

POSITION STATEMENT

In-Person Supply of Medicines

Position

The Pharmacy Guild of Australia (Guild) believes that in-person (face-to-face) interaction is the ideal way to conduct a health service. This includes dispensing and supply of medicines by a community pharmacy. The benefit of in-person interactions is that they provide the patient an opportunity to engage with a primary healthcare professional at the time of medicines supply, enabling the patient to ask questions and receive advice about their medicines and other health-related matters. In-person interactions also help create a strong patient-pharmacist relationship that builds trust.

The Guild acknowledges that advances in technology, use of e-commerce and a global pandemic have increased demand for contactless collection of medicines. Some patients may request to receive medicines from a pharmacy by means of indirect supply, and the Guild acknowledges that there are circumstances when this type of supply of medicine may be necessary and/or appropriate.

With the increasing incidence of indirect supply of medicines, particularly by internet and mail order, the Guild believes there should be a national regulatory framework for indirect health services to ensure all aspects of indirect and/or distance health services including the prescribing, dispensing and supply of medicines are adequately regulated. This should be supported by guidelines that define best practices for these health services. This work could be led collaboratively by the Australian Health Practitioners Regulation Agency (Ahpra) and the National Boards working with State and Territory regulators, health providers and patient groups.

The Guild strongly supports ensuring the rights of patients to have prescriptions, inclusive of electronic prescriptions, dispensed and supplied from their preferred local Section 90 approved¹ community pharmacy, including by indirect supply if required and appropriate. We actively oppose any arrangement that deliberately or unintentionally removes the patient's right to choose which pharmacy receives their prescription for dispensing and supply.

The Guild has the view that indirect supply could primarily be used for the supply of established therapies to patients. This would ensure that patients starting on new therapies receive the appropriate level of counselling and information about their medicine, including the demonstration of devices, and enables the pharmacist to provide lifestyle modification information and/or recommend adjunctive treatments or undertake physiological assessments that may be appropriate for the patient's condition.

The Guild has the strong opinion that dispensing of prescription medicines and the supply of non-prescription medicines should contribute to the Quality Use of Medicines (QUM) by facilitating access to health information and/or advice from a pharmacist or trained pharmacy staff member.









The Guild recognises that home deliveries and secure pharmacy collection units provide a useful means to enable patients to collect their prescriptions or other pharmacy goods from their preferred pharmacy, particularly when it may be difficult for them to attend the pharmacy during opening hours.

The Guild strongly opposes the use of vending machines for the supply of scheduled medicines, including via prescription, as we believe this is not consistent with the Quality Use of Medicines principles and has inherent patient safety risks. The Guild recognises the use of vending machines for the supply of non-scheduled medicines and other unrestricted items for small quantities in original manufacturer packs. This must only be permitted with systems in place to manage public safety risks, such as limiting the purchase of multiple packs. Restrictions should apply to vending machines that are not within or attached to a pharmacy that any non-scheduled medicine must be in an original manufacturer pack with a maximum quantity of two adult dosage units.

To maintain best practice in medicine supply and to address any potential associated risks, any indirect supply service must be provided at the same high service standard in a manner consistent with requirements for in person supply at a community pharmacy. This is particularly important for supply of medicines to new patients, and for supply of new or high-risk medicines to any patient. Any indirect supply service must meet all mandatory safety and quality standards, including the pharmacist's professional obligation to ensure that every patient understands how to use their medicines correctly, safely, and effectively.

The Guild recommends that where a pharmacy is contemplating the introduction of an indirect supply service for the dispensing and supply of medicines, a comprehensive due diligence review of professional requirements from the Pharmacy Board of Australia and Ahpra should be undertaken.

Pharmacies should seek independent legal advice to ensure all arrangements are compliant with all necessary regulations applicable to the location of the pharmacy (e.g. Commonwealth, state and territory) regarding pharmacy premises, clinical practice, medicines and poisons as well as use of Government identifiers such as Medicare or Concession cards. In addition, specific advice should be sought for cross border supply of medicines to ensure compliance.

The Guild supports established structures for the supply of medicines through pharmacy depots in certain circumstances and in accordance with Commonwealth and state or territory pharmacy regulations. This practice enables the supply of essential medicines to rural and remote locations and promotes ongoing pharmacist-patient communication and relationships.

Due to the nature of the indirect supply of medicines, the Guild believes video conferencing or telephone communication between the patient and the pharmacist should be a mandatory requirement of a community pharmacy's indirect supply of medicine service to ensure the safe, effective, and quality use of medicines. While the use of text messages, email, and instant messaging may also be used as support communication tools, these should not be an alternative option on their own.

The Guild does not support the use of indirect supply services for patients that do not have an established relationship with the pharmacy or have not spoken with the pharmacy via video conferencing or telephone, as supply to unverified patients is not considered best practice.

Additionally, consideration should be given to:

- how a system or process will integrate into the pharmacy's current practice
- under what circumstances a supply arrangement will be offered and development of clear service parameters
- ensuring communication between the pharmacist and patient is upheld to support the safe and quality use of medicines

- the benefits and risks to patients and to the pharmacy of an indirect supply service
- clinical governance and quality management systems, including establishing processes and procedures to support indirect supply of medicines consistent with QUM principles and Quality Accreditation (QCPP) requirements
- ensuring consistency with Consumer Policy in Australia
- ensuring patient autonomy in choice of provider is maintained
- ensuring Australian Privacy Principles and patient data are not compromised by the introduction of a new system or process.

Background

Indirect Supply

The term, 'indirect supply' describes the process of a pharmacy supplying medicine to a patient using a method that does not involve an in-person interaction with a pharmacist at time of collection. This contrasts with direct contact between the patient and the pharmacist when the patient presents to the pharmacy in person.

Indirect supply of medicines such as third-party medicine collection on behalf of a patient, home delivery of medicines or secure pharmacy collection units may be used by community pharmacies to supply medicines to patients with which the pharmacy already has an established relationship and understanding and have previously seen in-person. The supply of medicines to residential care facilities is considered indirect supply, and the use of a local community pharmacy for supply is an important factor in the residents and the pharmacy having the ability to establish a relationship. Other examples of indirect supply of medicines, where there may be no existing relationship between the pharmacy and patient, include supply of medicines by internet and mail order pharmacy.

A key attribute of community pharmacy practice in Australia is the personal interaction and often long-term established relationships between the pharmacist and the patient. A pharmacist's intimate knowledge of a patient's medicine regimen and personal medical history may avoid potentially serious complications for a patient. This personal understanding and contact is not achievable through internet and mail order pharmacy or from using a vending machine. The dispensing of prescriptions in these manners have the potential to undermine the value of community pharmacy as the key provider of medicine-related primary health care services throughout Australia and may lead to patient harm. The risks associated with this type of indirect supply include:

- lower capacity for pharmacist to meet legal obligations and professional requirements to assess safety and therapeutic appropriateness of medicine prescribed or requested
- non-provision of counselling on how to use the medicine safely and appropriately for optimal therapeutic effect
- inability to demonstrate use of medicine devices and assessment of patient's understanding
- pharmacist relying on patients to provide a true and accurate description of their condition without being able to assess the condition in person
- greater opportunity for consumer access to medicines at risk of abuse or misuse
- technical difficulties for communicating between the pharmacy and the patient

These risks are enhanced for people with hearing loss, learning difficulties or high-risk patients such as the elderly, children or people with serious and/or multiple co-morbidities. It may also be problematic for people who do not have adequate access to or understanding of the technological requirements for a remote consultation.

Pharmacy Collection Units and Vending Machines

For the purposes of this paper, the Guild regards the following as characteristics of pharmacy collection units and vending machines for medicines:

- Pharmacy Collection Unit a secure mechanised unit that a community pharmacy can use, only after a patient consult with the pharmacist, to allow after-hours and contactless collection of pre-dispensed and pre-paid medicines and other pharmacy goods by identified individuals. The collection unit must:
 - o be permanently secured to the community pharmacy premises
 - use personal identification access codes to ensure access only to the items intended for the identified individual
 - be accessible only by authorised persons i.e. pharmacy staff and persons with a personal identification access code
 - be tamper proof and have security in place to discourage any unauthorised interference
 - maintain goods within the recommended temperature range
 - not contain any routine imprest items
 - o not be used to process dispensing of prescriptions or payments
- **Vending machine** a secure mechanised medicine storage unit that enables contactless, automated, self-service selection and payment transactions to supply a non-scheduled medicine or other unrestricted pharmacy product. A vending machine may be free standing or securely attached to the premises and will typically consist of:
 - A storage unit of commonly used items for sale in original manufacturer packs, including:
 - Non-scheduled medicines in small quantities (preferably limited to a maximum quantity of two adult doses)
 - Unrestricted pharmacy items such as condoms, feminine hygiene products, sunscreen, skincare or first aid supplies
 - o digital payment arrangements for the supply of stored items
 - tamper-proof security arrangements to restrict access to stored items or interference by any non-authorised persons
 - storage controls to ensure items are stored within the recommended temperature and humidity range

Service Framework

The supply of medicines by community pharmacy is governed by a framework consisting of legislation, standards, and guidelines, including but not limited to:

- Commonwealth legislation:
 - <u>National Health Act 1953</u> along with subordinate regulations and instruments sets out the requirements for the supply of pharmaceutical benefits
 - <u>Therapeutic Goods Act 1989</u> along with subordinate regulations and instruments sets out the requirements for therapeutic goods supply, and provides exemptions for specific individuals and products
 - <u>Privacy Act 1988</u> and <u>National Health (Privacy) Rules 2021</u> along with subordinate regulations and instruments sets out the requirements to protect information collected under the Medicare and Pharmaceutical Benefits schemes (MBS and PBS)
 - Competition and Consumer Act 2010 and <u>The Australian Consumer Law</u> along with subordinate regulations and instruments sets out the requirements for businesses to act to protect consumer rights

- State and territory medicines and poisons legislation set out the requirements for prescribing, dispensing and supply of scheduled medicines with and/or without a prescription, storage of medicines, and possession of medicines.
- All state and territory medicines and poisons legislation prohibit the use of vending machines for scheduled medicines. Some provide an exemption with caveats for non-scheduled medicines.
- State and territory pharmacy premise regulations and guidelines set out the requirements and responsibilities of pharmacy services providers, including depots in relevant jurisdictions.
- Pharmacy Board of Australia <u>Guidelines for dispensing of medicines</u> provides guidance on the dispensing process and commonly encountered situations or requests (for example, indirect supply and dispensing multiple repeats).
- National Boards' <u>Information for practitioners who provide virtual care</u> provides information on how existing Board standards, codes, and guidelines apply to delivering safe and effective virtual care services.
- <u>Professional Practice Standards</u> set out the criteria and actions to demonstrate professional behaviour including for dispensing (Standard 7), safe and secure handling of therapeutic goods (Standard 10) and patient counselling (Standard 15).
- The <u>Community pharmacy quality accreditation standard</u> sets out the requirements that
 pharmacies must meet to obtain quality accreditation and covers medicines supply in-person in a
 pharmacy and also indirect supply.

The governance framework is subject to change at the discretion of Commonwealth and state or territory governments and pharmacy accrediting bodies. The Guild subsequently notes that members should not rely on the legislation, standards and guidelines outlined in this document as a comprehensive and exhaustive list of all governance with which a pharmacy must comply. The Guild recommends that pharmacists seek independent legal advice for their individual situation.

Patient and Pharmacist Communication

There are many steps involved in the medicine supply process, however the overarching function that is the key to ensuring appropriate supply of medicine is communication between the patient and the pharmacist.

Communication between the patient and pharmacist is imperative for the following components of medicine supply:

- Patient verification ensuring the patient ordering and receiving the medicine is correct by matching or adding them to the pharmacies dispensing system, including relevant Medicare and entitlement details.
- Patient history establishing medical conditions, medication history and allergies to ensure supply is safe and appropriate.
- Additional information such as brand preference and patient age (if required).
- Patient counselling ensuring the patient is familiar with the medicine including indication, adverse effect, correct use of device (if applicable), treatment expectations and review.
- Patient questions the patient should have the opportunity to ask questions to clarify information and seek further information on their medicine or other health concerns.

Consistent with in-person supply of medicine from community pharmacy, the patient maintains the right to refuse counselling in which case written information should be provided. If a patient and/or carer refuses to provide the necessary information to the pharmacist to enable safe dispensing and supply of a medicine, then the pharmacist needs to determine if indirect supply is appropriate under the circumstances.

Quality Care Pharmacy Program

The Quality Care Pharmacy Program (QCPP) has requirements that pharmacies must meet when providing indirect supply pharmacy services. These requirements can be applied to all types of indirect supply.

Harm Reduction

All jurisdictions permit the supply of injecting equipment via vending machines as part of their harm reduction strategy. In April 2024, Victoria <u>announced</u> 20 naloxone vending machines will be trialled alongside existing needle exchange sites as part of their Statewide Action Plan to save lives and reduce drug harms.

Depot provisions

In South Australia and Victoria, pharmacy practice regulations allow pharmacies to supply medicines through a pharmacy depot; this includes the supply of dispensed prescription medicines. Such pharmacy depots must be approved by the respective pharmacy regulation authorities. The Commonwealth recognises a non-pharmacy depot consistent with state and territory laws can be used for the collection of PBS prescriptions.

Authority

Endorsed

National Council – August 2024 National Council – June 2023

Internet/Distance/Mail order supply of medicines
National Council – June 2010
National Council – July 2004

Reviewed

Policy and Regulation Sub-Committee – August 2024 Policy and Regulation Sub-Committee – February 2023

References

¹ A community pharmacy must be approved under Section 90 of the *National Health Act* to dispense and supply pharmaceutical benefits