



4 August 2017

Professor Stephen King
Chair
Pharmacy Remuneration and Regulation Panel
c/- Review Secretariat

Via E-mail: pharmacy.review@health.gov.au

Dear Professor King

Review of Pharmacy Remuneration and Regulation

Thank you for the opportunity to make a submission to the consultation on the review of Pharmacy Remuneration and Regulation. This submission is provided jointly by the Pharmacy Board of Australia and the Australian Health Practitioner Regulation Agency (AHPRA). The submission provides some brief background on the National Registration and Accreditation Scheme (the National Scheme), then some joint comments from the Board and AHPRA and finishes with some specific comments from the Board.

Background to the National Registration and Accreditation Scheme

The National Registration and Accreditation Scheme (the National Scheme) commenced operation on 1 July 2010. The National Scheme is an outcome of the Council of Australian Government's reform program. It created a national registration and accreditation scheme for health practitioners through legislation passed in each state and territory, which established the Australian Health Practitioner Regulation Agency (AHPRA) and 14 National Boards.

AHPRA is the national organisation responsible for implementing the National Scheme across Australia, in partnership with the 14 National Boards:

- Aboriginal and Torres Strait Islander Health Practice Board of Australia
- Chinese Medicine Board of Australia
- Chiropractic Board of Australia
- Dental Board of Australia
- Medical Board of Australia
- Medical Radiation Practice Board of Australia
- Nursing and Midwifery Board of Australia
- Occupational Therapy Board of Australia
- Optometry Board of Australia
- Osteopathy Board of Australia
- Pharmacy Board of Australia
- Physiotherapy Board of Australia
- Podiatry Board of Australia
- Psychology Board of Australia

The National Scheme aims to protect the public by ensuring that only suitably trained and qualified practitioners are registered. It also facilitates workforce mobility across Australia; the provision of high-quality education and training of health practitioners; and rigorous

assessment of overseas-trained practitioners. Guided by a nationally consistent law, AHPRA and the National Boards work to regulate the health professions in the public interest.

This includes registering practitioners who are suitably trained and qualified to provide safe healthcare, and investigating concerns about registered health practitioners. As at 30 April 2017, the National Scheme regulated 676,108 registered health practitioners.

Comments on the interim report

We note that the interim report covers a wide range of issues and only some are relevant to the work of the National Scheme, and regulation of the pharmacy profession. Accordingly, our submission focuses on these aspects of the interim report.

There are two key issues which the Board and AHPRA wish to highlight. First, the Board and AHPRA note that the interim report proposes actions to assist in closing the gap. The National Boards and AHPRA support actions to contribute to improving Aboriginal and Torres Strait Islander health and closing the gap. The National Scheme is currently developing an Aboriginal and Torres Strait Islander Health Strategy to articulate how it can contribute to this important national goal. Accordingly, the Board and AHPRA support the aims of the proposed work to assist in closing the gap outlined in the interim report.

Second, the interim report raises the issue of inconsistent legislation impacting on pharmacist practice. The Board and AHPRA support proposals to harmonise legislation that would simplify the regulatory environment for pharmacist practice and help to improve patient safety. There is more detail in the specific comments attached from the Board.

Comments from the Pharmacy Board of Australia

The Board has additional comments on pharmacy-specific issues which are attached.

If you wish to discuss this submission, please contact Chris Robertson, Executive Director Strategy and Policy Directorate on (03) 8708 9037.

Thank you again for the opportunity to comment.

Yours sincerely



Martin Fletcher
Chief Executive Officer



William Kelly
Chair, Pharmacy Board of Australia

Attach: Review of Pharmacy Remuneration and Regulation – interim report

Review of Pharmacy Remuneration and Regulation – Interim Report

PharmBA comments

Option summary	Response
<p>LABELLING</p> <p>The label is a vital part of the supply of PBS medicines. It is relied on by patients and health professionals for the proper identification, dosage, categorisations and monitoring of medicines.</p> <p>OPTION 2-4: LABELLING</p> <p>1. All PBS medicines provided to patients should be appropriately labelled and dispensed. Where there is a system in place that involves ‘remote’ dispensing or ‘bulk supply’ then this system will require appropriate monitoring to ensure the quality of medicine supply.</p>	<p>The minimum labelling requirements for all medicines supplied are outlined in state and territory drugs and poisons legislation.</p> <p>The Board’s <i>Guidelines for the dispensing of medicines</i> for pharmacists (the guidelines) focus on safe dispensing and labelling of medicines. Guideline 7 ‘Labelling of dispensed medicines’ addresses a range of important considerations and outcomes to be achieved including:</p> <ul style="list-style-type: none"> • ensuring lawful possession by the patient • maximising the benefits of the therapy • improving the patient’s understanding of the treatment • enhancing adherence, and • minimising adverse effects. <p>The Board agrees that all medicines provided to patients, irrespective of the type of health practitioner responsible (for example nurse, medical practitioner, Aboriginal and Torres Strait Islander Health Practitioners) are labelled to support achievement of these outcomes.</p> <p>Monitoring of such matters may fall under the jurisdiction of particular entities in states and territories and would need to be monitored by those entities.</p> <p>Failure of pharmacists to meet legal and professional obligations in relation to the labelling of medicines in these circumstances can be reported to the Board as a notification by a responsible entity for any necessary action under the National Law. Under section 41 of the National Law, the Board’s 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.</p>
<p>CONSUMER MEDICINES INFORMATION</p> <p>While Consumer Medicines Information (CMI) leaflets are generally available, there are variances in how these are provided to consumers. Some consumers may be unaware of</p>	<p>The Board addresses the use of CMIs in Guideline 8 ‘Counselling patients about prescribed medicines’ of the Board’s <i>Guidelines for the dispensing of medicines</i> states:</p> <p>“Patient counselling is part of the process of dispensing medicines and provides</p>

Option summary	Response
<p>the availability of a CMI and there is a risk that these may not be provided, which could impact on quality of care.</p> <p>OPTION 2-6: CONSUMER MEDICINES INFORMATION</p> <p>A Consumer Medicines Information (CMI) leaflet should be offered and made available to consumers with all prescriptions dispensed in accordance with Pharmaceutical Society of Australia (PSA) guidelines. The PSA guidelines and the distribution of CMIs to consumers need to be audited and enforced to ensure compliance.</p> <p>Pharmacists and the pharmacy industry should continue to work on the improvement of CMIs and the use of technology to make medicines information more available to consumers.</p>	<p>an opportunity to elicit the necessary information from a patient, and to provide the required information to enable safe and effective use of medicines. Patients have the right to expect that the pharmacist will counsel them privately about their medicines.</p> <p>Counselling is also the final checking process to ensure the correct medicine is supplied to the correct patient. Lack of counselling can be a significant contributor in failing to detect dispensing errors. In this regard, the Board endorses the current patient counselling guidelines produced by the Pharmaceutical Society of Australia and The Society of Hospital Pharmacists of Australia, including the use of ‘Consumer medicines information’ (CMI) leaflets.”</p> <p>The Board periodically publishes reminders to pharmacists about compliance with Board guidelines, generally informed by the type of notifications (complaints) received about pharmacists and areas of risk noted by the Board.</p> <p>Instances where pharmacists have failed to provide a CMI to a patient can be reported to the Board as a notification for any necessary action by the Board under the National Law.</p> <p>Patient awareness of their right to receive available CMIs may need to be addressed more broadly.</p>
<p>THE BENEFITS OF AN ELECTRONIC HEALTH RECORD FOR CONSUMERS</p> <p>The current paper-based system of prescriptions used in Australia is outdated. It inhibits the creation of a universal medication record for Australians, creates excessive administration, is less convenient for consumers and presents significant challenges in meeting the standard required for quality use of medicines.</p> <p>OPTION 2-7: ELECTRONIC PRESCRIPTIONS</p> <p>The government should initiate an appropriate system for integrated electronic prescriptions and medicine records as a matter of urgency. Under this system the electronic record should become the legal record. Participation in the system should be required for any prescriber of a PBS-listed</p>	<p>The Board supports initiatives that improve the quality of patient health records and that facilitate access by health practitioners to detailed individual patient health records to support clinical decision making in the patient interest. The incorporation of some over-the-counter medicines into patient health records should also be included as the use of such medicines by patients also needs to be considered by health practitioners. The Board also notes there are numerous factors that impact on the successful development of systems to successfully implement such initiatives.</p> <p>The development and implementation of initiatives regarding patient records and prescribing need to complement the delivery of health services. Any new responsibilities and obligations need to be clearly articulated and not compromise a health practitioner’s ability to meet existing responsibilities and obligations.</p> <p>Such initiatives give rise to important issues for patients including privacy, confidentiality and choice about participation which require careful consideration.</p>

Option summary	Response
<p>medicine, any pharmacist wishing to dispense a PBS-listed medicine and any patient who is seeking to fill a PBS prescription.</p> <p>ELECTRONIC RECORD KEEPING</p> <p>Australia lacks an integrated and effective universal health record system. This reduces consumer access to best-practice care and continuity of care between providers.</p> <p>OPTION 2-8: ELECTRONIC MEDICATIONS RECORD</p> <p>The electronic personal medications record should cover all Australians and ensure appropriate access by, and links between, community pharmacy, hospitals and all doctors. This record should also include a vaccines register.</p> <p>MANAGING RISKS ASSOCIATED WITH ‘CHANNELLING’ PRESCRIPTIONS</p> <p>The introduction of a compulsory electronic prescription record could introduce risks of inappropriate behaviour, such as channelling of prescriptions, that will need to be managed appropriately.</p> <p>OPTION 2-9: ELECTRONIC PRESCRIPTIONS – CONSUMER CHOICE</p> <p>The choice of where a consumer has an electronic prescription dispensed should remain a decision for that consumer. The consumer may request that the electronic prescription be directed to a particular community pharmacy for dispensing (including an online pharmacy if that is the consumer's choice). For avoidance of doubt, a prescriber may not direct an electronic prescription to a particular community pharmacy for dispensing. This will require appropriate oversight and enforcement by professional bodies.</p>	<p>Patients’ right to choose where they access services (e.g. the pharmacy the patient usually attends) must also be maintained and consideration given to the risks that arise if continuity of care is compromised.</p> <p>Enforcement of the options suggested by the Review can be supported by professional bodies through incorporation into professional practice standards however, enforcement may require regulation by an appropriate entity and penalties for non-compliance.</p>

Option summary	Response
<p>THE ROLE OF COMMUNITY PHARMACY</p> <p>There are certain minimum services that all community pharmacies should provide in order to meet consumer and government expectations about the level of consistency that is required from a national pharmacy network.</p> <p>OPTION 3-1: COMMUNITY PHARMACIES – MINIMUM SERVICES</p> <p>The government should establish a process to determine the set of minimum requirements that a community pharmacy must meet in order to receive remuneration for dispensing. The government should initiate procedures to enforce these requirements and to have them updated at regular intervals. These requirements should be promoted by being incorporated within the Community Pharmacy Service Charter.</p>	<p>This matter must be considered within the context of the complex regulatory landscape in which pharmacy services are delivered. This requires careful consideration of issues including the regulatory requirements of pharmacy premises, legal obligations, professional obligations (including compliance with practice standards, guidelines and quality care standards), the requirements for participation in the Pharmaceutical Benefits Scheme and eligibility for receipt of remuneration, as well as the role of the relevant entities.</p> <p>The development and application of minimum requirements to be met in a pharmacy to respond to the needs of the community would need to be monitored and reviewed. The needs of different communities may vary and the impact of proposed minimum requirements, including costs should be carefully assessed. A proposal to set minimum services should not adversely impact the development of innovation in the delivery of pharmacy services.</p>
<p>PHARMACY ONLY AND PHARMACIST ONLY MEDICINES (SCHEDULE 2 AND SCHEDULE 3 MEDICINES)</p> <p>Complementary medicines pose a risk to consumers when they are not clearly separated from Pharmacy Only and Pharmacist Only (Schedule 2 and Schedule 3) medicines.</p> <p>OPTION 3-3: PLACEMENT OF PHARMACY ONLY AND PHARMACIST ONLY (SCHEDULE 2 AND SCHEDULE 3) MEDICINES WITHIN A PHARMACY</p> <p>Access to Pharmacy Only (Schedule 2) and Pharmacist Only (Schedule 3) medicines should be clearly separated from complementary medicines within a pharmacy. Options to achieve this might include:</p> <p>a. ensuring that all Pharmacy Only (Schedule 2) and Pharmacist Only (Schedule 3) medicines only be accessible from ‘behind the counter’ in a community pharmacy so that a consumer must always seek</p>	<p>The Board notes the lack of uniformity in the requirements for the storage of scheduled medicines in approved pharmacy premises across states and territories. Harmonisation of legislation or national regulation of premises requirements are options for achieving uniformity in practice.</p> <p>While Schedule 3 medicines are stored out of reach of the public, the inclusion of Schedule 2 medicines ‘behind the counter’ could necessitate significant structural changes in many pharmacies.</p> <p>Appropriate placement of scheduled and unscheduled medicines including complementary and alternative medicines can facilitate engagement between consumers and pharmacists or trained pharmacy staff. Ultimately the provision of medicines and advice in accordance with pharmacy practice standards and Board guidelines ensures that the potential health benefits and risks associated with use of these products are clear.</p>

Option summary	Response
<p>assistance or advice in obtaining these medicines</p> <p>b. requiring that complementary medicines are not displayed 'behind the counter' in a community pharmacy.</p>	
<p>HOMEOPATHIC PRODUCTS</p> <p>There are unacceptable risks where community pharmacies are allowed to sell homeopathic products.</p> <p>OPTION 3-4: SALE OF HOMEOPATHIC PRODUCTS</p> <p>Homeopathy and homeopathic products should not be sold in PBS-approved pharmacies. This requirement should be referenced and enforced through relevant policies, standards and guidelines issued by professional pharmacy bodies.</p>	<p>Complementary and alternative medicines includes homeopathic products.</p> <p>The Board previously advised the review panel that it has issued guidance to pharmacists about the provision of complementary and alternative medicines in its <i>Guidelines on practice-specific issues</i>.</p> <p>In addition to this, the <i>Code of conduct for pharmacists</i> (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.</p> <p>To further articulate good practice in the supply of such medicines, the Board's Guideline 5 <i>Complementary and alternative medicines</i> of the revised <i>Guidelines on practice-specific issues</i> states:</p> <p><i>“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.”</i></p> <p>The Board acknowledges the conclusions reached by the National Health and Medical Research Council (NHMRC) in 2015 regarding its assessment of the evidence of efficacy of homeopathy.</p> <p>In the provision of healthcare to the public, pharmacists have an important role in advising consumers about their medications including complementary and alternative medicines. This includes the provision of clear advice to avoid the public putting their health at risk if they reject or delay treatments for which there is good evidence for safety and effectiveness. This advice must not be limited to</p>

Option summary	Response
	<p>the risks of using homeopathic products in place of prescription and other scheduled medicines, and must also address the proposed use of any complementary and alternative medicines.</p> <p>In developing proposals for inclusion in its guidelines, the Board consults widely with stakeholders, the public and government. Additionally, its proposals need to be assessed by the Office of Best Practice Regulation for any potential impact on business and individuals. Proposals assessed as potentially having more than a minor impact on business and individuals may require a Regulation Impact Statement.</p> <p>For further consideration in relation to the proposal that homeopathic products should not be sold in PBS-approved pharmacies is:</p> <ul style="list-style-type: none"> • it is unclear how this would be enforced, what action would be taken and by whom if homeopathic products were sold • why unapproved pharmacies would be excluded • whether the same should apply to any other complementary and alternative medicines that lack evidence of efficacy and have sufficient evidence of non-efficacy to preclude their ethical sale in community pharmacies and that pose similar risks to consumers. <p>Pharmacist engagement with the consumers whose personal preferences about management of their health include non-evidence based approaches is important to facilitate good health outcomes. Any measures that impact such engagement should be carefully considered and managed.</p> <p>Of particular risk to the public is the provision of advice by individuals including pharmacists that homeopathic products are effective and can be used in place of conventional medicines with robust evidence of efficacy. Through the notifications management process under the National Law, the Board would investigate claims of this nature about pharmacists with consideration to its guidelines, for any required action.</p>
<p>REFORMS IF THE LOCATION RULES ARE RETAINED IN SOME PARTS OF AUSTRALIA</p> <p>The policy in respect of pharmacy location rules is unclear. This results in different interpretations of their purpose and intent and reduces the ability to monitor performance and the</p>	<p>The options do not clearly address the range of issues of relevance to a complex issue which is also impacted by ownership restrictions.</p>

Option summary	Response
<p>achievement of outcomes.</p> <p>OPTION 5-4: LOCATION RULES – POLICY OBJECTIVE</p> <p>If the government retains the pharmacy location rules (or some version of these rules) following the end of the Sixth Community Pharmacy Agreement then the policy objective of these rules should be clearly stated and the rules modified to ensure that the desired outcomes are achieved over the medium term.</p> <p>The objective of the pharmacy location rules should be to assist the Australian consumer to ensure equitable and affordable access to medicines for all Australians, consistent with the National Medicines Policy, with evidence to demonstrate the achievement of this objective.</p> <p>OVERLAPPING OWNERSHIP AND LOCATION OF PHARMACIES</p> <p>The pharmacy location rules have not established robust competition between independent pharmacies in some locations. Rather, in some locations, either individual pharmacists or small groups of pharmacists have been able to monopolise some or all pharmacies. This is inconsistent with the objective of Australia’s competition laws.</p> <p>OPTION 5-5: LOCATION RULES – OWNERSHIP AND LOCATION</p> <p>In areas where pharmacy location rules are maintained, any group of two or more pharmacies, each of which are located within 1.5 kilometres of another pharmacy in the group, that have an overlapping ownership should be considered to be a single pharmacy for the application of the location rules.</p> <p>The nominal ‘location’ of this single pharmacy would be the location of the pharmacy within the group that had the smallest turnover (in terms of the number of Pharmaceutical</p>	

Option summary	Response
<p>Benefits Scheme scripts dispensed) in 2016.</p> <p>For avoidance of doubt, a group of pharmacies would be considered to have an overlapping ownership if any individual or set of individuals have ownership of at least 20 per cent of the equity in each of the community pharmacies in that group.</p> <p>It is also considered that this option should be implemented five years after this Review to allow an appropriate time frame for transition.</p> <p>The oversight of this option should be undertaken by the Australian Competition and Consumer Commission.</p>	
<p>VARIATIONS AMONG STATE AND TERRITORY REGULATORY ARRANGEMENTS RELATING TO COMMUNITY PHARMACY</p> <p>The community pharmacy sector is subject to a complex array of regulations made by state and territory governments as well as the Australian Government.</p> <p>OPTION 5-9: HARMONISING PHARMACY LEGISLATION</p> <ol style="list-style-type: none"> 1. As early as practicable, the Australian Government, through the Australian Health Minister's Advisory Council, should seek to harmonise all state, territory and federal pharmacy regulations to simplify the monitoring of pharmacy regulation in Australia for the safety of the public. 2. In the long term, a single pharmacy regulator could be considered. 3. As an interim measure, state and territory registering bodies need to coordinate with the Australian Health Practitioner Regulation Agency to ensure that pharmacy regulations are being adequately monitored for best practice of pharmacy and the safety of the public. 	<p>The Board in principle supports the harmonisation of legislation relevant to pharmacy practice that is in the public interest. Currently, variation exists in state and territory:</p> <ul style="list-style-type: none"> • drugs and poisons legislation, and • pharmacy premises and ownership legislation. <p>Under the National Registration and Accreditation Scheme national registration standards, codes and guidelines for pharmacists apply and pharmacists are now registered by a national board to practise in all states and territories which provides a range of benefits.</p> <p>The harmonisation of other legislation impacting pharmacy practice may provide greater consistency in pharmacy practice noting that issues specific to particular states and territories may warrant alternative and/or additional regulatory measures.</p> <p>Greater consistency in regulation relevant to pharmacy practice could minimise errors, particularly for those pharmacists practising in locations close to state and territory borders or in multiple jurisdictions, and could benefit the public for example if less regulatory burden supports the delivery of improved services in accordance with common requirements.</p> <p>If consideration is to be given to a national regulator of pharmacy premises under which common requirements are applied to the establishment of</p>

Option summary	Response
	<p>pharmacies and the conduct of pharmacy businesses, various models may need to be considered through extensive consultation.</p> <p>Under the current multi jurisdictional arrangements for the regulation of pharmacy premises, in accordance with the provisions of the National Law AHPRA routinely engages with state and territory regulators to contribute to public protection. Where required, memoranda of understanding with authorised entities have been established. These arrangements assist the Board and AHPRA to take action under the National Law, where the practice of pharmacists is less than the standard expected and such action is necessary to mitigate risk to the public.</p>
<p>LEVERAGING PHARMACY AND PHARMACIST CAPABILITY</p> <p>Significant opportunities exist for the better use of community pharmacy and pharmacist programs and services in improving the health of Australians.</p> <p>OPTION 8-1: DOSE ADMINISTRATION AIDS – STANDARDS</p> <p>The government should establish clear, enforceable minimum standards for the supply of medicines by community pharmacies, including for dose administration aids (DAAs). There should also be appropriate compensation provided to community pharmacies for the dispensing of medicines using DAAs (in recognition that this tends to be a higher-cost activity than dispensing in manufacturer’s packaging).</p>	<p>In developing any enforceable minimum standards for the supply by pharmacists of medicines in dose administration containers consideration should be given to the existing guidance and practice standards (Pharmaceutical Society of Australia professional practice standards, the Quality Care Pharmacy Program and Pharmacy Board of Australia guidelines).</p> <p>Enhancing quality use of medicines by consumers and delivering improved patient safety/health outcomes should be appropriately funded given the widespread benefits to the public and the health care system.</p>
<p>OPTION 8-2: COMMUNITY PHARMACY PROGRAM – KEY PRINCIPLES</p> <p>The range of programs offered by community pharmacy should be underpinned by the following principles:</p> <ol style="list-style-type: none"> a. be based on evidence of effectiveness b. may or may not involve government paying for some or all of the cost of the service to some or all patients c. may in some cases be offered on the basis of each 	<p>In response to emerging opportunities for pharmacists to deliver new services in the public interest, pharmacists need to assess their skills and knowledge and plan and undertake any education and/or training in order to ensure the required competence is achieved. Given the impact on pharmacists to ensure the required standard of practice can be achieved and successfully and consistently delivered, suitable support should be provided including in the form of remuneration of services which is managed fairly, effectively and efficiently.</p>

Option summary	Response
<p>community pharmacy choosing whether or not to offer the program (with all community pharmacies being eligible to offer the program). In other cases, the program will only be available (with government payment) through pharmacies/pharmacists that are selected by the government (for example, through a tender process or as a result of negotiation between the government and the relevant pharmacies or pharmacists)</p> <p>d. for some programs, government remuneration for the program will be channelled through the users of the program (or their representatives) so that the users will decide which community pharmacies (or pharmacists) to use to deliver the program</p> <p>e. adequate funding for the above needs to be found outside PBS expenditure.</p>	
<p>PHARMACY OWNERSHIP AND OPERATIONS BY ABORIGINAL HEALTH SERVICES</p> <p>The current inability of an AHS to operate a community pharmacy poses a significant risk to patient health in some rural and remote areas of Australia.,</p> <p>OPTION 9-2: ABORIGINAL HEALTH SERVICE PHARMACY OWNERSHIP AND OPERATIONS</p> <p>All levels of government should ensure that any existing rules that prevent an Aboriginal Health Service (AHS) from owning and operating a community pharmacy located at the AHS are removed. As a transition step, these changes should first be trialled in the Northern Territory, and governments should work together with any AHS that wishes to establish a community pharmacy.</p>	<p>The Board reiterates its support of programs and other initiatives that improve access to pharmacy services and the quality use of medicines by Aboriginal and Torres Strait Islander people. National Boards and the Australian Health Practitioner Regulation Agency are currently developing an Aboriginal and Torres Strait Islander Health Strategy to articulate how the National Registration and Accreditation Scheme can contribute to closing the gap.</p> <p>Further ownership options should be explored, for instance, the owning and operating of community pharmacies by other than pharmacists, namely Friendly Societies, is currently allowed within certain limits in 6 states and one territory (NT). While the Board of such Societies as a corporate entity are still held to account for the ownership aspects, day-to-day clinical responsibilities usually resides with an appointed pharmacist manager.</p> <p>As with any corporate run entity, viability in addition to risk and liability is a paramount consideration. Such factors are often magnified in a rural or remote setting.</p> <p>The employment of pharmacists to work in AHS can also improve health outcomes and is both achievable and sustainable.</p>

Option summary	Response
<p>CHEMOTHERAPY COMPOUNDING – PAYMENTS</p> <p>The rationale for differential payments for compounding of chemotherapy preparations is not substantiated on the basis of patient risks or health outcomes for medicines that must meet an appropriate level of quality, whether prepared at a TGA licensed or non-TGA-licensed facility.</p> <p>OPTION 10-2: CHEMOTHERAPY COMPOUNDING – PAYMENTS</p> <p>There should be no difference in the remuneration paid by the government for the compounding of chemotherapy medicines in any facility that meets the minimum quality and safety standards. In particular, there should be no additional payment for medicines that are prepared in a facility that exceeds the minimum standards.</p> <p>CHEMOTHERAPY COMPOUNDING STANDARDS</p> <p>The current standards for the compounding of chemotherapy medicines in community pharmacy and other facilities appear to be overly complex. The oversight currently includes legislation, codes and guidelines. The overlap and inconsistency of these across Australia do not provide clear rules or guidance for compounders.</p> <p>OPTION 10-3: CHEMOTHERAPY COMPOUNDING – UNIFORM MINIMUM STANDARDS</p> <p>There should be a clear, uniform set of minimum quality standards for all approved chemotherapy compounding facilities based in a hospital, a community pharmacy or elsewhere. These minimum standards should:</p> <p>a. not require that a compounding facility be Therapeutic Goods Administration (TGA) licensed to meet the</p>	<p>The Board acknowledges that the Panel “considers that appropriate standards should be in place for chemotherapy preparations produced in any relevant facility to ensure that these preparations meet a required level of quality with minimum risks to patient harm.” The compounding of medicines is enabled under a complex regulatory framework.</p> <p>Further to the Board’s previous comments highlighting “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” the Board advises that on 1 August 2017 it published revised guidance titled <i>Compounding of sterile injectable medicines</i>, to replace the currently postponed section 'Expiry of compounded parenteral medicines' of its <i>Guidelines on compounding of medicines</i> (the guidelines).</p> <p>Compounding of sterile injectable medicines (which includes relevant chemotherapy preparations) poses significant risks to the public if the requirements of relevant legislation, guidelines and practice standards are not strictly adhered to throughout the compounding and supply process.</p> <p>This section of the guidelines is intended to provide additional guidance to pharmacists who compound sterile injectable medicines which carries additional risks for patients. The Board’s guidance highlights the importance of compliance with relevant standards and processes that support assigning appropriate beyond use dates for compounded sterile injectable medicines and supporting ongoing access by the public to the medicines they require.</p> <p>The section in the revised guidance titled <i>Compliance with legislation, guidelines and practice standards</i> states the following:</p> <p>“When compounding sterile injectable medicines (as described above), pharmacists must adhere to all relevant legislation, guidelines and practice standards as outlined in the section <i>Relevant legislation and practice standards</i> in these guidelines.”</p> <p>The Board’s guidelines also state that these guidelines must be read in conjunction with:</p> <ul style="list-style-type: none"> • codes and guidelines published by jurisdictional pharmacy premises regulatory authorities about pharmacy premises • the section <i>Extemporaneous dispensing</i> in the current edition of the

Option summary	Response
<p>minimum requirements</p> <p>b. mean that a TGA-licensed facility clearly satisfies the minimum standards</p> <p>c. reflect the variety of settings that are appropriate for the preparation of chemotherapy medicines, including 'urgent' preparation in a hospital setting or a community pharmacy setting.</p> <p>CHEMOTHERAPY COMPOUNDING PRACTICE MODELS</p> <p>There are a number of good practice chemotherapy compounding models that can be leveraged to improve access to existing compounding arrangements.</p> <p>OPTION 10-4: CHEMOTHERAPY COMPOUNDING – PRACTICE MODELS</p> <p>Existing practice models in place in public hospitals for limited trade of medicines prepared onsite, such as radio pharmaceuticals, should be considered for providing greater access to chemotherapy arrangements.</p>	<p><i>Australian Pharmaceutical Formulary and Handbook, and</i></p> <ul style="list-style-type: none"> • the following practice standards and guidelines: <ul style="list-style-type: none"> – the Pharmaceutical Society of Australia <i>Professional Practice Standards - Standard 10: Compounding</i> (also known as <i>Extemporaneous dispensing</i>) – the Pharmaceutical Society of Australia <i>Professional Practice Standards - Standard 11: Compounding sterile preparations</i> – The Society of Hospital Pharmacists of Australia <i>SHPA Standards of Practice for the Safe Handling of Cytotoxic Drugs in Pharmacy Departments</i> – The Society of Hospital Pharmacists of Australia <i>SHPA Standards of Practice for the Transportation of Cytotoxic Drugs from Pharmacy Departments</i> – The Society of Hospital Pharmacists of Australia <i>SHPA Guidelines for Medicines Prepared in Australian Hospital Pharmacy Departments</i> – The Society of Hospital Pharmacists of Australia <i>SHPA Standards of Practice for the Provision of Oral Chemotherapy for the Treatment of Cancer</i> – occupational, health and safety standards, and – Australian standards for clean rooms. <p>Additionally, pharmacists must adhere to the principles and procedures outlined in one of the following guides/standard, whichever is the most appropriate and relevant to their compounding practice:</p> <ul style="list-style-type: none"> • the PIC/S Guide to Good Practices for the Preparation of Medicinal Products in Healthcare Establishments (PE 010), or • the PIC/S Guide to Good Manufacturing Practice for Medicinal Products (PE 009), or • the USP–NF (797) <i>Pharmaceutical Compounding—Sterile Preparations</i>. <p>In choosing the most appropriate and relevant guide or standard listed above, consideration must be given to all relevant factors including the practice setting, the types of medicines compounded, the risks identified during the risk assessment process for compounded products outlined in these guidelines and the risks to the patient and other individuals handling or exposed to the compounded medicines.”</p>

Option summary	Response
	<p>The guidance also outlines that in accordance with good pharmaceutical practice, to ensure compliance with practice standards pharmacists are expected to audit their practice against the standards and that where required a third party assessor with expertise may be contracted to assist with auditing of compliance.</p> <p>The revised guidance <i>Compounding of sterile injectable medicines</i>, and the <i>Guidelines on compounding of medicines</i> apply to all pharmacists compounding medicines in pharmacies and pharmacy departments which are not TGA licensed facilities.</p>