

OUT18/70827



13 July 2018

Committee Secretary  
HCDSDFVPC  
Parliament House QLD 4000

By email: [pharmacy@parliament.qld.gov.au](mailto:pharmacy@parliament.qld.gov.au)

Dear Sir/Madam

### **Inquiry into the establishment of a pharmacy council and pharmacy ownership in Queensland**

Thank you for the opportunity to comment on the issues paper about the inquiry into the establishment of a pharmacy council and pharmacy ownership in Queensland.

#### **About the Pharmacy Board of Australia**

The Pharmacy Board of Australia (the Board) is the regulator of pharmacists in Australia and acts to protect the public by ensuring that suitably qualified and competent pharmacists are registered. The role of the Board as a regulator of pharmacists is one component of the complex regulatory environment that pharmacists practice within. This includes regulation by a range of entities including pharmacy registering authorities and state and territory health departments.

As outlined in the Health Practitioner Regulation National Law, as in force in each state and territory (the National Law), the functions of the Board include:

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

Within the National Registration and Accreditation Scheme established under the National Law, which has public safety at its core, the Board works in partnership with the Australian Health Practitioner Regulation Agency to exercise our respective functions.

The Board and AHPRA are required to exercise their functions in accordance with the objectives and guiding principles of the National Law and National Scheme which are outlined in the National Law as follows:

#### *Objectives and guiding principles*

1. *The object of this Law is to establish a national registration and accreditation scheme for—*
  - a. *the regulation of health practitioners; and*
  - b. *the registration of students undertaking—*
    - i. *programs of study that provide a qualification for registration in a health profession;*  
*or*
    - ii. *clinical training in a health profession.*

**Pharmacy Board of Australia**

2. *The objectives of the national registration and accreditation scheme are—*
- a. to provide for the protection of the public by ensuring that only health practitioners who are suitably trained and qualified to practise in a competent and ethical manner are registered; and*
  - b. to facilitate workforce mobility across Australia by reducing the administrative burden for health practitioners wishing to move between participating jurisdictions or to practise in more than one participating jurisdiction; and*
  - c. to facilitate the provision of high quality education and training of health practitioners; and*
  - d. to facilitate the rigorous and responsive assessment of overseas-trained health practitioners; and*
  - e. to facilitate access to services provided by health practitioners in accordance with the public interest; and*
  - f. to enable the continuous development of a flexible, responsive and sustainable Australian health workforce and to enable innovation in the education of, and service delivery by, health practitioners.*
3. *The guiding principles of the national registration and accreditation scheme are as follows—*
- a. the scheme is to operate in a transparent, accountable, efficient, effective and fair way;*
  - b. fees required to be paid under the scheme are to be reasonable having regard to the efficient and effective operation of the scheme;*
  - c. restrictions on the practice of a health profession are to be imposed under the scheme only if it is necessary to ensure health services are provided safely and are of an appropriate quality.*

I am pleased to make the attached submission on behalf of the Board and provide any additional information that you may require.

If you wish to discuss this matter further, please do not hesitate to contact me on [REDACTED] or e-mail on [REDACTED]. Alternatively, you may contact the Board's Executive Officer, Mr Joe Brizzi on [REDACTED] or e-mail on [REDACTED].

Yours sincerely



**William Kelly**

Chair

Enc. Attachment A Pharmacy Board of Australia Submission



## Pharmacy Board of Australia response to the Inquiry into the establishment of a pharmacy council and pharmacy ownership in Queensland (issues paper)

### Pharmacy ownership regulation in Queensland

1. ***Are pharmacy ownership restrictions imposed by the Pharmacy Business Ownership Act 2001 (Qld) (Act) necessary to protect consumers and deliver accessible and affordable medicines and services? Why or why not?***

#### Board response/comment

Although ownership restrictions are not consistent across states and territories, the type of restrictions that are currently in place in Queensland align with those in place in most other jurisdictions. It would appear that the public is currently well served by pharmacies which are subject to the current state and territory ownership requirements. While cases for other ownership restrictions might be made, perhaps modeled on international models, all potential impacts would need to be carefully explored and analysed.

2. ***Are the ownership restrictions sufficiently clear, particularly regarding the restrictions on corporations owning pharmacies? If not, how could the restrictions be made clearer?***

#### Board response/comment

Yes

3. ***Would changing the pharmacy ownership restrictions under the Act improve community outcomes? If so, how should the restrictions be changed?***

#### Board response/comment

The current ownership regulations provide protection to the public and access to pharmacy services. Any changes contemplated should not have a deleterious effect on the availability or delivery of safe and effective pharmacy services to the public

4. ***Should the Act be amended to allow any party to own a pharmacy, subject to requirements for dispensing only by a qualified pharmacist? Would the community be better off under such a scenario? Why or why not?***

#### Board response/comment

The public is currently well served by pharmacies which are subject to the current ownership requirements. Any consideration of change from current ownership regulations would need extensive consultation and discussion to ensure that the current standard of provision of professional, safe and competent provision of pharmacy services would be maintained.

5. ***Is there any difference in performance of pharmacies owned by non-pharmacists in Queensland (such as those run by friendly societies or the Mater Misericordiae Health Services Brisbane Limited) in relation to protecting consumers and delivering accessible and affordable medicines and services?***

**Board response/comment**

The Board is not aware of any difference in performance of pharmacies owned and run in Queensland by Friendly Societies or the Mater Misericordiae Health Services Brisbane Limited.

6. ***Does the Act provide adequate protections to promote the professional, safe and competent provision of pharmacy services, and to maintain public confidence in the pharmacy profession now and in the future? If not, what additional protections should be included in the Act and why?***

**Board response/comment**

Management of any risk to the public by jurisdictional pharmacy premises regulators is limited by the powers conferred under the relevant legislation. For example, the range of matters that the relevant entity may address through guidelines about pharmacy ownership and premises are limited in some jurisdictions. Comparing the current Act to similar legislation in other states and territories would demonstrate inconsistencies in powers to regulate premises.

The power and capacities to audit pharmacy premises on a range of matters including the standard of premises and facilities, for example to support compounding of medicines should be explored. Such compounding may include compounding of sterile injectable medicines which carries high risks and may put the public at risk if practices and facilities operate below acceptable standards.

**Administration of premises**

7. ***Are you aware of any transfers of pharmacy ownership which have not conformed to the requirements under the Pharmacy Business Ownership Act 2001 (Qld) (Act)?***

**Board response/comment**

The Board is not aware of any such transfers through its work under the National Law.

8. ***Are the offences prescribed in the Act necessary and sufficient to ensure the objectives and intent of the legislation are being met, and are the maximum offences that apply appropriate?***

**Board response/comment**

The prescribed offences should be compared to those that exist in other jurisdictions to ensure that an appropriate range of offences apply in the public interest.

**Pharmacy ownership regulation in other Australian jurisdictions**

9. ***Do you think there should be restrictions on the number of pharmacies a pharmacist may own in Queensland? Are the current restrictions under the Pharmacy Business Ownership Act 2001 (Qld) appropriate?***

**Board response/comment**

The current limitations that exist across states and territories appear to enable proprietors to safely deliver pharmacy services to the community. The current restrictions vary across jurisdictions and consideration should be given to any factors identified that warrant those differences and whether any variation to the

restrictions are required to meet the current needs of the community and improve the quality of services provided.

As the Board registers all pharmacists in Australia, including proprietor pharmacists, it was mindful that the potential variation in responsibilities of proprietor pharmacists given the variation in ownership requirements across state and territories. The potential impact on employed professional and skilled staff could therefore be impacted differently in different states and territories.

The Board also noted that the registration status required of proprietor pharmacists varied across states and territories where currently, general registration must be maintained by proprietor pharmacists (ACT, NSW, NT and TAS), whereas non-practising registration is an option in remaining jurisdictions (QLD, SA VIC and WA).

The Board has published *Guidelines for proprietor pharmacists* which focus on the professional responsibilities of proprietor pharmacists that impact on the safe, effective delivery of services to the public. In summary, the guidelines outline that a registered pharmacist who is a proprietor of, or who has a pecuniary interest in, a pharmacy business, must:

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

These guidelines are uniformly applied to all proprietor pharmacists in all jurisdictions and the Board has regard to these guidelines in the management of notifications (complaints) about pharmacist proprietors. The Board also has regard to the relevant legislation and requirements for pharmacy premises, and the practice standards and guidelines relevant to pharmacy practice.

**10. *Given there are no restrictions in the Australian Capital Territory and the Northern Territory, are community outcomes in the Australian territories different from the Australian states? If so, how are they different?***

**Board response/comment**

The Board is not aware of any difference in community outcomes in the ACT and NT due to unrestricted ownership regulation.

**Administration of pharmacy ownership regulation in other jurisdictions**

**11. *Has pharmacy ownership regulation in other Australian jurisdictions improved community outcomes (relative to Queensland)? If so, how?***

**Board response/comment**

The approval and regulation of pharmacy premises are matters not covered by the Health Practitioner Regulation National Law, as in force in each state and territory and are therefore not the responsibility of the Pharmacy Board of Australia. The powers of the relevant jurisdictional entities to protect the public under their respective legislation and the ownership and premises requirements that apply in each jurisdiction vary considerably.

Management of any risk to the public by jurisdictional pharmacy premises regulators is limited by the powers conferred under the relevant legislation. For example, the range of matters that the relevant entity may address through guidelines about pharmacy ownership and premises are limited in some jurisdictions. This means that there are varying powers and capacities to audit pharmacy premises on a range of matters including the standard of premises and facilities, for example to support compounding of medicines. Such compounding may include compounding of sterile injectable medicines which carries

high risks and may put the public at risk if practices and facilities operate below acceptable standards. Such practice does not require regulation by the Therapeutic Goods Administration as (TGA) as under therapeutic goods legislation, such premises do not require a licence to manufacture medicines and are therefore not subject to TGA auditing against the acceptable standard of GMP.

Varying premises requirements across jurisdictions also means that the matters that the Board may be asked to consider about individual pharmacist owners will vary according to the regulatory outcomes that can be achieved by each premises regulator based on their existing powers to take action. This means that the Board may have less information about risk to the public posed by particular pharmacists in different jurisdictions. It also means that owners of pharmacies in more than one jurisdiction may be able to operate pharmacy premises to different minimum standards which is not in the public interest.

Jurisdictional variation in the regulation of pharmacy ownership and premises may give rise also to variation in costs of regulation, knowledge, skills and experience of aspects of premises regulation (e.g. auditing of compounding pharmacies).

Further details about the differences between jurisdictional pharmacy ownership and premises regulation may be provided by the Pharmacy Premises Registering Authorities of Australia, a collaborative group which has representation of each state and territory regulator.

**12. *What functions might a pharmacy council perform in Queensland? How would these functions differ from the current functions performed by Queensland Health?***

**Board response/comment**

Other than a national regulator of pharmacy which could not be established under the national Scheme, it would be desirable and in the public interest to establish a premises regulator in Queensland that has similar powers to some existing jurisdictional premises regulators that have a broader range of powers to protect the public. Similar powers that would be in the public interest include the power to grant or revoke a licence to establish a pharmacy business in accordance with ownership requirements, the power to grant or revoke approval of premises, the power to inspect premises to ensure minimum standards are maintained as well as the power to take action when necessary.

**13. *How would the establishment of a pharmacy council in Queensland improve community outcomes?***

**Board response/comment**

The power to set guidelines for premises, sufficient inspection and auditing powers and the corresponding power to take appropriate action where premises and practice falls below minimum expected standards should be provided.

**14. *What would be the costs and benefits to the community of establishing a pharmacy council in Queensland?***

**Board response/comment**

Setting mandatory fees similar to those imposed in other state and territories by relevant authorities would mean additional costs to proprietors, however, these would be offset by the benefits to the public who can be provided assurances through routine inspection that minimum pharmacy business and premises standards are maintained and action taken when standards fall below minimum requirements.

**15. *What other viable alternatives should be considered to deliver superior community outcomes?***



### Board response/comment

Other than a national regulator of pharmacy which could not be established under the national Scheme, it would be desirable and in the public interest to establish a premises regulator in Queensland that has similar powers to some existing jurisdictional premises regulators that have a broader range of powers to protect the public.

- 16. *If a pharmacy council was established in Queensland, what issues would need to be considered in its interactions with other agencies or individuals involved in regulating pharmacy businesses and practice? What legislation would need to be changed?***

### Board response/comment

Varying premises requirements across jurisdictions means that the matters that the Board may be asked to consider about individual pharmacist owners will vary according to the regulatory outcomes that can be achieved by each premises regulator based on their existing powers to take action. This means that the Board may have less information about risk to the public posed by particular pharmacists in different jurisdictions. It also means that owners of pharmacies in more than one jurisdiction may be able to operate pharmacy premises to different minimum standards which is not in the public interest.

Jurisdictional variation in the regulation of pharmacy ownership and premises may give rise also to variation in costs of regulation, knowledge, skills and experience of aspects of premises regulation (e.g. auditing of compounding pharmacies).

Further details about the differences between jurisdictional pharmacy ownership and premises regulation may be provided by the Pharmacy Premises Registering Authorities of Australia, a collaborative group which has representation of each state and territory regulator.

Where a council obtains information that is of relevance to other regulators, it is important that legislation supports the sharing of information that is in the public interest. Additionally, memoranda of understanding between a council and other regulators may establish clear pathways for and facilitate information exchange in accordance with legislative requirements to ensure that each regulator can effectively regulate in the public interest.

### Competition issues with pharmacy ownership regulation

- 17. *What effect would relaxing pharmacy ownership restrictions have on community outcomes (such as protecting consumers and delivering accessible and affordable medicines and services) in Queensland? What are the potential risks to consumers?***

### Board response/comment

Any changes to current ownership restrictions that may be explored would require careful analysis of the potential impact on the standard and range of services that are delivered, whether the public's needs would be met and whether access to services would be adversely affected.

- 18. *Should the scope of practice of pharmacists and pharmacy assistants in Queensland be extended? If so, in what areas of practice?***

### Board response/comment

The growing need to improve safe and timely access to medicines to ensure the most efficient use of healthcare resources has seen a broader range of health professions authorised through legislation to provide this healthcare service.

Delivery of a broader range of health care services would need to be enabled by any required changes in legislation (if applicable) and setting of and completion of any education and training to ensure competence.

Where necessary, mechanisms available under the National Law can be explored e.g. endorsement of registration in relation to scheduled medicines or in relation to approved areas of practice or by relying on the requirements specified in the Board's registration standards for pharmacists (e.g. Registration standard: Continuing Professional Development).

Administration of vaccines by pharmacists is a recent development in Australia which has made a positive impact on health outcomes. State and territory health departments have set requirements for training and education for pharmacists to do so.

The education and training is not currently consistent across jurisdictions and this has the potential to impact workforce mobility which is an objective of the National Scheme. To minimise this impact, further efforts are required nationally to ensure that a trained pharmacist can administer vaccines in jurisdictions other than where the training was completed.

Similarly, there is variation in the range of vaccines that a pharmacist is authorised under state or territory legislation to administer. Consistency in these authorities will provide greater access to medicines. Expanding the range of vaccines under state or territory legislation to include a much broader range of vaccines that pharmacists administer (supported by suitable education and training) should be further explored based on public need.

### **Role of pharmacists**

The Board supports the investigation of opportunities for pharmacists to expand the use of their skills and knowledge to deliver services that are in the public interest.

The Board's *Code of conduct* addresses how pharmacists should work within the healthcare system and contribute to its effectiveness and efficiency, and outlines that pharmacists have a responsibility to promote the health of the community through disease prevention and control, education, and where relevant, screening.

The adequate remuneration of pharmacists for services provided is an important consideration to ensure that pharmacists are able to safely deliver the required services while continuing to meet their legal and professional obligations.

As part of the process of evaluating emerging opportunities for pharmacists to expand the use of their skills and knowledge to deliver services in the public interest, the Board assesses the need for any regulatory action under the National Law and considers the relevant objectives of the National Scheme, including:

- to provide for the protection of the public by ensuring that only health practitioners who are suitably trained and qualified to practise in a competent and ethical manner are registered; and
- to facilitate workforce mobility across Australia by reducing the administrative burden for health practitioners wishing to move between participating jurisdictions or to practise in more than one participating jurisdiction; and
- to facilitate the provision of high quality education and training of health practitioners; and
- to facilitate access to services provided by health practitioners in accordance with the public interest; and
- to enable the continuous development of a flexible, responsive and sustainable Australian health workforce and to enable innovation in the education of, and service delivery by, health practitioners.



## PharmBA prescribing forum

An example of this is consideration of the need and opportunities for expanding pharmacist involvement in prescribing.

A recent forum hosted by the Board explored the potential expanded role of pharmacists in prescribing in order to contribute to supporting access to medicines in Australia, which aligns with the objectives of the National Scheme, including 'to enable the continuous development of a flexible, responsive and sustainable health workforce and to enable innovation in the education of, and service delivery by, health practitioners.'

The day-long forum was an opportunity to explore, identify and articulate the roles of different stakeholders to successfully develop proposals about pharmacist prescribing that could be implemented and sustained as part of a broader range of health services to effectively meet the health needs of the community.

The Board's facilitation of the forum meant stakeholders could come together to share thoughts and opinions on the three models of non-medical prescribing proposed by the 2013 Health Professionals Prescribing Pathway Project — autonomous prescribing, prescribing under supervision or prescribing via a structured prescribing arrangement – in the context of pharmacy practice.

General opinion was that the forum had been worthwhile as it brought together stakeholders who would have a part to play in evolving pharmacy practice in order to further contribute to patient care through prescribing.

A report outlining discussions on the day and next steps will be published by the Board in coming weeks.

Next steps could include wider consultation on issues raised at the forum and how stakeholders could be involved to assist in progressing pharmacist prescribing.

Examples of this include exploring and defining what else pharmacists might do in practice that will better serve the public and identifying what legislative changes would be needed in the eight state and territories to allow pharmacists to prescribe under relevant models.

In identifying and progressing opportunities for pharmacists to expand the use of their skills and knowledge to deliver services to the public, careful assessment is required of the legal framework (relevant state, territory and Commonwealth legislation) and professional framework that pharmacists must practise within (including the relevant practice standards), as well as pharmacists' obligations under the National Law (including obligations to comply with Board registration standards, codes and guidelines) and any possible unintended consequences which may impact on the safe delivery of services to the public.

To support the development of such opportunities, careful assessment of any legislative reform, the need for development of professional practice standards or impact on existing Board registration standards, codes and guidelines is required.

## Role of Ancillary Staff

Ancillary staff in pharmacy include a range of personnel such as pharmacy assistants (in community pharmacy), community pharmacy-based dispensary assistants and hospital pharmacy technicians, however, such personnel and their training are not regulated by the Board.

To extend the scope of practice of pharmacy assistants, consideration would need to be given a range of issues such as:

- the competencies required to safely deliver additional services
- how these competencies can be met

- the financial impact on business
- the impact on the delivery of other professional services in community pharmacy
- who is held accountable in the event that service delivery is below acceptable standards
- how the public would be adequately protected and whether this requires some type of regulation to achieve this.

**19. What additional training for pharmacists/pharmacy assistants, or other risk reduction measures, should be implemented to ensure patient safety?**

**Board response/comment**

Training of pharmacy assistants who essentially work in community pharmacy is managed by employers/pharmacy owners and is not regulated by the Board. There is no regulation of training of pharmacy assistants.

Employers including pharmacist proprietors would need to ensure that their staff is suitably trained to provide services to the public. Training can be provided at the work place and may include education delivered by a training organisation which may include a Registered Training Organisation.

Pharmacists at entry level are required to meet particular management related competencies which covers ancillary staff supervision and development and other additional related competencies as their careers progress. Professional practice standards also specify expected standards in relation to these matters.

The Board's [\*Guidelines for dispensing of medicines\*](#) provides guidance for pharmacists about being assisted in the preparation, dispensing and supply of medicines, and other tasks in a pharmacy business or pharmacy department, by **suitably trained dispensary assistants, dispensary technicians or hospital pharmacy technicians** (dispensary assistants/technicians).

The guidelines state:

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

and

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

The guideline provides further guidance about options to consider to ensure competence of dispensary assistants/technicians including certificate qualifications, competencies and/ or workplace training and practice experience. The guidelines also state:

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