

30 August 2016

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Dear Members of the Review Panel

**Re: Review of Pharmacy Remuneration and Regulation – Discussion Paper – July 2016**

Thank you for the opportunity to comment on the discussion paper on the *Review of Pharmacy Remuneration and Regulation*.

While the Board is responsible for the regulation of pharmacists in accordance with the provisions of the Health Practitioner Regulation National Law, as in force in each state and territory (the National Law), it acknowledges that pharmacists practise in a complex regulatory environment that supports safe and effective access to health services by the public.

A number of the issues raised in the discussion paper are not directly related to the Board and its functions outlined in the National Law. Rather than providing a response to each question, the Board has elected to articulate how the work it has undertaken in the public interest through the National Registration and Accreditation Scheme (the National Scheme) in accordance with the National Law intersects with issues raised in the discussion paper.

In accordance with its role in protecting the public, the Board's comments are provided from the public interest perspective which it believes is at the core of this review.

The Board hopes that the information provided will assist the review panel in its assessment of these important issues.

**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.

There are 14 National Boards that regulate 14 professions under the National Registration and Accreditation Scheme (the National Scheme). The Australian Health Practitioner Regulation Agency (AHPRA) works in partnership with the National Boards to administer the National

Scheme, which has public safety at its heart. National Boards 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.*
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.*

### **Development of registration standards, codes and guidelines**

The National Law requires National Boards to develop registration standards about matters, including the:

- a. requirements for professional indemnity insurance arrangements for registered health practitioners registered in the profession;
- b. matters about the criminal history of applicants for registration in the profession, and registered health practitioners and students registered by the Board, including, the matters to be considered in deciding whether an individual's criminal history is relevant to the practice of the profession;
- c. requirements for continuing professional development for registered health practitioners registered in the profession;
- d. requirements about the English language skills necessary for an applicant for registration in the profession to be suitable for registration in the profession;
- e. requirements in relation to the nature, extent, period and recency of any previous practice of the profession by applicants for registration in the profession.

A National Board may also develop, and recommend to the Ministerial Council, one or more registration standards about the following—

- a. the physical and mental health of—
  - (i) applicants for registration in the profession; and
  - (ii) registered health practitioners and students;
- b. the scope of practice of health practitioners registered in the profession;
- c. any other issue relevant to the eligibility of individuals for registration in the profession or the suitability of individuals to competently and safely practise the profession.

A list of registration standards developed by the Board after wide-ranging consultation, and that were subsequently approved by Ministerial Council are published on the Board's website at [www.pharmacyboard.gov.au/Registration-Standards.aspx](http://www.pharmacyboard.gov.au/Registration-Standards.aspx).

In accordance with the National Law, a National Board may develop and approve codes and guidelines —

- (a) to provide guidance to the health practitioners it registers; and
- (b) about other matters relevant to the exercise of its functions.

The Board does not develop guidelines about all matters relevant to the practice of pharmacy and routinely seeks to provide clarity about particular aspects of practice, where it believes this is warranted and in the public interest.

A list of codes and guidelines developed by the Board after wide-ranging consultation are published on the Board's website at [www.pharmacyboard.gov.au/Codes-Guidelines.aspx](http://www.pharmacyboard.gov.au/Codes-Guidelines.aspx).

Each of the Board's published guidelines include the following (or similar) statement:

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

- *Pharmaceutical Society of Australia (PSA) ([www.psa.org.au](http://www.psa.org.au)), and*
- *The Society of Hospital Pharmacists of Australia (The SHPA) ([www.shpa.org.au](http://www.shpa.org.au)).*

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

### **Pharmacy Remuneration for Dispensing**

The Board noted the range of questions in the discussion paper regarding options for remuneration for dispensing. The Board supports pharmacy remuneration arrangements that facilitate access by the public to services and which promote the quality use of medicines.

The Board's *Guidelines for dispensing of medicines* reinforce the obligations of pharmacists during the dispensing of medicines within the broad legal and professional framework that pharmacists practise within.

The *Guidelines for dispensing of medicines* include guidance on obligations to counsel patients or their agents about dispensed medicines (Guideline 1) in the pharmacy premises setting as well as other circumstances such as the indirect supply of medicines including in remote settings (Guideline 5). The Board has also provided guidance on the need to deliver detailed advice to patients in a range of circumstances (Guideline 8) and its *Code of conduct for pharmacists* also outlines obligations in relation to patients who have additional needs (section 3.8).

Options for remuneration for dispensing need to support the safe dispensing and quality use of medicines and ensure that pharmacists are able to meet their legal and professional obligations. Inadequate resourcing can adversely impact pharmacists' workloads as well as exposing pharmacists to excessive workplace stress and may put the public at risk. The Board has developed and published guidance about pharmacists' workloads in Guideline 11 of its *Guidelines for dispensing of medicines*.

### **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.*

### **Administration of vaccines**

One recent example of pharmacists expanding the use of their skills and knowledge to deliver services in the public interest is the administration of vaccines.

Upon review of a consolidated set of competencies for the administration of vaccines by pharmacists the Board recognised that the administration of vaccines is included in the current scope of practice of pharmacists, provided that pharmacists demonstrate competency through adequate training.

State and territory governments subsequently granted authorities to pharmacists to administer particular vaccines, subject to completion of specific training requirements and meeting any other specified requirements, with vaccination by pharmacists now being undertaken in all jurisdictions.

Pharmacists who administer vaccines upon completion of jurisdictional training requirements have also addressed their obligations under the National Law by undertaking continuing professional development according to their scope of practice, in accordance with the Board's *Registration standard: Continuing professional development* and *Guidelines on continuing professional development*.

### *Prescribing*

The pharmacy profession is currently investigating opportunities for pharmacists to prescribe scheduled medicines. This could be particularly helpful in rural and remote communities where there may be limited access to authorised prescribers such as medical practitioners or nurse practitioners. This would facilitate the continuous development of a flexible, responsive and sustainable Australian health workforce, enable innovation in the education of, and service delivery by, health practitioners, and facilitate greater access to health services which are objectives of the National Scheme.

The Board would be required to assess the required regulatory action under the National Law to enable such innovations and to ensure that these services were delivered by competent and trained pharmacists. The Board would also consider any action in the context of relevant frameworks and resources including the Health Professions Prescribing Pathway and the National Prescribing Service *Competencies Required to Prescribe Medicines*.

However, prescribing by pharmacists that is outside of their scope of practice would be dependent on the authorities to prescribe being granted under state and territory drugs and poisons legislation as well as the relevant provisions of the National Law being met.

Under the National Law, the Board may submit a recommendation to Ministerial Council, that the Board endorse the registration of pharmacists to administer, obtain, possess, prescribe, sell supply or use a scheduled medicine or class of scheduled medicines. If approved, this would also require approval by Ministerial Council of a registration standard for the endorsement.

To have their registration endorsed, a pharmacist would be required to complete an accredited qualification and to meet any other requirements specified in a registration standard approved under the National Law and payment of the endorsement of registration fee.

If a proposal for the endorsement of pharmacists' registration is to be developed, the Board would also need to consider whether it should develop associated guidelines for pharmacists.

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.

### *Terminology*

The Board notes the Review Panel's description in the discussion paper of pharmacists as 'medicine specialists', acknowledging their expertise. The National Law includes provisions for the approval by Ministerial Council of specialties and specialist titles in a health profession. For the purpose of clarity, the Board highlights that the title 'specialist' is a protected title under the National Law and that there are no specialties or specialist titles in the pharmacy profession approved by Ministerial Council.

## Regulation

The Board's functions under the National Law exclude the regulation of pharmacy premises. The Board acknowledges that other entities have responsibility and authority to regulate a range of matters that are relevant to pharmacy premises.

In relation to the issues raised in the discussion paper regarding possible reform of pharmacy location rules, the Board is supportive of efforts that improve access by the public, including in rural and remote locations, to medicines and professional services delivered by pharmacists.

The Board is also supportive of programs and other initiatives that improve access to pharmacy services and the quality use of medicines by Aboriginal and Torres Strait Islander people.

## Supply of vitamins and complementary medicines from pharmacies

The Board has issued guidance to pharmacists about the provision of complementary and alternative medicines in its *Guidelines on practice-specific issues*. In addition to this, the *Code of conduct for pharmacists* (the code) states that good practice involves pharmacists practising in accordance with the current and accepted evidence base of the profession, including clinical outcomes. The code also highlights the importance of recognising and respecting the rights of patients or clients to make their own decisions.

Recognising that patients have a right to choose complementary and alternative medicine over other treatment options, and routinely seek health advice at a pharmacy, in order to best support patient safety when these medicines are sought Guideline 5 *Complementary and alternative medicines* of the revised *Guidelines on practice-specific issues* states:

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

## Chemotherapy arrangements

The Board has developed and published guidance to pharmacists in relation to compounding of medicines to ensure product quality, safety and efficacy. The *Guidelines on compounding of medicines* apply to all compounding (including the compounding of chemotherapy) by pharmacists.

Pharmacists must also meet their obligations outlined in relevant state, territory and Commonwealth legislation as they relate to the preparation, labelling, maintenance of records, storage, dispensing, supply and advertising of compounded medicines, and practise in accordance with relevant compounding practice standards and guidelines.

The *Guidelines on compounding of medicines* state:

*“A compounded medicine should be prepared only in circumstances where:*

- an appropriate commercial product is unavailable*
- a commercial product is unsuitable (e.g. if a patient experienced an allergy to an excipient in the commercial product), or*
- when undertaking research sanctioned by a recognised human research ethics committee.*

*The compounding of a medicine (whether prescribed or not) that would be a close formulation to an available and suitable commercial product, and would not be likely to produce a different therapeutic outcome to the commercial product, should not take place. In the case that such a*

*medicine has been prescribed, the pharmacist should notify the prescriber that this medicine cannot be compounded under these circumstances.”*

The Board acknowledges that pharmacists may compound medicines in premises licensed by the Therapeutic Goods Administration (TGA) subject to meeting specific requirements and standards of practice. As pharmacists may also compound medicines in pharmacy premises which are not licensed by TGA the Board has provided guidance about a range of issues including facilities, working environments, equipment, raw materials, quality standards and audit of practice in the public interest.

In considering the options for the funding of chemotherapy, the Board highlights the importance of the standard of practice required in all locations where pharmacists compound medicines (including chemotherapy) and the costs associated with meeting the standard.

While there may be opportunities for legislative reform in relation to the compounding of medicines that may benefit the public, the options for funding of compounding of medicines in the existing legislative framework should not adversely impact product quality, safety and efficacy.

Thank you for the opportunity to provide feedback on the discussion paper. If you would like to discuss the matter further, do not hesitate to contact me.

Yours sincerely

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

**William Kelly**

Chair