



Government of **Western Australia**
Department of **Health**

Review of Community Pharmacy Ownership in Western Australia

Discussion Paper

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Foreword

There are many challenges for our current health care system. We now have an ageing population, who are living longer, with an increased prevalence of chronic conditions. This places increasing strain on the costs and complexity of health care, demands on our health care workforce, and challenges the models to deliver this care.

Pharmacies are an established and essential part of our health care system. Pharmacists themselves are trusted and valued health practitioners, with specialist expertise in medicines management. Pharmacies have long been a fixture in our community, supplying medicines and providing medicines related advice. This traditional role is evolving, with pharmacies increasingly focusing on wellness and prevention, chronic disease management and providing other health assessments.

Due to the nature of the medicines they keep, pharmacies are subject to both State and Commonwealth regulation. These rules are important to protect consumers, and designed to drive safe and high quality care. As with any regulation, the legislation must meet the needs of the community and keep pace with a changing environment.

The Western Australian (WA) Government views community pharmacies as an integral part of primary health care in this State. Every day, thousands of us rely on pharmacists for our basic medicines and healthcare needs. To make sure we play the best role in regulating pharmacy, and that pharmacies continue to function as trusted partners in delivering health services, the Government is undertaking a *Review of Community Pharmacy Ownership in Western Australia*. The Review is focussed on four key areas:

- trends in pharmacy ownership and lessons from other States and Territories;
- adequacy of current WA ownership laws to protect the integrity of the sector in this State;
- roles of pharmacies in an integrated health care model and how the WA regulatory model can support this; and
- changes the WA Government can make to protect the pharmacy role in the WA health system.

I encourage all interested parties to submit their views and be a part of this important review.



Roger Cook MLA

MINISTER FOR HEALTH

The pharmacy sector

It is estimated that, each year, Australian pharmacies dispense almost 300 million prescriptions, totalling almost \$11 billion worth of medicines. Every pharmacy dispenses an average of 57,000 prescriptions per year.¹ The Pharmacy Guild of Australia reports that 94% of adults utilise a pharmacy, with most of us visiting about 14 times each year. Over 3.9 million Australians ask their pharmacist for health advice every year.²

Pharmacies sell a wide range of products; predominantly prescription medicines, over the counter medicines and complementary remedies. Pharmacies traditionally also sell health related products, including personal care, baby care, hygiene and grooming items. They also supply or hire medical devices and health related equipment.

Pharmacies have a recognised role in improving quality use of medicines, to assist patients manage use of multiple drugs at once, detect drug interactions, minimise adverse events, and improving adherence. Pharmacies now commonly offer other medicines related services, including such activities as:

- first aid and minor ailment treatments;
- influenza immunisation;
- compounding and extemporaneous manufacturing;
- methadone programs;
- medicines reviews;
- dose administration aids;
- return and disposal of unwanted medicines;
- medicines related services to Residential Aged Care Facilities; and
- supply of diabetes products and advice.

There are approximately 5,500 pharmacies Australia-wide, servicing an average of 4,300 people each.³ The sector employs over 60,000 people nationally.⁴ As at July 2017, there were 633 registered pharmacies in WA⁵, or about 11% of the national total.³

Regulation of pharmacy

History of pharmacy regulation

The practice of pharmacy, and the operation of pharmacies, has been controlled in WA for over 100 years. This dates to 1894, when pharmacies in the Colony of WA were first regulated under the *Pharmacy and Poisons Act*, to prevent “unqualified persons from representing themselves to be competent to practise as Chemists and Druggists”.

The 1894 Act established the Pharmaceutical Society of Western Australia, which was charged with the registration of individuals as qualified pharmaceutical chemists. Pharmacists of the day had to be proficient in practical pharmacy, chemistry, botany, *materia medica* and Latin. Poisons could only be sold by chemists, or other licensed persons. The *Pharmacy and Poisons Compilation Act 1910* stipulated that no person other than a pharmacist, friendly society or medical practitioner could operate a chemist and druggist business. The business had to be conducted under the personal supervision of the licensed operator.

In 1964, the introduction of the *Pharmacy Act* provided for a Pharmaceutical Council to administer the registration of pharmacists and protect against unqualified persons. The Act restricted operation of a pharmacy to a business registered to a licensed pharmacist (or friendly society). A pharmacist could only carry on business as a pharmaceutical chemist when living in WA. Pharmacists could only own, or have a pecuniary interest, in a maximum of two pharmacies. Business could only operate when a licensed pharmacist personally supervised

dispensing of medicines. The Act also restricted pharmacies to selling approved goods associated with drugs and medicines.

The *Pharmacy Act* and regulations were amended over the next 50 years, for emerging matters such as changes to qualifications, practitioners from other states or countries, and minimum standards for premises. In 1976, the Pharmacy Act Regulations required applicants to submit plans of their pharmacy and to disclose information about persons holding interests in the business. Premises needed to be well lit, separated from other businesses and adequately ventilated. They were also to be: clean and in good repair; able to be secured; of a minimum floor space; equipped with apparatus and reference texts for dispensing; able to make records of supply of medicines; and not have a public thoroughfare.

The history of pharmacy regulation outlined above shows increasing attention to public protection and the introduction of additional standards over time: the intent of these developments being to ensure the safety and security of pharmacists and pharmacies providing health care to the community.

Why regulate pharmacies?

Medicines themselves can be poisonous and represent a serious public health risk, unless used under supervision and monitoring by qualified practitioners. In 2014, the Western Australian Poisons Information Centre reported over 19,000 calls from people living in WA.⁷ A literature review of medicines safety in Australia by the Australian Commission for Quality and Safety in Health Care suggests that medicines are responsible for 2-3% of all hospital admissions, adverse events are seen in between 5-17% of people using medicines at home, and that upwards of 90% of residents of aged care facilities will have one or more medication related problems.⁸

The Pharmacy profession is considered to be heavily regulated; however, the reasons that drove the original regulation of pharmacists and pharmacies in 1894 are largely still present today. There appears little dispute that individual pharmacists should be appropriately qualified and meet minimum standards of competency.

Medicines are not seen to be ordinary items of commerce⁶ and pharmacies are unique amongst health practitioner businesses, in that they carry very large quantities of medicines, including significant stockholdings of drugs with a high potential for misuse and abuse, or illicit value.

There are good reasons for pharmacies to meet minimum standards as businesses. It is self-evident that pharmacies must be able to keep the drugs in their possession in acceptable condition for use and to prevent unauthorised access. They need to be safe places for patients to enter and suitable to delivery of the type of care they offer.

The intent of the existing regulation of pharmacies in WA is then to ensure protection of the public and result in overall community benefit. Specifically, the legislation is designed to give assurance that pharmacies are safe public spaces for consumers to visit and professional standards are met in relation to their business activities.

The legislation requires businesses to be registered and to meet minimum standards. These have the intended result of producing pharmacies that:

- are fit for purpose for the services they offer;
- contain minimum fittings and equipment that is operational and maintained in good order;
- maintain the security and patency of medicines in their care;
- only provide services by, or under the personal supervision of qualified persons; and
- promote professional and ethical delivery of care.

All pharmacy registration authorities around Australia have guidelines or standards that address matters such as:

- access, egress, lighting, cleanliness and workplace environment;
- security;
- staffing and workload;
- floor space;
- drug storage and temperature, including refrigerators;
- dispensing, specialist equipment, script checking technology;
- record keeping and privacy;
- reference texts; and
- waste disposal.

As outlined, there is a long history of restriction on who can own a pharmacy. The current legislative rules on pharmacy ownership have number of regulatory functions, including:

- making owners personally responsible and accountable for standards and service provided by the business they operate;
- preventing undue external influences that compromise standards or professionalism; and
- reducing conflicts of interest, including horizontal or vertical integration of the supply chain by pharmacists or other interests (such as drug companies).

In addition to these outcomes, the limits on numbers of pharmacies that may be owned is also intended to ensure competition and drive innovation, as well as creating differentiation between businesses and improving choice for consumers.

Current regulation of pharmacies

Since pharmacy and poisons laws were first envisaged, there have been major societal changes in many areas, most importantly in how health care is delivered. Possibly the most significant event for pharmacists over this period has been the modern manufacture, current complex safety standards and quality expectations of today's prescription drugs. The diversity of medicines, including the types, forms and potential medical uses, has greatly expanded over the same time. The introduction of a national universal health care funding system in Australia, particularly the Pharmaceutical Benefits Scheme (PBS), heavily affects how contemporary pharmacies operate and supply medicines.

Individual pharmacists continued to be registered by State based authorities, in the jurisdiction in which they lived, up until 2010. At this time, all States and Territories implemented respective national health practitioner regulation laws to provide a scheme for the consistent, single national registration of health practitioners. These laws cover a wider range of health practitioners, such as medical practitioners and nurses, as well as pharmacists. Pharmacists are now registered nationally by the Pharmacy Board of Australia, and the registration process is administered by the Australia Health Practitioner Regulation Agency.

Despite these changes, the registration and regulation of pharmacy premises remains a responsibility of State and Territory governments. At the time of national registration, WA laws were updated to remove provisions relating to registration of individual pharmacists and reflect contemporary registration requirements for pharmacy businesses.⁹

Registration of pharmacy businesses in Western Australia

In 2017, any business in WA that carries out the practice of pharmacy is controlled by the *Pharmacy Act 2010*. The Act requires every pharmacy to be registered and defines a pharmacy

business as one that provides pharmaceutical services, relating to the storage, dispensing and supply of medicines and poisons.

The Act establishes a body known as the Pharmacy Registration Board of Western Australia, appointed by the Minister for Health, and responsible for approving the registration of pharmacies and maintaining a public register. The Board may only register a pharmacy that meets prescribed standards set out in the Pharmacy Regulations 2010, for minimum premises requirements and fitness to carry out a pharmacy business. The Board has powers to enter and inspect a pharmacy at any time to ensure these requirements are being met.

The Act also outlines restrictions on pharmacy ownership. A person may only own or hold a proprietary interest in a registered pharmacy if they are:

- a pharmacist registered under the Health Practitioner Regulation National Law (Western Australia) Act 2010; or
- a close family member of a registered pharmacist who also owns a stake in the pharmacy.

A pharmacy may also be owned by:

- a pharmacist controlled company, where one or more directors are registered pharmacists and any other directors are close family members of a director who is a registered pharmacist;
- a friendly society under the *Corporations Act 2001 (Cth)*; or
- the preserved company, defined as St John of God Health Care, incorporated under the *Associations Incorporation Act 2015 (WA)*.

A pharmacist may not own, or hold a proprietary interest, in more than four pharmacies at any one time. The preserved company may own one pharmacy and a friendly society, no more than four. While the number of pharmacies a person may own is restricted, this does not stop businesses from operating under a common recognisable name or brand.

Pharmacy regulation in other States and Territories

Pharmacies are regulated businesses in all States and Territories of Australia. Jurisdictional legislation mandates the registration of pharmacies and establishes authorities responsible for registering premises; with Queensland operating a notification system. Pharmacies can only be registered where they meet criteria laid out in regulation and comply with standards issued by each authority.

Each jurisdiction has rules about who may own a pharmacy, which show some consistency across Australia. In general, all owners must be individual pharmacists, pharmacists operating in partnership, companies owned by pharmacists (and / or relatives of a pharmacist), or eligible trusts connected to a pharmacist. In some States and Territories, friendly societies, Aboriginal health services or other exempted groups may also own a pharmacy, under limited circumstances. Readers are directed to Appendix 1 and the individual registering authorities for specific details of how these rules apply in each State and Territory.

In the Australian Capital Territory and the Northern Territory, there is no limit on the number that can be owned. In Tasmania and WA, only four pharmacies can be concurrently owned. In New South Wales, Queensland and Victoria, a person may own five pharmacies at the same time. In South Australia, this figure is six pharmacies.

Location rules

Most medicines supplied in the primary care (community) setting in Australia today are subsidised by the Commonwealth Government as part of the PBS. To supply PBS medicines, pharmacies must be approved under the *National Health Act 1953*. The Community Pharmacy Agreement between the Commonwealth Government and the Pharmacy Guild of Australia contains rules that govern the location of an approved new pharmacy or the relocation of an existing pharmacy.

The location rules are intended to ensure that the objectives of the National Medicines Policy are met, specifically that there is *“timely access to medicines that Australians need, at a cost to individuals, that the community can afford”*. Approvals are considered by a statutory body, named the Australian Community Pharmacy Authority. The WA Government has no role in PBS-pharmacy location rules, which are distinct from State and Territory ownership laws.

Current issues

The ownership and location rules of pharmacy have been the subject of numerous reviews over time. More recently, the Productivity Commission released a Competition Policy Review⁶ that, in part, considered competition in pharmacy and outcomes for consumers. The Review Panel recommended an overhaul of location rules and suggested that current State and Territory laws could be replaced with legislation designed to meet National Medicines Policy objectives and maximise competition.

Subsequently, an independent review (the King Review) was commissioned into pharmacy regulation and remuneration as part of the Sixth Community Pharmacy Agreement. The Review Panel released an Interim Report in June 2017, which states that community pharmacy in Australia *“faces considerable challenges which threaten the viability of traditional pharmacy operating models, constraining the ability of pharmacists to deliver quality health outcomes.”*³

The Interim Report notes that changes to PBS remuneration structures, designed to contain continued increase in national expenditure on medicines, may be driving business changes. This pressure, amongst other drivers, has led to continued growth of the ‘big box’ discounter model, with proliferation of warehouse-style pharmacies. The Report states that *“Aggressive pricing strategies have eroded the profit margins and revenue streams of traditional pharmacy models”*. The Panel observed that retail banner groups drive competition within the sector.

The Interim Report also discusses the changing role of pharmacists, referring to a transition from a product supply focus to a service focus. The Review Panel suggest that recognition of the clinical knowledge held by pharmacists has resulted in an increase in the number of medicine-related services available in community pharmacy. It also acknowledges that disruptive technologies are affecting how pharmacies dispense medicines.

Although location and ownership rules are distinct and thus regulated separately, the two are still linked, and are therefore both discussed in the Interim Review. Specifically, the Review Panel considered that there is sufficient variation between jurisdictional ownership rules, which would warrant harmonisation of State, Territory and federal pharmacy regulations. They suggest consideration of a single national pharmacy regulator, but were of the opinion that regulations must be adequately monitored for best practice of pharmacy and the safety of the public.

A statutory review of the *Pharmacy Act 2010* was commenced by the WA Department of Health in 2015. The Review was undertaken according to the provisions of section 72 of the Act, to consider the effectiveness of operation of the Board, and the need for the continuation of functions of the Board. The Review sought submissions from interested parties on these matters, but also received commentary from stakeholders on other matters regulated by the Act, including ownership of pharmacies.

Specific items of note, raised as part of the Review and related to the current situation include:

- ownership by non-practising pharmacists;
- ownership by pharmacists registered with AHPRA, but not resident in WA; and
- consistency with respect to the number of pharmacies that can be owned in different jurisdictions.

Consultation

In summary, in the current health care environment, there are a number of recent and ongoing disruptors affecting pharmacies. As highlighted above, various sources suggest:

- post introduction of the national health practitioner regulation scheme, there is continued registration of pharmacy businesses by State and Territory authorities;
- pharmacy business models across Australia are changing, leading to different ownership patterns;
- pharmacies are seeking to offer additional health care services, relating to health promotion and chronic disease management; and
- there are reasonable arguments for the continued need to regulate pharmacy premises, in at least some manner, for public benefit.

Consultation questions

With these current challenges in mind, the Government wishes to hear from interested parties on matters relevant to the regulation of pharmacies. In particular, the following specific consultation questions are posed.

1. **What are the lessons on pharmacy ownership from other States and Territories, and what trends should we be aware of?**
2. **Are the current WA ownership laws (limiting a pharmacist to owning four pharmacies) sufficient to protect the integrity of the sector in this State?**
3. **What role can pharmacies play in an integrated health care model in WA, and how does the current pharmacy regulatory model support this?**
4. **What changes, if any, could the WA Government make to see the pharmacy role in the WA health system protected?**

Making a submission

Any person making a submission to this review can do so by directly addressing the four consultation questions in writing, and posting a response to:

Community Pharmacy Ownership Review
C/- Medicines and Poisons Regulation Branch
WA Department of Health
PO Box 8172 Perth Business Centre WA 6849

Submissions, including questions relating to the review, can also be sent via email, to:

communitypharmacyownershipreview@health.wa.gov.au

Submissions must be received before close of business on **Friday, 8 December 2017**. Late submissions will not be accepted. All correspondence must indicate the person or organisation involved in the submission, including a name, address and details of a suitable individual contact. Submissions may be made public, unless otherwise requested.

APPENDIX 1:

Pharmacy regulation around Australia

The following information is a brief summary of applicable legislation that governs the ownership of pharmacies in each State and Territory of Australia. Readers are referred to the individual regulatory authorities and various respective Acts for further details of full restrictions applicable in each jurisdiction.

Western Australia

- Pharmacies must be registered with the Pharmacy Registration Board of Western Australia under the Pharmacy Act 2010.
- A person may only own or hold a proprietary interest in a registered pharmacy if they are:
 - a registered pharmacist; or
 - a close family member of a registered pharmacist who also owns a stake in the pharmacy.
- A pharmacy may also be owned by:
 - a pharmacist controlled company, where one or more directors are registered pharmacists and the other directors are close family members of a director who is a registered pharmacist;
 - a friendly society; or
 - the preserved company.
- A pharmacist may not own, or hold a proprietary interest, in more than four pharmacies, at any one time.

Australian Capital Territory (ACT)

- Community pharmacies in the ACT need to be licensed by ACT Health under the Public Health Act 1997.
- A pharmacy business owner must be a pharmacist, a complying pharmacy corporation, or a former corporate pharmacist.

New South Wales (NSW)

- In NSW, the registration of pharmacies is regulated by the Health Practitioner Regulation National Law (NSW) No 86a, which requires the Pharmacy Council of New South Wales to maintain a Register of Pharmacies.
- Only a registered pharmacist, a partnership of registered pharmacists or a pharmacists' body corporate can hold a financial interest in a pharmacy in New South Wales.
- These persons may only hold a financial interest in a maximum of five pharmacies.

Northern Territory

- The Pharmacy Premises Committee registers pharmacies according to Schedule 7 of the Health Practitioners Act.
- A person must not own or exercise any control over a pharmacy business unless they are: a pharmacist; a partnership, of which all partners are pharmacists; a corporation, of which all shareholders and directors are pharmacists; or an exempted Aboriginal health service or friendly society.

Queensland

- In Queensland, the Queensland Department of Health has responsibility for pharmacy ownership under the Pharmacy Business Ownership Act 2001.
- Only a pharmacist or a corporation having only individual shareholders who are either pharmacists or their relatives, may own a pharmacy.
- A pharmacist or corporation may only own or have a beneficial interest in five pharmacies at the same time.

South Australia

- In South Australia, the Pharmacy Regulation Authority SA is the regulatory agency responsible for the administration of provisions related to pharmacies in the Health Practitioner Regulation National Law (South Australia) Act 2010.
- Ownership is restricted to pharmacists, pharmacist controlled companies and pharmacist controlled trusts.
- A person cannot provide pharmacy services at more than six pharmacies in South Australia.

Tasmania

- The Tasmanian Pharmacy Authority is responsible for the registration and regulation of pharmacies under the Pharmacy Control Act 2001.
- A pharmacy may be owned by: a pharmacist; a partnership of registered pharmacists; a body corporate where directors are registered pharmacists, controlling interest is held by registered pharmacists and other members of the body corporate are close relatives of the pharmacists; or an individual or body corporate for a trust, with certain limitations.
- A person must not hold an interest in more than four pharmacies in Tasmania.

Victoria

- In Victoria, the registration of pharmacies is regulated by the Pharmacy Regulation Act 2010 (Vic) and administered by the Victorian Pharmacy Authority.
- Business must be owned by a registered pharmacist(s) or company registered under the Corporations Act whose directors are all registered pharmacists.
- A pharmacist must not own or have a proprietary interest in more than five separate pharmacies.

APPENDIX 2:

References

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