatisfactory practice with the leaders and managers of the service (see Guideline 1: Leadership/management in practice).

In this case the employee pharmacist elects to discuss their concerns with the proprietor of the pharmacy, incorporating relevant references from the above information.

What additional information should the proprietor consider when dealing with this case?

Proprietors have an obligation to respond to safety concerns, and intervene immediately to address any safety risk, as described in the Board's *Guidelines for pharmacists on the safe provision of pharmacy services including medicines and advice*. If a manager is appointed in a community pharmacy, this does not absolve the proprietor of their responsibility to ensure that pharmacy services are delivered in accordance with legislation, professional practice standards, relevant guidelines and codes. As part of their response to this issue, the proprietor needs to review the relevant policies and procedures at the pharmacy and align them with the sources of information listed above and ensure that staff are familiar with and apply them in practice.

Case study 2 - Reducing the risk of dispensing errors

A proprietor has recently bought a pharmacy and is inspecting the dispensary to ensure it is adequately equipped to reduce the risk of dispensing errors. They notice that each dispensing station has a barcode scanner, but one of them is not working. Staff using that dispensing station are either not scanning products with barcodes at all, or using a scanner attached to another dispensing station, which is creating an interruption to the overall workflow in the dispensary. The proprietor wonders if they should replace the broken scanner.

The proprietor considers their obligations, as set out in the following:

- Standards and guidelines published by State and Territory pharmacy premises authorities which may include the use of specific equipment to reduce the risk of dispensing errors, such as barcode scanners.
- The Board's *Code of conduct* which sets out good practice in relation to risk management (refer to Section 7.1 Risk management).
- The Board's *Guidelines for pharmacists on the safe provision of pharmacy services including medicines and advice*, which describe obligations for leaders and managers to provide the necessary tools and resources to support safe delivery of pharmacy services, and the need to establish processes to prevent and manage incidents (refer to Guideline 1.2 (b) and (g)).
- Resources published by the Australian Commission for Safety and Quality in Healthcare such as the *NSQHS Standards Risk management approach.*
- Professional practice standards, guidelines and other resources published by member organisations and professional indemnity insurers that address risk management.

In this case, the proprietor considers that barcode scanners are a tool that can reduce the risk of dispensing errors and decides to purchase a replacement scanner. While waiting for its delivery, the proprietor directs staff to scan all products dispensed by using another scanner, and to alert patients that dispensing their prescriptions may take a bit longer than usual. The proprietor also reviews any internal policies or procedures on reducing the risk of dispensing errors, including alternative strategies to use when a product does not have a barcode.

Case study 3 - Effective communication when there's a safety issue

A pharmacist receives a prescription from a patient for a high-risk medicine. The pharmacist recognises immediately that the dose is well above the accepted therapeutic range and suspects that an error has been made by the prescriber. Without alerting the patient unnecessarily and potentially undermining their relationship with the prescriber, the pharmacist obtains consent from the patient to contact the prescriber to clarify the prescription. The prescriber disagrees with the pharmacist and insists there is no error, ending the call abruptly. The pharmacist contemplates their next steps.

Relevant sources of information in this case include:

- professional practice standards and guidelines which address communication, such as PSA's *Professional Practice Standards*, Standard 3: Collaborative practice
- the Board's *Code of conduct* which describes the importance of effective, respectful communication between all health practitioners, and the importance of communicating relevant and timely information about a patient clearly and accurately within the bounds of relevant privacy requirements (see section 3.2, Principle 5 and section 5.1 of the Code of conduct)

- the Board's *Guidelines for pharmacists on the safe provision of pharmacy services including medicines and advice* which stress the importance of patient safety in all clinical decisions and the obligation to raise safety concerns with relevant healthcare providers
- resources published by the Australian Commission for Safety and Quality in Health Care on communication, such as the *Communicating for Safety Standard.*

In this case, the pharmacist telephones the prescriber a second time to reiterate their concerns, highlighting the risks to patient safety, and offering to email written material to support their recommendation. Recognising that pharmacists are independent health care professionals, and bear responsibility for their actions and decisions they make, and that they have the right to refuse to dispense a medicine they believe to be unsafe, the pharmacist chooses not to dispense the prescription and explains to the patient their concerns. They caution the patient against getting the prescription dispensed elsewhere and strongly recommend they return to their GP for further assessment. The pharmacist makes a detailed file note to document the incident (which can be recorded in the patient's electronic record or, in the absence of one, a hard copy or other form of pharmacy incident log).

Case study 4 - Virtual care

A community pharmacist receives a prescription at their pharmacy from a neighbour of a patient. The neighbour advises that the patient asked for the prescription to be delivered to their home. The neighbour has no information about the patient and there is limited dispensing history at the pharmacy for the patient. The pharmacist considers how to best manage the situation in to ensure they can obtain the information they need to dispense the medicine safely, and also to ensure that the patient receives appropriate advice.

Relevant information to this case includes:

- professional practice standards and guidelines which address providing healthcare in a virtual environment, such as on the telephone or using video-enabled communication methods, such as PSA's Digital health guidelines for pharmacists
- the Board's Code of conduct which applies to pharmacy services delivered in all circumstances, including when the patient isn't physically present, along with the National Boards' *Information for practitioners who provide virtual care*, which demonstrates how the Code of conduct applies to virtual care delivery (available on the Ahpra website)
- the Board's *Guidelines for pharmacists on the safe provision of pharmacy services including medicines and advice* which stresses the importance of providing advice whenever medicines are supplied to patients by pharmacists (refer to Guideline 4.1)

In this case, the pharmacist telephones the patient before dispensing the prescription, to gather all the required information from the patient to assess the safety of the prescription, just as they would if the patient were physically present in the pharmacy. The pharmacist also telephones the patient back when they have completed the prescription and provides verbal advice, invites further contact if needed, and includes written advice with the medicine when it is delivered to the patient later that day.

Case study 5 - Supporting staff development to deliver evidence-based, person-centred care

A pharmacist working in a community pharmacy overhears a staff member assisting a woman with a request for a complementary medicine for severe nausea. The woman is also pregnant. The staff member is recommending a product for which the pharmacist knows there is no evidence of benefit in treating the condition. The pharmacist decides to intervene to ensure that the patient receives appropriate advice, and their practice aligns with information from the following sources:

- The Board's *Code of conduct*, which addresses issues around evidence-based practice, patient-centred care, and appropriate referrals (see sections 1.1 and 1.2 of the Code of conduct).
- Professional practice standards – for example PSA's *Professional Practice Standards*, Standard 1: Person-centred care.
- The Board's *Guidelines for pharmacists on the safe provision of pharmacy services including medicines and advice*, which addresses the need for pharmacists to support and guide their staff to practise safely (refer to Guideline 1.2 (a)).

In this case, the pharmacist assesses the patient, and:

- acknowledges their preference for a complementary medicine

- explains to the patient the lack of evidence for benefit, and the risks if adequate treatment is not accessed
- refers the patient to their GP, due to concerns of severe nausea warranting further assessment
- confirms appropriate management of patient queries with the staff member involved including when the patient should be referred to the pharmacist and agrees to further explore with them how to address any gaps in training to support their work.

Case study 6 - Managing workload safely

A pharmacy department in a hospital has several pharmacists call in sick on the same day. The manager wonders how to provide services to the hospital patients safely, considering they are understaffed, and staff who are present are likely to be under increased pressure to cope with the workload.

The following sources of information are relevant to this case:

- Workplace health and safety legislation which obliges leaders and managers to ensure that employees are adequately supported to deliver pharmacy services safely and effectively.
- Professional practice standards such as AdPha's Clinical Pharmacy Standards and PSA's Standards of Practice, Standard 4: Service Delivery.
- The Board's Code of conduct which contains information on practitioner performance and minimising the risk of fatigue, which can impact patient safety.
- The Board's *Guidelines for pharmacists on the safe provision of pharmacy services including medicines and advice* which oblige leaders and managers to balance patient service needs with available resources (refer to Guideline 1.2 (c)).
- The publication *Managing stress in Pharmacy: creating a healthier working environment in pharmacy by managing workplace stress* published by the Pharmacists' Support Service.

In this case, the manager undertakes a risk assessment to determine if any services could be provided on an alternative day, and whether any essential services could be temporarily modified. The manager also contacts the nurses in charge of any clinical areas with a modified pharmacy service to provide arrangements for any urgent requests for additional support.

What about ongoing workload issues?

Balancing patient service needs with available resources is obligatory for leaders and managers. In a community pharmacy for example, if additional staff cannot be engaged to safely manage the workload, services such as vaccination may need to be suspended, with patients given advice for obtaining the service at an alternative location. This is described in the Board's *Guidelines for pharmacists on the safe provision of pharmacy services including medicines and advice* (see Guideline 1, introductory information and guidance statement 1.2 (c)). The Board recognises that multiple factors need to be considered to determine whether the overall pharmacy service is adequately resourced, so this needs to be determined by the leaders and managers and informed by a risk assessment. A risk assessment considers several factors including the services provided at the pharmacy and whether these are suitably supported by things such as facilities and equipment, standard operating procedures and sufficient staff including pharmacists and support staff.

Case study 7 - Accessing reference material to support safe practice

A pharmacist working in a community pharmacy notices that the subscription for the pharmacy's online drug interaction resource has lapsed. They contemplate the value of renewing the subscription given they tend to rely on an alternative hardcopy reference book that is revised and reprinted annually. They look for guidance on this and note the following sources of information:

- The Board's *Guidelines for pharmacists on the safe provision of pharmacy services including medicines and advice*, Guideline 1: Leadership/management in practice, which provides general guidance and points to relevant external documents.
- Information published by pharmacy premises authorities about reference texts and other resources that must be maintained at community pharmacies.
- Professional Practice Standards, guidelines and other documents published by professional organisations about reference texts and other resources.

- Legislation such as State and Territory medicines and poisons legislation and Work Health and Safety legislation.
- Guides and other documents published by Commonwealth and State/Territory health departments (such as the *Guiding Principles for medicine management in the community* or program specific requirements such as protocols for opioid dependence therapy programs).

The pharmacist discusses this further with the proprietor. They review the last risk assessment on resources and note that the online drug interaction resource, updated monthly, will support pharmacists to practice safely by accessing up-to-date information on drug interaction management. The subscription is renewed and a process for regular review of information sources to support safe practice is confirmed and documented.

I'm an employee pharmacist in a community pharmacy. What if the proprietor refuses to provide me with adequate reference materials?

Proprietors of community pharmacies are responsible for adequately resourcing a pharmacy. If there are insufficient resources provided, employee pharmacists may not be able to make informed decisions about the safety of medicines or other services and therefore may not be able to routinely deliver some medicines or other services.

If the issue has been raised with the proprietor and they refuse to provide adequate tools and resources to enable their staff to practise safely, they may be subject to investigation by an authorised entity such as a pharmacy premises regulator, or the Board if a notification is made. Proprietors should be aware of these potential ramifications.

All pharmacists are responsible for their own practice and conduct. Pharmacy services, such as providing medicines and advice, should not be delivered unless pharmacists can access the information they need to support safe practice.

What if I work in a setting other than a community pharmacy or hospital pharmacy department?

All pharmacists need access to reference material that aligns with the services they are providing. For example:

- pharmacists who work in settings such as GP clinics or aged care facilities may be able to access reference material already in use at the practice setting but may need to supplement that with a subscription to other products, which can be raised with their employer
- self-employed pharmacists and some pharmacists who conduct home medicines reviews may need their own subscriptions to multiple reference products that are relevant to their work.

Pharmacists are professionals and by gaining general registration, have demonstrated competence to be able to identify the resources they need to practice safely and to ensure they use them when needed.

Case study 8 - Supporting staff training

A proprietor needs to employ a new pharmacy technician at their community pharmacy. They receive several applications but none of the applicants have completed any pharmacy technician training courses. The proprietor wonders whether they can employ someone who hasn't undertaken formal training.

The proprietor considers information from the following sources:

- The Board's *Guidelines for pharmacists on the safe provision of pharmacy services including medicines and advice* which describe obligations such as ensuring that staff are capable of performing their roles and suitably trained, identifying any training required and supporting staff to undertake it (see Guideline 1.2 (e))
- Professional practice standards which set the expectation that pharmacists actively support and encourage team members to improve their knowledge and skills, such as through appropriate training (for example, see PSA's *Professional Practice Standards*, Standard 2: Responsibility and accountability).

In this case, the proprietor:

- considers the tasks that need to be performed by the new staff member
- considers suitable training courses where the learning objectives align with the intended role
- employs a technician before training has commenced, limiting duties to low-risk tasks and providing close supervision

- periodically reassesses the technician's progress in training, until such time as they are capable of performing their role with modified supervision arrangements that support safe practice (noting that pharmacists are required to supervise support staff at all times).

How does this differ for training, education and continuing professional development obligations for pharmacists?

Pharmacists are obliged to identify and complete the training they need to maintain competence and perform their roles safely and professionally, in accordance with the Board's *Registration Standard: Continuing Professional Development*. Leaders and managers are obligated to ensure that staff are capable of performing their roles and supported to undertake any required training (see Guideline 1.2 (e) of the Board's *Guidelines for pharmacists on the safe provision of pharmacy services including medicines and advice)*. Mandatory training may be required for the lawful provision of some services, for example:

- administration of vaccines
- prescribing
- participation in local programs such as opioid treatment programs.

Questions for consideration

The Board invites responses to any or all of the questions outlined in the table below as well as general comments on the consumer fact sheet and the following draft guidelines:

- Guideline 1 – Leadership/management in practice
- Guideline 2 – Supporting informed patient choice
- Guideline 3 – Confidentiality and privacy
- Guideline 4 – Effective communication when delivering pharmacy services.

1.	**Is the overall content of the draft guidelines helpful?**
2.	The draft guidelines include additional content on leadership and management so that it is applicable to all practice settings. **Is the new content on leadership and management in Guideline 1 clear and helpful? Why or why not?**
3.	The draft guidelines do not set prescriptive requirements around workload, staffing and supervision, but emphasise the importance of risk assessment when determining staffing requirements. **Is the draft content in Guideline 1 around determining staffing levels according to a risk assessment clear and helpful? Why or why not?**
4.	The draft guidelines no longer include a mandatory list of reference texts but emphasise the importance of risk assessment when determining suitable reference material required in each practice setting. **Is the draft content in Guideline 1 around reference material clear and helpful? Why or why not?**
5.	**Do you have any other feedback about Guideline 1 Leadership/management in practice?**
6.	**Do you have any feedback about Guideline 2 Supporting informed patient choice?**
7.	**Do you have any feedback about Guideline 3 Confidentiality and privacy?**
8.	**Do you have any feedback about Guideline 4 Effective communication when delivering pharmacy services?**

9.	**Is there any content that needs to be changed, added or deleted in the draft guidelines?**
10.	**Are the language and structure of the draft guidelines helpful, clear and relevant? Why or why not?**
11.	**The Board is proposing to retire some of its current guidelines (refer to Attachment C). Do you agree that alternative sources of published information are accessible and fit for purpose to assist pharmacists encountering those issues in practice? Please provide details.**
12.	**Would the draft guidelines result in any potential negative or unintended effects? If yes, please describe.**
13.	**Would the draft guidelines result in any potential negative or unintended effects for people vulnerable to harm in the community, such as culturally and linguistically diverse, LGBTQI+ peoples, children, the aged, those living with disability, and people who are the potential targets of family and domestic violence? If yes, please describe.**
14.	**Would the draft guidelines result in any potential negative or unintended effects for Aboriginal and Torres Strait Islander Peoples? If yes, please describe.**
15.	**Do you have any feedback about the Consumer fact sheet?**
16.	**Do you have any other feedback?**

Options – guidelines

The Board considered the following options prior to its review of the guidelines.

Option one - Status quo

The current guidelines were published in 2015 and have not been reviewed until now, largely due to the impact of the COVID-19 pandemic which required the Board to focus on addressing emerging priorities. There have been several developments in practice since then and, while available information suggests the guidelines are working reasonably well, there are several opportunities to improve the guidance.

Maintaining the status quo of the guidelines would miss these opportunities for improvement and result in the guidelines becoming progressively less contemporary and relevant.

Option two – Develop revised guidelines

Reviewing and revising the guidelines will ensure that they continue to be relevant, contemporary and aligned with professional practice standards. It will capture the opportunities that would be missed in option one. It will provide an opportunity to consult stakeholders and in particular practitioners and the public to advise how the guidelines can be more relevant and helpful, in the public's interest.

Contemporary guidelines will provide consumer, regulatory, employer and professional bodies with clear guidance about the Board's expectations of the professional conduct of the practitioners they regulate in the public's interest.

Contemporary guidelines can enable pharmacists to respond to changes in practice whereas the current guidelines may be a barrier to innovation.

Option three – Retire the existing guidelines

Under option three, the Board would withdraw the existing guidelines and rely solely on the Code of conduct. While the Code of conduct sets out the Board's expectations of professional behaviour and conduct for pharmacists it does not provide specific guidance about particular issues relevant to pharmacy practice. The Board considers that relying solely on the Code of conduct would miss the opportunity to provide clear guidance to pharmacists that supports safe practice which meets expectations of the Board and the public.

Preferred option

The Board prefers option two.

Relevant section of the National Law

The relevant sections of the National Law are Sections 39, 40 and 41.

Estimated impacts of the draft guidelines

The Board anticipates that the draft guidelines will provide greater flexibility for pharmacists in the delivery of healthcare services. For example, as the guidelines no longer specify the training required by a dispensary technician, a pharmacist in a leadership/management position can choose the most appropriate training for their practice setting.

The impact for pharmacists can be minimised by providing advance notice before the draft guidelines take effect, providing pharmacists with the opportunity to become familiar with the draft guidance.

The Board will develop and publish supporting information where necessary to assist pharmacist in understanding their obligations.

The Board will undertake wide-ranging public consultation with pharmacists, consumers, governments, employers, regulatory bodies, professional organisations and other entities to gather feedback about the proposed changes.

Any unintended impacts of the draft guidelines raised during consultation will be considered and actions will be taken to mitigate any potential consequences for stakeholders including pharmacists, patients, Aboriginal and Torres Strait Islander Peoples and other priority groups in the community.

Further information about anticipated impacts is included in the Patient and Consumer Health and Safety Impact Statement at Attachment E.

Attachment A: Draft Guidelines for pharmacists on the safe provision of pharmacy services including medicines and advice

Date: TBA

These guidelines aim to inform registered pharmacists and the community about the Board's expectations of pharmacists in relation to the provision of pharmacy services, including medicines and advice.

They 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). The Board may publish additional information about the provision of pharmacy services.

Who needs to use these guidelines?

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

a) General.
b) Non-practising, if that pharmacist is a proprietor of a pharmacy business.
c) Provisional.
d) Limited.

Education providers and employers may also bring these guidelines to the attention of their students and employees respectively.

How to read this document

The Board guidelines have been separated into context and guidance. The information contained in the context provides important factual information and references to legislation, standards, other guidelines and other useful documents. The Board guidance must not be read in isolation of the contextual information.

Headings of sections of the Code of conduct have been displayed as an infographic at the top (right) of each guideline. This indicates which sections of the Code of conduct are relevant to the issue/s addressed in that guideline.

Guideline title

Code of conduct
(Relevant sections)

(Context:

- factual information about the issue, including references to relevant legislation, practice standards, other guidelines and other useful documents
- applicable explanatory information that is highlighted by the Board (not standards or requirements developed by the Board)).

The Board's guidance for pharmacists about the issue

- **(guidance statement)**

Introduction

These guidelines are intended to support safe practice by pharmacists delivering pharmacy services in accordance with relevant professional practice standards and legislation. The Board's Code of conduct for pharmacists and other relevant guidelines should also be considered

These guidelines address various matters including:

- responsibilities of pharmacists in leadership and management roles, that impact the safe, effective delivery of pharmacy services to the public
- patient choice about where they access pharmacy services
- patient confidentiality and privacy
- communication with patients and other healthcare practitioners.

Innovation and technology[2] have led to the development of new modes of delivery of health care, including pharmacy services. These guidelines apply regardless of how pharmacy services are delivered, as all pharmacists are responsible for delivering safe and appropriate care, and for ensuring that their own practice meets the standard expected by the Board and the community.

Pharmacists must ensure their own practice is:

- compliant with relevant legislation
- compliant with relevant pharmacy practice standards and guidelines
- aligned with the conduct expected of pharmacists as set out in the Code of conduct for pharmacists and the codes of ethics for pharmacists
- compliant with all relevant Board guidelines for pharmacists
- covered by professional indemnity insurance arrangements that comply with the Board's Registration standard: Professional indemnity insurance arrangements.

These guidelines are not a substitute for – and should be read in combination with – the above sources of information.

If there is any conflict between these guidelines and the law, the law takes precedence.

Failure to adhere to these guidelines and the above standards and requirements may result in poor practice, which may be referred to the Board for investigation and possible action under the National Law.

The term 'patient' in these guidelines means a person receiving healthcare from a registered health practitioner. It includes clients and consumers. Depending on the context of practice and recognising the importance of patient-centred care, the term 'patient' can also extend to families and carers (including kinship carers), and to groups and/or communities as users of health services.

Refer to *Definitions* at the end of this document for more terminology explanations.

Cultural Safety

In 2022, Cultural safety was enshrined in the National Law (see Section 3A of the National Law).

The National Registration and Accreditation Scheme's (the National Scheme) statement of intent[3] includes a commitment to apply the National Law to ensure a culturally safe health workforce supported by nationally consistent standards, codes and guidelines across all professions in the National Scheme. Aboriginal and Torres Strait Islander health and cultural safety is addressed in Part 2 of the Board's Code of conduct.

The definition of cultural safety for the National Scheme can be found in the *Definitions* section of these guidelines.

[2] For information on the use of artificial intelligence in healthcare including pharmacy services, refer to the Ahpra website https://www.ahpra.gov.au/Resources/Artificial-Intelligence-in-healthcare.aspx

[3] Refer to https://www.ahpra.gov.au/About-AHPRA/Aboriginal-and-Torres-Strait-Islander-Health-Strategy.aspx#statement-of-intent

In developing the *Guidelines for pharmacists on the safe provision of pharmacy services including medicines and advice*, the Board is guided by the principles as set out in the National Law, including:

- protection of the public
- public confidence in the safety of services provided by registered health practitioners and students
- development of a culturally safe and respectful health workforce.

Therefore, whenever pharmacy services are delivered, it is fundamental to ensure that the care that is given:

- is responsive to Aboriginal and Torres Strait Islander Peoples and their health; and
- contributes to the elimination of racism in the provision of health services.

There are a range of initiatives relevant to pharmacy practice that address the health needs of Aboriginal and Torres Strait Islander Peoples and contribute towards addressing inequity.

The Pharmaceutical Society of Australia has published *Guideline for pharmacists supporting Aboriginal and Torres Strait Islander peoples with medicines management* which describes the professional obligations of pharmacists when supporting Aboriginal and Torres Strait Islander peoples with culturally safe and responsive care and medicines management.

Relevant legislation, quality standards and practice standards

Safe pharmacy practices require compliance with legislation, quality and practice standards and related guidelines.

Legislation

Pharmacists must comply with all legislation relevant to the practice of pharmacy in their jurisdiction. Failure to practise in accordance with legal requirements may lead to action by authorities. Under the National Law, such matters may be referred to the Board for appropriate action or to a relevant regulatory body in a co-regulatory jurisdiction (see *Definitions*).

Legislation referred to in these guidelines includes:

- state and territory medicines and poisons legislation
- state and territory pharmacy ownership legislation
- Commonwealth legislation such as the Privacy Act, and associated Privacy Principles
- Health Practitioner Regulation National Law (the National Law), as in force in each state and territory.

Other legislation not listed in these guidelines may also be relevant to pharmacists' practice as well as any other standards referenced in relevant legislation, for example the Poisons Standard (the SUSMP[4]).

[4] SUSMP refers to the Standard for the Uniform Scheduling of Medicines and Poisons. Refer to https://www.tga.gov.au/how-we-regulate/ingredients-and-scheduling-medicines-and-chemicals/poisons-standard-and-scheduling-medicines-and-chemicals/poisons-standard-susmp

Quality standards, practice standards, codes and guidelines

Adhering to principles in quality standards/guides is crucial for safe pharmacy practice. Depending on a pharmacist's practice setting, relevant standards and guides may include, but are not limited to those set out in the table below. Note that the resources included in the below table were current at the time of publication of these guidelines.

Organisation	Standards / Guides
Advanced Pharmacy Australia (AdPhA)	Standards of Practice Series
Australian Commission for Safety and Quality in Healthcare (ACSQHC)	Various standards and guidelines
Australian Government Department of Health and Aged Care	*Guiding principles for medicine management in the community* Other guidelines and relevant documents
Australian Government Office of the Australian Information Commissioner (OAIC)	*Australian Privacy Principles* *Australian Privacy Principles guidelines* *Guide to health privacy* *Guide to securing personal information*
Pharmaceutical Society of Australia (PSA)	Professional Practice Standards, guidelines and other relevant documents.
Pharmacy Board of Australia / National Boards / Ahpra	Code of conduct Guidelines for pharmacists Guides and resources for health practitioners
Pharmacy premises regulatory authorities or equivalent	Various standards, codes and guidelines
Standards Australia	*AS 85000: – Australian Community Pharmacy Standard* and other relevant standards
State and Territory Health Departments	Guidelines and other relevant documents
Therapeutic Goods Administration	Codes, guidelines, product standards and other relevant documents

Other referenced documents

- *The Australian Charter of Healthcare Rights* – published by the ACSQHC
- *'Managing Stress in Pharmacy: creating a healthier working environment in pharmacy by managing workplace stress'* – published by the Pharmacists' Support Service.

Note: Refer to the websites of the above listed organisations for further information and document access.

How may these guidelines be used?

The purpose of these guidelines is to assist the Board in its functions under the National Law relating to the protection of the public, by setting and maintaining standards of practice to guide pharmacists in relation to the provision of safe pharmacy services which often includes the provision of medicines and advice.

Conduct that is not consistent with these guidelines and/or laws, practice standards or other guidelines may result in a notification to the Board or jurisdictional regulatory body. Such notifications may be made by an individual or through other processes such as audits carried out by state/territory pharmacy premises regulators (or equivalents).

Whilst these guidelines are not legally binding rules or regulations, under section 41 of the National Law and other jurisdictional laws these guidelines can be used in disciplinary proceedings, as evidence of what

constitutes appropriate professional conduct or practice for pharmacists. When considering notifications against pharmacists, the Board considers whether the pharmacist's conduct is consistent with these guidelines. The Board will also consider legislation, practice standards and guidelines relevant to pharmacy practice as well as the Code of conduct and its other guidelines for pharmacists.

If a pharmacist's professional conduct varies significantly from these guidelines, the pharmacist should be prepared to explain and justify their decisions and actions. Serious or repeated failure to meet these guidelines may have consequences for a pharmacist's registration.

Further information for pharmacists on the possible outcomes of notifications is available on the of the Australian Health Practitioner Regulation Agency (Ahpra) website.

Guidelines

1. Leadership/management in practice

Code of conduct
All sections

By meeting the requirements of general registration in the profession, pharmacists have demonstrated self-leadership and an ability to manage professional contribution in practice. During ongoing practice under general registration, pharmacists may accomplish higher performance levels in these and related competencies, in a range of leadership and management roles in various practice settings. Pharmacists are responsible for their own practice and conduct, and are required to show the leadership and management necessary to perform their role effectively and safely. This includes demonstrating accountability when utilising support staff in the delivery of pharmacy services. All pharmacists, regardless of their role are encouraged to use this guidance where applicable, including in their professional development in preparation for future roles.

The settings where pharmacists practise and where pharmacy services are delivered are varied, including private settings and public and private healthcare organisations. The leadership and management obligations of pharmacists in different practice settings will depend on their roles, for example:

- proprietor of a community pharmacy (a pharmacist holding a proprietary or pecuniary interest in a pharmacy or as defined in state and territory legislation)
- director of pharmacy in a hospital pharmacy or healthcare service
- owner of a business employing, contracting or otherwise engaging pharmacists as consultants
- self-employed pharmacist providing pharmacy services.

In certain practice settings, there may be shared leadership and management responsibilities, such as between a proprietor of a community pharmacy and a pharmacist employed to manage the day-to-day operation of the community pharmacy. However, while a pharmacist employed to manage day-to-day operations of a community pharmacy may be held responsible for the services that are provided to each member of the public, proprietors remain accountable for ensuring that the pharmacy business is conducted safely, ethically, professionally and in accordance with legislation and related information such as guidelines.

Pharmacists in leadership/management roles are responsible for ensuring that good governance arrangements are in place at their practice setting. They are accountable for making sure that pharmacy practice and services delivered from their practice setting are safe, and in accordance with:

- all applicable state, territory or Commonwealth legislation
- applicable professional practice and quality-assurance standards and guidelines
- Pharmacy Board of Australia registration standards, codes and guidelines, including codes, guidelines, position statements and other relevant documents jointly developed with Ahpra and other National Boards.

Pharmacists in leadership/management roles are also responsible for ensuring that pharmacists and other staff under their management are:

- capable of performing their roles
- able to demonstrate and exercise the self-leadership and self-management expected of individuals in those roles

- providing culturally safe practice for Aboriginal and Torres Strait Islander Peoples and working to eliminate racism in the provision of health services[5].
- supported to provide safe pharmacy services in accordance with the above and any other applicable information that underpins the ethical, legal and safe provision of quality pharmacy services.

Note for proprietor pharmacists

Pharmacists who are proprietors should note the following:

- State and territory pharmacy ownership legislation specifies the type of registration a proprietor pharmacist must hold or is entitled to hold.
- Where the ownership provisions in legislation set out non-practising registration (as provided for under the National Law) as being a registration type suitable for ownership of a pharmacy business, the Board deems the leadership/management responsibilities set out in these guidelines to apply equally to proprietor pharmacists holding non-practising registration or general registration.
- A pharmacist who holds non-practising registration and holds a proprietary or pecuniary interest in a pharmacy business cannot abrogate or delegate their legal and professional responsibilities (including those relating to leadership and management) to another proprietor/partner or employee of the pharmacy business.
- All proprietors of a pharmacy (regardless of where they are physically located) are obligated to:
    - ensure that the requirements of relevant legislation, professional practice standards and guidelines and Pharmacy Board of Australia registration standards, codes and guidelines are met at the pharmacy
    - vigilantly maintain an active interest in how the practice of pharmacy is being conducted at the pharmacy and to intervene to address any imminent safety risk, or inadequate operation or practice
    - ensure that all service delivery in the pharmacy, including that carried out by other practitioners (regulated or unregulated), is carried out by individuals who are suitably qualified and legally able to provide those services.

Leading and managing professional conduct

The Code of conduct published by the Board sets out the standards of professional conduct expected of all pharmacists, which the public also expects. Pharmacists in leadership/management roles are primarily responsible for monitoring and taking steps to ensure that the staff under their management deliver healthcare services in a professional manner. The *Code of conduct* also highlights responsibilities for pharmacists in a leadership/management position, for example:

- fostering a safe work environment through leadership to support the rights and dignity of Aboriginal and Torres Strait Islander people and colleagues (refer to 2.2 Cultural safety for Aboriginal and Torres Strait Islander Peoples in the *Code of conduct*)
- taking appropriate action against discrimination, bullying and harassment (refer to 5.3 Discrimination, bullying and harassment in the *Code of conduct*).

[5] Ahpra's Aboriginal and Torres Strait Islander Health Strategy Unit is currently working with the Cultural Safety Accreditation and Continuing Professional Development (ACPD) Working Group, with oversight by the Aboriginal and Torres Strait Islander Health Strategy Group, in undertaking a project to inform National Board's future requirements for cultural safety training. The Board will publish information about these requirements when available.

Risk management

Pharmacists in leadership/management roles may be responsible, either wholly or in part, for identifying, assessing and managing risks to patients, staff, and their organisation. Risk management is an important component of clinical governance[6], and assists in demonstrating accountability to patients and the community for assuring the delivery of safe, effective and high-quality, patient-centred healthcare services.

Standards, frameworks and supporting documents on risk management have been published by the Australian Commission on Safety and Quality in Health Care (ACSQHC), pharmacy professional bodies, membership organisations including those who provide professional indemnity insurance, and other organisations. These resources may assist pharmacists when:

- establishing systems, processes, policies and procedures
- driving quality improvement
- responding to change
- implementing a new service
- managing incidents and adverse events.

Although the *Code of conduct* outlines under *7.1 Risk management* a number of obligations for all pharmacists, pharmacists in leadership and management roles need to identify their roles and obligations in supporting pharmacists to practise good risk management.

Resources

Pharmacists in leadership/management roles are responsible for adequately resourcing the practice setting where pharmacy services are delivered, to ensure that services are provided in a safe and professional manner. Resources include human resources, such as pharmacists and other staff, as well as equipment, reference material, and any other resources necessary to operate a pharmacy service.

A thorough and systematic assessment of potential risks associated with quality and safe service delivery enables a pharmacist in a leadership/management position in the practice setting to determine what is needed to safely provide a pharmacy service. This includes consideration of the type of service/s provided in the practice setting, the existing resources, workload, the scope of practice of each individual participating in service delivery, and any other relevant factors. Pharmacists in leadership and management roles also have obligations under work health and safety laws to ensure that employees are adequately supported with resources that enable them to deliver pharmacy services safely and effectively.[7]

[6] As defined in the *Code of conduct*: 'Clinical governance describes a systematic approach to maintaining and improving the quality of patient care within a clinical setting. It ensures that everyone – from frontline clinicians to manager and members of governing bodies, such as boards – is accountable to patients and the community for assuring the delivery of safe, effective and high-quality services.' For additional information see ACSQHC National Model Clinical Governance Framework and ACSQHC Clinical Governance Standard. Pharmacy member organisations may also have customised clinical governance resources.

[7] https://www.safeworkaustralia.gov.au/safety-topic/managing-health-and-safety/mental-health/psychosocial-hazards/poor-support

Human resources – pharmacists and other staff

Pharmacy services that are inadequately resourced place pharmacists at risk of poor performance and impacts on their health, which ultimately places the public at risk. The Code of conduct directs all pharmacists to be aware of the factors that lead to poor practitioner performance and take responsibility for managing them, for example recognising and taking steps to minimise the risk of fatigue (refer to *7.2 Practitioner performance* in the *Code of conduct*).

Pharmacists in leadership and management roles have an obligation to assist pharmacists and other staff to identify and respond to the factors that may lead to poor performance. They may also need to take other steps such as employing additional staff and/or other resources. Appropriate induction, onboarding and training is also part of ensuring a pharmacy service is adequately resourced.

'Managing Stress in Pharmacy: creating a healthier working environment in pharmacy by managing workplace stress' published by the Pharmacists' Support Service, contains useful guidance on workplace pressures, including workload.

The demand for pharmacy services is dynamic and at times unpredictable, creating pressures that can cause patient safety issues. In responding to demand, pharmacists in leadership roles can adapt elements of service delivery to safely manage an overall pharmacy service. For example, a vaccination service may need to be suspended in a community pharmacy and other service access pathways identified when there aren't enough staff to safely manage other essential areas of the pharmacy service.

Where a shortage of staff is occurring at an increasing frequency, safe practice can be supported by prompt action to secure the required resources, or alternatively modifying or ceasing impacted services during periods when they cannot be provided safely.

The Board does not specify parameters, such as prescription numbers, for resource requirements in practice as this needs to be determined on a case-by-case basis, according to a risk assessment conducted by the pharmacist in a leadership/management role at each practice setting. Evidence of completion of a risk assessment may be requested by the Board in circumstances where allegations of unsafe service delivery are under its investigation.

Reference material

The practice of pharmacy takes place in a diverse range of practice settings by pharmacists with varying scopes of practice. While it is the responsibility of individual pharmacists to use appropriate references in their practice, the reference materials required in each practice setting to support the delivery of quality and safe pharmacy services is ultimately determined by pharmacists in leadership/management roles completing a thorough and systematic assessment of potential risks associated with the service delivery. Professional practice standards describe the quality and recency of reference material that should be included in facilities provided by pharmacists for the safe delivery of pharmacy services.

The Australian Department of Health and Aged Care's Guiding principles for medicine management in the community provides an extensive list of recommended references in Principle 4 – Information resources, and guidance to healthcare professionals around the use of quality and evidence-based medicines information. Pharmacists may also be required to have access to specific references as part of their authorisation to participate in local health service programs or operate a pharmacy.

Guidance

1.1 All pharmacists should raise any concerns around any identified deficiencies at their practice setting with the leaders and/or managers of the service.

1.2 Pharmacists in leadership/management roles should thoroughly and systematically assess the risks associated with quality and safe service delivery, and:

a. support and guide pharmacists and other staff to practise safely, ethically, professionally and in accordance with legislation and related information such as guidelines, and confirm their undertaking to do so
b. provide access to and confirm routine use of current, relevant evidence-based tools, systems and resources that are fit for purpose to support safe delivery of pharmacy services by pharmacists and other staff
c. balance patient service needs with available resources, in order to provide the greatest benefit for patients, engaging additional available human resources to support ongoing health service delivery when required
d. ensure staff are appropriately supervised according to any legal requirements, and also commensurate with their experience, education and training, and role description
e. identify training required for staff to perform their roles and support staff to undertake the required training
f. ensure all pharmacists understand they are accountable when utilising support staff in the delivery of pharmacy services
g. establish processes and systems to monitor near misses and errors to identify individuals involved in clinical activities with a focus on accountability and transparency as well as a systems approach to understand, prevent and manage incidents.
h. document and respond to any concerns raised by staff about deficiencies at their practice setting.

2. Supporting informed patient choice

Code of conduct
1.1: Providing good care
4.1: Partnership
4.2: Informed consent

The Board's Code of conduct highlights that providing good care includes that pharmacists recognise and respect the rights of patients to make their own decisions about their current and future healthcare (refer to 1.1 Providing good care in the *Code of conduct*). The Code of conduct also describes informed consent and the risk of exploitation of patients, including financially, which can impact a patient's perception of their right to choose (refer to 4.1 Partnership and 4.2 Informed consent in the *Code of conduct*).

The Australian Charter of Healthcare Rights describes the rights a patient can expect when receiving healthcare. It addresses principles such as patients having their choices recognised and respected, and making decisions with their healthcare provider, to the extent that they choose and can do so.

Patients also have a right to choose where they obtain their medicines and access other pharmacy services, including when accessing virtual care.

Patients who request or consent to having their prescriptions exclusively dispensed at a particular pharmacy can choose to withdraw their consent at any time without providing a reason.

Guidance

As it is open to the patient to decide where to access their health care[8], pharmacists who have entered into arrangements with particular healthcare practitioners or other third parties, must not advise a patient or give them the impression that they are obliged to obtain, or continue to receive care from the health practitioners who have established the arrangement.

[8] There may be circumstances where health service provision options may be limited.

3. Confidentiality and privacy

Code of conduct
3.3: Confidentiality and privacy
8.3 Health records

Pharmacists receive confidential information from patients routinely as part of their practice. Private and sensitive information is shared with pharmacists in various ways, including verbally, in a hard copy document such as a prescription, or electronically. Patients may share information directly with pharmacists, or information may be received via other health practitioners or various platforms that are accessed electronically.

Commonwealth, state and territory privacy laws set out the privacy principles applicable to health providers, including pharmacists. The Australian Privacy Principles are legally binding and the Australian Privacy Principles guidelines provide guidance on how the principles are applied and interpreted under the Privacy Act 1988. The Office of the Australian Information Commissioner (OAIC) has also published the Guide to health privacy which provides further guidance on how the Australian Privacy Principles relate to healthcare environments including the circumstances where confidential information may be disclosed.

The Code of conduct describes the professional behaviour and conduct expected of pharmacists in relation to confidentiality and privacy (refer to 3.3: Confidentiality and privacy in the *Code of conduct*). Ahpra's website contains resources that provide guidance on confidentiality and privacy in relation to the use of emerging technologies in healthcare, such as the use of artificial intelligence.

State and territory premises regulators are responsible for ensuring the premises where pharmacy services are delivered are compliant with applicable legislation, standards and guidelines. This includes any requirements around premises design which ensure privacy and confidentiality for patients who access pharmacy services.

The importance of ensuring privacy and confidentiality for patients is emphasised in quality assurance and professional practise standards. Professional organisations may provide additional information to assist pharmacists in applying privacy laws to their practice.

Protecting confidential patient information

Information collection, storage and management (including disposal) by pharmacists poses significant risks to patient privacy. The Code of conduct requires that pharmacists ensure that records (including electronic records) are held securely and not subject to unauthorised access (refer to 8.3: Health records in the *Code of conduct*).

The OAIC has published a Guide to securing personal information which outlines a number of strategies that may be taken by pharmacists to protect their patients' confidential information.

Guidance

Every pharmacist is required to comply with the requirements around confidentiality and privacy and should ensure that the staff they manage and supervise understand how to comply with the requirements.

Pharmacists should keep abreast of current and emerging risks which may lead to breaches of confidentiality and privacy.

4. Effective communication when delivering pharmacy services

Communicating with patients

Code of conduct
3.2: Effective communication
5: Working with other practitioners
5.1: Respect for colleagues and other practitioners

Effective communication between a pharmacist and a patient is crucial to ensuring that patients are adequately informed and understand how to manage their health, for example, how to manage their medicines safely.

The Code of conduct states that patients should be encouraged and supported to be well-informed about their health. It also reminds pharmacists that patients have a right to choose whether to participate in treatment or accept advice (refer to 3.2 Effective communication in the *Code of conduct*).

Professional practice standards describe the expectations of pharmacists when communicating with patients about their health or their medicines. Patients have the right to expect that these discussions will take place in a private area.

When part of the dispensing process, a constructive two-way conversation is an integral part of enabling the safe and effective use of medicines. It is also an opportunity to perform a final check that the correct medicine is supplied to the correct patient. When presenting for repeat prescriptions, patients also can be engaged to discuss whether the medicine is having the desired outcome or if there are unwanted effects. Dispensing errors can also be detected if the opportunity is taken to further discuss patients' medicines with them at these times.

The Board's *Guidelines for advertising a regulated health service* discuss communication through advertising.

Communicating with members of the healthcare team

Effective communication between pharmacists and other members of the healthcare team is critical in ensuring safe patient care. The *Code of conduct* states that good care is enhanced by good relationships with colleagues, and when there is mutual respect and clear communication between all health professionals involved in the care of the patient (refer to Principle 5: Working with other practitioners and 5.1 Respect for colleagues and other practitioners in the *Code of conduct*). The code also highlights the importance of communicating relevant and timely information about a patient clearly and accurately, and that this should occur within the bounds of relevant privacy requirements (refer to 3.2 Effective communication in the *Code of conduct*).

Professional practice standards set the expectation that pharmacists discuss and resolve any concerns they identify about the safety or appropriateness of prescribed medicines with the prescriber. Patient safety concerns that are unrelated to a particular prescription may also come to a pharmacist's attention and may warrant communication with the patient's other healthcare providers. The patient's consent should be sought when communicating with a patient's other healthcare providers in accordance with privacy requirements (see Guideline 3: Confidentiality and privacy) except in circumstances where consent may not be required or possible.

There are patient safety risks when effective and timely communication does not occur, or when communication breaks down. Breakdowns in communication have led to patient harms, and in some cases patient deaths. Occasions may arise where a pharmacist may have concerns about the safety of a prescription or some other aspect of the patient's healthcare needs, which may not be resolved despite a reasonable attempt to discuss these with the prescriber.

Pharmacists understanding their professional obligations and responsibilities regarding their decisions about the delivery of healthcare to their patients is crucial for patient safety. This includes not supplying prescribed medicines when there is a reasonable expectation that it would be unsafe to do so.

Guidance

4.1 Providing advice to patients about their medicines

Whenever medicines are supplied to patients by pharmacists, the pharmacist should make every effort to provide advice, or offer to provide advice to the patient, whether in person or via available modern communications technologies that are fit for purpose. In circumstances where a patient refuses advice, the pharmacist should use their professional judgement to determine whether it is appropriate to supply, and safe for the patient to receive, a medicine without the patient receiving accompanying advice. Any decision not to supply a medicine in these circumstances must be explained to the patient and should be documented.

4.2 Communicating when there are safety concerns

Pharmacists are independent health care professionals and bear responsibility for their actions and the decisions they make in the course of their practice.

If a pharmacist determines that some aspect of the patient's healthcare may place the patient at risk (such as a concern about their prescribed medicine or other healthcare interventions), the pharmacist has a professional obligation to raise this with the relevant healthcare provider.

At all times, the pharmacist's decision to supply or not supply a prescribed medicine must be consistent with the safety of the patient. If the pharmacist has unresolved safety concerns, the pharmacist should not supply the prescribed medicine. In these cases, the patient should be informed about the reasons for the decision and the alternative options available to the patient regarding their medication and healthcare needs.

If a safety issue with the patient's healthcare has been identified, the pharmacist should document their communication with the patient and the patient's other healthcare providers, to inform any future decisions about the patient's healthcare.

Definitions

The following definitions are used for the purpose of these guidelines.

Clinical governance describes a systematic approach to maintaining and improving quality of patient care within a clinical setting. It ensures that everyone – from frontline clinicians to managers and members of governing bodies, such as boards – is accountable to patients and the community for assuring the delivery of safe, effective and high-quality services.

Communication means all forms of communication, whether verbal or written, and includes face to face and any digital form of communication, including but not limited to email, online meeting technologies, internet and social media.

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.

Cultural safety definition

Principles

The following principles inform the definition of cultural safety:

- Prioritising the Ministerial Council's goal to deliver healthcare free of racism supported by the National Aboriginal and Torres Strait Islander Health Plan 2013-2023
- Improved health service provision supported by the Safety and Quality Health Service Standards User Guide for Aboriginal and Torres Strait Islander Health
- Provision of a rights-based approach to healthcare supported by the United Nations Declaration on the Rights of Indigenous Peoples
- Ongoing commitment to learning, education and training[9].

Definition

Cultural safety is determined by Aboriginal and Torres Strait Islander individuals, families and communities. Culturally safe practise is the ongoing critical reflection of health practitioner knowledge, skills, attitudes, practising behaviours and power differentials in delivering safe, accessible and responsive healthcare free of racism.

How to

To ensure culturally safe and respectful practice, health practitioners must:

- Acknowledge colonisation and systemic racism, social, cultural, behavioural and economic factors which impact individual and community health.
- Acknowledge and address individual racism, their own biases, assumptions, stereotypes and prejudices and provide care that is holistic, free of bias and racism.
- Recognise the importance of self-determined decision-making, partnership and collaboration in healthcare which is driven by the individual, family and community.
- Foster a safe working environment through leadership to support the rights and dignity of Aboriginal and Torres Strait Islander people and colleagues.

Dispensing is the provision of a medicine to a patient, their agent, or another person who is responsible for the administration of the medicine to that patient. It involves reviewing an order for a medicine (e.g. prescription, medication chart, patient request) in the context of the patient's medical history, and the preparation, packaging, labelling, documentation and transfer of the medicine. It includes providing advice to the patient, their agent, or another person who is responsible for the administration of the medicine to that patient.

Kinship carer means a person providing kinship care. Kinship care is family-based care within the child's extended family or with close friends of the family known to the child, whether formal or informal in nature (United Nations, 2010)

National Registration and Accreditation Scheme (National Scheme) is a partnership between 15 National Boards, Ahpra and other entities with the purpose of ensuring the community has access to a safe health workforce across the participating professions. For more information refer to https://www.ahpra.gov.au/About-Ahpra/What-We-Do/The-National-Registration-and-Accreditation-Scheme.aspx

Patient means a person who has entered into a therapeutic and/or professional relationship with a registered health practitioner. The term 'patient' includes 'clients' and 'consumers'. It can also extend to their families and carers (including kinship carers), and to groups and/or communities as users of health services, depending on context.

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.

Virtual care means health care services provided by practitioners to patients through digital communication channels such as video calls, phone consultations, online messaging or similar, that allows them to interact with patients without a physical presence. It encompasses such terms as telehealth, telepharmacy, telemedicine and others.

Interpretation

In these guidelines, unless the context requires otherwise:

- ‘must’ means that, in the view of the Board, the appropriate standard of practice requires that the relevant course of action be taken. ‘Must not’ has a corresponding meaning.
- ‘should’ means that, in the view of the Board, the appropriate standard of practice requires that the relevant course of action generally be taken and that there may be certain circumstances in which after proper consideration a difference course may be taken. ‘Should not’ has a corresponding meaning.
- ‘may’ means that, in the view of the Board, a number of different courses of action may be available to the practitioner, depending on the circumstances. The practitioner must exercise good judgment and have regard to the particular circumstances when deciding the appropriate course of action in each case.

Review

Date of issue: XXX

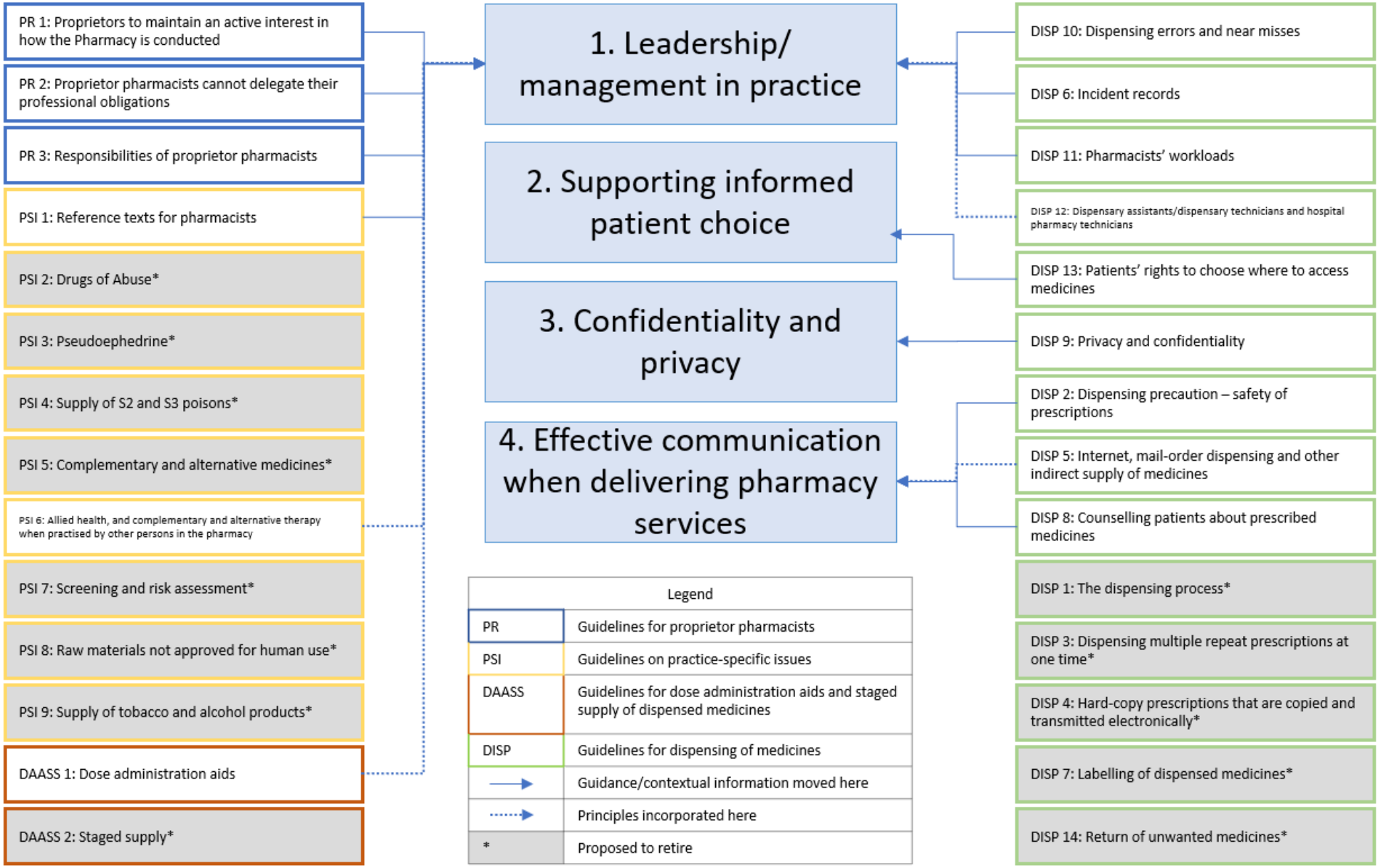
In effect from: XXX

Date of review: XXX

These guidelines will be reviewed at least every five years.

From XXX, these guidelines replace *xxx* published xxx.

Attachment B: Overview of guideline changes



Attachment C: Summary of proposed changes to current guidelines

Legend:

PR – Guidelines for Proprietor Pharmacists 2015
PSI – Guidelines on Practice-Specific Issues 2015
DISP – Guidelines for Dispensing of Medicines 2015
DAASS – Guidelines on dose administration aids and staged supply of dispensed medicines 2015

Current Guidelines	Action	Destination - Draft guidelines	Explanatory information
PR 1: Proprietors to maintain an active interest in how the pharmacy business is conducted	Retained	**1. Leadership/management in practice** • Note for proprietor pharmacists	
PR 2: Proprietor pharmacists cannot delegate their professional obligations	Retained	**1. Leadership/management in practice** • Note for proprietor pharmacists	
PR 3: Responsibilities of proprietor pharmacists	Partially retained	**1. Leadership/management in practice** • Preamble (summarised and removed duplication such as confidentiality/privacy and multiple references to following legislation, codes, developing procedures) • Retained and developed risk management • Retained and developed 'suitably resourced' - into a section titled 'resources' • Expanded to apply more broadly to leadership and management in settings other than community pharmacy	• Ensuring PII cover and compliant advertising removed, as these are covered in the Board's registration standard and the Ahpra Guidelines for advertising a regulated health service, as well as in the Therapeutic Goods (Therapeutic Goods Advertising Code) Instrument 2021 and associated explanatory resources. • Premises related guidance removed • Guidance relating to non-PBS approved pharmacies removed as this is related to premises, which is the remit of the state and territory pharmacy premises authorities.
PSI 1: Reference texts for pharmacists	Partially retained	**1. Leadership/management in practice** • 'Resources' section in preamble • Principle retained of being adequately resourced with suitable references according to a risk assessment.	• List of mandatory references removed, as prescriptive and input focused.
PSI 2: Drugs of abuse	Retired		• Current guideline is largely contextual in nature and duplicated in other sources (e.g. Medicines and Poisons legislation)
PSI 3: Pseudoephedrine	Retired		• Current guideline is largely contextual in nature and duplicated in other sources (e.g. Medicines and Poisons legislation)
PSI 4: Supply of Schedule 2 poisons (Pharmacy Medicines) and Schedule 3 poisons (Pharmacist Only Medicines)	Retired		• Current guideline is largely contextual in nature and duplicated in other sources (e.g. Medicines and Poisons legislation) • Fact sheet for consumers may be considered to explain responsibilities of pharmacists in handling requests for S2 and S3 medicines
PSI 5: Complementary and alternative medicines	Retired		• No special status for these medicines that requires additional guidance from the Board
PSI 6: Allied health, and complementary and alternative therapy when practised by other persons in the pharmacy	Partially retained	**1. Leadership/management in practice** • Retain principle of ensuring that service delivery in a pharmacy is carried out by individuals who are suitably qualified and legally able to provide those services • Note for proprietor pharmacists and guidance statement	• Information about employment arrangements, or business practices such as leasing of consulting rooms is related to premises which is the remit of state and territory pharmacy premises authorities

Current Guidelines	Action	Destination - Draft guidelines	Explanatory information
PSI 7: Screening and risk assessment	Retired		• The guideline described the requirement to follow external standards and guidelines and there was no unique Board guidance required.
PSI 8: Raw materials not approved for human use in medicines	Retired		• Addressed in the Compounding guidelines and other sources
PSI 9: Supply of tobacco and alcohol products	Retired		• Regulation of these products is managed by other regulatory bodies. Pharmacy premises authorities may set restrictions in relation to the operation of a pharmacy business.
DISP 1: The dispensing process	Retired		• This was largely factual information describing the process of dispensing. • A consumer fact sheet may be a way of retaining some useful information about what dispensing is and what consumers can expect. • This also contained a list of what technicians can't do – which could be a barrier to innovation
DISP 2: Dispensing precaution – safety of prescriptions	Retained	**4. Effective communication when delivering pharmacy services** • Strengthened in response to coroner's case which recommended strengthening guidance • Broadened to include issues unrelated to a prescription • Renamed and combined with counselling guideline, as the issue relates to communication	
DISP 3: Dispensing multiple repeat prescriptions at one time	Retired		• Addresses PBS rules which are addressed on the PBS website (https://www.pbs.gov.au/info/healthpro/explanatory-notes/section1/Section-1-3-Explanatory-Notes) • Dispensing in accordance with prescribers' instructions does not require a guideline from the Board
DISP 4: Hard-copy prescriptions that are copied and transmitted electronically	Retired		• Current guideline is duplicated in other sources (Medicines and Poisons legislation)
DISP 5: Internet, mail-order dispensing and other indirect supply of medicines	Partially retained	**4. Effective communication when delivering pharmacy services** • Retained principle around counselling regardless of whether it is delivered face to face or remotely	• Practice has evolved and technology has advanced to improve health care delivery in remote areas, such that some statements contained in this guideline may be perceived to be creating a barrier.
DISP 6: Incident records	Partially retained	**1. Leadership/management in practice** • Principle of risk management retained and developed	• Some of this content was largely contextual information that is duplicated in Code of conduct, and covered by guidance produced by professional organisations, accrediting bodies and professional indemnity insurers.
DISP 7: Labelling of dispensed medicines	Retired		• Duplicated information covered in other sources (legislation such as the Poisons standard[10], standards produced by the Australian Commission on Safety and Quality in Health Care and Professional Practice standards and guidelines)
DISP 8: Counselling patients about prescribed medicines	Retained	**4. Effective communication when delivering pharmacy services** • Added reference to code of conduct, separated contextual information, removed duplicated statements • Updated to include all types of prescription presentations (face to face or otherwise) • Strengthened guidance around patients who refuse counselling	

[10] The Poisons Standard, or SUSMP refers to the Standard for the Uniform Scheduling of Medicines and Poisons. Refer to https://www.tga.gov.au/how-we-regulate/ingredients-and-scheduling-medicines-and-chemicals/poisons-standard-and-scheduling-medicines-and-chemicals/poisons-standard-susmp

Current Guidelines	Action	Destination - Draft guidelines	Explanatory information
DISP 9: Privacy and confidentiality	Retained	**3. Confidentiality and privacy** • Aligned title with Code of conduct • Removed duplication and strengthened contextual information for pharmacists • Broadened to include non-pharmacist staff	
DISP 10: Dispensing errors and near misses	Partially retained	**1. Leadership/management in practice** • Risk Management principles retained	• Some of this content was largely contextual information and duplicated in guidance produced by professional organisations, accrediting bodies and professional indemnity insurers.
DISP 11: Pharmacists' workloads	Partially retained	**1. Leadership/management in practice** • 'Resources' section in preamble – 'Human resources – pharmacists and other staff' • Principle described of being able to adapt service delivery to cope with the changes in demand for pharmacy services, using available human resources.	• Number of prescriptions to be dispensed per hour removed, as this is input focused and inflexible and does not consider the availability of new technology, resources and tools. Also does not consider the impact of other services that may be provided in the pharmacy.
DISP 12: Dispensary assistants/dispensary technicians and hospital pharmacy technicians	Partially retained	**1. Leadership/management in practice** • 'Resources' section in preamble – 'Human resources – pharmacists and other staff' • Guidance statement – 'ensure staff are appropriately supervised according to any legal requirements, and also commensurate with their experience, education and training, and role description'	• Removed list of units of study for technicians and assistants as the Board does not regulate these individuals • Removed supervision ratios as these are input focussed
DISP 13: Patients' rights to choose where to access medicines	Retained	**2. Supporting informed patient choice** • Added additional contextual information (Australian Charter of Healthcare Rights), broadened from just prescriptions to other pharmacy services, explained patient consent and patient centred care.	
DISP 14: Return of unwanted medicines	Retired		• Factual information rather than guidance. Accepted part of practice that no longer requires further guidance from the Board.
DAASS 1: Dose administration aids (DAAs) **1.1 Packing of DAAs** **1.2 Labelling of DAAs** **1.3 Checking of DAAs** **1.4 Records of DAA packaging** **1.5 Packing oral cytotoxic and other hazardous medicines into DAAs** **1.6 Automated and semi-automated dose packaging systems** **1.7 Packing by a third party**	Retired		• Largely a risk management issue • Originally published when there was less guidance available about DAAs • Now that guidance has been published by professional practice organisations, this guideline is no longer necessary.
DAASS 2: Staged supply	Retired		• Largely a risk management issue • Originally published when there was less guidance available about staged supply • Now that guidance has been published by professional practice organisations, this guideline is no longer necessary.

Attachment D: Consumer fact sheet

Information for members of the public about receiving medicines from a pharmacist

When you need a medicine

Many medicines require a prescription from a doctor or another prescriber. The prescriber usually writes or types a prescription which then needs to be taken or sent to a pharmacist. Prescriptions can be:

- paper prescriptions (handwritten or printed by the prescriber using a computer)
- electronic prescriptions with a special code to show to your pharmacist (sent by the prescriber to your mobile phone, to your email, or to your Active Script List).

You get to choose where to take your prescriptions to get your medicines.

Sometimes, for example, when you need a medicine that requires a prescription but haven't been able to see your doctor, they might contact your preferred pharmacist by telephone and ask them to get some medicine ready for you to collect. When doing this, a prescriber must also send a prescription to the pharmacist so that the supply of medicine is legal.

Pharmacists use a prescription to prepare the medicine that you receive, usually referred to as dispensing.

You do not need a prescription to buy all medicines. Some medicines can be bought in a pharmacy without a prescription and some of these can only be bought if you speak to the pharmacist so that they can be sure that a medicine is appropriate for you and that you know how to use it safely.

Some medicines can be bought in other places like a supermarket (for example, a tablet for headaches). If you are unsure about whether those medicines are the best ones for you or if you are feeling unwell, consider visiting a pharmacy for advice.

What to expect from your pharmacist when you collect your prescribed medicine

There are many activities pharmacists must do when they dispense your medicine, which can take some time.

Pharmacists must:

- prioritise your health and safety by performing any required checks
- act to ensure your rights according to the Australian Charter of Healthcare Rights
- follow all relevant laws, which can be different in states and territories
- follow what's expected of them by their profession
- provide culturally safe care to Aboriginal and Torres Strait Islander Peoples and work to actively eliminate racism from healthcare
- provide care that respects everybody's culture and helps you keep safe.

A pharmacist might need to contact your prescriber to change your prescribed medicine, quantity or dose, or to clarify your prescription.

What your pharmacist might ask you

Pharmacists are required to check that any medicine that they supply to you is safe for you. This may mean asking you about things such as:

- your general health
- any medical conditions you have and how they are being managed
- any other medications you are currently taking or have recently taken
- anything else that might be relevant to your prescription.

In some cases, pharmacists may also need to ask questions to confirm your identity, or the identity of your prescriber, in order to legally dispense the medicine.

For some medicines, pharmacists may also be required by law to check your prescription history using technology, to see whether similar medicines have been prescribed or dispensed to you recently from other places.

If you are uncomfortable with providing any of this information, or do not want the pharmacist to contact your prescriber, a pharmacist may not be able to determine that a medicine is safe for you and may not be able to provide you with the medicine that has been prescribed.

What to expect when you request a medicine that is available without a prescription

When you need a medicine from a pharmacy that doesn't need a prescription, there are still rules that pharmacists and pharmacy staff must follow to ensure the medicine is safe for you.

You may be asked similar questions to when the medicine is requested on a prescription. If the advice you need is about something like a rash, you may want to (or be asked to) show the pharmacist so they can assess the problem.

You have the right to privacy at any time that you are sharing any personal information. Pharmacists and pharmacy staff are required to respect your privacy and talk to you where others can't overhear your conversation or see any of your personal information.

If you are uncomfortable with providing any of this information, pharmacists and pharmacy staff may not be able to determine whether a medicine is safe for you. In some cases, they may not be able to give a medicine to you and you may need to be referred to another healthcare professional like your doctor.

Information you need about your medicine

When you receive your medicine, regardless of whether you or someone else collects it from the pharmacy or if it is delivered to you, you can expect your pharmacist to:

- provide you with information about:
    - how to take your medicine correctly and safely
    - possible side effects and what to do if you experience any
    - possible interactions with other medicines
    - how to store your medicine
    - anything else relevant to manage your health condition
- give you the opportunity to ask questions about your medicine.

Keeping your personal information safe

When pharmacists provide medicines to you, they may need to keep a copy of some of your information and make notes about your medicine or what was discussed with you. There are privacy laws in Australia that pharmacists must follow. These laws cover what information is allowed to be collected, which ensures that they only collect the information that they need and that they keep it safe and private.

When you are receiving a pharmacy service, you can expect:

- your health information is kept safe and only requested and used when it's really needed
- your health information will not be shared without your permission, unless it is required by law
- conversations about your health or your medicines to occur in a space where other people can't hear or see your personal information
- any examination or procedure to occur somewhere where others can't see or hear what's going on.

If you are asked about your health or your medicines in a place that isn't private, you can request to move to an area where others cannot hear your conversation.

For more information about your privacy rights and health information, including what to do if you feel your privacy has not been respected, you may find the information on the website of the Office of the Australian Information Commissioner helpful – this can be found here: www.oaic.gov.au/privacy/your-privacy-rights/health-information.

Where to go for more information

Ahpra's website has a section to help the public understand the code and standards registered health practitioners including pharmacists are expected to follow. You can find that here:

www.ahpra.gov.au/Resources/Code-of-conduct/Resources-for-the-public.aspx

Attachment E: National Boards Patient and Consumer Health and Safety Impact Statement

Guidelines for pharmacists on the safe provision of pharmacy services including medicines and advice

Statement purpose

The National Boards Patient and Consumer Health and Safety Impact Statement (Statement)[11] explains the potential impacts of a proposed registration standard, code or guideline on the health and safety of the public.

The Statement particularly focuses on potential impacts for:

- people vulnerable to harm in the community which includes those subject to stigma or discrimination in health care
- people experiencing health disadvantage
- Aboriginal and Torres Strait Islander Peoples.

The four key components considered in the Statement are:

1. the potential impact of the proposed revisions to the registration standard, code or guideline on the health and safety of patients and consumers, particularly those vulnerable to harm in the community, including approaches to mitigate any potential negative or unintended effects
2. the potential impact of the proposed revisions to the registration standard, code or guideline on the health and safety of Aboriginal and Torres Strait Islander Peoples, including approaches to mitigate any potential negative or unintended effects
3. engagement with patients and consumers, particularly those vulnerable to harm in the community about the proposal
4. engagement with Aboriginal and Torres Strait Islander Peoples about the proposal.

The National Boards Patient and Consumer Health and Safety Impact Statement aligns with the National Scheme's Aboriginal and Torres Strait Islander Health and Cultural Safety Strategy 2020-2025, National Scheme engagement strategy 2020-2025 , the National Scheme Strategy 2020-25 and reflects key aspects of the Ahpra Procedures for the development of registration standards, codes, guidelines and accreditation standards.

Below is our initial assessment of the potential impact of proposed draft *Guidelines for pharmacists on the safe provision of pharmacy services including medicines and advice* (the draft guidelines) on the health and safety of patients, particularly those vulnerable to harm in the community, and Aboriginal and Torres Strait Islander Peoples. This statement will be updated after consultation feedback.

[11] This statement has been developed by Ahpra and the National Boards in accordance with section 25(c) and 35(c) of the Health Practitioner Regulation National Law as in force in each state and territory (the National Law). Section 25(c) requires Ahpra to establish procedures for ensuring that the National Registration and Accreditation Scheme (the National Scheme) operates in accordance with good regulatory practice. Section 35(c) assigns the National Boards functions to develop or approve standards, codes and guidelines for the health profession including the development of registration standards for approval by the Ministerial Council and that provide guidance to health practitioners registered in the profession. Section 40 of the National Law requires National Boards to ensure that there is wide-ranging consultation during the development of a registration standard, code or guideline.

1. How will this proposal impact on patient health and safety, particularly those vulnerable to harm in the community? Will the impact be different for people vulnerable to harm in the community compared to the general public?

The Pharmacy Board of Australia (the Board) has carefully considered the impacts that the draft guidelines could have on patient health and safety, particularly those vulnerable to harm in the community, in order to put forward what we think is the best option for consultation. The proposed option is based on best available evidence and was developed with consideration of the objectives and guiding principles of the National Scheme, which has public protection at its heart.

The Board recognises that patients are particularly vulnerable to risks involving medicines and other pharmacy services. The draft guidelines aim to reduce regulatory burden for pharmacists and streamline advice, which contributes to improved patient and practitioner understanding of the Board's expectations and has an anticipated flow-on effect to improve the safety and quality of healthcare provided by pharmacists.

The assessment of the Board is that there will be no negative impact on the health and safety of patients, particularly those vulnerable to harm in the community.

Ahpra's Community Advisory Council was consulted for input and advice during preliminary consultation and their feedback has been considered in the redrafting for public consultation. Other consumer bodies were also consulted during preliminary consultation and their valuable feedback has also been considered.

Our engagement through public consultation will help us to better understand possible outcomes and meet our responsibilities to protect patients and the community.

2. How will National Boards engage with patients, particularly those vulnerable to harm in the community during consultation?

In line with our consultation processes and our obligations under the National Law, the Board is undertaking wide-ranging consultation. We will engage with patients, peak bodies, other relevant organisations and the community to get input and views from people vulnerable to harm in the community. We have included specific questions about impacts on patients, particularly those people who are vulnerable to harm in the community.

3. What might be the unintended impacts for patients, particularly people vulnerable to harm in the community? How will these be addressed?

The Board has carefully considered what the unintended impacts of the draft guidelines might be, as the consultation paper explains. Consulting with relevant organisations and those vulnerable to harm in the community will help us to identify any other potential impacts. We will fully consider and take actions to address any potential negative impacts for patients that may be raised during consultation particularly for people vulnerable to harm in the community.

4. How will this proposal impact on Aboriginal and Torres Strait Islander Peoples? How will the impact be different for Aboriginal and Torres Strait Islander Peoples compared to non-Aboriginal and Torres Strait Islander Peoples?

The Board has carefully considered any potential impact of the draft guidelines on Aboriginal and Torres Strait Islander Peoples and how the impact compared to non-Aboriginal and Torres Strait Islander Peoples might be different, in order to put forward the proposed option for feedback as outlined in the consultation paper.

The Board's initial assessment is that there will be no negative impacts on Aboriginal and Torres Strait Islander peoples. Our engagement through consultation will help us to identify any other potential impacts and meet our responsibilities to protect safety and healthcare quality for Aboriginal and Torres Strait Islander Peoples.

5. How will consultation about this proposal engage with Aboriginal and Torres Strait Islander Peoples?

The Board is committed to the National Scheme's Aboriginal and Torres Strait Islander Health and Cultural Safety Strategy 2020-2025 which focuses on achieving patient safety for Aboriginal and Torres Strait Islander Peoples as the norm, and the inextricably linked elements of clinical and cultural safety.

As part of our consultation process, the Board will continue to engage with Aboriginal and Torres Strait Islander stakeholders to ensure there are no unintended consequences for Aboriginal and Torres Strait Islander Peoples. The Board received feedback during preliminary consultation from Ahpra's *Aboriginal and Torres Strait Islander Health Strategy Unit* (HSU) and has used this to revise the material for public consultation. We will also invite the HSU to comment on any proposed changes to the guidelines after public consultation.

6. What might be the unintended impacts for Aboriginal and Torres Strait Islander Peoples? How will these be addressed?

The Board has carefully considered and has not identified any unintended impacts for Aboriginal and Torres Strait Islander Peoples from the draft guidelines. Continuing to engage with relevant organisations and Aboriginal and Torres Strait Islander Peoples will help us to identify any other potential impacts. We will consider and take actions to address any other potential negative impacts for Aboriginal and Torres Strait Islander Peoples that may be raised during public consultation.

7 How will the impact of this proposal be actively monitored and evaluated?

Part of the Board's work in keeping the public safe is ensuring that all Board standards, codes and guidelines are regularly reviewed.

In developing the draft guidelines, and in keeping with this, the Board will regularly review the guidelines to check they are working as intended.

Attachment F: Statement of assessment against Ahpra's Procedures for the development of registration standards, codes and guidelines

Guidelines for pharmacists on the safe provision of pharmacy services including medicines and advice

Introduction

Section 25 of the Health Practitioner Regulation National Law as in force in each state and territory (the National Law) requires Australian Health Practitioner Regulation Agency (Ahpra) to establish procedures for the purpose of ensuring that the National Registration and Accreditation Scheme (the National Scheme) operates in accordance with good regulatory practice.

The Ahpra *Procedures for the development of registration standards, codes and guidelines* (2023) is available on the Ahpra Resources webpage

Scheduled review of guidelines

The Pharmacy Board of Australia (the Board) reviews its guidelines on a planned, regular basis to test their workability, clarity, and continued relevance, in accordance with good regulatory practice. There are 4 sets of guidelines due for review, which have all been in effect since 2015. These are:

1. Guidelines for dispensing of medicines
2. Guidelines on practice-specific issues
3. Guidelines for proprietor pharmacists
4. Guidelines for dose administration aids and staged supply of dispensed medicines

In undertaking the review of the above guidelines, the Board considered three options, described below:

Option one – Status quo

The current guidelines were published in 2015 and have not been reviewed until now, largely due to the impact of the COVID-19 pandemic which required the Board to focus on addressing emerging priorities. There have been several developments in practice since then and, while available information suggests the guidelines are working reasonably well, there are several opportunities to improve the guidance.

Maintaining the status quo of the guidelines would miss these opportunities for improvement and result in the guidelines becoming progressively less contemporary and relevant, which may create unnecessary barriers to practice and risks to public safety.

Option two – Develop revised guidelines

Reviewing and revising the guidelines will ensure that they continue to be relevant, contemporary and aligned with professional practice standards. A review also provides an opportunity to retire any guidelines or content no longer deemed necessary for the Board to publish given the development of new practice resources by the profession. It will capture the opportunities that would be missed in option one. It will provide an opportunity to consult stakeholders, in particular practitioners and the public, to advise how the guidelines can be more relevant and helpful.

Contemporary guidelines will provide consumers, regulators, employers and professional bodies with clear guidance about the Board's expectations of the professional conduct of the pharmacists they regulate in the public's interest.

Contemporary guidelines can enable pharmacists to respond to changes in practice whereas the current guidelines may be a barrier to innovation.

Option three – Retire the existing guidelines

Under option three, the Board would withdraw the existing guidelines and rely solely on the Code of conduct. While the Code of conduct sets out the Board's expectations of professional behaviour and conduct for pharmacists it does not provide specific guidance about particular issues relevant to pharmacy

practice. The Board considers that relying solely on the Code of conduct would miss the opportunity to provide clear guidance to pharmacists that supports safe practice which meets expectations of the Board and the public.

Preferred option and proposal for consideration

The Board prefers option two. The Board proceeded to develop a consolidated, single set of guidelines to replace the four separate sets of guidelines. The draft consolidated guidelines have a more contemporary format and a new title 'Guidelines for pharmacists on the safe provision of pharmacy services including medicines and advice' (the draft guidelines).

Assessment

Below is the Board's assessment of the draft guidelines, taking into account the Ahpra procedures.

1. Describe how the proposal:

- takes into account the paramount principle, objectives and guiding principles in the National Law[12]
- draws on available evidence, including regulatory approaches by health practitioner regulators in countries with comparable health systems

The draft guidelines take into account the National Scheme's paramount principle by informing registered pharmacists and the community about the expectations of pharmacists in relation to a range of issues in the public's interest. The proposed revisions seek to protect the public without creating unnecessary barriers for the public to access services provided by pharmacists.

When considering if a guideline was required, the Board determined to examine closely whether there was a problem and determine if guidance was required. The Board also considered the following:

- Objectives and guiding principles of the National Scheme.
- The Regulatory principles of the National Scheme.
- Policy Direction 2019-02 issued by the Ministerial Council.
- *Aboriginal and Torres Strait Islander Health and Cultural Safety Strategy 2020-2025*.
- Ahpra's procedures for the development of registration standards, codes and guidelines.

The Board also agreed some principles to inform the review of its guidelines. These include:

g. **Within our remit**: is within the functions of the Board under the National Law.
h. **Risk-based**: is proportionate to the risk and evidence based.
i. **Outcome-focused**: leads to outcomes that protects the public.
j. **Achievable**: is relevant and achievable in practice.
k. **Streamlined:** acknowledges primary sources of information and reduces unnecessary duplication.
l. **Transparent:** is developed in a fair, transparent and consultative manner.

In keeping with the above, a review of the Board guidelines supports the National Scheme to operate in a transparent, accountable, efficient, effective and fair way.

The Board has drawn from available evidence to inform the review, including:

- input and feedback from stakeholders
- feedback from members of the profession
- feedback from the Board's Committees
- research of international approaches to guidelines for pharmacists.

2. Outline steps that been taken to:

- achieve greater consistency within the National Scheme (for example, by adopting any available template, guidance or good practice approaches used by National Scheme bodies)

[12] See section 3 and section 3A of the National Law

- meet the wide-ranging consultation requirements of the National Law

The National Law requires wide-ranging consultation on the proposed standards, codes and guidelines. The National Law also requires National Boards to consult each other on matters of shared interest. Preliminary consultation was the first step in a wide-ranging consultation process, where the Board sought feedback and tested proposals with key stakeholders including National Boards and refined them before proceeding to public consultation. The Board sought input from both professional stakeholders and patient safety and healthcare consumer bodies. The Board also conducted early testing of some of the proposed changes with its stakeholders in a range of meetings to further inform the draft guidelines, before beginning preliminary consultation.

The Board has published several guidelines for pharmacists to support safe and professional practice, which increases the potential for unnecessary duplication of information published by other entities and may cause confusion about what is expected of pharmacists in this space. Based on earlier testing, there is an appetite to consolidate guidance and remove anything that is considered a duplication of existing information or guidance (e.g. legislation, professional practice standards and guidelines). This includes incorporating suitable references to requirements set out in the *Code of conduct*.

The Board considered the feedback received at preliminary consultation when preparing the draft guidelines for public consultation, where there will be an opportunity for broader public comment. This public consultation will include publishing a consultation paper on the Board and Ahpra websites and informing health practitioners and the community of the review via the Board's newsletter and Ahpra's social media channels.

3. Address the following principles:

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

The Board considers having a consolidated set of guidelines (option 2) will likely be the best option to contribute to the quality and safety of healthcare, as well as informing registered pharmacists and the community about the expectations of pharmacists in relation to a range of issues.

Proposed revisions to the guidelines are also expected to ensure that the Board's guidance continues to be relevant, contemporary and aligned with professional practice standards. Through public consultation, the Board will seek feedback on whether stakeholders and the public support the approach taken by the Board, to revise its guidelines which received support during preliminary consultation.

b. whether the proposal results in an unnecessary restriction of competition among health practitioners

The Board does not expect any change in competition impacts as revised guidelines (if approved by the Board) will continue to apply to all registered pharmacists.

c. whether the proposal results in an unnecessary restriction of consumer choice

The Board does not expect any change or unncessary restriction of consumer choice. Clear and contemporary guidelines for pharmacists will support consumer choice in accessing safe and effective pharmacy services.

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

The Board has had guidelines in place since 2015. The Board has considered the potential costs to members of the public and registered pharmacists associated with the draft guidelines. The Board anticipates that the draft guidelines may result in a small reduction in costs and regulatory requirements for practitioners through consolidating four sets of guidelines (comprising 28 guidelines) into one guideline publication (comprising four guidelines). This includes removing unnecessary context and rules such as mandating a list of reference texts that all pharmacists must access.

The Board does not expect there will be any cost impacts on members of the public and did not receive any feedback during preliminary consultation that raised cost impacts. This will be tested with key stakeholders during public consultation and feedback is being sought on whether there are any other costs or impacts that the Board needs to be aware of arising from the draft guidelines.

e. whether the proposal's requirements are clearly stated using 'plain language' to reduce uncertainty, enable the public to understand the requirements, and enable understanding and compliance by registrants, and

The Board is committed to a plain English approach that will help practitioners and the public understand and apply the requirements of the draft guidelines. The draft guidelines have been written in plain language and complementary material is being developed to support public understanding of what to expect from pharmacists providing pharmacy services including medicines and advice.

f. whether the Board has procedures in place to ensure that the proposed standard remains relevant and effective over time.

The Board has procedures in place to support a review of the guidelines at least every five years as it is good regulatory practice to do so.

However, the Board may choose to review the guidelines earlier, in response to any issues which arise, or new evidence which emerges to ensure its continued relevance and workability.

4. Closing statement

Feedback on any regulatory impacts identified during the consultation process and/or in developing the draft guidelines will be provided to the Board to inform decision-making.

The Board has completed a **patient and consumer health and safety impact statement** for public consultation, provided at Attachment E. The Board will provide a **patient and consumer health and safety impact assessment** when publishing guidelines approved by the Board.