



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

# Review of Community Pharmacy Ownership in Western Australia -

## Final Report

March 2019

## Contents

Executive summary	4
Review background	9
Terms of Reference	9
Consultation process	9
Submissions received	10
Targeted interviews and forums	12
Interim Report	13
Regulation of community pharmacy businesses	14
The pharmacy registration process in Western Australia	14
Compliance monitoring	15
Pharmacy business regulation around Australia	16
Queensland	17
Victoria	18
Northern Territory	19
Review questions	20
1. What are the lessons on pharmacy ownership from other States and Territories, and what trends should we be aware of?	
Community pharmacy in Western Australia	20
Community pharmacy ownership in Western Australia	22
Trends in Western Australia	23
Entry of discount pharmacy model	24
More banner groups	25
Focus on price versus service	26
Service / management groups	27
Vertical and horizontal integration	28
Reduced ownership transparency	28
Potential for external influence over pharmacy businesses	29
Interstate owners	30
Numbers of pharmacies owned	31
Other commercial arrangements	31
Workforce effects	32
Consumer views	33
Summary and Findings	34
2. Are the current Western Australian ownership laws (limiting a pharmacist to owning four pharmacies) sufficient to protect the integrity of the sector in this State?	
Regulation of pharmacies	36
Registration of pharmacies	38

Pharmacists responsible for providing pharmacy services	39
Pharmacy ownership	40
Consumer opinion	42
Views of pharmacy organisations	43
Other views on ownership	43
Professional responsibility and conflicts of interest	44
Pharmacies in private hospitals	46
Numbers of pharmacies that may be owned	50
Ownership concentration	51
Owners being resident in Western Australia	51
National consistency in ownership laws	52
Current practising status of pharmacists	53
Aboriginal health services and pharmacy	54
Findings and Recommendations	55
3. What role can pharmacies play in an integrated health care model in Western Australia, and how does the current pharmacy regulatory model support this?	
Value of pharmacy to the health system	61
Underutilised capability in the pharmacy sector	61
Types of additional services proposed	62
Opinions of pharmacy organisations	63
Opinions of medical organisations	65
Consumer views	67
Practitioner scope	68
Considerations related to changes to scope	69
Changes to other legislation	70
Opinions of younger pharmacists	72
Funding issues	73
Regulations as an enabler	76
Other health professionals providing services from a pharmacy	78
Government engagement	79
Findings and Recommendations	80
4. What changes, if any, could the WA Government make to see the pharmacy role in the Western Australian health system protected?	
Reviews of the pharmacy sector	88
Efficiency and operation of the pharmacy registration scheme	88
Fees and charges for registration	89
Resources and capability of Pharmacy Registration Board of Western Australia	90
Changes to registration processes	91
Composition and operation of the Board	92

Specific circumstances of registration	93
Enforcement of existing legislation	93
Powers and penalties	94
Profile of the Board	95
Other amendments	96
Findings and Recommendations	97
APPENDIX 1: Discussion Paper	103
APPENDIX 2: Application requirements for pharmacy registration around Australia	116
APPENDIX 3: Summary of pharmacy regulation around Australia	117
APPENDIX 4: Pharmacy registration fees around Australia (2016-2017)	119
APPENDIX 5: Selected responses from online submissions	120
APPENDIX 6: Proposed WA Pharmacy registration fees	131

## Executive summary

On 24 October 2017, a Review of community pharmacy ownership laws in Western Australia was announced by the Hon Roger Cook, Deputy Premier; Minister for Health; Mental Health.

The scope of the Review included consideration of: current ownership trends in Western Australia and elsewhere in Australia; the adequacy of current legislation; the role of pharmacy in an integrated model of health care; and changes that may be necessary to protect the integrity of the sector.

Public consultation ran for approximately two months until the end of 2017. A large number of submissions were received, predominantly from pharmacists and pharmacy groups.

A number of industry based interviews were conducted with key stakeholders and regulatory authorities in Western Australia and in other jurisdictions. Additional materials and information was collected and considered during 2018.

- 1. What are the lessons on pharmacy ownership from other States and Territories, and what trends should we be aware of?*

The Review found a number of evident trends and that the pharmacy sector felt these were important to recognise and address.

These trends include: more complex ownership structures; entry of discount pharmacies; alignment of community pharmacies with large banner groups; marketing on the basis of price or professional service; and use of service/management groups.

The industry expressed a concern that these trends exposed the sector to a potential for vertical and horizontal integration; reduced ownership transparency; and increasing external influences.

There was a reported trend of interstate ownership, which raised concerns in relation to maintaining minimum standards within a pharmacy.

The combination of these trends are said to be having a negative effect on the pharmacy workforce and younger pharmacists appear to be less optimistic about their profession.

- 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?*

As a result of these trends, the Review found that the current laws may no longer be entirely suitable to protect the integrity of the sector and regulatory amendment may be warranted. In particular, there is a case for harmonisation of these laws across Australia, so long as this does not disadvantage Western Australia.

Medicines are not ordinary items of commerce and for this reason there is ongoing public interest in the regulation of pharmacies. Pharmacists are appropriate persons to own a pharmacy and dispense medicines, as well as to run and maintain standards in a pharmacy business.

There is no support from any quarter for ownership by large corporate entities that have no health focus. The Review did receive arguments for other certain types of persons to own a pharmacy, including pharmacies that supply medicines in private hospitals. The pharmacy industry categorically opposes such changes and there is reasonable evidence that certain types of dysfunction, as seen in other markets, might result. The Review does not recommend changes at this time, or making any changes in Western Australia alone, without consideration of the national picture.

Most pharmacists believe the current limits on ownership numbers are generally appropriate, but should be standardised between States and Territories. There is also support for owners to be resident in Western Australia when owning a Pharmacy located in Western Australia. The Review recommends that these matters be taken up nationally.

All proprietors should have current, practising status as a pharmacist.

*3. What role can pharmacies play in an integrated health care model in WA, and how does the current pharmacy regulatory model support this?*

Community pharmacy is seen as a valuable health network and resource; however, pharmacists do not always feel they are working at top of scope. Pharmacy and pharmacist capacity is considered underutilised, which seems to be resulting in a degree of dissatisfaction and frustration among the pharmacy workforce.

Changes could be made to improve pharmacist utilisation, which is argued as needed to enhance efficiency of the health system. These changes could include services to provide additional vaccinations, health screening, chronic disease management, health promotion, and other medicines-related activities. Pharmacists could offer a wider range of medication management reviews and related services in collaboration with General Practitioners. Scope extension for pharmacists might also include some models of prescribing. The Review recommends that progress on these proposed directions should be supported, within certain limits, but only where safe to do so and when they add to the overall quality of primary care.

The *Pharmacy Act 2010* and Pharmacy Regulations 2010 may have only a limited role in promoting any of the changes recommended and other policy approaches by Government may be more appropriate for this purpose. In particular, funding models are felt to be a significant barrier to delivery of some services from pharmacies.

Based on the material received and the specified scope of the Review, it is not possible to make recommendations as to particular services that might improve outcomes and reduce costs, which the Government should consider funding. It is recommended that the Government establishes a mechanism to obtain this type of advice in a way that is objective, evidence based and independent. This advice needs to be considered in the context of national medicines funding programs in primary care.

There are also opportunities for workforce development and research that should be considered by Government.

It is recommended that aspects of the Pharmacy Regulations are amended to improve flexibility and responsiveness with respect to standards for premises and to reflect changing pharmacy practice.

4. *What changes, if any, could the WA Government make to see the pharmacy role in the WA health system protected?*

The pharmacy registration process in Western Australia is comprehensive and rigorous. More complex work and an increasing quantity of work mean that there is an increasing demand on the Pharmacy Registration Board of Western Australia. The Board requires adequate resources and powers to meet its remit. There is an urgent need to update existing fees and charges to reflect current costs and to ensure that the Board can continue to meet its obligations.

Complex ownership structures require particular attention to ensure compliance with provisions for proprietary interests and the registration process should allow for additional scrutiny in these cases. The costs of this scrutiny should be met by applicants and corresponding amendments to fee structures are recommended.

The regulatory authority requires adequate resources to be able to audit compliance, investigate non-compliance, and fully and properly examine proprietary structures. It is recommended that the legislation be amended to ensure that the Board has all the necessary powers it requires to prevent changing ownership trends from undermining its ongoing ability to make sure that the legislation, and its core intent, is complied with.

The current Board structure is not ideal and requires review, including the number of members and their remuneration. This is considered urgent. The Board should also make changes to manage workload and ensure performance and responsive service to the pharmacies it regulates.

The legislation is inadequate to deal with some specific issues, such as the professional deregistration of a proprietor. Legislative amendment is recommended to deal with these matters.

There is a real concern over issues of undue influence over a pharmacy proprietor. The legislation does not explicitly address this matter and appropriate amendments should be explored. Current penalties are inadequate as a deterrent and require urgent attention. Other miscellaneous changes are recommended by the Review to ensure the continued effective and efficient operation of the legislation.

### *Recommendations*

The Review makes recommendations to the Minister for Health in the following areas.

#### ***Pharmacy Act 2010***

##### [Recommendation 1](#)

Legislation should continue to require a pharmacist to be a proprietor of a pharmacy business and be responsible overall for managing the public risks posed by that type of business.

##### [Recommendation 2](#)

Ownership restrictions in relation to pharmacists owning pharmacies remain in place, at this time.

### [Recommendation 3](#)

Ownership restrictions in relation to pharmacists owning pharmacies in hospitals remain in place, at this time.

### [Recommendation 4](#)

The ownership limit of four pharmacies should remain, as is, until such time that there is agreement between States and Territories on alignment of this limit between Australian jurisdictions.

### [Recommendation 6](#)

Pharmacy ownership by interstate pharmacists continues to be allowed, at this time.

### [Recommendation 8](#)

Pharmacists hold general registration, and be practising, to be a pharmacy proprietor.

### [Recommendation 17](#)

The legislation should support the ability of the Pharmacy Registration Board of Western Australia to define a type of application as complex, by nature of the ownership vehicle used.

### [Recommendation 18](#)

Legislative amendments are considered that will provide the Pharmacy Registration Board of Western Australia adequate powers to compel provision of any information or documents relevant to a proprietary interest in a pharmacy.

### [Recommendation 19](#)

The legislation should be amended to require a proprietor to advise the Board of all changes to ownership or proprietary interests within a reasonable time. The Board should be able to require any individual attend before it to provide evidence on matters of registration, proprietary interest or any other aspect of the legislation as relates to a pharmacy.

### [Recommendation 20](#)

The legislation should be urgently amended to increase the membership of the Board to be at least five members, include new members with a suitable knowledge or experience of pharmacy and / or public interest, and retain a suitable and achievable quorum for Board meetings.

### [Recommendation 21](#)

The legislation should be amended to include suitable “undue influence” clauses.

### [Recommendation 22](#)

Penalties in the legislation should be reviewed and increased.

### [Recommendation 23](#)

The legislation should be amended to require a proprietor to immediately inform the Board of any condition or change in registration, or any other legislated professional authority to handle medicines, relevant to the ownership of a pharmacy. The legislation should be amended to provide for situations of de-registration (or similar) where ownership must be transferred, similar to those already in place for the death of a proprietor.



## **Pharmacy Regulations 2010 and Administration**

### [Recommendation 7](#)

The Board should be able to take a lack of personal oversight by the proprietor, including situations of residence in other States and Territories, into account in relation to any failure to meet standards.

### [Recommendation 14](#)

That there is consultation over revision of the existing standards for premises, including any required impact assessments and as a matter of urgency the existing standards in the Regulations are updated accordingly.

### [Recommendation 15](#)

The Pharmacy Registration Board of Western Australia consider whether suitable standards could be practically implemented, that might support co-location of a pharmacy, with a medical practice, while maintaining ongoing business separation and appropriate protections, to ensure the established and expected level of security for medicines held.

### [Recommendation 16](#)

The registration fees should be amended, as soon as possible, by the amount needed to properly reflect the current costs of the Pharmacy Registration Board of Western Australia in processing registration applications.

## **Pharmacy policy**

### [Recommendation 9](#)

The Government acknowledge that there is a potential underutilisation of pharmacies and pharmacists.

### [Recommendation 11](#)

Western Australia should closely monitor national developments and discussions relating to non-medical prescribing for pharmacists.

### [Recommendation 12](#)

The Government should establish a standing mechanism to provide it with robust, evidence based advice, on the future of pharmacy services.

### [Recommendation 13](#)

Western Australia should fully support national and Commonwealth programs, including those under the Community Pharmacy Agreements, related to improving the quality use of medicines.

## **Related legislation and national consistency**

### [Recommendation 5](#)

Western Australia actively pursue, or at least engage in, progress with other State and Territories, towards harmonisation of pharmacy legislation around Australia.

### [Recommendation 10](#)

Western Australia allow additional access to immunisation via pharmacies that is at least consistent with that already permitted in other States and Territories.

## Review background

The commencement and purpose of the Review was publicly announced by the Hon Roger Cook, Deputy Premier; Minister for Health; Mental Health on 24 October 2017.

## Terms of Reference

The Review was undertaken with the aim of understanding whether the existing pharmacy ownership regulations remain appropriate in the current health care environment, and to ensure they continue to support community pharmacy in its role as a trusted partner in delivering health services.

In order to do this, the Review sought feedback from stakeholders on the following consultation questions:

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?

## Consultation process

The consultation period for the Review opened on the 24 October 2017 and officially ran until 8 December 2017.

To support the Review a Discussion Paper was published. This summarised the past and current regulation of community pharmacy in Western Australia, including commentary around the intent of this legislation and the changes that have occurred over time. The Discussion Paper also provided background information on similar regulatory schemes in other States and Territories. The Discussion Paper posed a number of issues and questions relating to how community pharmacy is currently regulated.

The full Discussion Paper is provided at [Appendix 1](#) to this Report and can be viewed online at:

<http://ww2.health.wa.gov.au/~-/media/Files/Corporate/general%20documents/Pharmacy%20review/Review-of-Community-Pharmacy-Ownership-Discussion-Paper-v2.pdf>

Information to guide the Review was obtained from three main sources:

- consultation with key Western Australian stakeholder groups
- consultation with pharmacy registration bodies in other jurisdictions
- public submissions received.

The Review was reported by a number of Western Australian media outlets. This news was also widely circulated throughout a number of pharmacy dedicated media vehicles including: Pharmacy Daily; AJP.com.au; and PostScript.com.au.

The Review was advertised to Western Australian community pharmacies. All existing pharmacies, registered with the Pharmacy Registration Board of Western Australia, received both email and written notification explaining the Review and inviting submissions.

Key pharmacy and other potential health or medical stakeholders were identified. Written notification of the Review was provided along with an invitation to provide a submission. Key pharmacy stakeholders included:

- Pharmacy Registration Board of Western Australia
- The Pharmacy Guild of Australia (WA Branch)
- Pharmaceutical Society of Australia (WA Branch)
- Society of Hospital Pharmacists of Australia (WA Branch)
- WA Pharmacy Students Association
- Professional Pharmacists Australia.

The Review was advertised via a dedicated page on the WA Health corporate website at: [http://ww2.health.wa.gov.au/Articles/N\\_R/Review-of-pharmacy-ownership](http://ww2.health.wa.gov.au/Articles/N_R/Review-of-pharmacy-ownership).

A dedicated space for submission was provided in the WA Health Consultation Hub. This is a purpose designed web-based tool for conducting public consultations, see: <https://consultation.health.wa.gov.au/medicines-and-poisons-regulation-branch/review-of-community-pharmacy-ownership/>.

This tool allows users to provide structured feedback and collects responses electronically. Users were led by the tool to provide comments and opinions according to each Review question. The tool allowed responses to be readily collated and themed.

## Submissions received

There was a strong response to the Review, with a large number of submissions received. As expected, the majority of these were from pharmacists, or from the pharmacy sector. There were very few submissions received from the general public or individual health consumers. The nature of the submissions received is broken down in more detail below.

A total of 93 written submissions were received in response to the Review. Submissions could be provided via email, post or online. The majority of public submissions were responses posted via the Department of Health web-based consultation tool.

Online and other stakeholders were asked for permission to post submissions on the Department of Health website. A sizeable number of submissions indicated that they did not

wish for the contents to be made public, and so, for consistency, the Review has chosen not to publish the submissions received.

### Individual and/or business

There were 78 submissions received from individuals or businesses. This included:

- consumers 4
- pharmacists 8
- pharmacy owners (or owners' groups) 65
- other health professionals 1.

### Organisational

One or more submissions were received from organisations representing:

pharmacy -

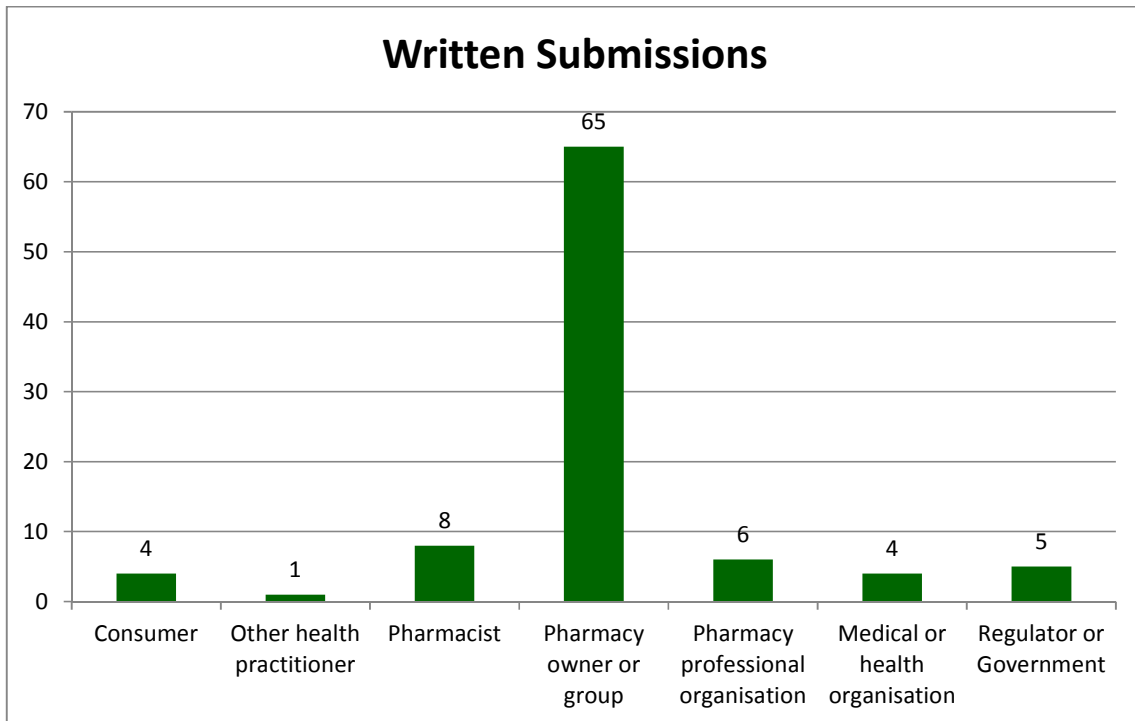
- Pharmaceutical Society of Australia
- Pharmacy Guild of Australia
- Western Australian Pharmacy Students Association
- Society of Hospital Pharmacists of Australia
- Small Pharmacies Group
- Private Hospital Pharmacy Owners.

regulatory and related bodies -

- Pharmacy Board of Australia
- Pharmacy Registration Board of Western Australia
- Small Business Development Corporation.

medical and health -

- Australian Medical Association
- Royal Australian College of General Practitioners
- Aboriginal Health Council of Western Australia
- Western Australian Primary Health Alliance.



### Targeted interviews and forums

Targeted interviews here held, either by teleconference or in person, with a selection of key stakeholders. This included a range of pharmacist and pharmacy owner professional organisations, as well as representatives of jurisdictional pharmacy premises / ownership regulation bodies from other States and Territories. Interviews were held with:

Pharmacy and other groups, representatives of -

- Health Consumers' Council
- Pharmaceutical Society of Australia
- Pharmacy Guild of Australia
- Pharmaceutical Society of Australia Early Career Pharmacist Working Group
- Western Australian Pharmacy Students Association.

Regulators, representatives of -

- ACT Health
- Pharmacy Premises Committee - Northern Territory
- Victorian Pharmacy Authority
- Tasmanian Pharmacy Authority
- Pharmacy Registration Authority of South Australia.

Not all jurisdictional regulators agreed to participate in interviews.

A number of interviews were held with the Pharmacy Registration Board of Western Australia. As the regulating authority for the sector, the Board is in a privileged position to understand the current issues and trends in ownership, as it is the only body with:

- a complete picture of every pharmacy in Western Australia
- extensive information provided by pharmacies at initial registration and annual re-registration
- authority to conduct regular audits on compliance with standards
- frequent and continuous interactions with pharmacists and pharmacy owners over time on ownership matters.

For this reason, the views of the Board have been given corresponding weight in this Report when considering differing stakeholder responses to the Review questions.

The Board was kind enough to provide the Review with:

- written submissions
- annual reports and financial records
- additional statistics on ownership and activities of the Board
- copies of forms and advice on internal registration processes
- access to staff and Board members.

## Interim Report

The *Review of Pharmacy Community Pharmacy Ownership in Western Australia – Interim Report September 2018* was completed and delivered to the Western Australian Minister for Health for consideration, in October 2018.

Subsequent to the Finalisation of the Interim Report, the findings and recommendations were put to a core group of key stakeholders, including the Pharmacy Registration Board of Western Australia. The intention of this process was to ensure accuracy of registration information contained in the Report, as well as validating the feasibility and practicality of a number of specific recommendations relating to the Board. The number and nature of the recommendations have not changed between the Interim and Final reports; however, in some cases the phrasing has been edited to improve clarity of the intent and any suggested actions.

In addition, a number of other relevant national documents and findings have been published since the provision of the Interim Report. These have been considered and included in the Final Report.

# Regulation of community pharmacy businesses

## The pharmacy registration process in Western Australia

A pharmacy business must make initial application to the Pharmacy Premises Board of Western Australia when first opening a pharmacy; that is, registering a new pharmacy business. At this time, the applicant must show how the business satisfies requirements for registration including any regulations, standards or guidelines.

The decision to register the business is made by the Board. At this time, a test of ownership is made, so that the Board is satisfied the ownership and proprietary interests are consistent with the Regulations.

Application must also be made to the Board when the business:

- moves premises
- changes hands (i.e. is sold)
- makes other changes to ownership make-up
- plans to make major alterations or changes to premises layout or structure.

Any registered pharmacy must also annually re-register with the Board.

The Board has an established process for the registration of a pharmacy business, including standard application forms that must be used. The *Application for registration of premises as a pharmacy*<sup>1</sup> form includes a comprehensive questionnaire and requires applicants supply evidentiary documentation of:

- plans
- bill of sale over any fittings or equipment
- lease
- security interests documentation
- finance/guarantee documentation
- partnership agreement/company constitution or memorandum of articles/trust deed
- ASIC business name registration
- ASIC company extract
- franchise/banner group agreement
- service agreement
- sale agreement
- person with overall responsibility specified
- planning permit restrictions on what can be sold from the premises
- declaration.

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<sup>1</sup> Note: Pharmacy Registration Board of Western Australia Forms can be viewed at:  
<https://www.pharmacyboardwa.com.au/index.php?page=forms>

A comparison of information collected during registration by different Australian pharmacy registering authorities, as at the end of 2017, is provided in [Appendix 2](#).

The information required for registration in Western Australia is rigorous and appears to be more extensive than requested on application forms used in other States and Territories. The exception is Victoria, which requires applicants to also provide:

- evidence to support relationship to beneficiaries declared to be close relatives
- Australian Business Number Registration
- proof of identification
- services to be provided from the premises
- persons other than the licensee that will be conducting a business or activity in the premises
- a list of other pharmacy businesses the applicant has a proprietary interest in.

The Pharmacy Registration Board of Western Australia uses the information provided in the application, and any supporting documentation submitted with the application, to assess whether the business demonstrates suitable compliance with the *Pharmacy Act 2010*. The assessment involves:

- review of the pharmacist's registration status on the AHPRA register of practitioners
- review of the Board pharmacy premises register database - to ensure no pharmacist has a proprietary interest in more than four pharmacies in WA
- assessment of the pharmacy premises compliance with the minimum standards set out in Schedule 1 of the Regulations
- assessment of whether persons other than those allowed under the Act have a beneficial interest in the pharmacy business.

The annual pharmacy re-registration (renewal) process requires applicants to answer a series of questions confirming ongoing compliance with multiple areas of the Act, and sign a declaration that "there has been no breach of the ownership or proprietary interest provisions of Section 55 of the Pharmacy Act 2010".

## Compliance monitoring

Ongoing compliance with the minimum standards for a pharmacy premises is monitored through the regular audit activities conducted by officers employed by the Pharmacy Registration Board of Western Australia.

Each year the Board selects a number of metropolitan and regional pharmacies for routine inspection. Inspection is also conducted wherever concerns are reported, such as by members of the public or via correspondence from Government agencies, like the Australian Health Practitioner Regulation Agency.



During the inspection process, Board officers will assess:

- compliance with minimum standards
- the pharmacy business is being carried on at registered premises
- personal supervision by a pharmacist
- any other business carried on at the premises
- no tobacco products are being sold
- the pharmacy is well lit, adequately ventilated and air-conditioned
- fixtures and fittings are in a safe, clean and hygienic condition, and in good repair
- location with respect to a supermarket and entry from or to a supermarket
- plans of the premises are current
- name(s) of the proprietor(s) are displayed at each public entry
- name of pharmacist in charge and pharmacists on duty are displayed
- certificate of registration is displayed
- if not Pharmaceutical Benefits Scheme approved, that the recommended signage is displayed.

In the financial year ended 30 June 2017, the Board entered and inspected fifteen pharmacies; ten metropolitan and five regional. The Board also conducts desktop audits.<sup>2</sup> Furthermore, in respect of compliance with reference documents in the Minimum Standards, the Board conducted one inspection audit and two desktop audits at metropolitan pharmacies and fifteen desktop audits at regional pharmacies.

Where inspection or desktop audits do not support the declaration of compliance, the Board will take steps to ensure ongoing compliance. This can include imposing a condition on the registration of a pharmacy premises.

The Board advises that due to the large distances to be covered in Western Australia, and the limited resources available, new methods of conducting compliance audits are being considered to ensure there is widespread coverage of all regions.

## Pharmacy business regulation around Australia

An outline of the regulation of pharmacy business around Australia is provided in the Discussion Paper. A comparative summary of the key areas and differences in pharmacy regulation in each State and Territory can be found in [Appendix 3](#).

All bodies appear to have a process of registration that involves provision of certain key information and a check with varying degrees of rigor to ensure compliance with local legislation.

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<sup>2</sup> Pharmacy Registration Board of Western Australia Annual Report for the year ended 30 June 2017. Available at: [http://www.parliament.wa.gov.au/publications/tables/papers.nsf/displaypaper/4011103ae885e41dacf739df48258233002b0fb2/\\$file/1103.pdf](http://www.parliament.wa.gov.au/publications/tables/papers.nsf/displaypaper/4011103ae885e41dacf739df48258233002b0fb2/$file/1103.pdf)

Fees for registration of a pharmacy business do vary between jurisdictions. A full list of fees for each jurisdiction can be found in [Appendix 4](#).

Due to the complex nature of the many commercial documents that are required to be reviewed as part of the pharmacy registration process, some registration bodies advised that they may occasionally need to seek outside legal or accounting advice, in order to be able to determine compliance with their legislation.

In interviews with the pharmacy organisations, other State and Territory regulators, and the Pharmacy Registration Board of Western Australia itself, it was apparent that the pharmacy business registration process in Western Australia was viewed as being amongst the most comprehensive of any of the States and Territories.

Registering authorities were queried around current reviews, or intentions to conduct review of registration processes or legislation, controlling this.

## Queensland

Queensland appears to require the least information; however, it is noted that a notification system is employed. At the time of conducting the Review, this approach was under review with a Parliamentary Inquiry<sup>3</sup> in progress.

Subsequently, the findings of this Inquiry have been published.<sup>4</sup> Although entirely independent of this Review, the Inquiry employed a generally similar methodology, including publication of a discussion paper, consideration of public submissions and holding public hearings. The Inquiry sought the opinions of experts and other jurisdictional regulators. It also commissioned an audit of administration of transfers of pharmacy ownership by the Queensland Department of Health against compliance with the *Pharmacy Business Ownership Act 2001(Qld)*.

The Inquiry focused on the:

- benefits of extending the scope of practice for pharmacists and pharmacy assistants
- administration of transfers of pharmacy ownership by the Queensland Department of Health
- pharmacy ownership requirements specified in the *Pharmacy Business Ownership Act 2010 (Qld)*
- merits of establishing a separate statutory authority, such as a pharmacy council, to administer transfers in pharmacy ownership.

The Inquiry also compared regulatory schemes in other States and Territories.

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<sup>3</sup> See: <https://www.parliament.qld.gov.au/work-of-committees/committees/HCDSDVFVPC/inquiries/current-inquiries/Pharmacy>.

<sup>4</sup> Inquiry into the establishment of a pharmacy council and transfer of pharmacy ownership in Queensland. Report No. 12, 56th Parliament Health, Communities, Disability Services and Domestic and Family Violence Prevention Committee October 2018. Available at: <https://www.parliament.qld.gov.au/Documents/TableOffice/TabledPapers/2018/5618T1639.pdf>

The eleven final recommendations of the Inquiry include:

- the minimum patient age requirement for pharmacist-administered vaccinations be lowered to 16 years of age
- options be developed to provide low-risk emergency and repeat prescriptions, and low risk vaccinations through pharmacies, subject to a risk-minimisation framework and any necessary credentialing
- support be sought for nationally consistent education and training requirements and scope of practice for pharmacists administering vaccinations
- the benefits and risks of allowing community pharmacy assistants to handle dangerous drugs be explored
- there is exploration of the benefit of community pharmacy assistants and hospital pharmacy assistants undergoing the same basic mandatory training
- establishing a Queensland Pharmacy Advisory Council to advise the Queensland Department of Health in administration of the *Pharmacy Business Ownership Act 2001 (Qld)*
- the Queensland Department of Health develop and implement a risk-based strategy for testing arrangements for pharmacy ownership comply with the *Pharmacy Business Ownership Act 2001 (Qld)*
- the *Pharmacy Business Ownership Act 2001 (Qld)* be amended to more effectively manage the pharmacy ownership notification process, including offence provisions for breaches
- pharmacy ownership requirements of the *Pharmacy Business Ownership Act 2001 (Qld)* be retained
- there is improved transparency regarding the compliance of pharmacists with the *Pharmacy Business Ownership Act 2001 (Qld)*
- investigation of ways to improve communication to consumers about the services individual pharmacies provide, such as vaccinations.

## Victoria

In December 2016, the Victorian Pharmacy Authority commissioned an external review of their licence application and renewal processes. The Victorian Review aimed to ensure that processes were adequate to determine compliance with the *Pharmacy Regulation Act 2010* in the current environment where more complex ownership structures exist.<sup>5</sup>

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<sup>5</sup> Final Report Review of the Pharmacy Business Licence Application and Renewal Processes in Victoria 18 July 2017. Available at: [https://www.pharmacy.vic.gov.au/cms\\_files/VPA-Review%20of%20Pharmacy%20Business%20Licence.pdf](https://www.pharmacy.vic.gov.au/cms_files/VPA-Review%20of%20Pharmacy%20Business%20Licence.pdf)

Key recommendations of the Victorian Review were:

- introduction of risk-based audits of businesses, including obtaining declarations from the applicant's accountant and legal counsel of compliance with the Act
- modification of the license application process, including additional identity checks, more comprehensive application forms, a declaration of compliance, and establishing an independent committee to assess "high-risk" applications
- modification of the license renewal process, including declarations regarding changes to business arrangements and a standard condition to notify the Victorian Pharmacy Authority of changes to business arrangements.

As a result of the Victorian Review findings, the Victorian Pharmacy Authority made a number of changes to their processes when considering complex licence applications including:

- examination of additional commercial documents (bill of sale, mortgage, lease and other commercial arrangements)
- referral of all complex applications to determine if additional documentation is required
- referral of documents submitted to the Authorities' lawyers and/or accountants to ensure compliance with the legislation.

## Northern Territory

A 2011 review<sup>6</sup> of pharmacy regulation in the Northern Territory suggested a number of deficiencies in that jurisdiction including:

- lack of an effective system for monitoring the pharmacies that are operating
- lack of effective sanctions
- the provisions designed to protect public health may be undermining provision of health services
- weak regulation of "drug storage rooms" in aboriginal health care services.

The Northern Territory Review recommended a number of changes, not restricted to:

- pharmacy supervision
- owner's responsibilities
- pharmacy registration
- membership of the Northern Territory Pharmacy Premises Committee.

While this is an older review, at least some of these issues appeared to be still current and relevant to Western Australia.

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<sup>6</sup> Edward Tilton Consulting. Review of Schedule 8 of the Northern Territory Health Practitioners Act and the Pharmacy Premises Committee FINAL REPORT. 2011. Available at: <https://digitallibrary.health.nt.gov.au/prodjspu/bitstream/10137/1008/1/Review%20of%20Schedule%20of%20the%20Northern%20Territory%20Health%20Practitioners%20Act%20and%20the%20Pharmacy%20Premises%20Committee.pdf>

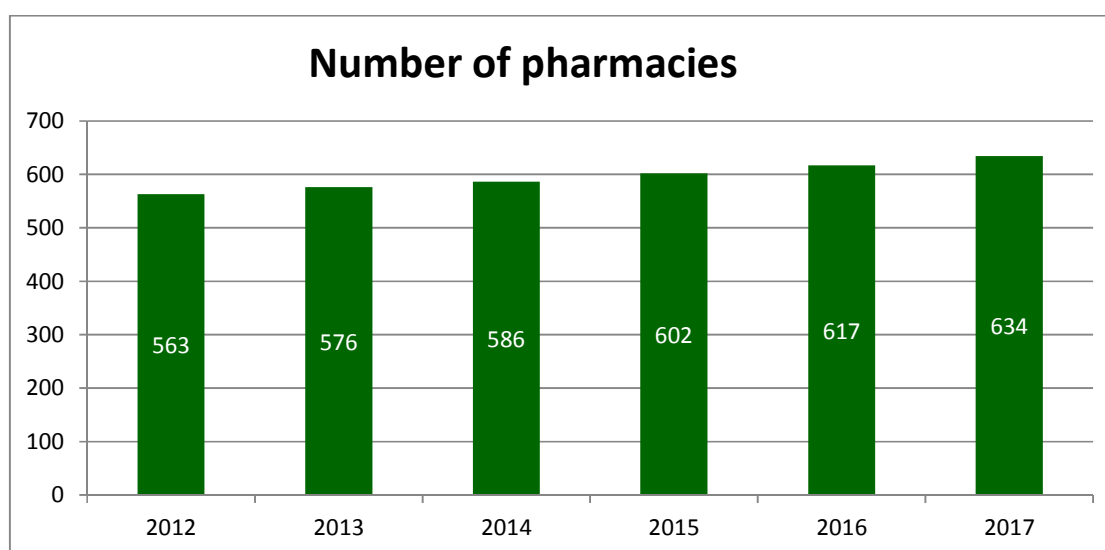
## Review questions

### 1. What are the lessons on pharmacy ownership from other States and Territories, and what trends should we be aware of?

#### Community pharmacy in Western Australia

There are over 5,500 pharmacies across Australia.<sup>7</sup> The make-up of the pharmacy sector Australia-wide is well described elsewhere, such as in part of the “King Review”<sup>8</sup>, and so, has not been outlined further in this Report.

For the purposes of this Review, the Pharmacy Registration Board of Western Australia provided access to de-identified data relating to pharmacy registration in Western Australia. In regard to the sector within this State, as at the end of 2017, there were 634 pharmacies registered with the Board. The number of registered pharmacies appears to have increased slowly between 2012 and 2017. These increases averaged 2%, per year, over this period.



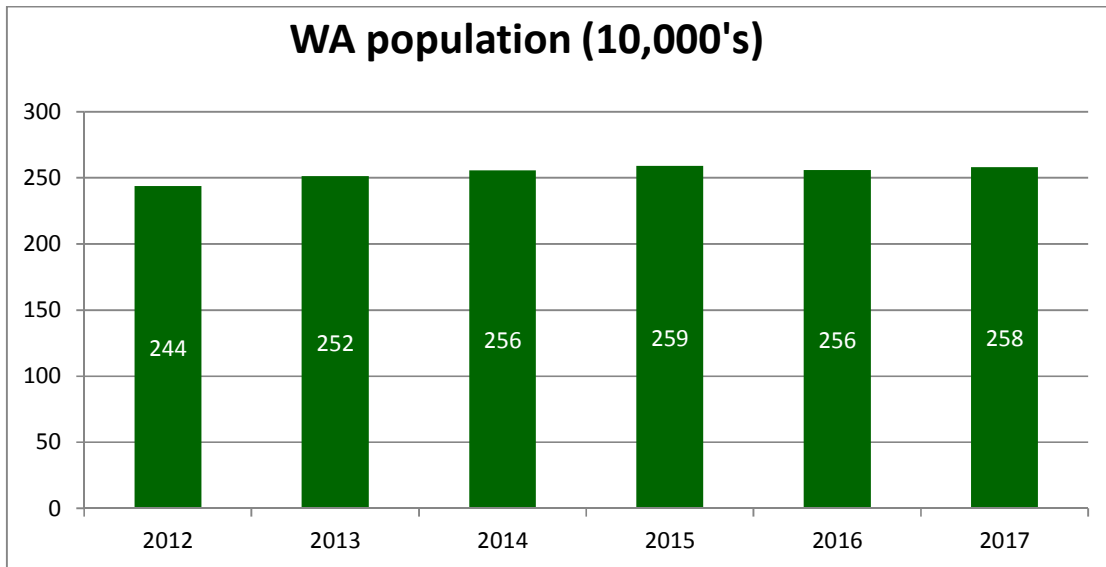
Over the same period the Western Australian population appears to have marginally increased and then stabilised.<sup>9</sup>

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<sup>7</sup> Review of Pharmacy Remuneration and Regulation Discussion Paper 2016. Available at: [http://www.health.gov.au/internet/main/publishing.nsf/content/7E5846EB2D7BA299CA257F5C007C0E21/\\$File/Discussion%20Paper%20-%20Review%20of%20Pharmacy%20Remuneration%20and%20Regulation.pdf](http://www.health.gov.au/internet/main/publishing.nsf/content/7E5846EB2D7BA299CA257F5C007C0E21/$File/Discussion%20Paper%20-%20Review%20of%20Pharmacy%20Remuneration%20and%20Regulation.pdf)

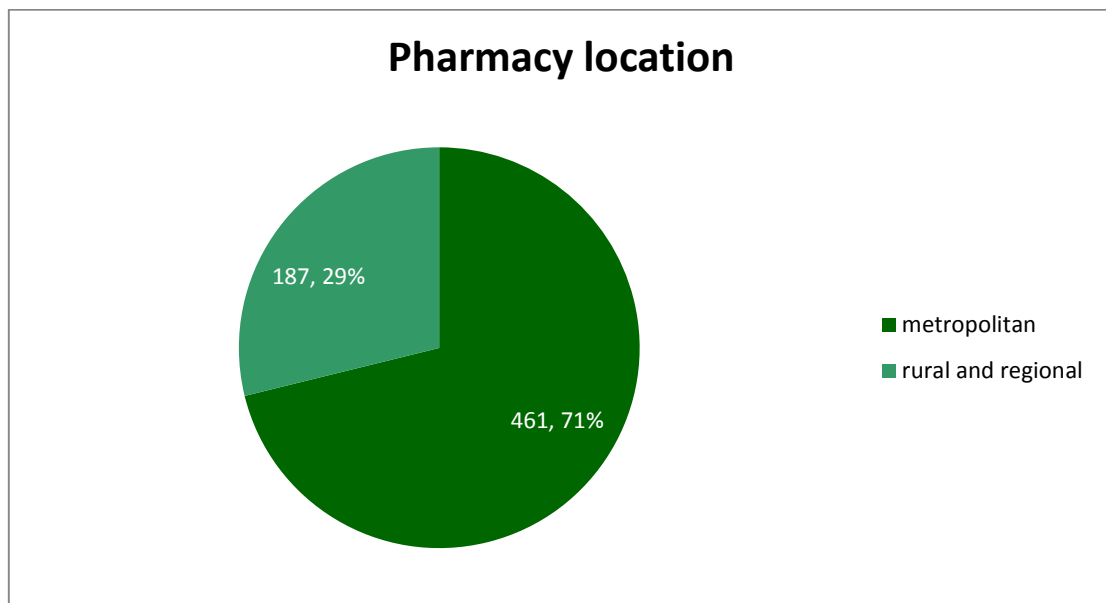
<sup>8</sup> Review of Pharmacy Remuneration and Regulation Discussion Paper 2016. Available at: [http://www.health.gov.au/internet/main/publishing.nsf/content/7E5846EB2D7BA299CA257F5C007C0E21/\\$File/Discussion%20Paper%20-%20Review%20of%20Pharmacy%20Remuneration%20and%20Regulation.pdf](http://www.health.gov.au/internet/main/publishing.nsf/content/7E5846EB2D7BA299CA257F5C007C0E21/$File/Discussion%20Paper%20-%20Review%20of%20Pharmacy%20Remuneration%20and%20Regulation.pdf)

<sup>9</sup> Source ABS: [www.stats.abs.gov.au](http://www.stats.abs.gov.au)



The average number of Western Australians serviced by each pharmacy over this period is 4,263 persons. The King Review suggested that, as at 2015, this figure was 4,303 for Western Australia, and ranged between 3,464 (Tasmania) and 7,171 (Northern Territory).<sup>10</sup> The number and distribution of pharmacies is heavily dictated by Commonwealth location rules, and therefore is not discussed further in this Report.

Of the 634 pharmacies registered in 2017 in Western Australia, 461 (71%) were defined as metropolitan and 187 (29%) as regional.<sup>11</sup>



<sup>10</sup> Review of Pharmacy Remuneration and Regulation Discussion Paper 2016. Available at: [http://www.health.gov.au/internet/main/publishing.nsf/content/7E5846EB2D7BA299CA257F5C007C0E21/\\$File/Discussion%20Paper%20-%20Review%20of%20Pharmacy%20Remuneration%20and%20Regulation.pdf](http://www.health.gov.au/internet/main/publishing.nsf/content/7E5846EB2D7BA299CA257F5C007C0E21/$File/Discussion%20Paper%20-%20Review%20of%20Pharmacy%20Remuneration%20and%20Regulation.pdf)

<sup>11</sup> Source: Review submission - Pharmacy Registration Board of Western Australia

## Community pharmacy ownership in Western Australia

At present, the *Pharmacy Act 2010* permits pharmacy ownership in Western Australia by:

- a registered pharmacist, or pharmacists in partnership
- 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
- the preserved company (as defined in the *Pharmacy Act*).

As at 2017, there were no registered pharmacies owned by a friendly society and only one pharmacy owned by the preserved company.

With respect to ownership of pharmacies by pharmacists, as at 2017, of the pharmacies registered:

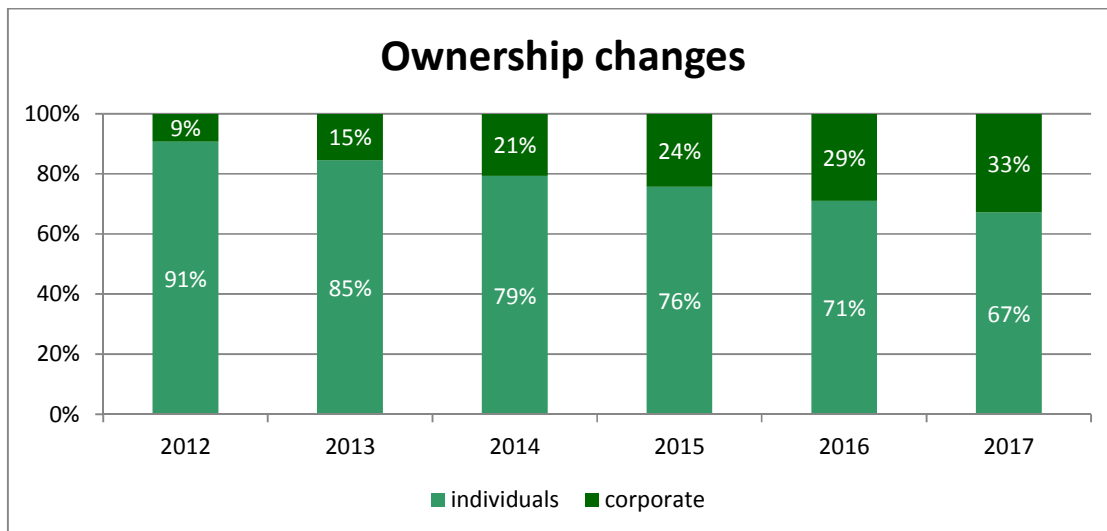
- 266 were owned as sole traders (41%)
- 228 were owned in partnership (35.2%)
- 154 were owned by a single company or held in a single trust (23.8%).<sup>12</sup>

For the purposes of this section, “corporate ownership” refers to the pharmacy controlled company consistent with the current provisions of the Act. It should be noted that elsewhere in this document “corporate ownership” refers to another usage of this phrase, as given by stakeholders, that generally means ownership by a non-pharmacist controlled company or the ownership of a large number of pharmacies by any one entity, which may not be consistent with the current provisions of the Act.

There is a clear trend over time in relation to ownership structures. Previously, shortly after the time of the last major update to the legislation, 9 out of 10 pharmacies were owned by individual pharmacists or partnerships. There has been a noticeable and rapid movement, from individual and partnership ownership, towards corporate ownership. In the seven years from 2012 to 2017, the number of corporate structures involved in owning a pharmacy has increased from 9 to 33%.

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<sup>12</sup> Source: Review submission - Pharmacy Registration Board of Western Australia



During the Review, it was suggested that pharmacist controlled companies and trusts were being increasingly employed as ownership vehicles because they provided certain taxation or financial advantages.

### Trends in Western Australia

Information provided from submissions and during interviews with Western Australian stakeholders suggested the presence of a number of notable local trends. The themes derived from online submissions, with selected illustrative commentary, are contained in [Appendix 5](#).

These included:

- entry of discount style pharmacies
- increasing interests of banner groups
- use of service or management companies
- suggestions of movement toward vertical and horizontal market integration.

Western Australian data was available to examine these trends; however, detailed information was not accessible from other jurisdictions to make direct comparisons with other parts of Australia. In general, the regulatory authorities interviewed as part of the Review could confirm that, at least anecdotally, patterns similar to those in Western Australia were also being observed elsewhere.



In the submissions received from pharmacists, there was an almost universal concern expressed in relation to an increasing influence of these different business models on the industry and on pharmacy practice. The concerns covered a range of issues and included:

- lack of owner control over the business
- reduction in direct oversight of the business by owners
- concentration of ownership to a small number of large pharmacies and ownership in the hand of a reduced number of individuals
- market dominance by some chains
- professional care being placed as secondary in importance to corporate objectives
- emergence of conflicts of interest between matters of business versus health care
- best practice delivery of care being eroded in favour of cheapest prices
- unprofitable, but consumer valued, services being withdrawn
- reduced opportunities for early career pharmacists
- reduced ability to practice at top of scope and a resultant exit of talent from the workforce.

### Entry of discount pharmacy model

The sector in Western Australia has seen an increase of the number of pharmacies affiliated with a “discount” pharmacy business model. This model is associated with low prices, a wide range of retail products and high turnover.

A number of submissions indicated a belief that, due to the retail practices and staffing approach, that these pharmacies offered a reduced range of professional services, when compared to pharmacies that identified with a non-discount (usually referred to as a “professional service”) focus.

As at the end of 2017, the register of pharmacy premises in Western Australia included 49 pharmacies that were suggested to identify with a discount model:

- Chemist Warehouse (My Chemist) 19
- Discount Drug Store 18
- Superchem Discount Pharmacy 12

Together, these pharmacies represent almost 8% of the pharmacies in Western Australia.

The number of pharmacies of this type in Western Australia appears to be lower than in some other States, but still increasing. For example; at the same time there were around 380 Chemist Warehouse (My Chemist) pharmacies in Australia, including: 161 in Victoria, 89 in New South Wales and 72 in Queensland.<sup>13</sup>

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<sup>13</sup> Source: Review submission – Pharmacy Guild of Australia

## More banner groups

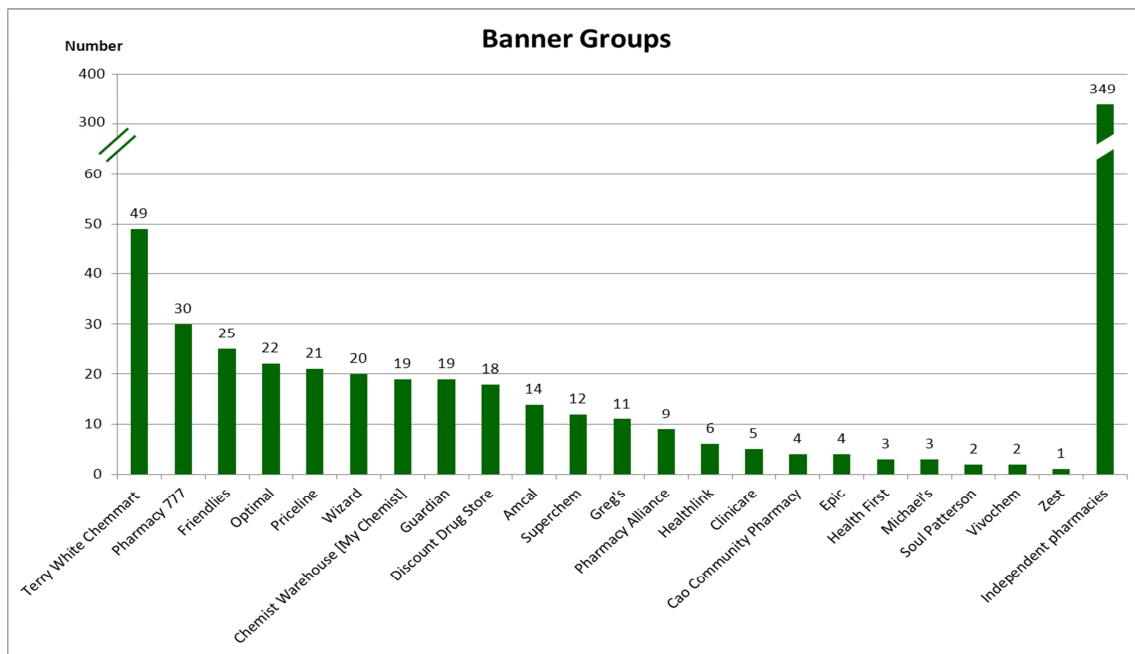
Many pharmacies, while still needing to be owned by a pharmacist or pharmacist controlled company, are affiliated with a recognisable pharmacy brand. Within the sector, this style of identification of an individual pharmacy with a particular marketing group is commonly termed a “banner group” pharmacy. Banner groups operate Australia wide, but can have a base in a specific State. This includes banner groups that have originated within Western Australia.

As the current legislation in Western Australia only permits ownership by pharmacists or a pharmacist controlled company, and restricts the number owned, banner group pharmacies are still owned by pharmacists, even though they may outwardly appear to belong to a single company that has a readily identifiable brand.

The pharmacies in these groups may be best described as operating in a similar fashion to a franchise, where they may use the same store layouts, banners, advertising and marketing. They may also use standardised business operating policies and procedures. These matters are commonly controlled by a central or corporate office. In some cases, buying groups and other shared business support resources are involved.

Banner groups are not new and well-known brands have existed in community pharmacy for many decades, suggesting that pharmacies can be individually owned and readily belong to a common promotion or marketing group, in compliance with ownership laws.

Increasing affiliation with a banner group, and a corresponding reduction in the number of independently identified pharmacies, was highlighted as an additional ownership trend. As at the end of 2017, there were 299 pharmacies identifying with a banner group in Western Australia.<sup>14</sup> This is 46%, or just under half of the 643 pharmacies registered.



<sup>14</sup> Source: Review submission - Pharmacy Registration Board of Western Australia

There did appear to be well formed perceptions within the sector in relation to the different banner groups. This seemed to be connected to whether the group had a particular focus on products, price or service. Compared to the discounter label, some groups were certainly seen as having a stronger focus on professional services. These banner labels were generally held in high regard by pharmacy groups interviewed, including many younger pharmacists who provided materials to the Review.

Despite any concerns, there was at least some suggestion that there are distinct benefits provided by association with a banner group; for example, capabilities and economies of scale that supported and promoted high quality services and innovation. There was a regulatory viewpoint that, overall, banner pharmacies were normally compliant with standards, and that any problems, where they occurred and although infrequent, more often seemed to be related to independent operators.

During the Review, the pharmacy stakeholder sentiment was that such groups were now becoming larger and commercially more aggressive in nature. Stakeholders suggested that the corporate bodies of banner groups were financially powerful. It was also suggested that these groups might be commercially positioning so as to be able to capitalise on any future changes to ownership restrictions that may occur.

### Focus on price versus service

Extending this theme, there was clear belief amongst many stakeholders that the emergence of “big box” discounters in community pharmacy in Western Australia was not necessarily in the long-term best interests of the public.

There was a generally negative sentiment towards discount models apparent in the pharmacy submissions received. For example:

*“Discount Brands are dominating the markets in most of Australia. Their push is for turnover and profit ahead of professionalism.”*

*“Large chain discount stores focus on ‘supply of a commodity at lowest price’ virtually eliminates any quality of health care service/counselling/advice that a pharmacist can provide to his/her local community.”*

It was a common opinion that discount retailers would only focus on the most profitable products or services. It was suggested that this was already, or may continue to, lead to a reduction in choice and access for consumers; for example, shorter opening hours:

*“I have been advised by many acquaintances that they will shop at the ‘X Pharmacy’ for cheap stuff but would never go there for health advice. Imagine if every pharmacy in Australia was to become like this?”*

*“As the population ages, it is individual, family owned pharmacies with their familiar, caring faces and dispositions, and willingness to go the extra mile for their patients, become more important than ever as a source of respect, care and safety in the knowledge that they are being looked after to the best of the pharmacist's ability.”*

While it is not necessarily considered that this type of market issue is intended to be regulated by the current legislation, there was certainly frequent suggestion from pharmacy stakeholders that this was an issue that the Government should be concerned about and consider intervention in:

*“The existing ownership structure in Western Australia needs to ensure a dispersed ownership structure with low levels of ownership concentration otherwise the distribution of many local pharmacies will be lost to a few large warehouse style pharmacies.”*

It was suggested by many that vital, but complementary, or marginally profitable ancillary services, were unattractive in a lowest cost model; these include, home medicines delivery, dose administration aid packaging, or services to residential aged care facilities. Pharmacists believed that these were being withdrawn in some cases, or were at risk of being inaccessible to vulnerable patients that needed them the most.

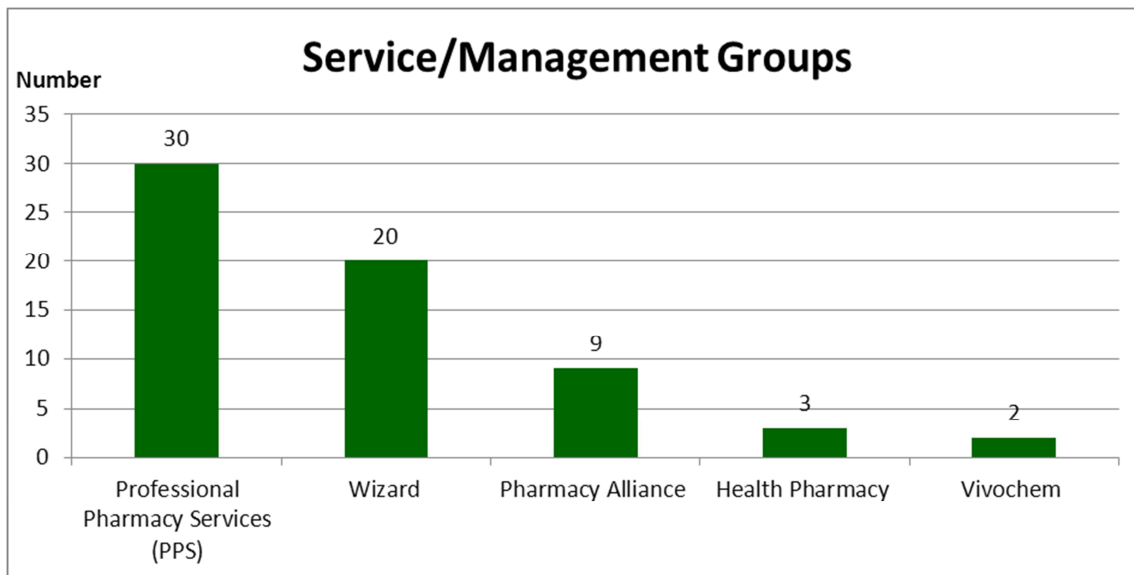
## **Service / management groups**

Service and management groups appear to be increasingly being utilised by pharmacy owners to assist with the running of their businesses.<sup>15</sup> As the name suggests, these groups provide support services that assist in the operation of a pharmacy business. They do not own the pharmacy and derive income from services that are provided in assisting the running of the pharmacy business.

A number of submissions raised concerns that service/management groups were being used by pharmacists who have already maximised their pharmacy ownership interest to derive income from other pharmacies. Concerns were also raised about who may have ultimate control of a pharmacy associated with a service/management group. For example, it was queried as to where, in practice, the responsibilities of the pharmacist with overall responsibility (as defined under the Regulations) finished and those of the service/management group, assisting to run the pharmacy, started and finished respectively.

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<sup>15</sup> Source: Review submission - Pharmacy Registration Board of Western Australia



## Vertical and horizontal integration

Many submissions indicated a perceived trend towards increasing vertical integration of health services and horizontal integration in the sector. Noting that, in Western Australia, current regulation prevents ownership by persons other than pharmacists, there is suggestion that other entities that provide health or related services are positioned in such a way that this type of integration was likely.

For example, it was noted that Ramsay Health Care had moved into pharmacy ownership in other jurisdictions. There are now around 35 Ramsay Pharmacies around Australia, although none in WA.

Other examples cited of this type of integration included large pharmaceutical wholesalers possessing common banner brands, which, at the end of 2017, was understood to include<sup>16</sup>:

- Symbion - TerryWhite Chemmart (49 pharmacies)
- API - Priceline (21 pharmacies), Soul Pattison (2 pharmacies)
- Sigma - Amcal (14 pharmacies).

## Reduced ownership transparency

A submission was received from the Small Business Commissioner. This indicated concerns about allegations they had received of behaviour of some chains that was described as predatory. The submission indicated that such complaints lead to serious concerns regarding “corporatisation” of the sector.

They suggested that the complaints commonly involved complex ownership structures and undisclosed proprietary interests. It was the Commissioner’s opinion that corporate structures should not be allowed to be used to manipulate current ownership laws. The Commissioner

<sup>16</sup> Source: Review submission - Pharmacy Registration Board of Western Australia

recommended that ownership interests needed to be transparent, there should be proper disclosure of interests to the regulating authority, and that the meaning of proprietary interests should not be open to different interpretations.

This view was echoed by some stakeholder submissions, which held the opinion that some owners could manoeuvre around the current ownership rules. Comments included:

*"Already there have been a couple of examples of ownership models that do not meet the requirements of the Act."*

*"There are occurrences where a few people own in silent partnerships or corporate structures own many pharmacies."*

*"...I understand that some groups have been allowed to create complicated agreements, aimed at directing the flow of money away from the pharmacy owner, to corporates groups."*

It is noted that there was no single individual or business directly named in any submission provided to the Review. Any direct evidence of non-compliance provided to the Review would have been referred to the regulating authority.

This issue was put to the Pharmacy Registration Board of Western Australia for comment. Consistent with its remit and the legislation, the Board will only register a pharmacy that complies with the Regulations. The Board was firmly of the opinion that every pharmacy registered was compliant with the regulations, based on the information provided, and with respect to the limits of the ability of the Board to verify and assess such matters. Registration processes and information requirements have been outlined above.

The Board did note that, increasingly, the ownership structures are more complex and involve more individuals. As a result, there is an effect on the ability of the regulating authority to fully and transparently assess ownership during the registration of a pharmacy. There was at least some concern, based on experience and industry feedback, over interests that may not be disclosed during registration. The reasons for this concern and the suggested responses to address this situation are discussed in more detail below and throughout the Report.

## **Potential for external influence over pharmacy businesses**

The Pharmacy Registration Board of Western Australia noted that there are different businesses and entities whose interests could potentially influence the practice of pharmacy within a pharmacy business.

This included:

- Banner groups
- Service and management groups
- Wholesaling groups
- Funding from non-finance entities
- Family groups
- Non-family associates.

There were also concerns around whether there might be tacit or implied requirements with some of these external interests in relation to ownership. In particular, many stakeholder submissions felt that different groups had some power to control the sale and purchase of pharmacies, which, in theory, they should have no direct financial interest in.

It was suggested that due to contractual, financial or other relationships that there was potential for these interests to exert undue influence on the owner. This influence was said to possibly extend to the purchase of medicines, the range held, brands stocked, or other aspects of medicines supply that might be dictated by someone other than the owner. Furthermore, this was stated as having the potential to extend to decisions related to professional practice of pharmacy being influenced by persons that are not pharmacists.

It was also suggested that banner groups appeared to be taking on a bigger role in particular areas within branded pharmacies. There was a perception that these central groups now determined overall policy for the chain. For example; directing which professional services might be implemented and how, such as immunisations for influenza; use of other health practitioners inside a pharmacy business (e.g. nurse practitioners); and prices, such as whether or not the voluntary \$1 Pharmaceutical Benefits Scheme co-payment discount was applied.

Similarly, pharmacy professional organisations suggested that more business policy decisions for individual pharmacies are being made centrally by banner groups. An example given was in relation to the over-the-counter supply of codeine based medicines (prior to the re-scheduling of these products to prescription only), where some larger chains chose a position of not supporting access to an industry based real-time monitoring system.<sup>17</sup>

## Interstate owners

The Pharmacy Registration Board of Western Australia also outlined changes over time where more pharmacists who own Western Australian pharmacies are permanently residing interstate. It is not known how many Western Australian pharmacists own pharmacies in other jurisdictions.

It was suggested that registration applications from interstate resident pharmacists were at times more difficult to process and assess with respect to compliance with the Regulations. It was also noted that there are differences in Western Australian laws that these owners still needed to be aware of, and comply with, irrespective of their familiarity with laws in other States or Territories.

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<sup>17</sup> Note: this refers to MedsASSIST, a voluntary, industry-based system that allowed the recording and review of sales of codeine products. All codeine products were re-scheduled to prescription only status in February 2018.



The issue of living in another State or Territory and still being able to have a close enough connection to the Western Australian business was also raised by a number of stakeholders. In short, all stakeholders felt that regardless of place of residence, standards for pharmacies needed to apply, and be complied with, in full.

It was not suggested that interstate ownership meant that a pharmacy could not comply with relevant standards, but it was argued by a number of individuals and organisations, that the amount of time spent physically in the business was indeed connected to the ability to ensure compliance, and that this was an important consideration with regard to ongoing regulation of pharmacies.

There were calls by some groups and individuals to limit ownership to pharmacists ordinarily resident in Western Australia. At present, this type of regulatory amendment would seem to be inconsistent with the situation elsewhere in Australia. Alternative suggestions included establishing and instituting a minimum requirement to be physically present in a pharmacy over any time period, although serious consideration is necessary as to whether this is possible to practically implement and enforce.

## Numbers of pharmacies owned

Registration statistics suggested that the proportion of pharmacists owning multiple pharmacies was increasing. The Pharmacy Registration Board of Western Australia suggested that as a result, fewer individuals are now directly working as a pharmacist in the pharmacies that they own. Ownership of multiple pharmacies would often require an owner to employ a pharmacist to manage day to day operations and in some cases to act as the responsible person.

While every pharmacy must allocate a pharmacist with overall responsibility, fewer owners are now listed with the Board as holding this role. There was also a suggested increase in the number of owners and pharmacists with overall responsibility having full-time positions outside of the pharmacy they are “responsible” for.

There were related and frequent comments that suggested stakeholders strongly felt the purpose of the current regulatory scheme was to ensure that the owner was directly involved and accountable for the standards and the practice in the pharmacy they owned:

*“I believe the intent of pharmacy ownership rules is to ensure the pharmacist proprietor has direct responsibility and involvement in the running of the pharmacy.”*

## Other commercial arrangements

A small number of submissions observed that private health funds had commenced arrangements with pharmacies, either as owning a banner group or having arrangements in place that provided entitlements to access services of the pharmacy for fund members.

For the most part, comments about such arrangements can be classified into the particular themes already described above; however, there was also concern expressed about equity of access to services for consumers who are not fund members.



## Workforce effects

There was a general view from most quarters that the various trends already outlined were making it harder for younger pharmacists to become pharmacist owners. The reasons suggested included reduced opportunities due to a combination of:

- entry of owners from interstate
- owners in Western Australia holding more pharmacies at any one time
- owners holding onto a business for longer, whether working as a pharmacist or not
- increasing business size and larger financial outlay required
- other factors.

It was suggested that more young pharmacists were taking on smaller stakes in a pharmacy (i.e. very small percentage ownership) and having limited influence in the operation of the business.

There were numerous submissions that felt that this was having a direct effect on workforce retention in the industry. Reduced ownership prospects were said to be making the profession less desirable and affecting the number of people choosing to pursue the profession as a career, although no direct quantitative evidence of this nature was provided to the Review.

There were numerous views from younger pharmacists interviewed that they greatly preferred to work in a pharmacy with a stronger focus on professional service. The reasons for this typically reflected satisfaction with the type of work, belief they were fully utilising skills and capabilities, and a connection to improved health outcomes that had a real impact on patients.

There was a common view from younger pharmacists and students, that employment in high volume dispensing or discount environments did not provide the same professional opportunities, and these positions were therefore much less desirable to obtain.

One pharmacy organisation noted it was harder for intern pharmacists<sup>18</sup> to find intern training positions. It was observed that a number of pharmacy groups had made a decision not to employ interns and, instead, to employ registered pharmacists for fewer hours.

Related changes to working conditions and employment hours were also noted. It was suggested that the workforce was now more fragmented and more mobile, such as pharmacists working variable shifts and at multiple pharmacies, to meet the hours they needed to make a suitable living wage.

Some submissions held the belief that discount models had put downward pressure on pharmacist wages. There was a consistent viewpoint that pharmacist wages were currently very low and did not reflect the level of training and the responsibility involved in being a practising pharmacist.

There was suggestion that the current industrial conditions also made a career in pharmacy unattractive for many, and was a direct contributor to pharmacists abandoning the profession for other types of employment. Furthermore, it was suggested that the impacts of these factors on the workforce had not been fully felt and the situation would continue to worsen.

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<sup>18</sup> Note: upon completion of a recognised course of study, pharmacists must complete the equivalent of 12 months of supervised practice as an intern, prior to being permitted to practise alone.

## Consumer views

From stakeholder interviews, it was a clear theme that the role of the pharmacist, and the medication advice and interventions they offer were valued and necessary. It was stated that the pharmacist was known and trusted for this service, and it was felt that overall, consumers would usually seek out care from a pharmacy where they had already received quality information or assistance.

However, it was also suggested to be increasingly common for consumers to purchase medicines at a discount pharmacy, but seek other care from a pharmacy that focused professional service. This phenomenon was confirmed in pharmacist submissions.

Although there were a limited number of consumer submissions, these did suggest that recent changes had resulted in improved competition and better prices for consumer medicines. Several supported a “low cost, high volume” business model, on the basis that they can purchase many of their Pharmaceutical Benefits Scheme medicines for less at these pharmacies.

A similar viewpoint was put forward by a number of pharmacist submissions, which believed that there was already significant competition in the marketplace and good prices for consumers. Falling returns on medicines and difficult economic conditions was a common theme across most pharmacy submissions.

There was suggestion that aggressive marketing by some pharmacy chains was shaping consumer attitudes and behaviour adversely. The particular criticism of this marketing was that it lead consumers to believe that the cheapest price is what they should be looking for, rather than quality service and advice that lead to the most effective and the safest use of medicines.

It might be argued that many other recent changes, most notably to the Pharmaceutical Benefit Scheme, have had more of an effect on the price of prescription medicines for consumers. However, the Review accepts there is certainly a perception that there have been reduced costs to consumers. These may be related to existing competitive forces in the community pharmacy market. It is noted that, if so, this competition has occurred under existing ownership rules.

During interviews with the Health Consumers’ Council, the long term monitoring and optimised medication management was highlighted as more important than price alone. It was suggested that a connection between the pharmacist and the patient was required for this to occur and this was thought less likely where consumers followed lowest price. It was a perception that this therapeutic partnership may be less likely at a pharmacy that focused only on decreasing price and increasing sales.

Consumers did not suggest that every pharmacy should offer the same products or service, and in fact supported differences. For example, it was suggested that different medicines-related services would be needed, dependent on the particular demographic of a local community, or the location of the pharmacy, such as those in regional or rural areas.

## Summary and Findings

Over the last five years, the number of pharmacies in Western Australia has increased marginally, by about 2% per year. This is slightly ahead of population growth. About a third of pharmacies are located outside the Perth metropolitan region. This might be viewed simply as good for consumer access to medicines and positive for Western Australians. Whether it is an indicator of the state of health of the industry, and how, is not clear.

At present, ownership of a pharmacy is restricted to a pharmacist or pharmacist controlled company, and to a proprietary interest in a limit of four pharmacies. These restrictions are diligently enforced by the regulating authority and there is no suggestion of any systematic failure by the authority in administering these rules. In fact, as outlined elsewhere in this Report, the system in Western Australia was often commended.

Irrespective, there was a general feeling that the legislation was somehow allowing “corporate ownership, by stealth”. It is more likely that this actually reflects patterns across Australia, more recent changes to other legislation and the fact that ownership rules remain independently contained within State and Territory legislation.

Registration figures of community pharmacies do indicate a number of trends in ownership. These seem to be related to increasing use of companies or trusts, which are permitted by the legislation. These so called “complex structures” are less transparent and the industry appeared concerned that this allowed the creep of external influences into the ownership of pharmacies, which are meant to be independent. As outlined in following sections, there is at least some evidence of this influence.

One trend put to the Review as worthy of attention and action, was around corporate groups, which have an interest in pharmacies, being able to negatively influence the market; through banner group arrangements, service agreements, or other financial interests.

There was a generally negative view of discounting pharmacies, although there seemed to be a concession that competition had improved and consumers did welcome lower prices. There was a very clear opinion that market integration and concentration of ownership was not desirable and if not prevented, would lead to worse outcomes for consumers in the long run.

There were also trends evident of increased ownership by pharmacists who are resident interstate and increased numbers of pharmacies owned by individual proprietors. There are suggested impacts of this trend on the personal and direct attention of a proprietor in being able to meet expected standards and practices within the business.

The industry seems broadly of the view that corporatisation and discount focus are eroding a professional focus on quality use of medicines and detrimental for the profession in the long term. This is at a time when pharmacists are looking toward more fully applying their knowledge and expertise towards quality use of medicines services, beyond the traditional aspects of supply of medicines.

There was certainly opinion from younger pharmacists that suggests these ownership trends affect how they view their career opportunities and longer term prospects in the profession.

Some of the issues summarised above appear connected to the legislation that regulates pharmacy premises. Others, as outlined in further detail in the following sections, do not.

Issues of regulation and recommendations relating to the current legislation are also more fully explored in other sections of this Report.

The Review finds that, in relation to pharmacy ownership, the trends that the Government should take note of include:

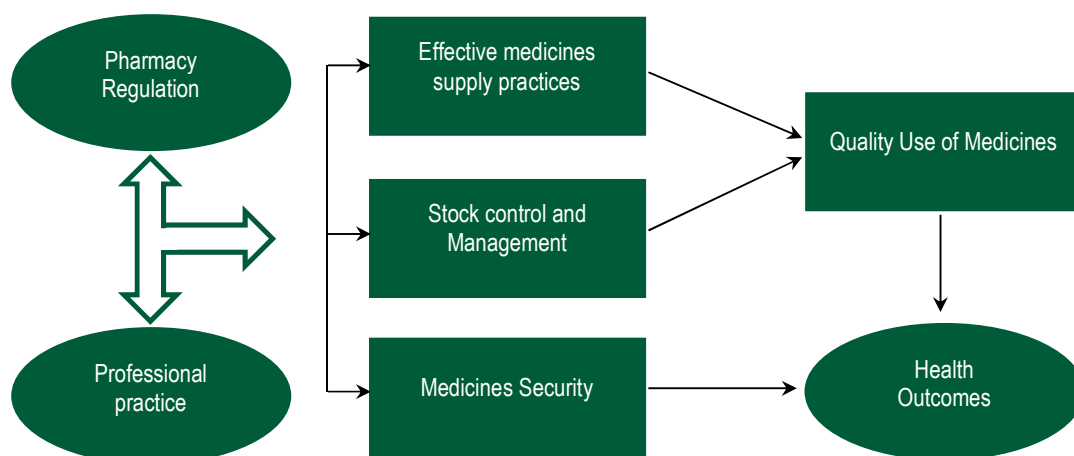
### Finding 1

- more complex ownership structures, such as pharmacist controlled companies and trusts are increasingly being used
- discount pharmacies have entered the community pharmacy market in Western Australia
- there is increasing alignment of community pharmacies with large banner groups
- various pharmacy groups may choose to market themselves on the basis of a focus on either price or professional service
- there is use of service/management groups
- there is suggested potential for vertical and horizontal integration of the medicines supply chain, that includes pharmacies
- complex ownership structures are being utilised for financial reasons, but may be contributing to reduced ownership transparency
- these structures and other arrangements mean that there may be increasing potential for external influence by a third party over the operation of a pharmacy business
- there is an increase of interstate ownership of Western Australian pharmacies
- there is concern about the ability of absent owners to accountably meet their ownership responsibilities, in relation to maintaining minimum standards within a pharmacy
- the combination of these trends are said to be having a negative effect on the pharmacy workforce
- younger pharmacists are less optimistic about the profession on the basis of perceived ownership trends.

## 2. Are the current Western Australian ownership laws (limiting a pharmacist to owning four pharmacies) sufficient to protect the integrity of the sector in this State?

### Regulation of pharmacies

The intention of, and need for, the regulation of pharmacies, has been well captured in other reviews. This can be summarised in the relationship between supply practices, stock management practices and security of Scheduled medicines.<sup>19</sup>



There is complex intersection between Medicines and Poisons Legislation, Health Practitioner Regulation National Law and pharmacy regulation. These laws seek to regulate different public risks and are best considered as complementary in nature. Regardless, it is suggested by some sources that pharmacy may be over regulated.<sup>20</sup>

A key finding of this Review is that stakeholders universally believed that, medicines, and the pharmacies that supply them, should continue to be subject to some form of regulation, for the greater good. Beyond this, different stakeholder groups differed in relation to exactly what they felt should be regulated, the specifics of any restrictions, and how they should be applied.

A number of organisations referenced recent national reviews into the pharmacy sector. Past reviews have not recommended removal of all regulation relating to pharmacies. For example, the 2015 National Competition Policy Review<sup>15</sup> stated:

*“...given the key role of pharmacy in primary healthcare, ongoing regulation of pharmacy is justified and needs to remain in place”.*

<sup>19</sup> Diagram adapted from: Review of Schedule 8 of the Northern Territory Health Practitioners Act and the Pharmacy Premises Committee FINAL REPORT. Edward Tilton Consulting. 2011. Available at: <https://digitalibrary.health.nt.gov.au/prodjspei/bitstream/10137/1008/1/Review%20of%20Schedule%208%20of%20the%20Northern%20Territory%20Health%20Practitioners%20Act%20and%20the%20Pharmacy%20Premises%20Committee.pdf>

<sup>20</sup> Commonwealth of Australia. Competition Policy Review Final Report. 2015. Available at: [http://competitionpolicyreview.gov.au/files/2015/03/Competition-policy-review-report\\_online.pdf](http://competitionpolicyreview.gov.au/files/2015/03/Competition-policy-review-report_online.pdf)

What is debated by such reviews is best summarised as matters of:

- whether or not ownership should continue to be restricted to pharmacists
- the exact mechanism of regulation employed
- achieving national consistency in the regulation of pharmacies
- the most appropriate regulatory body to provide this regulation.

When considering the regulation of pharmacies, one written organisational submission to the Review eloquently stated:

*“Medicines remain the most common therapeutic intervention available to clinicians; however, the burden of patient harm relating to inappropriate medicine use continues to be reported.”*

*“Pharmacy regulation is an important method of ensuring ‘safe and effective’ use is maintained at a minimum standard and that protections exist for the public interest.”*

Various stakeholders referred to any regulation of the sector as needing to support and assist in achieving the principles of National Medicines Policy.<sup>21</sup> For example, one stakeholder suggested that changes must “result in positive health outcomes for patients and a sustainable health system that benefits all Australians”. It was also suggested that regulation needed to be patient centric and that the long-term implications of any changes needed to consider whether any health results will be aligned with the National Medicines Policy.

Currently, pharmacy regulation is managed by States and Territories. There appears to be reasonable recognition that while the various jurisdictional regulatory schemes are broadly similar overall and seek to achieve the same outcome, they do vary in their exact detail. One stakeholder suggested that the presence of the various jurisdictional schemes was evidence that regulation was considered important:

*“The universality of this legislation across Australia is recognition that pharmacy regulation promotes certain benefits”.*

Pharmacies are a unique type of private business, commonly considered to have a high potential public risk, due to the nature and quantity of the substances they store and supply. The regulation of pharmacy seeks to protect the public in relation to the related risks posed from the high concentration of medicines located on site at that type of premises.

A non-pharmacy submission cautioned against conflating different issues when considering the regulation of pharmacy. This group queried the actual intentions of this regulation and whether it was correct to seek to address other emerging issues in the pharmacy market, including those identified in relation to ownership. This stakeholder also pointed out that it was not in the public

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<sup>21</sup> See: Australian Government. National Medicines Policy. 2000. Available at: [http://www.health.gov.au/internet/main/publishing.nsf/Content/B2FFBF72029EEAC8CA257BF0001BAF3F/\\$File/NMP2000.pdf](http://www.health.gov.au/internet/main/publishing.nsf/Content/B2FFBF72029EEAC8CA257BF0001BAF3F/$File/NMP2000.pdf)

interest to allow regulation to protect retail practices that were not in the public interest; for example, the promotion of non-evidence based products and therapies.

## Registration of pharmacies

Throughout the consultation process and without exception, stakeholders expressed the clear view that medicines were high-risk and potentially dangerous goods that should not be considered as an ordinary item of commerce. While the safety of medicines themselves as dangerous products and therapeutic goods is an issue separately regulated through State and Commonwealth legislation, there was a strong view that any place of business that kept large quantities of these items, such as pharmacies, was by definition also a significant potential public risk that deserved and demanded Government regulation.

As part of the Review, interviews were held with pharmacy registering authorities in other States and Territories. The objective of these discussions was to understand similarities and differences in the relevant legislation in each jurisdiction. The interviews specifically sought to identify any difference in approaches to regulation in practice, application of the legislation, and any difficulties faced by the regulatory authority which appear to be common problems.

Regulators provided the united opinion that the registration of pharmacies held significant and ongoing public benefit. These regulators supported the view that, because a pharmacy business holds large quantities of poisons (Scheduled medicines), they represented a public risk that needed close management and legislated controls. Fundamentally, each State and Territory regulatory scheme for pharmacies seeks to ensure that the locations where these poisons are held and the persons responsible for their safe and secure storage are known to the respective regulatory body at any time.

At present, the Western Australian Pharmacy Registration Board is required by law to maintain, at any time, a complete and accurate register of every community pharmacy in this State. The register<sup>22</sup> is made publically available through the Board website and can be searched by any person. The presence of this register has obvious value to the State, in terms of understanding the number and locations of all pharmacies, to assist with managing the potential public risk posed by Scheduled medicines.

The view that registration of pharmacy businesses is necessary was not challenged by any of the individual submissions. Overall, there appeared to be consensus that registration was necessary and that it also provided a mechanism to also apply standards relating to the safe storage of poisons in those registered businesses.

Although initial registration and annual reregistration is an administrative burden, regulators generally indicated a belief that this was not an onerous task for a business. It was noted that the fees charged for registration are quite small in comparison to the average size and turnover of a pharmacy business. Independent submissions from pharmacists did not challenge the current administrative process involved in registration.

In addition, it was noted that the Western Australian pharmacy registering authority operates entirely on monies received from registration and there is no additional cost to the public or Government. There was opinion offered that the pharmacy premises regulatory scheme in each jurisdiction, including Western Australia, were cheap to run, met a sound and justifiable community need, and offered good public protection; in short “good value for money”.

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<sup>22</sup> Register available at: [https://www.pharmacyboardwa.com.au/index.php?page=premises\\_register](https://www.pharmacyboardwa.com.au/index.php?page=premises_register)



Prior to 2017, medicines supply in Western Australia was regulated by the Poisons Act 1964. This Act required the licensing of all “pharmaceutical chemists”; however, given the presence of the *Pharmacy Act*, this was viewed as duplicate licensing. In 2017, the Poisons Act was replaced by the Medicines and Poisons Act 2014. With the intention of reducing red tape, this legislation removed some unnecessary licensing requirements: specifically where a business was already licensed by an appropriate authority, such as community pharmacies. Pharmacies as the keepers and sellers of medicines and poisons, are now only licensed under the *Pharmacy Act*. Any amendment to the current registration of pharmacies may then result in these businesses not being licensed by the Government at all.

Notwithstanding arguments for a national consistency and a single regulator in the future, it is strongly recommended, that at this time the existing scheme of pharmacy registration for Western Australian pharmacies is accepted as necessary for the public interest, is continued, and that no major changes are made to current registration requirements.

### **Pharmacists responsible for providing pharmacy services**

Pharmacies are businesses, operated by registered health practitioners, responsible for the custody and supply of Scheduled medicines. These medicines are those that have been nationally classified as meeting a threshold for toxicity and/or public risk that necessitates controls to be placed on their availability. Submissions suggested that in the interest of patient safety and broader public health needs, that alongside medicines supply, pharmacies also provide:

- effective supply and distribution practices
- appropriate stock control and management processes
- professional advice to support safe medicines use
- support for appropriate and effective use of medicines to improve health
- limit to inappropriate consumer access
- reduced inadvertent and accidental use
- prevention of illicit diversion.

Pharmacies remain the fundamental component of the legal medicines supply chain in Australia; they are designed to meet community needs to safely access medicines, while protecting the public from associated harms. This is a serious and significant professional responsibility that has been entrusted to pharmacists.

It seems obvious that any business supplying medicines, due to the nature of the risks that medicines pose, should only be permitted to be operated by a fit-and-proper person. By nature of their qualifications and training, pharmacists are considered, by definition, to be suitable persons to provide these functions to the public.

While some submissions to the Review focussed on the issue of who could own a pharmacy, there was no dispute that pharmacists were considered the most appropriate person to supply medicines and be professionally responsible for the delivery of services in a pharmacy.



This was acknowledged by submissions from non-pharmacist professional groups:

*“...supports the control of dispensing remaining the responsibility of professional pharmacists...”*

## Pharmacy ownership

Although the Review question was about the adequacy of laws to protect the sector (specifically the limit of ownership to four pharmacies), the issue of persons other than pharmacists owning a pharmacy was a matter raised in some organisational submissions, and, therefore, requires some discussion in this Report.

Some organisational submissions suggested that the current ownership restrictions were not required and could therefore be relaxed. The main argument of those suggesting the broadening of ownership of pharmacies is that the current situation is anticompetitive and does not apply to other health practitioner businesses. Some went as far as to refer to the existing rules as a “profit protection mechanism”.

Medical groups questioned why such regulations should apply exclusively to pharmacy; however, in regard to ownership in the sector, they did not support the proliferation of commercial conglomerates that may not necessarily be invested in the therapeutic outcomes of patients.

The issue of competition in pharmacy has been comprehensively debated elsewhere by dedicated reviews. It was not the objective of the Review to examine competition, and information was not specifically canvassed on this matter. For this reason, findings regarding competition are not possible by the Review; however, it is still reasonable to outline the respective arguments offered in various submissions.

One argument put forward, is that by excluding pharmacies from “typical market forces”, incentives to drive improvement and innovation have been absent. Arguments of this nature, for improved competition, productivity or efficiency, seem to consider medicines as ordinary items of commerce. This view is flatly rejected by pharmacy groups.

These stakeholders, who referred to reviews on competition, referenced conclusions from these reports that ownership rules “stifle innovation and restrict patient choice”. However, little or no additional objective evidence was provided to support this viewpoint.

A converse opinion was that while competition might have benefits for business, through reduced wholesale cost of medicines, this could not necessarily be assumed to translate into lower prices for consumers. One organisational stakeholder noted that, in regard to the predicted patient benefits:

*“...even assuming the benefits of lower prices were experienced, it isn’t clear who might benefit from this and who might not”.*

Pharmacy organisations categorically supported ongoing ownership by pharmacists. Submissions received by individual pharmacists, understandably, also strongly recommended continuation of the existing legislative requirements.

As summarised by one stakeholder, the rationale for limiting ownership is to:

*“...promote patient safety and competent provision of high quality pharmacy services, and helps maintain public confidence in those services by ensuring pharmacists are in control of policy and determine the model of practice in that pharmacy”.*

It was also observed that, in addition to pharmacy ownership, other regulation and policy measures assist in promoting safety of medicines, including Pharmaceutical Benefits Scheme programs, incentives and rules; health practitioner regulation; and professional standards and codes of ethics. It was suggested that these may be enough on their own to ensure high quality care and protect the public from risks of misadventure with medicines.

Those backing changes to the current legislation, often point to different approaches to pharmacy regulation, seen in other comparable health systems overseas. The argument here being that international experience suggests pharmacies can be owned by other persons, while providing safe professional services. There was said to be at least some evidence of benefit from these different models, such as access to more pharmacies and shorter wait times for consumers.

Pharmacy organisations provided detailed commentary in relation to this international experience. In particular, examples of poor results of deregulation in specific countries were highlighted. It was suggested that the outcomes were negative for consumers and included:

- rapid market consolidation
- market concentration and dominance
- reduced choice
- vertical integration
- conflicts of interest driven by corporate (shareholder) motivations.

These submissions pointed out that, in some cases, there was significant dysfunction, which had necessitated external Government intervention. These examples, and others, were used to argue that deregulation had not empirically delivered expected results or improved competition, and therefore is not in the long-term interests of consumers. Specifically, it was pointed out that, in the case studies provided, there were disadvantages to consumers, such as anticipated price benefits not translating to cheaper medicines for patients; reductions in ranges and quantities of medicines available to consumers; and corresponding loss of product choice.

Furthermore, it was suggested that, even in health systems that have deregulated ownership of pharmacies, rules remain in place to prevent certain types of integration, such as between different health professionals, to ensure ongoing independence between the prescribing and dispensing of medicines.

One submission cited cases in other health practitioner industries, which also had components of both retail sales (of health devices, not medicines) and service. It was suggested that this had been investigated by the ACCC and significant risks were reported to consumers around incentive programs imposed by business owners, which had undermined integrity and independence of professional services. The inference here is that the pharmacy sector would

be highly susceptible to this failure, should the rules be changed without adequate protections in place.

One stakeholder summed up the literature relating to regulation and deregulation of pharmacy ownership in the following way:

*“A number of arguments both for and against deregulation of pharmacy ownership exist, however evidence on both sides is weak – there is a lack of data, what is available is limited in its applicability or by quality. In addition to this, stakeholders have competing interests, making it challenging to determine the most appropriate approach”.*

The Review considers this statement to be an accurate and succinct appraisal of the actual position. During the consultation process, there was no material received that could be judged as greatly adding to what is already known or has been previously reported on this issue.

In considering the best approach to ongoing regulation, the Government must consider whether or not there is a real and significant failure of the current regulation, reasonable expectations that the proposed benefits are not only worthwhile, but will actually be realised, and taking into account any possible risk of a worse outcome for consumers.

## **Consumer opinion**

The Review was open to public submissions; however, very few were received from health consumers. Interviews were conducted with the Health Consumers' Council and separate written submissions also encouraged.

The Health Consumers' Council expressed a view that pharmacies are an important and vital part of the primary health care. The value, trust and quality of this sector were referenced, but as for any part of the health care system, it was accepted as also having certain areas of complaint, worthy of improvement.

The consumer viewpoint outlined was one less that was concerned with ownership specifically, and centred more on consumer experiences and needs. Specifically, the relationship between the pharmacist and patient was considered as most important. It was suggested that high quality interactions with pharmacists as professionals would be what consumers sought out in preference.

A number of services were singled out as specifically needing greater accessibility and therefore worthy of greater attention from Government. This included ensuring continuity of care with respect to medicines when moving between community and hospital, where pharmacists could assist with continuing care and reducing adverse medicines events. Additional services to support management of chronic disease were suggested to be valuable, as were services provided by other health practitioners from within a pharmacy.

In particular, opinion was expressed that the sale of medicines or therapeutic goods that were not evidence based (e.g. homeopathy, some nutrition and other supplements) was a point of criticism of pharmacists and providing these goods did not serve consumers well.

One submission stated that a commissioned survey, performed by the Institute for Choice, found that 90% of consumers believe pharmacies should be owned by pharmacists.<sup>23</sup>

## Views of pharmacy organisations

Organisations representing community pharmacists and pharmacy owners unequivocally supported the current provisions relating to the ownership of pharmacies. It was proposed that the ongoing presence of ownership laws and limits are essential to the integrity of the sector in Western Australia.

Pharmacy organisations believed that the current regulatory approach had delivered the existing pharmacy network, which was a good thing for the Western Australian community in general. Pharmacies were said to have a large footprint which was evenly distributed, that maximised access to supply of essential medicine to consumers; which is in the public interest to maintain.

Almost every pharmacist group interviewed by the Review predicted that deregulation would lead to poor outcomes. These included:

- unpredictable and unintended consequences
- market concentration
- changes to pharmacy distribution - greater centralisation of locations
- reduced consumer access to medicines supply
- greater focus on increasing volume of sales
- time taken away from non-sale activities; that is - providing advice, education and support to consumers
- reduced out of hours services (e.g. late nights and weekends)
- reduced product selection
- reduced career pathways and options for pharmacists
- detrimental effects on retention of the pharmacy workforce.

## Other views on ownership

There were many submissions that sought to demonstrate the personal and professional commitment of pharmacists. There were many stories and evidence provided that pharmacies were more than just places supplying retail products, and there was a connection between professionalism and care to the ownership of a pharmacy by a pharmacist. Similarly, many submissions related the achievement of existing standards, the quality of service, as well as innovation and other benefits, directly to the presence of the current ownership scheme.

In these cases, it was highlighted that this unrecognised aspect of pharmacy would be at risk if the sector was changed in a way that might “corporatise” ownership. It was commonly believed that this would affect adversely the existing professional connection to practice of pharmacy.

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<sup>23</sup> Source – Submission 44

Throughout the submissions there were numerous examples of the free services that pharmacies currently provide:

*“One of my currently terminally ill customers, who requires Dilaudid urgently, has no assistance in bringing in the prescription for us to dispense. I, as a pharmacy owner, actually went to her place after I finished work at 6 pm, to get the prescription and deliver the medication to her.”*

*“My pharmacy, like many, provides an infant health nurse who provides ante- and post-natal advice and monitoring to mothers in our community. In addition, we provide a senior health nurse who provides blood pressure testing as well as health advice to those most vulnerable in our community. These services are provided at my cost with no charge to patients or subsidy from the state. I believe this demonstrates our commitment to the health and welfare of our community above profit.”*

Most of these submissions believed that changes to ownership regulations would result in negative impacts on the level of service provision in pharmacies. It was argued that this may in turn require Government to contribute more funding, so as to incentivise the continued delivery of these services.

It was also said that ownership is a recognised career pathway for most pharmacists, which many younger pharmacists aspire to. Interviews with younger pharmacist groups, as outlined elsewhere in this Report, suggested that wages and conditions for employee pharmacists are judged as poor, when compared to other similarly qualified health practitioners, and that this makes pharmacy ownership attractive. Lack of ownership opportunities due to current ownership trends were cited as already problematic and negatively influencing the pharmacy workforce.

Although issues of financial sustainability were outside the strict remit of the Review, there were a number of references made to challenging economic conditions, including lower margins on medicines, and high rents for premises. Pharmacists felt that in such difficult times, there was a real need for business certainty. Pharmacy organisations were concerned that any changes to ownership rules would have large implications for current owners, and could put investments and livelihoods at risk.

There was also mention of disruptive technologies and an expectation that this would have a disruptive effect on medicines supply. The exact impact on pharmacies was not well described and the likely future-state where pharmacies employed these innovations was not specifically outlined by any submission. This makes it difficult for the Review to determine what needs to be considered in designing regulation to allow for these technological predictions.

## **Professional responsibility and conflicts of interest**

Pharmacists relayed a well-defined conviction understanding of the intent of ownership regulation is to ensure that professional standards and principles are not subordinated to commercial objectives and pressures.

In interviews with pharmacist groups, a strong theme emerged of pharmacists considering themselves as health practitioners first, with a primary duty of care to patients, and as business owners second. A common observation of submissions was that, as registered practitioners, there is a far greater incentive to adhere to standards of practice and ethical behaviour in business. This was on the basis that individual practitioners are additionally regulated under Health Practitioner Regulation National law.

Pharmacists were acutely aware that unacceptable practice or behaviour could lead to inability to practice at all, and therefore, potentially to a complete loss of livelihood. It was argued that this was not the case for a corporate owner, and, in the case of a non-pharmacist owner, there was no equivalent mechanism for personal or professional reprimand in relation to misconduct.

A number of individual submissions from individual pharmacists detailed their account of their experience working in a deregulated environment in overseas health systems. They outlined either direct experience or close observation of situations where professional judgement was overridden by business interests. These included claims of pressure from corporate owners, leading to inappropriate use and supply of medicines, unreasonable sales and wages targets, non-pharmacist managers considering business before patients, and unethical working practices. These pharmacists were particularly scathing in their criticism of the rules that allowed these situations to occur.

During interviews, there were examples provided to the Review of situations where a corporate brand a pharmacy was affiliated with had sought to direct processes within the business that were not considered compliant with legislation, by the individual proprietor or by employed pharmacists. There were accounts of queries of this nature being regularly received by professional organisations from their members. These types of concerns were also raised by premises regulators in other jurisdictions. A similar experience was noted by the Western Australian regulatory authority.

Commonly, the situations appear to relate to the display, storage or access to different Scheduled medicines, normally surrounding promotion and marketing. In at least some cases, there was description of regulatory non-compliance, where storage conditions were sought to be dictated by another party and were not compliant with Western Australian legislative requirements. While these instances seemed limited, it is still evidence that conflict between corporate and professional interests are a very real concern and need due consideration in any regulatory model.

Pharmacists suggested that having a pharmacist as owner, provided in-built protection against such conflicts occurring. They argued that any change to ownership restrictions would be a dilution of the current protections.

Individual submissions indicated that it can already be difficult to manage such conflicts, and that, in the case of a corporate owner, a large imbalance of power all but removes any ability of a pharmacist to refuse unreasonable requests. They argued that, although personally professionally responsible for any practice not meeting standards of a registered health practitioner, the business would not be accountable in the same way. That is to say, if non-pharmacists could own a pharmacy, they could direct certain practices to occur, where the practitioner could be held accountable under the law, but the owner would not.

It was pointed out that some jurisdictions have specific legislative clauses in pharmacy regulation to prevent this type of external interference with the individual judgement of the pharmacist as a health practitioner.



## Pharmacies in private hospitals

Submissions from medical groups and a comprehensive submission from an operator of private hospitals proposed that pharmacies in hospitals should be able to be owned and operated by the hospital itself. This is not expressly permitted by the current *Pharmacy Act* and Regulations in Western Australia.<sup>24</sup>

The argument presented for such a change is primarily that this is allowed in several Australian jurisdictions, and that there are hospital operators who have experience in owning and running a pharmacy service in a private hospital. It was stated that this was being performed safely and ethically, to an equivalent standard, and without detriment to consumers. Evidence offered in support of this included current pharmacy operations in a number of hospital facilities across Australia.

Beyond this, it was argued that amending the Regulations to permit ownership of a “private hospital pharmacy” by others would provide additional benefits for consumers and improved health outcomes. The hospital operator suggested that experience in health management and expertise derived from running hospitals and delivering acute care could be transferred to the supply of medicines and management of the pharmacy as a business. Specifically, this was argued to improve the quality of clinical care and medication management, and consistency of service provision.

It was suggested that any large health care organisation, with experience running a hospital, would certainly have adequate capability to successfully run a pharmacy to supply the hospital. The standards and controls that ensure safe and high quality care in the hospital were argued as also being appropriate for the management of a hospital pharmacy. It was believed that any organisations that could achieve required standards for other types of acute care, and meet standards for running a pharmacy in another jurisdiction, could do so in Western Australia.

This submission outlined a number of hospital policies and procedures in place in hospitals to ensure safe care, such as, continuous quality improvement cycles, audit calendars, accreditation and assessment against Standard 4 of the National Safety and Quality Health Service Standard.<sup>25</sup>

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<sup>24</sup> Note: public hospitals are excluded from the *Pharmacy Act* and are independently regulated as permitted entities under the *Medicines and Poisons Act*.

<sup>25</sup> See: <http://www.nationalstandards.safetyandquality.gov.au/4.-medication-safety>

The submission also cited improvements that had been made elsewhere and suggested there was ability for potential improvements in Western Australian private hospitals, in relation to:

- ward pharmacy clinical services
- admission and discharge medication reconciliation
- coordination of sterile drug manufacture
- onsite compounding
- contributions as members of the multidisciplinary health care team
- drug information
- clinical (drug) trial management
- medicines cost containment
- drug imprest<sup>26</sup> and procurement management
- use of information technology and transfer of patient health records for medicines
- adherence to standards for hospital pharmacy practice.

In addition, it was argued that there were other positive benefits for pharmacists themselves, including improved professional support, training and education opportunities, better career pathways and more personal development options.

Submissions on this issue were also received from current private hospital pharmacy owners; both from individuals and as a representative group. These submissions argued forcefully that the current rules should not be changed.

The overall rationale for no change was that the current system already works well to deliver high quality services that are owned and operated by pharmacists, which best serves consumer needs, as well as Western Australia more broadly. They argued that there are no deficiencies in the current quality or safety of pharmacy services delivered, and therefore no pressing driver to consider any change. They stated that the benefits proposed from making any changes are largely already present and therefore there is unlikely to be any additional consumer or health care benefit actually realised from regulatory amendments.

This group pointed out that the situation in Western Australia was no different to that in South Australia and Tasmania. Furthermore, they noted that even in States or Territories where ownership of a private hospital pharmacy was permitted, many hospital operators chose not to do so, on the basis that pharmacists could perform these functions better.

The group outlined that many pharmacists in Western Australia had developed expertise in running hospital pharmacies and held capabilities unique to this part of the pharmacy sector. This included specialised IT capabilities, knowledge, staffing, clinical expertise, management practices and other processes tailored for hospital needs. It was therefore suggested that the sector already had sufficient capability, which would not be greatly leveraged by any corporate management practices, as argued in alternative submissions. Overall, the message was that the proposed benefits of ownership by a corporate hospital operator in relation to improved resources and supports are already present.

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<sup>26</sup> Note: “imprest” refers to medicines stocks held on a ward, in a hospital



Furthermore, it was argued that hospital pharmacy owners already have strong incentives to provide a high quality service. The reasons for this are the large capital investment, personal liability, commercial pressure to be efficient and other financial drivers, competition with other pharmacists, service agreements with hospitals that include key performance indicators, as well as the simple imperative of “keeping the client happy and maximising goodwill”. Current owners provided extensive examples of the existing services they offered in support of this opinion.

Importantly, the proposed clinical benefits suggested by alternative submissions were also cited by current owners as the exact reasons not to consider amendments. They argued that private hospital pharmacies already deliver all of these benefits as part of existing agreements with hospitals, do so to a high quality and are already bound by practice standards. They said they were already required to meet National Safety and Quality Health Service Standards, did so, and in some cases provided examples of achieving these standards with a degree of merit. They pointed to examples of service integration with hospitals and clinical governance efforts in relation to medicines safety provided for the pharmacy and the wider hospital. It was pointed out that these standards needed to be met regardless of who the owner of the pharmacist was.

On the basis that the needs of consumers in relation to medicines supply was already met to a high standard under existing ownership models, it was suggested that there was likely to be little gain, but there was certainly new risk connected to any change. It was stated that this risk extended to potentially diminished quality of services, the range of additional services offered, convenience issues such as opening hours, and loss of additional consumer value offered without charge as a professional courtesy.

A particular risk cited was that there was potential detriment to the hospital pharmacist workforce. Examples were provided to illustrate how current owners positively managed and developed the pharmacists in their employ, pursued practice related innovation and research, and conducted quality assurance and improvement in relation to medicines supply and patient safety.

Like other pharmacies, the pharmacists owning hospital pharmacies also highlighted personal, professional accountability as a greater obligation that drives achievement in service quality and performance.

Current proprietors pointed out that there are a range of large and small hospitals in Western Australia owned and operated under various different corporate structures. They noted that, while there may be some corporate operators with experience, qualifications or adequate resources to deliver pharmacy services, there were others that did not have these capabilities. Extending ownership more broadly in this way was then said to expose consumers to risks of inexperienced owners and was therefore not acceptable.

It was questioned as to whether the legislation could adequately determine, who, outside a pharmacist, may or may not be an appropriate and safe private pharmacy operator; on what basis this assessment might occur; and whether or not it was practically possible to limit ownership to those determined as suitable corporate “health related” entities, versus those that were not.

These submissions stated that there are currently 22 pharmacist owned pharmacies that service larger private hospitals and that all of these businesses would be adversely affected by any changes. It was clear that these owners expected their own investments to suffer greatly.

In summary, this group did not believe there was any failure in this sub-sector of the industry, there was no particular reason to believe there would be great benefits from interference, and there would be serious disadvantages from any changes.

It is accepted that some organisations can and do own pharmacies that service private hospitals in other jurisdictions. It is also accepted that pharmacy owners already provide high quality and ethical pharmacy services to hospitals in Western Australia and will continue to do so regardless of the legislation. Furthermore, it is reasonable to believe that any changes would have the potential to significantly affect the business interests of current owners.

On the basis of evidence provided, both for and against any changes, the Review did not identify convincing evidence that ownership changes would result in either radical changes to existing medicine supply practices, or lead to dramatic improvements in health outcomes. Regardless, there may be expectation of efficiencies gained, in some cases. However, it does not appear that there is necessarily any barrier to these efficiencies already being implemented, without a change to ownership rules.

It is certainly possible that non-pharmacist owners might provide lower quality services, rather than equivalent or higher as argued. The Review did not identify specific evidence of serious failure, or receive any suggestions of consumer harm, that might serve as a pressing or urgent justification for change.

Any changes requested for this sub-sector would require significant modification to the *Pharmacy Act*. Regardless of who the owner is, they would need to be fit and proper persons, and the legislation would therefore need suitable protections to manage this. There was suggestion that health entities, with certain expertise or experience related to hospitals or other care areas, might be more appropriate owners than others. Determining suitability is potentially a more challenging task with a corporate entity and it may be equally difficult to distinguish between a “health” and non-health entity. Assessments of suitability or capability may then pose serious practical issues.

Changes, if made, would need to consider, and then properly place into legislation, any necessary limits and restrictions to ownership. For example: only a person or entity licensed to run a private hospital would be appropriate to own a hospital pharmacy; the pharmacy owned should be that which services the hospital owned; and any authority should not extend to other hospitals, other pharmacies or different care settings. Irrespective of the proprietor, the overall responsibility for pharmacy professional practice must remain with a registered pharmacist. The legislation would need to be robust enough to ensure that any owner was also directly responsible for the business and practices, standards, and safety of the public, in the pharmacy owned, just like any other registered pharmacy.

There would need to be careful consideration around transition periods and any transfer of ownership to seek to minimise commercial disadvantage to incumbent owners, and prevent short-term market disruption or dysfunction.

It is noted that pharmacies that service private hospitals, can in some instances, supply medicines to persons who are not patients of the hospital, as in a normal community pharmacy. In these situations, the wider case for ownership should apply, as already assessed for the entire sector. Consideration of ownership changes for hospital providers should be based only on arguments that relate to the acute care setting and not extended to different circumstances. In cases where a pharmacy services a wider population outside the hospital, the arguments already presented for ownership of community pharmacy more widely, are still be valid.

## Numbers of pharmacies that may be owned

Many submissions provided by individual pharmacists discussed the appropriate number of pharmacists for a pharmacist to own. At least some suggested no restrictions. However, this situation might be thought of as equivalent to corporate ownership and hence is best considered alongside arguments related to ownership by other persons.

Some suggested minor increases to the current number limit of four. These submissions generally suggested six, on the basis of consistency with some other States and Territories, where the number is slightly higher. There was opinion from both pharmacists and some pharmacy groups that multiple pharmacy ownership, within reason, was important to retain, as it provided opportunities for scale in the market. Almost all submissions were wary of large increases that could provide the potential for market concentration and unchecked corporate power.

The majority of individual submissions recommended retaining the current limit of four on the basis that this was a sufficient number to allow some standardisation of business processes and commercial efficiency, while being small enough to permit personal connection, care and attention of the owner in the operation of the pharmacy. Four was stated to be the right balance that ensured personal accountability and responsibility for maintaining standards and compliance.

There was also suggestion that small, independent pharmacies are important. A small pharmacy was defined by a stakeholder group as one that dispensed less than 35,000 scripts per annum. It was stated that these often provide medicines supply services in areas that are unattractive to larger operators. They quoted literature suggesting improved customer satisfaction at small sites (overseas data). Evidence was proffered that, contrary to the generally held belief that larger pharmacies were more efficient and cheaper, financial data suggested lower operator costs per prescription in a small pharmacy. It was argued that small pharmacies also drove competition and innovation.

At least some pharmacists argued that the limit was too high and that the number could be reduced to around two. It is noted that the permitted number was previously set at two in Western Australia.

*“I believe that a Pharmacist can only have a meaningful impact upon the operations of 2 Pharmacies at any one time. To be directly responsible, and aware of what happens, requires you to actually be there.”*

During interviews with other State and Territory regulatory bodies, the question of the most appropriate number was specifically canvassed. There did not appear to be one standard process or method that jurisdictions had used to determine this number. Most suggested that, although possibly partly historical, the number would be considered a balance that sought to ensure that the owner was able to be directly responsible for maintaining public safety and standards on the premises. These bodies did not provide opinion as to the most appropriate number, but all noted that there was inconsistency between various States and Territories.

In their response to the Review, the Pharmacy Board of Australia<sup>27</sup> noted their Guidelines for Proprietor Pharmacists (2015)<sup>28</sup> that outline expectations of owners as registered practitioners. This includes that the proprietor pharmacist must maintain an active awareness of the manner in which the business is being conducted, and, where necessary, intervene to ensure that the practice of pharmacy is conducted in accordance with all applicable laws, standards and guidelines.

## Ownership concentration

A few submissions raised concerns that the legislation does not prevent the purchase of multiple pharmacies in a specific district; for example, owning several in close proximity or next to each other, even if they appear to be unrelated and branded differently.

Several regulatory authorities noted examples where several pharmacies in one regional town had the same owner. In general, the overriding concern in these cases appeared to be related to lack of competition and the suggested ability to dictate price and service in a region.

## Owners being resident in Western Australia

The trend of pharmacists resident outside of Western Australia owning pharmacies within Western Australia has been outlined in Question 1. Since 2010, pharmacists who are nationally registered, but not necessarily resident in Western Australia, have been more readily able to own a pharmacy business in this State.

Accepting that the intention of the Regulations is to ensure that a pharmacist, as a fit-and-proper person, has oversight and accountability for the manner of which the practice of pharmacy is being conducted, and, where necessary, can intervene to ensure it is conducted according to applicable, laws, standards and guidelines, the question was raised as to how a person that was not ordinarily physically present at the pharmacy premises could adequately discharge these responsibilities.

There was suggestion that the legislation needed to ensure that an owner spent an adequate amount of time directly connected to the business. One submission suggested that the pharmacist with overall responsibility, as well as any pharmacist with a proprietary interest in a pharmacy, should be in attendance in the pharmacy for a minimum of 40 hours (equivalent to a week full-time) in any three month period.

Trends of increasing numbers of pharmacies owned have also been outlined in Question 1. This appears to be directly related to the matter of interstate ownership.

It was pointed out to the Review that a pharmacist can own the maximum number of four pharmacies in Western Australia, and also attain the maximum number permitted, at the same time, in other States and Territories. Altogether, this could be a relatively large number. It is

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<sup>27</sup> Note: The Pharmacy Board of Australia is a distinct authority from the Pharmacy registration Board of Western Australia and has the function of regulating registered pharmacists, as opposed to pharmacy businesses.

<sup>28</sup> Pharmacy Board of Australia. Guidelines for Proprietor Pharmacists. 2015. Available at: <http://www.pharmacyboard.gov.au/documents/default.aspx?record=WD15%2F17691&dbid=AP&checksum=38U9CgE45JL%28BPCUEpSjWw%3D%3D>

noted that a pharmacist resident in Western Australia could do this, as well as a pharmacist resident elsewhere in Australia.

Individual stakeholders suggested that this situation meant that a type of corporatisation could be achieved by pharmacist owners, if they took full advantage of this ability. It was believed that this was neither in the spirit of the legislation, nor desirable for the industry or consumers.

Regulators also suggested that this was not always felt to be consistent with the intent of ownership limits in each jurisdiction. Furthermore, the greater the number, the less likely it was considered that the individual pharmacist could have adequate ability to know what was occurring in any specific business, and intervene if necessary.

Other submissions varied by pharmacy group. Most did not wholly support closing off interstate ownership, although it was acknowledged as a matter that needed to be adequately addressed. Some different options were presented, such as interstate ownership being permitted, so long as at least one business partner was local and physically present to meet supervision principles.

It is noted that to address this concern, the various regulators would need legislative powers and mandate to consider the number of pharmacies owned by a pharmacist in another jurisdiction. They would require the ability to direct that this information be provided by an applicant, and to be able to verify it with other regulators.

Appropriate ownership numbers are then a complex national issue that is unlikely to be solved by changes in Western Australia alone. In addition it does not seem equitable to the Review to allow only Western Australian pharmacists to access the local market, but for these pharmacists to not be similarly constrained from owning more pharmacies elsewhere in Australia.

Any changes to ownership numbers, or the need to be resident in Western Australia, could mean many pharmacists no longer qualify for ownership, and a number of businesses would need to change hands. Figures are not available to adequately assess this impact. Prior to considering amendments, the exact impact and the most appropriate way to minimise disruption to consumers would need to be examined. It was suggested that transition requirements would be needed or, alternatively, any existing interstate owner might be grandfathered, but new cases not permitted.

The Pharmacy Registration Board of Western Australia stated that it needed to be assured that standards in a pharmacy were being maintained regardless of where the owner might be ordinarily resident. They indicated that, as the regulator, they needed sufficient powers to ensure this was the case, and to be able to remedy any non-compliance. The Board does not believe it has suitable powers in this regard.

## **National consistency in ownership laws**

Overall, pharmacy groups did not support radical changes to the number of pharmacies that could be owned. The differences in numbers permitted between States and Territories was commonly acknowledged. One stakeholder group rightly observed that in principle, any variation in regulation between jurisdictions was inherently inefficient.

Pharmacy organisations supported consistency between jurisdictions, as well as the concept of harmonisation of pharmacy regulation laws. Although, one organisation felt that, as this was a complex issue, it was outside the scope of this Review. Pharmacy organisations also believed

that they should be the primary stakeholders for developing any approach to harmonisation of jurisdictional pharmacy legislation.

Previous national reviews<sup>29</sup> have suggested that there might be one regulatory body that could administer the registration of pharmacies and manage the application and enforcement of any respective regulations. This is likely to require the agreement and entry of all States and Territories into such a scheme, and for an appropriate way to transfer existing legislative powers to a central authority.

The concept of a single regulator was an idea known to the Pharmacy Registration Board of Western Australia; however, it was suggested this was not an issue that had been properly considered by all regulators and the exact opinions of the equivalent jurisdictional boards were unknown.

There was preliminary opinion expressed that it would be expected that most States and Territories might wish to retain at least some local regulatory control, and that this would necessitate retaining local boards, while potentially applying harmonised legislation.

## Current practising status of pharmacists

Current Regulations require a pharmacist owner to be a registered pharmacist; meaning a pharmacist registered under the *Health Practitioner Regulation National Law (Western Australia) Act 2010*.

There are a number of possible registration categories and it was raised that not all of these may be suitable to own a pharmacy. In particular, it was pointed out that the ability of a pharmacist who is registered in a non-practising category needed review.

The current requirements across Australia are:

- ACT general registration
- New South Wales general registration
- Northern Territory general registration
- Tasmania general registration
- Queensland general or non-practising registration
- South Australia general or non-practising registration
- Victoria general or non-practising registration
- Western Australia general or non-practising registration.

In comparison to general registration, non-practising pharmacists are subject to different requirements for maintaining minimum practice contact and meeting annual continuing professional development needs. It was queried as to how a pharmacist that had not met the usual expectations to maintain professional knowledge and standards would be able to adequately discharge their obligations as the owner of a pharmacy and responsible for practice of pharmacy in that business.

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<sup>29</sup> Commonwealth of Australia. Review of pharmacy remuneration and regulation final report. 2017. Available at: <http://www.health.gov.au/internet/main/publishing.nsf/content/review-pharmacy-remuneration-regulation>



It was suggested that should the requirements be changed, that there would need to be a suitable period of grace to allow transition of ownership for those affected. There are very few non-practising owners in Western Australia.

It was also noted by the Pharmacy Registration Board of Western Australia that a pharmacist may be registered, but also have conditions imposed on their registration, by the Pharmacy Board of Australia, that affects their ability to discharge their obligations as an owner. It was suggested that the conditions could have relevance as to whether the person remained suitable to be the owner, or the responsible pharmacist in charge.

They suggested that this was an area of the legislation that required clarity and suitable authority for the Board to make a determination when required. As outlined already, divestment of ownership may take time and provisions would be needed to adequately manage this in a reasonable and just way.

## Aboriginal health services and pharmacy

Submission was received from the Aboriginal Health Council of Western Australia, who raised the issue of supply of pharmaceuticals in rural and remote areas. Commonwealth funded prescription medicines are currently supplied to Aboriginal peoples in remote areas, where a pharmacy does not exist, under section 100 provisions<sup>30</sup> of the *National Health Act 1953*.

They noted that an Aboriginal Community Controlled Health Service could not register a pharmacy in Western Australia, but could do so in the Northern Territory. It was argued that permitted this would result in a safer more secure, integrated health model.

They also cautiously supported additional pharmacist related medicines based services, but noted that there were many existing professionals already providing successful health promotion programs for Aboriginal people.

The exact model envisaged was not detailed, however it was implied that it would involve greater inclusion of pharmacists in the health service. It is not clear whether or not the pharmacist role (either in supply, or performing services such as medicines reviews) in these cases would be consistent with the definition of a pharmacy business, and how they might then be regulated under the *Pharmacy Act*, if at all. Regardless, it is understood that the Aboriginal Community Controlled Health Services are not proposing to open and run a chain of community pharmacies.

Northern Territory regulators suggested that the ability to register a pharmacy quoted here was not well utilised. It is noted that the facility does not exist in other jurisdictions. At present, it is viewed that medicine storage and supply in these are adequately able to be regulated under the *Medicines and Poisons Act*. Further changes would require amendment to the *Pharmacy Act*, and any registration would still require persons to be fit and proper, to meet appropriate standards and be subject to regulation by the Pharmacy Registration Board of Western Australia.

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<sup>30</sup> Note: Alternative rules for the supply of some PBS medicines to Aboriginal and Torres Strait Islander peoples in remote areas have existed since 1999. More information can be found on the scheme at:

<http://www.health.gov.au/internet/main/publishing.nsf/Content/health-pbs-indigenous-faq>

## Findings and Recommendations

That Scheduled medicines are potentially dangerous if used incorrectly, or without appropriately qualified health practitioner oversight, is not disputed. Any medicine is a potential poison if used indiscriminately. Medicines are not ordinary items of commerce and therefore pharmacy businesses have unique risks.

Pharmacies are the main distribution point for medicines in the community, and as such, represent a significant public risk, should the integrity of the normal medicines supply chain be compromised. Given the significant and serious harm that can occur to individuals from misuse of pharmaceuticals, the regulation and registration of pharmacies is absolutely necessary, to provide adequate public assurance that the safety and security of this supply chain remains intact. There is ongoing value and public interest in the regulation of pharmacies and the registration of pharmacies should continue.

### Finding 2

- Overall, the Review finds that the current regulatory system is fit for purpose and sufficiently rigorous to protect integrity of the sector. There are however, minor areas of potential weakness that could be strengthened.

The registration and regulation of pharmacies is currently managed by a statutory Board which is wholly self-funded by the industry it regulates. The entire regulatory system is cheap, effective, and the Board is considered successful in achieving its stated mission of protecting the public.

There is some burden and minor cost to pharmacies in achieving registration and annually reregistering; however, this is judged to be acceptable, in return for the value provided to the community. Removal of these requirements would not make a large difference to pharmacies, but would be expected to eventually allow the system to be undermined, with serious long-term effects.

### Finding 3

- The registration and regulation of community pharmacies serves an important purpose to manage risks to the public posed by these businesses. There is ongoing community benefit in retaining pharmacy registration and this legislation should remain in place.



Ongoing publicly visible registration of these businesses and regulation of standards that support the integrity of the medicines supply chain in pharmacies is endorsed. However, the regulatory system surrounding this should continue to only concern itself with matters related to risks from the storage and management of large quantities of Scheduled medicines by private pharmacy businesses. There is no reason to extend the reach of this legislation and it should not unnecessarily increase regulatory burden or duplicate other controls that already apply to pharmacists.

Registered pharmacists are appropriate persons to own a pharmacy due to their training and profession. It seems universally agreed that pharmacists are the appropriate people to dispense medicines, as well as run and maintain standards in the pharmacy itself.

#### **Finding 4**

- Pharmacists remain wholly suitable persons to be a proprietor of a registered pharmacy and the existing regulations rightly make the pharmacy proprietor accountable for standards and practices conducted at that business.

#### **Recommendation 1**

- Legislation should continue to require a pharmacist to be a proprietor of a pharmacy business and be responsible overall for managing the public risks posed by that type of business.

Arguments were put forward by some groups that the current ownership of pharmacies should be deregulated. This included proposals for other types of persons owning pharmacies.

Arguments for this change include better competition that may then benefit consumers. However, despite this view, no submission, from any group, seemed to support entry of large corporations into community pharmacy.

Arguments against such changes are based on significant potential risks to standards and accountability, as well as reasonable evidence of a failure of this approach in some other countries. The pharmacy industry argues that other persons owning pharmacies could lead to market dysfunction in Western Australia, as it has done elsewhere.

Any changes would, by nature, be significant, and the public must continue to have reasonable assurance of integrity over the sector and confidence in accountability of owners. Pharmacists owning pharmacies certainly provides this. Regulation, outside pharmacists alone, would introduce new and different risks to public safety, and therefore may actually be more complex, costly and challenging to manage. In the absence of a compelling argument that there is gross regulatory failure in the sector or major gains in health outcomes might result, there is a limited rationale to support such changes.

In addition, any major changes to legislation in Western Australia, while restrictions are still in place in other jurisdictions, could allow interests from anywhere in Australia to buy into the State and influence the sector locally. There could well be rapid and large ownership shifts; this would be akin to running a regulatory experiment run in this State alone. For obvious reasons this is not recommended.

Pharmacists do not support ownership changes and there is no support from any quarter for ownership by large corporate entities that do not have a health focus.

On the balance of evidence provided to the Review, it is recommended that:

## **Recommendation 2**

- Ownership restrictions in relation to pharmacists owning pharmacies remain in place, at this time.

Western Australia should not consider changes to restrictions that are inconsistent with the situation in other States and Territories.

There were similar proposals put forward for ownership of hospital pharmacies. The assessment for this sub-sector of the industry should be no different; the public still requires assurance that all possible regulatory concerns can be adequately addressed. While certain health organisations could potentially operate a hospital pharmacy safely, should appropriate protections be codified in legislation, it is less certain that there would be any noticeable difference for consumers. There is little doubt from the Review, that changes would be disruptive inside the local industry.

On the balance of evidence provided to the Review, it is recommended that:

## **Recommendation 3**

- Ownership restrictions in relation to pharmacists owning pharmacies in hospitals remain in place, at this time.

Should the Government consider such legislative changes necessary, based on more robust evidence of significant public interest then they should be constrained to this sub sector alone and include suitable regulatory protections to provide the exact same assurances of accountability demanded of other community pharmacies.

Most pharmacists believe the current ownership number is appropriate, while noting there are differences in numbers that can be owned between States and Territories. There was support for improved national consistency.

Pharmacists themselves supported a general status quo in relation to numbers of pharmacies that could be owned. There was common agreement that alignment of ownership limits with other States and Territories was desirable. This would require either some jurisdictions to decrease their limits, or for Western Australia to slightly increase the limit.

#### Recommendation 4

- The ownership limit of four pharmacies should remain, as is, until such time that there is agreement between States and Territories on alignment of this limit between Australian jurisdictions.

This alignment is a matter that should be progressed nationally.

What may be of more importance is attention to the number that can be owned nationally. There is likely to be limited value from more stringent regulation in Western Australia, while a pharmacist can still obtain the maximum number in each State and Territory simultaneously. Western Australia should then only consider changes to limits in the context of any national debate on pharmacy regulation and ownership limits.

Harmonisation of pharmacy legislation between States and Territories was universally supported and can be readily endorsed by this Review; assuming that the controls in place in Western Australia are not materially diminished. Considering that the intent of any ownership limit is in relation to personal accountability and intervention by a pharmacy proprietor, this should provide the basis for discussions in any suitable national forum.

## Recommendation 5

- Western Australia actively pursue, or at least engage in, progress with other State and Territories, towards harmonisation of pharmacy legislation around Australia.

This should be progressed at a suitable Ministerial and intergovernmental level, through an appropriate forum for such agreements.

In any discussions of this type, Western Australia should seek to ensure that harmonisation does not lead to a material lessening of the robust regulatory system already in place in this State.

These discussions should consider whether maximum ownership limits in each state allows a form of corporate ownership that is contrary to the intentions of individual jurisdictional law.

Pharmacists identified as being health practitioners over and above business owners. The Review commends the high expectations of pharmacists in relation to their responsibilities to the community in general and in particular their duty to patients. There was an obvious internal lack of tolerance within the industry for any non-compliance by pharmacists with regulations, standards or expected best practices.

There were related opinions that pharmacist proprietors could not meet their obligations if they did not have a physical presence in the business; with minimum requirements proposed by some. There is at least some support for owners to need to be resident in Western Australia when owning a pharmacy located in Western Australia; however, proprietors are already accountable and there was no specific evidence that these pharmacies are less safe.

Amendments of this nature would increase overall regulation and may be difficult to implement in practice. Regardless, should standards not be met, it is entirely relevant to consider appropriate regulatory actions on the basis of the ability of the proprietor to understand what is occurring in the business and to intervene when necessary.

The Review notes that there is nothing to prevent increased audit and closer scrutiny of these businesses, to ensure compliance or to gather evidence, either way, in relation to maintenance of standards. This is recommended to the regulatory authority, acknowledging the current limits of available resources.

Any additional legislative amendments in this space are best considered as dependent on whether interstate ownership trends continue and any developments in relation to nationally harmonised regulation.

### **Finding 5**

- There is rationale and support for ensuring that pharmacist proprietors are able to discharge their responsibilities to manage risks posed by the business. This should not be diminished by nature of place of residence.

### **Recommendation 6**

- Pharmacy ownership by interstate pharmacists continues to be allowed, at this time.

The matter should be revisited at a suitable interval and reassessed in relation to any ongoing ownership trends and national discussions on ownership.

### **Recommendation 7**

- The Board should be able to take a lack of personal oversight by the proprietor, including situations of residence in other States and Territories, into account in relation to any failure to meet standards.

It is also reasonable that the public is assured that a pharmacist is competent and up-to-date with contemporary practice, to be able to discharge the responsibilities of a proprietor. A requirement for full general registration of the proprietor is a requirement in some jurisdictions and this should also be the case in Western Australia.

### **Recommendation 8**

- Pharmacists hold general registration, and be practising, to be a pharmacy proprietor.

The legislation should be suitably amended to include this condition, and allow for a reasonable transition period for any pharmacist that may be affected.

### **3. What role can pharmacies play in an integrated health care model in Western Australia, and how does the current pharmacy regulatory model support this?**

#### **Value of pharmacy to the health system**

Submissions from professional pharmacy organisations highlighted the important social and community value of community pharmacies. It is not disputed that pharmacies are established and well recognised health care delivery practices, generally situated in readily accessible locations, easy for patients to access, typically open on weekends and normally offering extended trading hours. There are few, if any, access restrictions, appointments are not required, and wait times are usually short.

The argument was made that there are over 600 pharmacies across Western Australia, and that these were evenly distributed, more so than other health practitioners. In particular, it was noted that there are pharmacies in most regional towns and that, in many cases, there may be a pharmacy where there is no other accessible, resident health practitioner in the private sector. It is estimated that these pharmacies have contact with around 140,000 Western Australian health consumers every day. One pharmacy organisation stated that there were 72 pharmacies in Western Australia in the PhARIA category 4-6, defined as being only moderately accessible or located in remote locations.

There are approximately 2,500 registered pharmacists employed in the community pharmacy sector in Western Australia. Many submissions pointed out that pharmacists are highly qualified experts in medicines and consistently ranked as highly trusted amongst the health professions. They also pointed out existing links with other health professionals, ongoing continuous evolution of services offered and increasing capabilities of the sector.

As a result of these attributes, it was suggested that this network of community pharmacies and skilled pharmacists represents a valuable and “irreplaceable” private infrastructure that could be further leveraged to deliver additional health care services and value to health consumers.

One submission argued that the established regulatory model and the existing ownership structure had resulted in the current network and that it still provided the best opportunity for the Government to interact constructively with the sector. They suggested this approach represented the greatest chance of achieving integration objectives.

#### **Underutilised capability in the pharmacy sector**

Without exception, pharmacy submissions indicated that the pharmacists themselves were willing to deliver additional services and believed that they could safely and effectively do so. There was a consistent theme present that pharmacists believed that they did not always operate at the top of their existing scope. Submissions stated that a number of aspects of the basic university training and skills of a pharmacist are not always fully utilised in their day-to-day roles. Underutilisation of pharmacists’ full capability was a frequent complaint in both individual and organisational submissions.

On this basis, most submissions suggested that the scope of professional pharmacist practice should be expanded to include a wider range of health care activities. For the most part, these were deemed to be “logical” extensions of existing services and probably represent incremental extension of scope rather than any major shift in scope.

A number of submissions illustrated this point with reference to the administration of influenza immunisation services. They argued that pharmacists were already experts in medicines, such as vaccines, and with only limited additional competency training could readily administer these safely.

In terms of potential benefits, it was argued that community pharmacies provide a large footprint for provision of health care in Western Australia, including, a wide coverage in rural areas. Pharmacies were offered as a suitable hub for provision of services, especially in rural areas, where it may reduce the need for additional infrastructure, and could host other health practitioners. In metropolitan areas it was suggested that a major advantage was as an accessible health destination in the community, open longer hours than most medical centres, and often being the first point of contact for patients.

## Types of additional services proposed

The additional services that individual pharmacist submissions recommended could be delivered through community pharmacies included:

- expanded immunisation services and range of vaccinations
- increased involvement in hospital discharge
- pharmacist prescribing for chronic illness (e.g. asthma, diabetes)
- increased range of medicines covered by “continued dispensing”<sup>31</sup> provisions
- supporting mental health
- health screening (for chronic disease)
- involvement in public health programs (e.g. STI management)
- health promotion activities
- monitoring and managing chronic diseases
- minor ailment clinics / services
- pain management programs
- wound care
- falls prevention
- medical research
- patient worn devices and telehealth.

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<sup>31</sup> Note: “continued dispensing” refers to a program whereby for patients already under stable treatment with certain medicines, resupply can be made, in the absence of a prescription. This is limited to the oral contraceptive pill and medicines to treat hyper-lipidaemia. There are restrictions on the quantities, frequency and repetition of this supply.

These submissions argued that these services would have measurable health benefits and save on costs to the health system. For example:

*“My pharmacy was part of the latest diabetes trial where 15% of patients tested were found to have elevated blood sugar levels. If we can catch these patients early we can save the taxpayer millions in healthcare costs. These patients were not seeing a doctor at the time.”*

## Opinions of pharmacy organisations

Pharmacy organisations endorsed the list of services outlined above, and specifically supported immunisation services, minor ailment schemes and integration in health care teams. They strongly believed that pharmacies could provide additional value to the current health system and that the State Government could “leverage” off the existing private infrastructure to the benefit of Western Australian consumers.

Extended immunisation services were proposed on the basis that pharmacists already provide some services, but the limits in place meant they were currently underutilised. It was stated that any extension would simply mirror the current scope in other comparable countries. It was argued that this would increase population coverage and thereby could further reduce the health burden of vaccine preventable diseases. Limited Australian literature suggests that pharmacist vaccination, for select vaccine types, may be safe, and that consumers immunised in pharmacies are highly satisfied. Opposition to this argument typically points to a lack of robust data to support claims that pharmacist vaccination results in a meaningful increase in overall immunisation rates across the entire population.

It was argued that minor ailment clinics in a pharmacy could replace other high cost options, such as visiting hospital emergency departments. Specifically, this was proposed for areas where access to primary care services was limited. Models in the UK and Canada were cited as evidence of successful implementation, and of cost effectiveness. One group highlighted the Supercare Pharmacy Initiative<sup>32</sup> in Victoria as a successful example. They suggested that, of the 81,000 patient visits in the Victorian initiative over 18 months of initial operation, around 30% of patients might have otherwise gone to a hospital for care.

The concept of pharmacist integration in primary care teams involves pharmacists working outside pharmacy businesses, such as in General Practice locations, to review medication prescribing and use. It was argued that this strategy would reduce preventable medication related harms and costs, such as adverse effects, drug interactions, over or under-dosing, poor adherence, medication related events (errors), and so on. Literature was cited that supports reductions in hospital admissions, costs and improved outcomes as a result of these initiatives.

It is beyond the scope of this Review to conduct a systematic review of the academic literature to quantify the benefit and safety of all extended scope professional services that could be provided by pharmacists. However, the Review is aware of a body of published material that supports pharmacist medication review services in a number of settings as having a significant effect on improving therapeutic outcomes, avoiding expensive medication related incidents and being cost effective. This evidence was also acknowledged by medical groups.

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<sup>32</sup> Note: the Supercare program involves selected pharmacies operating 24/7 and providing nursing services between 6 am and 10 pm, supported by the Victorian Government.



One pharmacy organisation argued that Government should fund services to deliver care in the places it was most needed. This submission recommended investing in models for delivery of additional, comprehensive medication reviews, as an evidence-based intervention, with delivery integrated across both acute and primary care. It was suggested that, to be successful, this strategy needed to be less about the premises medicines are supplied from and more about a focus on standards and requirements related to the professional service itself, including increased attention to staff training and accreditation.

In January 2019, the Pharmaceutical Society of Australia published a report titled *Medication Safety in Australia*.<sup>33</sup> This report outlines that 250,000 hospital admissions annually are a result of medication-related problems and that half of these are considered preventable. The cost of these admissions is placed at \$1.4 billion each year, suggesting that there is significant scope for investment in initiatives to avoid medication harms and reduce the associated health care costs.

The report stated that medication-related problems are common:

- at the time of discharge from hospital
- in residential aged care facilities
- for those taking medicines in the community.

The magnitude and nature of medicines related harm in Australia has been well described over time, since the publication of literature reviews by the Australian Commission on Safety and Quality in Health Care in 2002.<sup>34</sup>

The most recent report from the Pharmaceutical Society of Australia does not define a new phenomenon, but does illustrate that the harm and health care costs from medication-related problems are still present and might even be increasing. It clearly highlights an ongoing need for effective quality use of medicines strategies. Pharmacy organisations point to these statistics as a justification for increasing the investment in pharmacists working across the health system.

In February 2019, the Pharmaceutical Society of Australia released a report titled *Pharmacists in 2023: for patients, for our profession, for Australia's health system*.<sup>35</sup> The report lists key actions to “see the role of pharmacists optimised... as principal partners in the Quality Use of Medicines (QUM) in Australia”. The report argues that in comparison to the \$11 billion spent on medicines in Australia each year, there is insufficient spending on efforts to reduce the occurrence and severity of medicines errors.

To address this deficiency, the report calls for the embedding of pharmacists “wherever medicines are used, including pharmacists working within General Practices, residential aged care facilities and Aboriginal health services.”

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<sup>33</sup> Pharmaceutical Society of Australia 2019. *Medicine Safety: Take Care*. Canberra: PSA. Available at: <https://www.psa.org.au/wp-content/uploads/2019/01/PSA-Medicine-Safety-Report.pdf>

<sup>34</sup> Roughhead L, Semple S, Rosenfeld E, Literature Review: Medication Safety in Australia (2013). Australian Commission on Safety and Quality in Health Care, Sydney. Available at: <https://www.safetyandquality.gov.au/wp-content/uploads/2013/08/Literature-Review-Medication-Safety-in-Australia-2013.pdf>

<sup>35</sup> Pharmaceutical Society of Australia 2019. *Pharmacists in 2023: For patients, for our profession, for Australia's health system*. Canberra: PSA. Available at: <https://www.psa.org.au/wp-content/uploads/2019/02/Pharmacists-In-2023-digital.pdf>

The report makes a number of recommendations across several action areas. Those related to matters raised in this Review include:

- pharmacists being employed (“embedded”) in primary care locations, such as General Practice, aged care and Aboriginal Community Controlled Health Organisations
- a collaborative model of prescribing in partnership with medical practitioners
- expansion of vaccination services
- attention to pharmacist staffing to optimise medicine management during transitions from hospital care to the community
- allowing pharmacies to differentiate into health care hubs
- health prevention activities in mental health and drug and alcohol
- running screening and risk assessment activities
- funding models for proposed services, including fee-for-service, such as through Medicare Benefits Schedule
- rural incentives for pharmacies.

## Opinions of medical organisations

In submissions received, medical groups did support “integration and partnership”, which used pharmacist training and expertise, within their specific scope of practice.

Medical groups did not support any changes to the role of community pharmacy that was not evidence based, and argued that some changes, such as immunisation, could fragment care and jeopardise patient safety. There was an opinion that some claims for extension of scope were profit driven and beyond relevant expertise. In addition, it was suggested that any extension could lead to duplication of services, which might be confusing for consumers and wasteful of health resources.

It was accepted that pharmacists add value relating to improving medication management. For example, the current federally funded program of home medicine review<sup>36</sup> was described as valuable, evidence-based and cost effective. It was also said to be underutilised.

There was support for increased opportunity to co-locate medical practitioners and pharmacists, and allowing General Practice to lead multidisciplinary health care teams that incorporate pharmacy services. This was said to have the potential to maximise patients’ access to pharmacy services and more effectively meet the therapeutic needs of patients.

It was suggested that, although pharmacies and General Practices were linked via their respective roles in medication prescribing and dispensing, they operated in respective silos.

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<sup>36</sup> See: <http://6cpa.com.au/medication-management-programs/home-medicines-review/>

It was proposed that there are opportunities for pharmacists to be incorporated into General Practice, to work in partnership with medical practitioners to provide:

- medication safety initiatives
- drug surveillance
- identify and monitor medication use
- optimisation of therapy and achievement of treatment goals
- health literacy promotion, patient self-management and shared decision making.

Specifically, these partnerships might be directed at chronic disease and related medication management. Submissions noted research trials and/or overseas models that might provide future direction. Although additional details were often limited in the submissions, the descriptions of these models elsewhere do not normally seem to involve supply or dispensing of medicines.

It is not clear whether or not the models envisaged may involve authority to modify treatment, cease or initiate new medicines - that is aspects of prescribing. It is loosely understood that pharmacy groups hold the view that this type of integration would be of most value when pharmacists were operating at “top of scope” and would benefit from certain changes of scope related to prescribing, similar to those already outlined.

Existing medication review services typically involve an assessment of current treatment and recommendations for improvement; to add, cease, or change therapy. They include patient counselling and education on medicines, but not medicines supply services. A report based on the medication review process is usually provided to the medical practitioner, and any adjustments are first considered by that practitioner, prior to issuing any necessary prescriptions.

Medication review services are commonly conducted outside the community pharmacy, such as in residential aged care facilities or the patient’s home. There are a number of rules for these reviews when funded by the Commonwealth Government, relating to patient eligibility, how such services are provided, and a need for medical referral. There is no specific restriction under pharmacy regulation in Western Australia as to where such services can be delivered, including in a General Practice setting.

An independent pharmacist working as a consultant to provide medicines reviews does not necessarily improve integration of a community pharmacy, as the medicines supplier, with the rest of the primary health system. The provision of medicines review services, by a pharmacist specialising in this type of activity, when performed in a medical practice, while evidence based and expected to improve consumer outcomes, would not automatically improve connections with a community pharmacy.

Medical groups did support investment in technologies such as electronic prescribing that would create efficiencies and facilitate communication between sectors of the Western Australian health care system. This was similar in theme to comments made in submissions by a number of pharmacy organisations.

Electronic prescribing is certainly a necessary, and potentially long overdue objective, to improve health care sustainability. However, it is also a complex and costly goal that is regulated under a number of other federal, and State and Territory laws. For the reasons of privacy, security and Australia wide portability, it is ultimately a national concern. Implications for the Pharmaceutical Benefits Scheme are also relevant. It is noted that there are already Federal

budget measures announced in relation to e-prescribing.<sup>37</sup> In addition, there are large-scale national initiatives related to transfer of health information already established. The *Pharmacy Act* and Regulations should not be considered to have any specific enablers or barriers in relation to the introduction of this type of technology.

One health organisation observed that pharmacy was undergoing a transition from product to service focus and recognised an emerging role for pharmacists. It was noted that the Sustainable Health Review<sup>38</sup> was exploring better use of the health workforce in ways that utilise the expertise and capacity available, and recognition of professional skill sets. This submission suggested that an integrated health system requires “a collective focus on placing the person at the centre of care and delivering service in the most appropriate setting through connected multidisciplinary teams.”

The submission suggested there could be appropriate roles for pharmacists in health prevention and in multidisciplinary teams led by medical practitioners. It noted a range of current projects of this nature involving pharmacists including, health screening for stroke<sup>39</sup> in New South Wales and non-dispensing pharmacists in General Practice in Western Australia<sup>40</sup>. Specific mention was made of unmet need in rural and regional Western Australia. The My Health Record was supported as an enabler of these services.

## Consumer views

Consumer views on pharmacy are also outlined in other parts of this Report. In relation to integrated care, consumer feedback suggested a belief that:

- increased price competition had occurred and was welcome
- pharmacists were an important and valued part of the health care sector
- the sector was well regulated
- pharmacists already worked well with general practitioners
- pharmacists were often accessible when other health professionals were not
- the specific medicines advice received from pharmacists was not replicated elsewhere
- changes should be determined by asking consumers what they wanted
- changes should be driven by the health outcomes that could be achieved, not other motives.

While specific services were not directly endorsed, those acknowledged included preventative health checks, medication reviews and visiting child health nurses.

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<sup>37</sup> See: <http://www.health.gov.au/internet/budget/publishing.nsf/Content/budget2018-factsheet14.htm>

<sup>38</sup> See: <https://ww2.health.wa.gov.au/Improving-WA-Health/Sustainable-health-review>

<sup>39</sup> See: <https://www.health.nsw.gov.au/factsheets/Pages/pharmacy-health-check-program.aspx>

<sup>40</sup> See: <https://www.wapha.org.au/primary-health-networks/cpc/>

## Practitioner scope

The majority of suggestions from all types of submissions were appropriately related to pharmacist activities in respect of their relationship to the prescribing, supply, administration or improved use of medicines. This should be considered broadly consistent with the expertise and competence of pharmacists in the community setting.

The exact details of these services and the expectations of workable models for the Western Australian context were not outlined in most submissions. There was limited specific evidence provided by most individual submissions; however, examples of working practice models in other countries with comparable health systems were quoted, including in submissions from pharmacy organisations. There is international and Australian research available relating to most, if not all, of these proposed services, suggesting to the Review that they are not wholly inconsistent with the competence and functions of pharmacists in other health systems.

A number of stakeholders, including those representing consumers, suggested that the health care services offered by a pharmacy needed to reflect the needs of the local community. Specifically, it was suggested that should additional services be provided by the sector that they need not be offered uniformly across all community pharmacies. Rather, there may be room for some pharmacies to develop certain expertise or specialised services in area of practice or for delivery in a particular physical region.

A number of submissions cited existing specialised services, where a particular pharmacy had already adopted a business model that offered unique or extended types of care. For example, a comprehensive diabetes care clinic, that involves multidisciplinary collaboration, and is co-located with a pharmacy in East Victoria Park,<sup>41</sup> is one such example.

The current *Pharmacy Act* and Regulations pertain to the suitability of premises to operate as a pharmacy business. The legislation defines a pharmacy business as one that provides pharmaceutical services and related goods and services are provided. Similarly, the practice of pharmacy is defined as compounding, dispensing or supply, and advice or counsel on the effective and safe use of a medicine or drug.

This legislation is not intended to, and does not, specifically determine what a pharmacist scope of practice is restricted to. During interviews with various organisational stakeholders, most identified that the *Pharmacy Act* and Regulations did not necessarily constrain what specific services they offered.

For many of the new services suggested, stakeholders did not always identify a specific legislative barrier preventing their provision. Instead there appears to be other complex and interrelated reasons why pharmacies choose to offer certain services, or conversely, why pharmacists believed they could not pursue these options. For example, it was mentioned in interviews that pharmacists have no formal mechanism to refer a patient to another health practitioner, even where they felt they may be able to triage a problem and provide preliminary treatment advice, prior to more expert assessment.

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<sup>41</sup> See: <https://www.perthdiabetescare.com.au/>

## Considerations related to changes to scope

What constitutes the practice of pharmacy, and the scope of care that a pharmacist is considered qualified and competent to deliver, is regulated by the Pharmacy Board of Australia<sup>42</sup> under Health Practitioner Regulation National Law. The Pharmacy Board is a national authority responsible for:

- 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
- approving accreditation standards and accredited courses of study.

For example, in 2013, the Pharmacy Board advised of opinion that vaccination by pharmacists was in scope of practice of a pharmacist, acknowledging that attention was needed in relation to the competence to do so, standards and training required.

Several of the new activities suggested by the industry would require a pharmacist to be able to supply a prescription medicine without the direct involvement or direction of a medical practitioner (i.e. via a prescription). This includes prescribing for chronic illness, continued dispensing, additional immunisations, and possibly other public health programs.

Historically, the model of supply of prescription medicines in Australia is one of a medical practitioner (or dentist) making a diagnosis and prescribing a medicine, and the dispensing of the medicine being performed by the pharmacist. This separation of function and specialisation has many benefits, not least of which is the independent safety check that the pharmacist provides during dispensing.

Over time, a number of other professions have been afforded prescribing rights, within their particular professional scope and areas of expertise. This includes optometrists, podiatrists, nurse practitioners and endorsed midwives. While the legislation in each Australian jurisdiction varies to a degree, a similar pattern is seen. The rationale that changes to the traditional model of prescribing should and can occur, are commonly cited to include:

- improved quality and safety standards, including packaging and labelling of medicines
- enhanced availability and transfer of scientific medicines information for both consumers and health practitioners
- information technology and other technological supports
- changing health literacy
- barriers to timely consumer access to urgent or important treatment
- specific public need / unmet demand
- workforce shortages or limitations
- improved or advanced training and competence of different health professions
- consistency and health workforce mobility
- consumer expectations and increased mobility.

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<sup>42</sup> See: <https://www.pharmacyboard.gov.au/>



In summary, this might be viewed as improved utilisation of the health workforce, such that the health care (in this case, the medicine) can be ordered by the most appropriate practitioner, with the correct qualifications, where safe to do so, within their expertise.

## Changes to other legislation

There are continuing calls from non-medical practitioner groups for the prescribing of medicines to be extended to other professional groups, where this might reduce waste, improve efficiency and result in the same health outcomes.

Pharmacists do prescribe under various models in other comparable countries, usually with additional training and qualifications. Pharmacists frequently argue that, as medicines experts, they are well qualified and placed to prescribe in some circumstances.

For example, pharmacists already have access to the supply of a range of over-the-counter medicines that they can recommend and supply. The suggestion is that pharmacists may be able to safely deliver certain routine care, in accordance with accepted standards of practice, at potentially lower cost and more efficiently than other more specialised practitioners.

It was contended that prescribing by pharmacists can reduce the overall cost and burden for managing lesser complexity care, free up medical resources for complex care, address workforce shortages, and ultimately improve patient access to timely treatment.

A number of submissions suggested that such change was necessary for the ongoing sustainability of the Australian health care system and should be considered under the Sustainable Health Review.

Any activity that requires the prescribing or supply of a prescription medicine without the involvement of a medical practitioner (or other authorised prescriber) is currently outside the existing scope of a pharmacist. For example, the ability to prescribe medicines for the purposes of managing a chronic condition would be a matter that requires consideration by the Pharmacy Board of Australia, in relation to the requisite training, assessment of competence, and additional qualifications necessary of a pharmacist.

The National Health Practitioner Accreditation and Regulation Scheme allows practitioners to be recognised consistently across all States and Territories. This extends to acknowledgement of qualifications or credentials, scope, specialty or endorsements. This Scheme certainly applies to the advanced practice of pharmacy. Rather than establishing roles for Western Australian pharmacists that are inconsistent with other jurisdictions, advance practice is best considered to be a national concern.

In June 2018, the Pharmacy Board of Australia held a national stakeholder forum<sup>43</sup> to discuss public need and safety issues, legislative considerations, stakeholder engagement and education and training for prescribing by pharmacists. The forum engaged a “diverse group of health practitioners from within and outside the pharmacy profession”.<sup>44</sup>

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<sup>43</sup> Source: <https://www.pharmacyboard.gov.au/news/newsletters/march-2018.aspx#forum>

<sup>44</sup> Pharmacy Board of Australia. Pharmacist prescribing forum Report. 14 September 2018. Available at: <https://www.pharmacyboard.gov.au/documents/default.aspx?record=WD18%2f26421&dbid=AP&chksum=0kZRM%2bj%2baORXeyEmXOHSw%3d%3d>



The findings from the forum were published after completion of the body of this Review. The document<sup>45</sup> produced by the Pharmacy Board of Australia concluded that the forum showed support for:

- pharmacists being able to enhance the quality use of medicines through the ability to prescribe
- ongoing separation of prescribing and dispensing functions
- team-based collaborative care
- pharmacists being well placed to participate in structured prescribing arrangements under supervision, through jurisdictional legislation and policy controls
- knowledge and skills for supervised prescribing being present at initial pharmacist registration
- additional education is required for autonomous prescribing, including competency in diagnosis
- acknowledgement of current barriers including legislative, political and funding requirements
- uniformity of prescribing arrangements across States and Territories to ensure mobility of workforce and equity of access by consumers
- implementation of structured arrangements and supervised models first, followed by autonomous prescribing, as well as collaborative or team prescribing.

On 4 March 2019, the Pharmacy Board of Australia opened public consultation and released a discussion paper on this topic.<sup>46</sup> The purpose of the consultation is to further explore models of prescribing for pharmacy, to review the supporting evidence, including any gaps in evidence that may need to be addressed, and to assess the regulatory need for a registration endorsement for prescribing of scheduled medicines.<sup>47</sup>

Should matters of practice, scope accreditation and training be resolved, corresponding amendments would be required in Medicines and Poisons legislation in Western Australia.

It is noted that changes to scope of competence and authority to prescribe medicines are likely to have extremely limited practical applicability unless the users have access to Government funding, both for any service provided and for the medicines supplied. The bulk of prescription medicines supplied in the community are funded by the Commonwealth under the Pharmaceutical Benefits Scheme. Without corresponding access to the Pharmaceutical Benefits Scheme, the out-of-pocket costs to patients would represent a significant barrier to uptake by pharmacists and the level of demand received from consumers.

It must also be recognised that the historical and current separation of prescribing and dispensing, where these functions are performed by independent professional groups, provides a number of consumer benefits, including additional assurances of safety, as well as protections

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<sup>45</sup> Pharmacy Board of Australia. Pharmacist prescribing forum Report. 14 September 2018. Available at: <https://www.pharmacyboard.gov.au/documents/default.aspx?record=WD18%2f26421&dbid=AP&chksun=0kZRM%2bj%2baORXeyEmXOHSw%3d%3d>

<sup>46</sup> Pharmacy Board of Australia. Discussion Paper. 4 March 2019. Available at: <https://www.pharmacyboard.gov.au/documents/default.aspx?record=WD19%2f27950&dbid=AP&chksun=IsZCyaAVTyyUIKLuUox%2b0A%3d%3d>

<sup>47</sup> See: <https://www.pharmacyboard.gov.au/News/2019-01-09-prescribing-forum.aspx>

from some types of conflict of interest. For this reason, the concurrent prescribing and dispensing of medicines is usually not recommended as ideal by quality and safety advocates in health care. As can be seen in the Pharmacy Board of Australia consultations, this concept seems to be well accepted by the pharmacy industry itself and such separation viewed as important to retain. For this reason, any new service model or change of scope that includes prescribing for pharmacists needs to adequately address public safety in regard to this separation.

## Opinions of younger pharmacists

Interviews with representatives of early career pharmacists were conducted as part of the Review. In general, these pharmacists were optimistic about the potential of community pharmacy towards the overall health system and the additional value it could provide. These pharmacists strongly felt that their training had suitably prepared them for an enhanced role in patient care and medicines management.

Most indicated that pharmacy ownership was still a key objective of many early career pharmacists, but suggested that this was perceived as increasingly difficult to achieve, without excessive personal financial risk. They also indicated their belief that the sector should be able to provide both ownership opportunities, as well as rewarding and challenging careers in professional service fields.

Early career pharmacists felt that the future of the profession lay in what they called professional services. Broadly the term, as used here, relates to those activities related to medicines use, but not directly related to the technical task of dispensing (supplying) the product. These included screening, identifying, treating, managing and monitoring both minor, acute and major, chronic conditions.

In particular, they strongly believed that their background training was not fully utilised in existing dispensing roles and that this affected both job satisfaction and retention in the profession. This group referred the Review to a published White Paper.<sup>48</sup> The Paper has the stated intent of considering issues of “pharmacists working to their full potential” and to “correct structural and funding barriers”. The Paper is stated to be a response to early career pharmacist dissatisfaction related to:

- inadequate remuneration
- insufficient opportunities and support for career progression
- inability to innovate, develop and diversify practice
- lack of access to community pharmacy ownership.

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<sup>48</sup> Pharmaceutical Society of Australia. Early Career Pharmacist White Paper. 2017.

The White Paper recommends that the profession:

- take action to ensure a robust and sustainable community pharmacy sector
- negotiate to raise the award rates
- advocate for alternative remuneration models for pharmacy services
- identify and propose new roles and models of practice - with supported pathways to enable progression in these areas
- work with researchers, policy makers and practitioners to translate evidence into delivery of services by frontline pharmacists
- ensure productive collaboration between pharmacy organisations
- engage with consumers and other health professionals to promote the full extent of pharmacist scope, skill and expertise
- recognise all practising pharmacists as clinical pharmacists
- explore the development and recognition of specialties
- develop Quality Indicators for individual pharmacist practice.

## Funding issues

During interviews with pharmacy groups, it was noted that pharmacists already provide some of these new services, to a greater or lesser degree, and had been doing so for some time. These services are then assumed by the Review to be already in scope for pharmacists and that there are no specific barriers to their continued delivery.

For example:

- health screening, such as diabetes and cholesterol checks
- chronic disease management, including assistance with asthma plans and blood pressure measurements
- advice and assistance with minor ailments.

It was noted by some groups that historically pharmacies are remunerated predominantly through the supply of medicines, or sale of a related health product. They described business practices where any person could present to a pharmacy, without an appointment and be seen quickly.

In the case of services provided, remuneration may arise from:

- the associated, resultant sale of a product
- be absorbed as part of payment for professional service in providing a prescription
- a nominal fee being charged to the patient.

From submissions and during interviews it was clear that in many cases, a service provided would not be remunerated at all. A more recent development for pharmacies appears to be where some chains will provide this type of service under arrangements with a health insurance fund, as a member benefit.

Most submissions were quick to point out that professional services needed to be provided to accepted standards, independent of gain, and therefore should not be dependent on product sales. They highlighted that a service that did not result in a product sale or attract a fee of some kind was not sustainable for any business, but was a frequent occurrence in a pharmacy.

It was clear from the interviews and submissions that a significant barrier to the implementation of extended services was often the funding source. As noted by many pharmacists, it is not possible as a small business to absorb the costs of providing time and expertise that is not remunerated. It was also pointed out that some existing services, such as sleep apnoea and wound care, are time consuming and overall demand is lower, such that there is a need to charge a commensurate fee. Therefore, not every pharmacy may be willing to offer more complex services of this nature.

It was argued that, at present, much of the unremunerated professional services in a pharmacy are provided by cross subsidisation with the supply of prescription medicines. Changes to the Pharmaceutical Benefits Scheme, and general reduction in remuneration and margins, were cited as a significant economic pressure, which meant the traditional practice of cross subsidisation was becoming less viable.

Some submissions outlined an increasing trend where consumers may attend a “discount” pharmacy to purchase a medicine, but present at a different pharmacy, recognised as having a strong professional service based model, for follow up care or advice on that medicine. It was noted that, in these cases, there was normally no remuneration for one of these pharmacies, but consumers were usually still provided with service, on the basis of either professional obligation, or a duty of care to prevent harm. This does suggest that consumers themselves may be self-selecting on the perception of differences in expertise regarding product and service, and supports the notion that there is a divergence within the industry towards one or other business focus.

On these grounds, some submissions argued that where such service was provided that there then needed to be an appropriate Government funding mechanism. During some interviews, pharmacy groups suggested that remuneration for service, such as other practitioners can access via Medicare, was necessary for pharmacists. This is also the public position of some pharmacy organisations.

Medicines supplied in the community are funded under the Pharmaceutical Benefits Scheme, which is managed and administered by the Commonwealth Government. The Western Australian Government has no direct influence over the Pharmaceutical Benefits Scheme. Remuneration rates and structure of payments is negotiated by the Commonwealth Government with the Pharmacy Guild of Australia under five year agreements. The Agreements also contain programs that provide alternative funding mechanisms, which may not be directly related to individual cases of medicines supply, for:

- medication adherence – dose administration aids, clinical interventions, staged supply
- medication management programs – home medicines review, meds check, diabetes check, residential medication management review, community pharmacy in health care homes
- rural support programs
- Aboriginal and Torres Strait Islander specific programs
- pharmacy trial programs – diabetes screening trial, indigenous medication review service feasibility study, getting asthma under control.

The Western Australian Government does not directly fund the supply of medicines, in the manner of the Pharmaceutical Benefits Scheme, or otherwise have an existing funding mechanism to directly deliver services in community pharmacy. There are noteworthy, but limited, pockets of service funding in other States or Territories; however, these seem confined to research programs, or targeted to specific services in areas of need. It is understood that there may also be individual arrangements between local pharmacies and some public Health Services in Western Australia, such as providing medicines-related services (like dose administration aid packaging) to high risk patient groups under the outpatient care of a hospital.

The Pharmaceutical Benefits Scheme is a well-established, national framework for the supply and funding of essential medicines to Australians, based around the principles of the national Medicines Policy. The funding of medicines on the Pharmaceutical Benefits Scheme is dependent on robust assessments of evidence-based cost-effectiveness, and the scheme itself is often viewed as an international standard in this regard. There is limited logic behind Western Australia transferring existing Commonwealth expenditure under this scheme back to the State, or for the State to consider funding medicines that have already been judged to lack cost-effectiveness. During the Review, no submission or group suggested, in any way, that Western Australia should consider funding medicines supply in the community.

In most pharmacy submissions, there was an implied, or a direct call, for Government funding for associated services, on the basis that this would improve health outcomes and reduce costs either to the Commonwealth (avoided General Practice attendance) or the State (avoided hospital admissions or emergency department attendance). In some cases, such as for medicines reviews, there is good evidence of both reduced harms and avoided costs. For other services, there is at least reasonable evidence of improved safety and some clinical outcomes, but long-term results on health costs may be harder to quantify.

As outlined, the Commonwealth does maintain mechanisms to fund some services; however this is via the Community Pharmacy Agreement rather than through the standard mechanisms used for other health practitioners.

Western Australia should expect to have a viable community pharmacy sector, with well-trained practitioners, operating at the top of their scope during most of their practice. Ideally, Western Australian consumers should get maximal benefit from this workforce and greatest utility from the community pharmacy network and infrastructure. Most stakeholders seemed to believe there was role for Government in ensuring this occurred.

Noting that medicines and some pharmacy services are already nationally funded, where and how the State might consider supporting new services, to improve integration, needs to be carefully considered in relation to opportunity costs elsewhere in the Western Australian Health system.

## Regulations as an enabler

The Regulations describe minimum standards for fitness for the “safe and competent practice of pharmacy”. These stipulate requirements for:

- access to the premises by the public
- safe clear and hygienic fixture and fittings
- security devices to prevent burglary, robbery or theft
- specific equipment to be held
- reference document to be held
- consulting areas
- minimum dispensary size
- access to hot and cold water.

A pharmacy proprietor must make application to the Pharmacy Registration Board of Western Australia and receive approval before any significant alteration to the premises. The Regulations also prohibit direct entry to the pharmacy from adjoining premises.

The Pharmacy Registration Board of Western Australia does issue a limited number of guidelines, to advise owners of the Board expectations on their responsibilities, such as in relation to the safe storage of medicines.

At interview, various stakeholders were specifically asked how they believed that the *Pharmacy Act* and Regulations either impeded or promoted an integrated health care model as relates to pharmacies. Most stakeholders suggested that this piece of legislation did not specifically or directly prevent the services outlined above from being implemented. It was also noted that there was probably only a limited ability, or indeed little recognised role, for legislation alone to positively drive innovation of this nature.

Stakeholders did observe that the standards in the Regulations relating to physical requirements for premises were thought to be inflexible and were generally considered outdated. For example, it was noted that, in the case of pharmacist immunisation, the accepted professional standard was for access to an area that was private and suitable for the purposes of safely injecting and monitoring clients, but this is not referenced in the Regulations.

Similarly, at least one pharmacy organisation believed that the current standards were not sufficient to adequately describe privacy or space requirements for pharmacists when delivering professional services, especially in relation to patients with special needs. It is noted that a small number of public submissions did criticise pharmacies for having inadequate ability to manage certain matters of privacy, when questioning or counselling patients.

The current Regulations do discuss consulting rooms, but as these predate the introduction of some services in pharmacies such as immunisation, they are considered to primarily relate to the purpose of providing a private place to conduct sensitive discussions relating to medicines supply more generally. The Regulations therefore do not specifically mandate exact standards for an immunisation area, such as minimum size, equipment or safe layout. For many pharmacies the introduction of a new or additional private immunisation area did require the pharmacy to make significant alterations. In these cases, approval from the Pharmacy Registration Board of Western Australia would have been required.



There are obvious additional costs for any business to ensure that it has certain purpose designed spaces in the premises, so as to be able to provide high-quality and safe services. However, it is also self-evident that a pharmacy must have a clean, private and safe area to conduct any potentially high-risk activity such as immunisation. It was argued by some that self-regulation of standards in relation to these premises issues is possible.

However, it is also completely reasonable for a health consumer to expect that there should be minimum standards that the pharmacy must achieve and that there is the ability for an independent regulator to take action when a business (as opposed to an individual health practitioner) does not meet this standard.

It was also pointed out that not every pharmacy provides all existing types of services or would choose to enter into any new or novel service. The current Regulations apply to all pharmacies regardless of service mix.

Where a pharmacy does specialise, the Regulations do not require higher level of fittings or equipment specific to that activity, or outline what any increased requirements may need to be. For example, the Regulations outline a simple list of the most basic equipment for extemporaneous manufacturing. This list is not considered excessively onerous or costly to comply with and, conversely, is likely to be well below the required equipment of a specialist compounding pharmacy.

There are professional standards and guidelines that relate to compounding; however, these do not necessarily relate to the premises and mostly apply to the practitioner, rather than to the business itself. The Pharmacy Board of Australia does issue Guidelines on compounding of medicines<sup>49</sup> that refer to State and Territory legislation in this regard, although it might be considered that the *Pharmacy Act* and Regulations do not currently articulate as well as they could with this National Law. There were other examples provided of how future services might provide similar difficulties and inconsistencies.

The Pharmacy Registration Board of Western Australia already publishes a number of Guidelines<sup>50</sup> on various matters relevant to the environment, equipment and physical layout of a pharmacy premises. These outline the Board's interpretation of certain regulations and expectations of how these might be adequately satisfied by pharmacist proprietors.

Aspects of these Guidelines, while seeming to be appropriate as the ideal level of safety or quality required, do not appear directly enforceable by the Board. These Guidelines might then be a suitable starting point when considering any necessary regulatory amendments relating to standards.

As currently constructed, the Regulations do not allow the Pharmacy Registration Board of Western Australia to adopt or enforce external standards, such as those issued by national professional organisations. They do not allow the Board to readily issue their own mandatory standards, apply standards only where a relevant service is being provided, or to adapt standards to respond in a reasonable time frame to emerging practice changes that might have a bearing on the physical layout of pharmacy.

Some stakeholders suggested that integration could be better achieved with closer physical location between medical practices and pharmacies. Notwithstanding other ownership

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<sup>49</sup> See:

<https://www.pharmacyboard.gov.au/documents/default.aspx?record=WD15%2f16205&dbid=AP&chksum=3QInioMt0DhIOPsjaoB83A%3d%3d>

<sup>50</sup> See: <https://www.pharmacyboardwa.com.au/index.php?page=guidelines>



restrictions, there appears little reason that co-location might not be acceptable to provide consumer convenience and closer working relationships between professionals. A significant feature of the Pharmacy Regulations is adequate protection around the security against the theft and loss of medicines. The legislation should continue to regulate this in the public interest; however, it could also consider suitable adjustments to accommodate both security and co-location outcomes.

## Other health professionals providing services from a pharmacy

In interviews with other regulatory authorities around Australia, the matter of other independent health practitioners contracted to provide services within a community pharmacy was raised. This might include nurses, midwives, other registered health practitioners, and non-registered health practitioners. The Pharmacy Regulations were designed to control pharmacy practice and do not relate to other registered practitioners, who may or may not have their own professional requirements under Health Practitioner Regulation National Law. This was suggested to be an inconsistent regulatory gap.

Just as there were calls for pharmacists to provide medication review services in other settings, such as in General Practice locations, there was acknowledgement of commonly seen existing practises where a health practitioner other than a pharmacist provided services from a community pharmacy premises.

These practitioners may be registered, such as a nurse practitioner, or un-registered, such as a practitioner of complementary and alternative medicine. The exact arrangements in place appear to be varied and may be as an employee, contractor or independent business. Consumers suggested that such co-located services with access to multiple types of practitioners were useful, potentially desirable and might be encouraged.

These arrangements pose a number of questions in relation to pharmacy registration, responsibility and standards for premises. Such arrangements are permitted and are acknowledged by the Pharmacy Board of Australia, which provides a Practice Specific Guideline<sup>51</sup> on the matter. In summary, these Guidelines state that activities are expected to complement the role of the pharmacist, be provided by suitably qualified persons, and those persons are not to be involved in compounding or dispensing activities that are deemed to be the practice of pharmacy.

Where the practitioner is classed as an independent business, and is effectively using or leasing space, how any premises standards apply to this person is of interest. Who has the responsibility for the quality of these services and exact applicability of pharmacy premises standards to an independent business inside a pharmacy is somewhat unclear. For example, standards for consulting rooms might apply to the pharmacy business, but how they apply to any sub-leased space, and whether they should, was said to be less well tested.

While any registered practitioner is fully accountable for their own practice and separately regulated, the independence of these practitioners, exchange of information, privacy and other concerns were mentioned as still being very important. The obligations of un-registered health (and therefore unregulated) practitioners is also worth consideration. The consumer point of view appeared to be that quality and standards should apply across the board in a pharmacy, regardless of the practitioner, or the specific business arrangements in place.

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<sup>51</sup> Pharmacy Board of Australia. Guidelines on practice specific issues. 29015. Available at: [file:///C:/Users/he46124/Downloads/Pharmacy-Guidelines-on-practice-specific-issues%20\(1\).PDF](file:///C:/Users/he46124/Downloads/Pharmacy-Guidelines-on-practice-specific-issues%20(1).PDF)

The Pharmacy Registration Board of Western Australia indicated that, while it may have a position on the best approach to such arrangements and could offer guidance, it was not an area explicitly named in the legislation that allowed regulations to be applied.

## **Government engagement**

A number of submissions indicated a belief that pharmacists and pharmacy organisations were not always consulted and involved as a central stakeholder in primary health care matters. In particular, it was suggested that community pharmacy was not always a recognised voice when seeking to shape health policy, or in discussions about integrated approaches to health care.

There were calls for a “seat at the table” with Government and for ongoing pharmacy input to State and National initiatives that involved tackling the burden of chronic disease (e.g. asthma, mental health). There was also suggestion that community pharmacy should be included in all high level, system wide, strategic planning, as well as regional and local advisory groups and boards.

## Findings and Recommendations

Community pharmacy is seen as a valuable health network and resource, but pharmacists are not always felt to be working at top of scope. Pharmacy and pharmacist capacity is considered to be underutilised which appears to be causing a degree of dissatisfaction and frustration amongst the pharmacy workforce.

As a whole, pharmacists responded to the question of improved integration with the health care system, as being able to be solved by allowing or supporting provision of enhanced medicines-related services as part of the primary care team.

Submissions to the Review describe a sector that sees itself as capable and ready to assume new roles and provide additional value to the primary care health system. It also suggests that pharmacists do see a variety of barriers that prevent this type of innovation and development. It was evident that this is causing a significant amount of industry frustration.

### Finding 6

- The industry believes that the value of community pharmacy to the health system should be better recognised by Government.

### Recommendation 9

- The Government acknowledge that there is a potential underutilisation of pharmacies and pharmacists.

The Government should seek to work on an ongoing basis, with the industry, towards adopting policy approaches that will make best use of the sectors' specific capabilities.

Western Australian consumers are not best served by any loss of professional services that pharmacists already provide, and any industry contraction or workforce deskilling is undesirable. Throughout the Review, loss of consumer access to existing services, were suggested as a predictable result of workforce concerns, if no action occurred to better utilise available pharmacy capability.

Changes could be made to improve pharmacist utilisation that might improve efficiency of the health system. Pharmacist scope might be extended to include additional vaccinations, health screening, chronic disease management, health promotion, and other medicines-related activities. Scope extension might also include some models of prescribing. Pharmacists could offer medication management reviews and related services in collaboration with General Practices.

The services the industry recommended for support by Government were mostly related to extension of current scope and connected to medicines use, generally consistent with the existing training and skill of pharmacists, although additional training and/or competence may be required in some instances. Additional practice scope is supported to various degrees by published evidence, although a comprehensive analysis of this research was not part of the Review.

Many of the issues raised as problematic are either regulated nationally, or there is a strong argument for national consistency in any industry changes. The recommendations reflect this.

Arguments for changes to the role of Western Australian pharmacists must be considered in the proper context of needs of primary care consumers, the evidence base for safe and high quality care, and with due thought to ensure coordinated and collaborative care is maintained alongside other health practitioners.

Some changes to scope seem to be readily achievable and are “low hanging fruit”. Specifically, immunisation is one such example. At a minimum, the range of immunisations available in pharmacies should be consistent with other states. Further extension should be considered on a consistent national basis. Any requisite training or competence should also be accredited and recognised on a national basis.

Subsequent to the completion of the interim Report the issue of a nationally consistent approach to pharmacist vaccination in Australia has been endorsed by the COAG Health Council.<sup>52</sup>

## Recommendation 10

- Western Australia allow additional access to immunisation via pharmacies that is at least consistent with that already permitted in other States and Territories.

Western Australia should endorse or pursue a nationally consistent approach to pharmacist immunisation, including with respect to matters of competence, credentialing and accreditation of training.

National consistency should apply to any further extension of pharmacy immunisation.

The relevant legislation controlling a pharmacist authority to immunise should be amended accordingly.

The matter of pharmacists prescribing was a common theme and is a topical one nationally, for this and other health professions. There is certainly literature to support non-medical prescribing in various models, by a number of professions, in Australia, and overseas.

There is a justifiable rationale for non-medical prescribing; however, there are also many caveats, which should be viewed as non-negotiable, to ensuring that anyone performing this

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<sup>52</sup> See: <https://www.coaghealthcouncil.gov.au/Portals/0/CHC%20Communique%20121018.pdf>

activity is suitably qualified and regulated, practises safety and operates in scope, enhances medicines outcomes, does not fragment care and is properly integrated into the primary health care team.

The current independence between prescribing and dispensing is important to maintain, and this is a particular challenge for pharmacists, if prescribing. Limitations to the information provided to the Review prevent recommendations to be made as to the exact model(s) that should be used for pharmacists.

It is noted that prescribing is not a regulatory matter connected to the legislation that controls pharmacy businesses. As this matter is currently being explored by the Pharmacy Board of Australia, it is recommended that Western Australia support these consultation activities in principle, and continue to monitor the outcomes. Changes, as with immunisation, and where appropriate, might best be made with the greatest degree of national consistency in mind.

### Recommendation 11

- Western Australia should closely monitor national developments and discussions relating to non-medical prescribing for pharmacists.

Western Australia should participate in national discussions on models that address public need, are safe, improve outcomes, and support coordinated and integrated, patient centric care.

There was a variety of services that were suggested as being suitable for adoption by pharmacies and argued as providing improved health outcomes and better utilisation of health resources. Which areas might provide the greatest benefit or be most achievable was not necessarily answered by the material provided to the Review.

For the most part, there does not appear to be specific legislative barriers to pharmacies pursuing this type of innovation. When explored through stakeholder interviews, it was apparent that complex and inter-connected factors seem to be an impediment to change within the industry. Primarily, these barriers appear to relate to matters of practitioner scope and funding. Pharmacy organisations called on the Government to use “policy levels” to address these concerns.

Other legislation and national health practitioner regulation may require amendment for some of the changes to pharmacy practice desired by the industry to be possible. In particular, funding models were said to be a significant barrier to delivery of service from pharmacies.

It is recommended that the Government should seek to make better use of the sector; however, to do so requires an ability to determine what to pursue, in what order, and how to evaluate the success, or otherwise, of any changes. The finer details of these matters are a large body of work and beyond the ability of this Review to definitely answer.

These questions should be answered systematically, be properly informed by evidence, and guided by impartial experts. Rather than pursue small, discrete projects, as seems to be occurring elsewhere, a longer-term, larger coordinated plan is recommended. There would be

an ongoing need for such direction to be provided to Government, from time to time. At present, there is no standing mechanism that meets this description in place to guide the Western Australia Government on these matters.

It is noted that this issue is intimately connected to funding and the recommendations should be read alongside those related to where and how Government funds might be best employed.

## Recommendation 12

- The Government should establish a standing mechanism to provide it with robust, evidence based advice on the future of pharmacy services.

This should have appropriate representation from the pharmacy industry, pharmacy and other academia, consumers, and other primary health care sectors.

Any reference group established should have a remit that is about pharmacy specifically and of safe, cost effective, integrated patient centric care that provides value to consumers, improves outcomes and/or reduces cost to the Western Australian health system.

Advice received should be put into policy practice by Government, to achieve these aims.

This mechanism should be able to consider associated matters of research, funding, or other key requirements necessary to meet these objectives.

The industry clearly believes that uptake and success of any changes are dependent on health funding. As the majority of funding for medicines supply and related services in the community setting is a Commonwealth concern, this requires careful consideration as to what the State of Western Australia might support.

It is well described elsewhere that health spending continues to proportionally increase and this means that there is a need for fiscal responsibility to make the health dollar extend as far as possible. Funding new services in pharmacy may well require the redirection of spending away from other essential areas. Most arguments for spending are based on avoidance of other, greater costs elsewhere in the health system, but these costs may, or may not, belong to the State Government.

There is no logic to Western Australia funding services already provided under national schemes, taking over funding of services that are already privately funded, or promoting duplication and waste. Although submissions were non-specific as to what should be funded, there is a general sense that there are areas of need where consumers “slip through the cracks”, such as in rural areas, or during transfer from the acute setting in a hospital to a primary care setting at home. These are obvious priority areas.

These funded services could relate to medicines supply, quality use of medicines activities, health prevention or promotion, or even to services provided by other health practitioners when delivered out of a pharmacy premises.

### Recommendation 13

- Western Australia should fully support national and Commonwealth programs, including those under the Community Pharmacy Agreements, related to improving the quality use of medicines.

The Government consider establishing a mechanism to examine and make recommendations on the limited, targeted funding for health and medicines-related services, delivered from pharmacies, in high priority areas of need or demonstrated lack of access.

The Government should advocate or provide support for extension of, or more rational application of, national funding programs for quality use of medicines and pharmacy services, to meet any areas of need in Western Australia, that are not adequately met under existing arrangements.

At least some submissions suggested that the way forward for pharmacy was in education, training, credentialing and research. It was suggested that this was where any Government was best directing its efforts, including in relation to any funding. The Review considers that it is important this be designed to speed the translation of completed research into services and practices that will benefit consumers.

Recommendations 12 and 13, and finding 7, involve the establishment of mechanisms to advise the Minister on relevant pharmacy policy matters.

As envisaged by the Review, any advisory body appointed as part of this mechanism would be charged with considering the best utilisation of pharmacists and pharmacies, maximising consumer value delivered by the sector, and the sustainability of community pharmacies. It is obvious that as for all industries, there are potential conflicts of interest between such policy decisions and possible gains for an individual, commercial entity, or particular sector of the industry. These conflicts should be acknowledged and addressed, to ensure that the resultant advice is truly in the best interests of health consumers.

The composition of an advisory body is then expected to be something that generates strong opinions from both pharmacy and non-pharmacy stakeholders. It is accepted that any advisory body must, by nature, have suitable pharmacy expertise. Peak pharmacy groups have already indicated expectations of adequate representation on an advisory body of this type.

For this reason, the objectives and membership of any constituted group with a remit of advising Government requires careful consideration. The Review has not made specific suggestions about how this body might be composed or how it should operate, as these issues are best explored at a time after the recommendations have been accepted, or otherwise.



## Finding 7

- The Government should support local programs of research and workforce development that would drive innovation and excellence in pharmacy in Western Australia.

An appropriate mechanism should be considered for achieving these objectives, which may include advising the Government on potential priority areas for grants and funding, and improving connections of the sector with existing research and development programs and activities.

There are a number of perceived barriers to implementing changes to services offered; however, the *Pharmacy Act* and Regulations may have only a limited role in promoting the desired change. The Pharmacy Regulations could be amended to improve flexibility and responsiveness with respect to standards for premises to better accommodate changing pharmacy practice.

Any changes to professional services that pharmacists offer would have a link to any requirements of the premises they are provided from. The *Pharmacy Act* and Regulations do mandate standards relating to a pharmacy premises and these appear to require an urgent update.

These standards need to be suitably flexible to account for the different business operations that can vary between pharmacies. They should be able to accommodate new requirements that may be necessary for new services such as immunisation. They must also be able to adequately address any requirements of other independent health practitioners operating within a pharmacy.

This is considered a reasonably complex program of regulatory reform. Suitable advice is required on the most appropriate and contemporary legislative approach to achieving this objective, on the development of the standards themselves, and the exact impact on the industry.

## Recommendation 14

- That there is consultation over revision of the existing standards for premises, including any required impact assessments.
- That as matter of urgency the existing standards in the Regulations are updated accordingly.

That new standards be considered, as above, where appropriate based on new types of services provided at a pharmacy and any minimum requirements for the premises, fixtures, fittings or other equipment, deemed necessary for public protection, that are not adequately regulated by any other authority.

It is recommended that regulatory amendments be explored to allow:

- ability to use multiple standards and apply these where applicable, rather than as “one size fits all”
- flexible development, adoption and update of any standards
- referral to, or adoption of, guidelines issued by another recognised, competent authority or body.

Standards be considered, where necessary, for introduction to allow and support other health practitioners operating within a pharmacy, but to ensure this does not result in a different or lesser standard applying, in respect of the pharmacy premises in any way.

Pharmacy Regulations currently prohibit the direct access of a pharmacy to any adjoining premises. The practical effect of this restriction is to require that pharmacies are completely physically separate, enclosed businesses. Beyond this, there appears to be limited regulation to restrict the exact location where a pharmacy might be physically situated, relative to any other type of business or building.

It was suggested to the Review that integration could be better achieved via co-location of medical practices and pharmacies. This included mention that some regulations relating to physical connections between these businesses may be overly restrictive. The Review considers that this type of change might be considered, so long as there is no reduction in the overall security of the medicines stored and supplied by the pharmacy premises.

In considering whether any relaxation is possible and might lead to any particular unwanted results, the Review does make clear recommendations that ownership restrictions should remain, that non-interference provisions should be enhanced, and that relevant standards for pharmacy premises should not only continue to apply, but be updated and made more relevant.

It is also noted that all existing Medicines and Poisons laws in Western Australia would continue to apply, regardless of any changes to premises regulations. Nothing within this existing regulatory scheme authorises any person other than a pharmacist, including a landlord, agent, or other health practitioner, to have any access to medicines in any pharmacy premises.

Recommendations in this area were not necessarily supported by pharmacy organisations. They suggested that many pharmacies were already located in close proximity to medical practices or multidisciplinary health centres. Overall, they believed that if a pharmacy was physically located within another business there was generally only a limited expected gain in convenience for consumers, but in contrast, there would be a very real potential for reduced security and interference in the operation of the pharmacy by the other business entity.

### Recommendation 15

- The Pharmacy Registration Board of Western Australia consider whether suitable standards could be practically implemented, that might support co-location of a pharmacy, with a medical practice, while maintaining ongoing business separation and appropriate protections, to ensure the established and expected level of security for medicines held.

Dependent on the feasibility of implementing and enforcing such a standard, that Regulatory amendments to permit these changes be considered, as necessary.

The industry views itself as not being always included in policy decisions relating to primary care. It was suggested that there is no mechanism for pharmacy to engage with Government on problems within, and plans for, the sector. This concern may also be partly addressed by other recommendations in this section regarding ongoing advice to Government on services, funding and research in the sector.

### Finding 8

- The pharmacy sector should be recognised in health policy, acknowledged and included in any forum providing policy advice to Government on medicines or related activities in the primary care sector.

## 4. What changes, if any, could the WA Government make to see the pharmacy role in the Western Australian health system protected?

### Reviews of the pharmacy sector

Several submissions highlighted that there had been a number of different reviews conducted relating to community pharmacy. This is likely to refer to national reviews commissioned by the Commonwealth Government as well as published reports from bodies in relation to competition. It is noted that there have also been State and Territory reviews of the pharmacy sector.

These submissions suggested that, as a result, the sector felt under constant review, and there was a degree of stress amongst pharmacists. In particular, it was said that these reviews encourage uncertainty, which negatively affects business investment. These submissions called for retention of existing rules and for the legislation to provide improved long-term certainty to allow pharmacists to have increased confidence over current and future business investments.

### Efficiency and operation of the pharmacy registration scheme

A key focus of the Pharmacy Registration Board of Western Australia is in regard to its own performance as a regulator and in service responsiveness.

The Pharmacy Registration Board of Western Australia noted increased workload and pressure to provide rapid decisions to applications for registration. This was believed to be at least partly due to business and commercial pressures being applied to the applicants themselves. For example, corporate landlords in large retail centres could require changes to premises or movement of the business to a new location within a short time frame, without being cognisant that such changes first required regulatory approval.

The registration statistics for the financial year 2016-17 for the Board included:

- new pharmacies 29
- change of ownership 60
- alterations and additions 46
- change of name 72
- relocation 11

The Board was mindful of these pressures and has an internal philosophy of responsive service to the pharmacies it regulates. It was stated that over time the Board had made a number of changes to continue to maintain performance in administering registration requests, in a competent and timely manner. For example, decisions must be made by the Board at meetings conducted monthly. To meet demand, Board meetings were now often more frequent. Further improvements were said to be achievable, but were dependent on matters such as, Board member availability, remuneration of Board members, administrative resources and new IT systems for applications.

The Board provided the following registration statistics of the average time (during the ongoing operations of the Board) to process and approve registrations:

- new applications 88 days
- premises alterations 220 days
- relocation of pharmacy 93 days
- change in ownership 45 days

These time frames appear lengthy, but are noted to represent the total time taken for the entire process; that is, not just the time for a decision by the board, but also for all further correspondence and engagement with the applicant to be concluded. As most cases involve significant additional work in preparation, the time frames include the acts of seeking and receiving additional information, correspondence to and from the applicant, and any information that may be required to be provided by other authorities. In addition, the figure for premises alterations includes the time for the physical changes to the premises to occur.

It was also reported that the applications themselves and ownership structures heavily dictated the decision making process. The Board noted that many applications required additional information and there was a significant role for the secretariat to support applicants through the application process.

In addition, as the ownership structure increased in complexity, so did the complexity of any application for registration, as well as the resultant process of review and decision making applied by the Board. It was suggested that a decision could not reasonably be made unless all necessary documents and information was provided at least 10 days prior to a meeting, for simple applications, and 20 days, if complex.

## Fees and charges for registration

The Board noted that it was required to meet its statutory remit and it needed to do so based on available resources. The revenue of the Board is entirely derived from monies received as a result of pharmacy registrations. The schedule of fees is fixed, and the total number of pharmacies in Western Australia is relatively stable. Current registration fees include:

- new business,  
relocating existing business,  
change of owner of existing business \$850
- annual renewal of registration \$650
- alterations/extension to premises \$500
- change of pharmacy name \$30

Registration fees for pharmacies are set as part of regulation and, therefore, any changes require amendment of the Pharmacy Regulations 2010. These fees were last amended in 2012. Current fees are not large and, for the size and turnover of most pharmacy business, should be considered more than reasonable. A comparison of fees in other jurisdictions is provided at [Appendix 4](#). Western Australian fees are higher than other jurisdictions, but do need to be contrasted with the total number of pharmacies registered in that State or Territory.

The annual income of the Board in 2017 was around \$520,000; comprised of \$401,000 in licence fees and \$111,000 in application fees. The income of the Board is then relatively fixed and for a regulator should be viewed as low. Income for the Board was around one fifth that of the corresponding regulator in the largest Australian jurisdiction. Two thirds of Board expenses are related to secretarial and administrative functions.

The issue of the Board having sufficient resources to achieve its aims and to adequately ensure regulatory compliance was strongly endorsed by both pharmacy groups and individual submissions. There was a view that fees needed to be adequate for the Board to carry out its business effectively and that those fees should appropriately reflect any costs of adequately protecting the public. However, the financial pressure currently faced by community pharmacies in Western Australia was also raised; any increase in registration fee, even if small, is still an additional business cost, and therefore needs to be justified.

The Pharmacy Registration Board of Western Australia recorded a small loss in the 2016-2017 financial year and believes it may continue to do so in future years. This was due to a significant increase in legal fees. In addition, the operating costs of the Board have been increasing due to the growing complexity of pharmacy ownership structures, and time needed to ensure that there are no proprietary interests involved in any application, which may not be compliant with the Act.

The current application fee for registration of a pharmacy business is the same for all applicants. The Board provided a suggested new schedule of fees with amendments for the type of registration, the service offered and with updated costs, proportional to the workload involved.

There was an argument made that applications which involved complex ownership structures utilised far more time and resources of the Board, which was not adequately covered by the standard fee. The additional workload required for these applications is increasing. As a result, it was felt that a differential fee structure may be more appropriate, where a user pays model was applied to those applications that required additional diligence and care. This was argued as consistent with fee structures of some other State and Territory regulatory authorities.

The Board has recommended:

- increases of all fees by 8.5% (Perth CPI since 2012)
- a variable fee structure commensurate with the complexity of the application.

The full list of proposed fees can be found in [Appendix 6](#).

## **Resources and capability of Pharmacy Registration Board of Western Australia**

Many submissions felt strongly that both the intent and letter of the law needed to be upheld. These submissions also supported the concept that the body charged with administering the legislation needed to be capable in practice of strictly enforcing the legislation. It was suggested that the Pharmacy Registration Board of Western Australia required the appropriate tools to achieve this imperative.

Submissions indicated that the Board was perceived as not always being able to uphold the legislation, as it did not have sufficient resources. It was suggested that the Board could do more in the areas of:

- more thorough analysis complex pharmacy business registration applications to ensure ownership structures and all other business arrangements are compliant with the legislation
- undertaking ongoing monitoring/auditing of ownership structures and business arrangements to ensure they continued to be compliant with the legislation after a pharmacy business has been registered
- investigating suspicious commercial arrangements.

The Board suggested it had limited resources to monitor ongoing compliance with proprietor requirements of the Regulations. Persons who intend to acquire or dispose of any proprietary interest in a pharmacy business are required to notify the Board. Information on any changes to the directors of a company, or the trustees or beneficiaries of a trust, are requested in the annual registration renewal.

Ongoing monitoring of compliance with pharmacy ownership regulations could be undertaken, with adequate staffing; however, the Board suggests this could still be challenging. For companies, changes to shareholders and directors can be tracked via ASIC. For trusts, changes to trustees and beneficiaries could be monitored through obtaining pharmacy businesses financials and tax returns on a periodic basis; however, this process would be very resource intensive. These monitoring activities would be an additional cost to the Board and would require funding.

## Changes to registration processes

Interviews with pharmacy groups and other State and Territory regulators provided the Review with the impression that the Pharmacy Registration Board of Western Australia was well regarded and generally viewed as having an approach of diligently enforcing the legislation, as written, in regard to pharmacy registration.

It was suggested that this reputation may in part be due to the specific background of the secretariat staff, and the fact that certain expertise was available to the Board due to administrative functions being provided by a firm with accounting credentials. There was an implied competence in dealing with financial and contractual documents and belief that this led to a strong focus in such matters when assessing applications submitted to the Board.

The Board provided general examples of complex ownership structures, including trusts and partnerships. In some cases, there were a large number of parties involved in these structures that needed to be considered.

Specific mention was made of arrangements and agreements between the owner or ownership structure and another party. In particular, buying groups and banner groups were mentioned. The Board provided an opinion that some agreements had the potential to remove or constrain control over the business, such that it could be argued that there was proprietary interest by another party. The Board believed that these agreements were not always recognised as relevant by the applicant and such information was not provided as part of applications for assessment. The Board would ask for copies of such documents, where it was believed that these were relevant.



Furthermore, the Board felt that although these arrangements were not always transparent, they did not necessarily have legislative powers to direct that such documents were produced for inspection. The Board can require a pharmacist to appear before the Board. Ultimately, if not fully satisfied that the application satisfies the requirements of the Regulations, the Board would be obliged to refuse to register a pharmacy. Regardless, the Board suggested that, in their opinion, this was not always sufficient, and additional powers to compel provision of information are necessary to protect against manipulation of ownership rules.

The pharmacy business registration process in Western Australia was considered by many to be among the most comprehensive, if not the most comprehensive, of any of the States and Territories. The process involves the review of a range of commercial information and documents, as well as a number of checks to enable the Board to make a decision as to whether the application complies with the requirements of the Act.

Due to the complex nature of many of the commercial documents that are required to be reviewed as part of the pharmacy registration process, some registration bodies have needed to seek outside legal or accounting advice in order to be able to determine compliance with the legislation. To date, the need for this in WA has been somewhat minimised due to the background of the registrar in forensic accounting.

Nonetheless, to ensure the intent of the legislation is upheld, a number of changes were suggested to both the initial pharmacy business registration process and the ongoing monitoring of compliance with the pharmacy ownership regulations.

With respect to the initial pharmacy business registration process, suggestions included:

- requiring applicants to sign a statutory declaration attesting that commercial arrangements satisfy the requirements of the Act
- the referral of commercial documentation to a lawyer for assessment where the Board is not satisfied that it complies with the legislation, with the applicant required to pay an additional fee to cover this cost.

With respect to ongoing monitoring of compliance, suggestions included:

- implementation of an ongoing review process of pharmacy ownership structures for registered pharmacy businesses to ascertain if they continue to comply with the legislations.

## Composition and operation of the Board

The composition of the Pharmacy Registration Board of Western Australia is set out in the *Pharmacy Act 2010*. The Board has four members appointed by the Minister for Health. Three members must be pharmacists and one must be a consumer representative. The members are appointed as individuals and not representative of any specific organisation.

The Board suggests that, for the duration of its life, it has had a collegial approach and the independence of members is important to deliberations. It was noted that decisions require a breadth and depth of experience in “pharmacy management, service provision and community engagement”.

There was concern expressed that the small size of the Board posed significant risks for continuity, corporate memory and consistency of decisions, should any number of members cease to be appointed.

The size of the Board posed difficulties in managing meetings and ensuring a quorum. Limited flexibility meant the Board could struggle with the rigid deliverables in relation to decisions required each month. The simple solution proposed was a minor increase in the number of Board members.

The Board also noted that the workload and time imposition on Board members has increased. There is a remuneration schedule for members, which has not been updated, and is currently set at:

- presiding member                      \$350 per meeting
- other member                              \$250 per meeting.

It is suggested by the Board that these are no longer commensurate with the time involved and do not adequately cover the costs of the members. It was recommended that these be updated and raised.

### Specific circumstances of registration

The Board highlighted experience with specific circumstances relating to the registration of pharmacy that were not currently addressed by the existing legislation. These related to real events, which although infrequent, could not be adequately managed within the law, without undue disruption to the business or consumers.

One concern is the issue of suspension or deregistration as a pharmacist. The Board noted that, in at least one case, it was not notified of change of registration status of an owner, which disqualified the person under the *Pharmacy Act*, for many weeks. The Board argued that there should be a statutory requirement for the owner to provide such information within a reasonable time frame (suggested as not more than two days).

It is noted that any other regulatory agency taking such action, such as the Pharmacy Board of Australia, should ideally be able to provide the Pharmacy Registration Board of Western Australia with this information, where relevant to the ongoing qualification of a pharmacy owner.

In these cases, there also needs to be adequate interim provisions to account for the continued operation of the pharmacy, to prevent disruption of essential services to the community (for example, in a rural setting), and allow the lawful transition of the business. The Board noted similar issues with respect to death or bankruptcy of a proprietor. The legislation does have provision for cases of an owner's death, but not for loss of professional registration. In such cases the Board advised it had no lawful option but to cancel registration of the pharmacy.

### Enforcement of existing legislation

A perception that existing pharmacy ownership regulations are being exploited, was highlighted through both public submissions and interviews with stakeholder organisations.

There appeared to be a widely held belief within the pharmacy sector that the intent of the legislation is not always being upheld. The Review has not found or been provided any direct evidence that this is the case. There is no suggestion by the Review, that if this has occurred, it is due to any omission or lack of diligence by the Pharmacy Registration Board of Western Australia.

Nonetheless, given that many submissions have felt this way, this provides strong support for improvements to pharmacy business registration processes, as well as changes to give the Pharmacy Registration Board of Western Australia greater resources and increased powers to enforce the existing legislation. This includes greater penalties for anyone found to be functioning outside the legislation.

## Powers and penalties

The Pharmacy Registration Board of Western Australia noted that it has yet to issue a monetary penalty during its time of operation. Ultimately, the most severe penalty the Board might consider is the refusal of registration or the termination of registration, which would prevent operation of the business. However, the closure of any pharmacy would be particularly disruptive for the patients reliant on that pharmacy's services and it should then be considered that this course of action is highly undesirable and be reserved as a final resort only.

It was argued that monetary penalties for an offence may then be more appropriate, but they do need to be of sufficient magnitude to act as an adequate deterrent. The Board suggested that the current monetary penalties were small, and for a moderate size business, did not represent any substantial disincentive. It was recommended that the penalties in the legislation be increased several fold.

This viewpoint was supported in a number of independent submissions from pharmacists themselves, who felt that any penalty was insufficient to represent a barrier to deliberately breaching the legislation.

In order to give the Board greater authority to investigate and enforce the legislation, a number of amendments were suggested. Those proposed by the current regulator, on the basis of their experiences with problematic cases, included:

- making it an offence not to provide information to the Board relating to ownership of, or a pecuniary interest in, a pharmacy business
- provisions for the Board to require an individual to attend before the Board in relation to any aspect of the Act or Regulations (not just in relation to a registration application)
- authority for the Board to demand production of any and all information or documentation (including financial information), which may not unreasonably be withheld in respect of each application, to determine whether a proprietary interest is held or there is a possibility of undue influence
- that all changes to ownership / proprietary interest, either directly or indirectly must be advised to the Board, within a timeframe suitable for the Board to consider them (at least ten business days before the next Board meeting was proposed).

Most other submissions that supported these changes were non-specific as to the exact provisions necessary, but were generally consistent with the intent of the recommendations put forward by the Board. Exactly how achievable the broader industry feels these recommendations are, in practice, is uncertain.

The matter of undue influence has been outlined in other sections of this Report. There was a common opinion that an individual or entity that is exercising, directly or indirectly, undue influence on a pharmacy business, should be taken as having a proprietary interest in a pharmacy business.

The Board acknowledged that, in some other jurisdictions, legislation dealt with the concept of undue influence exerted over a proprietor in respect of the practice of pharmacist within that business.

By way of example, the *Pharmacy Regulations Act 2010 (VIC)* were suggested to be a potentially suitable template for adoption in Western Australia. The Victorian legislation includes under the definition of undue influence:

- a) the right to control the manner in which the pharmacy business is carried on; or*
- b) the right of access to books of accounts or records kept in respect of that business, otherwise than for the purpose of determining whether or not the conditions of the relevant document are being complied with; or*
- c) the right to receive any consideration that varies according to the profits or takings in respect of the business.*

## **Profile of the Board**

There was mention by some submissions of a perceived lack of awareness of the legislation, the Board or standards that relate to pharmacy premises. It was proposed that the Board might increase promotional activities to pharmacists to improve compliance.

The Board itself indicated a belief that there was reasonable awareness amongst pharmacies of the regulatory scheme and the Board. They said this was due to the program of audit and inspection, as well as interactions conducted as part of the pharmacy registration process.

It might be argued that registration of a pharmacy is not a common event, and that it is up to proprietors specifically to comply with the legislation, rather than every pharmacist. The Review does not consider it an onerous expectation that a pharmacist would have a working knowledge of the legislation or be able to readily access the necessary information, in relation to running or owning a pharmacy business.

## Other amendments

A number of other potential legislative amendments and their rationale have been outlined in other sections of this Report. Those proposed in submissions include:

- requirements for the proprietor and pharmacist with overall responsibility to be resident in Western Australia
- minimum requirements for attendance within any set period of proprietors and pharmacists with overall responsibility
- requirements for proprietors to be practising
- ability to adopt and issue multiple standards, that can be applied as appropriate to the specific activities conducted by the business
- standards for other health practitioner businesses conducted within a registered pharmacy premises
- standardisation of the number that can be owned in each State and Territory
- harmonisation of State and Territory legislation.

## Findings and Recommendations

There appeared to be a certain amount of frustration and fatigue amongst the industry in relation to continued reviews of the sector. It does appear that over time the issue of pharmacy regulation has been repeatedly considered both nationally, and by some States and Territories, with little significant change as a result. The sector desires more business certainty.

### Finding 9

- To provide greater business certainty for pharmacy proprietors, the Government should acknowledge a need for stability in relation to regulation of pharmacy.

There is an increasing workload for the Pharmacy Registration Board of Western Australia and registration fees are outdated and do not cover the actual costs of administering the legislation.

There are an increasing number of pharmacies registered in Western Australia and the registration of these pharmacies is increasing in complexity. The workload of the regulatory authority has been proportionally increased. To meet requirements of the legislation and to provide adequate service to those regulated the regulatory authority needs to be suitably resourced. The authority is currently self-funded from registration fees, but these have not kept pace with associated costs.

### Recommendation 16

- The registration fees should be amended, as soon as possible, by the amount needed to properly reflect the current costs of the Pharmacy Registration Board of Western Australia in processing registration applications.

All registration fees and charges should be indexed regularly to meet costs and prevent large price rises.

The fees and charges structures should be revisited regularly and the adequacy of the income received be considered in respect of the overall financial condition of the Pharmacy Registration Board of Western Australia, and its ongoing ability to fully meet obligations to register pharmacies, monitor compliance and enforce regulation.

The registration process in Western Australia is comprehensive and rigorous; however, complex ownership structures require particular attention to ensure compliance with provisions related to proprietary interests. Fee structures do not currently reflect the differences between simple and complex registrations.

With a more complex ownership structure involved in the registration of a pharmacy it appears to be harder for the regulatory authority to evaluate compliance with the legislation as relates to proprietary interests. There was a clear indication from the industry that a “level playing field” was expected and necessary, and that the regulatory authority should continue to consistently and fully apply restrictions relating to proprietary interests.

To do so, and meet the letter and spirit of the legislation, some types of applications should be acknowledged as more complex and requiring additional scrutiny. Amendments to allow for a more robust review, as suggested in these cases, are endorsed by the Review. Registration processes could be enhanced by allowing referral for additional scrutiny where applications may not meet proprietary rules.

### Recommendation 17

- The legislation should support the ability of the Pharmacy Registration Board of Western Australia to define a type of application as complex, by nature of the ownership vehicle used.

For complex applications there should be additional scrutiny to ensure that there are no features involved that are not in compliance with the legislation, or constitute a proprietary interest by another party.

The Board requires the ability to refer complex applications for additional legal or accounting opinion, as necessary. This should be at the cost of the applicant.

The Board should develop appropriate instructions, advice, supporting information, forms, etc., to explain and guide pharmacists with respect to complex applications, proprietary interests and meeting requirements for registration in these cases.

The standard fees and charges for a complex application for registration should be proportionally higher than a simple application. These should meet the true cost of the work involved in assessing this type of application.

Amendments to the schedule of fees and charges should be made to account for complex applications.

In this, and other sections of this Report, the notion of proprietary interests that fall outside of direct ownership of a pharmacy are discussed. Although the Review was not informed of specific non-compliant arrangements, there was a strong perception that these may exist, despite the acknowledged current diligence of the regulatory authority. Complex ownership structures are by nature less transparent, and there also appears to be a need to protect



against other arrangements and agreements that may place some aspects of proprietary control with another party.

The regulating authority suggested that it could only base decisions on compliance with the legislation on the materials provided to it by the applicant. If information or documents relating to a potential proprietary interest were not fully and transparently provided, then a positive decision might result for a non-compliant business. To regulate effectively, and to make a correct decision, the regulatory authority requires the tools to require provision of such information.

The regulator requires adequate powers to be able to request information and deal with other matters of suspected non-compliance with the Regulations.

Similarly, withholding information should be considered unacceptable, as should provision of deliberately misleading information. The authority should be able to access the information it requires, at registration, or at any time an ownership structure changes, or where non-compliance is reasonably suspected.

### **Recommendation 18**

- It is recommended that legislative amendments are considered that will provide the Pharmacy Registration Board of Western Australia adequate powers to compel provision of any information or documents relevant to a proprietary interest in a pharmacy.

Amendments should include suitable offences and penalties for omission, withholding or misleading conduct related to these provisions.

The regulating authority is small, has constrained resources, and as noted, is increasingly busy. It does conduct an audit program to ensure compliance with standards, but acknowledges that it does not have capacity to monitor all parts of the legislation, all of the time. This limitation applies to audits of registered pharmacies for continuing compliance with ownership rules, after initial registration. The onus should always be on the proprietor to inform the Board of any major changes that could affect the registration of the pharmacy.

### **Finding 10**

- The Board should conduct a suitable number of post-registration audits and reviews each year to determine ongoing compliance with the requirements of the legislation.

## Recommendation 19

- The legislation should be amended to require a proprietor to advise the Board of all changes to ownership or proprietary interests within a reasonable time.
- The Board should be able to require any individual attend before it to provide evidence on matters of registration, proprietary interest or any other aspect of the legislation as relates to a pharmacy.

Current provisions in the legislation should be expanded to accommodate these needs.

The Board structure is not ideal and requires review, including numbers and remuneration of members.

The Board is comprised of only four members and has a quorum of three. This existing make-up appears to be less workable as the pressures on the Board increase. It is entirely reasonable to update the Board to meet current and future demands.

As the composition of the Board is laid out in legislation, this requires amendment. Remuneration of the members and other matters related to efficiency and flexibility of the Board should be addressed for current needs. These changes should be considered urgent.

Pharmacies are businesses with financial obligations, there should not be any unreasonable delays to receiving a decision on a registration application. The Pharmacy Registration Board of Western Australia is acutely cognisant of the pressures on pharmacy businesses and aims to provide a responsive and prompt level of service in regard to registration.

However, the quality of registration decisions should not be compromised by registrations provided without due time for consideration, and external time pressures on a pharmacy business, should not be allowed to interfere with decisions made on registration. It is strongly recommended that the Board should not lower any of its current standards in relation to assessing applications.

Ideally, the Board would establish achievable performance standards for its administrative functions, which allow for robust decisions and provide a level of visible certainty of time frames for pharmacies when applying for registration.

## Recommendation 20

- The legislation should be urgently amended to:
  - increase the membership of the Board to be at least five members
  - include new members with a suitable knowledge or experience of pharmacy and / or public interest
  - retain a suitable and achievable quorum for Board meetings.

The remuneration of Board members should be updated to adequately compensate for the expected duties, based on the provisions of the legislation.

The Board should establish and promulgate administrative guidelines on time frames for pharmacist proprietors to meet when applying for registration or other matters, and in relation to receiving a decision.

There is concern over undue influence over pharmacy proprietors and, at present, the legislation does not explicitly address this matter.

There is at least some evidence that pharmacies may come under pressure from other parties to make decisions relating to pharmacy practice. The fact that these pressures may relate to the storage or supply of medicines and could impede the ability of a pharmacist to independently meet legal and ethical obligations is a serious concern.

Pharmacists felt that protection from such interference was warranted and the regulator also supported provisions to explicitly clarify what should be considered to be an unacceptable influence. There is precedent for this in other jurisdictions. The Review considers that it should be a minimum expectation that the proprietor operates independently in all decisions on practice, or meeting standards and legislative requirements.

## Recommendation 21

- The legislation should be amended to include suitable “undue influence” clauses.

Provisions in other equivalent legislation on other States and Territories could act as a suitable template.

The current penalties for non-compliance with the legislation are not large, and are not considered a particular disincentive, especially for a moderate size business. Outside of

deregistration, or imposition of conditions on registration, there is a need for an alternative penalty that is reasonable, proportional and acts as an effective deterrent.

### Recommendation 22

- Penalties in the legislation should be reviewed and increased.

This increase should be an amount that is a suitable monetary disincentive for this type of business and in proportion to other equivalent pieces of contemporary Western Australian legislation.

The legislation is constructed to deal with certain matters where the continuity of ownership is broken, for example the death of a sole proprietor. In such cases, the ownership of a pharmacy needs a suitable period from lawful transfer to occur. It is in the public interest that the pharmacy might continue to service the community supplying essential medicines for a limited period (when safely under the oversight of another suitable and responsible pharmacist), until this transfer can be achieved.

In the case of a proprietor no longer being registered as a pharmacist, or having personal conditions on registration that may preclude ownership, there are no provisions to manage this transfer of ownership. It is noted that almost any concern with practitioner registration, for example misconduct in relation to medicines supply, may have a significant bearing on whether the pharmacist remains a fit and proper person to be a proprietor.

### Recommendation 23

- The legislation should be amended to require a proprietor to immediately inform the Board of any condition or change in registration, or any other legislated professional authority to handle medicines, relevant to the ownership of a pharmacy.
- The legislation should be amended to provide for situations of de-registration (or similar) where ownership must be transferred, similar to those already in place for the death of a proprietor.

The amendments should allow for interim arrangements in such cases, to permit ongoing medicines supply, under the care of an appointed responsible pharmacist, so as to prevent disruption to the community.



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

# Review of Community Pharmacy Ownership in Western Australia Discussion Paper

October 2017

## Contents

<a href="#">Foreword</a>	105
<a href="#">The pharmacy sector</a>	106
<a href="#">Regulation of pharmacy</a>	106
<a href="#">History of pharmacy regulation</a>	106
<a href="#">Why regulate pharmacies?</a>	107
<a href="#">Current regulation of pharmacies</a>	108
<a href="#">Registration of pharmacy businesses in Western Australia</a>	108
<a href="#">Pharmacy regulation in other States and Territories</a>	109
<a href="#">Location rules</a>	110
<a href="#">Current issues</a>	110
<a href="#">Consultation for the Review</a>	111
<a href="#">Consultation questions</a>	111
<a href="#">Making a submission</a>	111
<a href="#">Pharmacy regulation around Australia</a>	112
<a href="#">References</a>	114

## 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 health care 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 focused 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.<sup>1</sup> 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.<sup>2</sup>

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.<sup>3</sup> The sector employs over 60,000 people nationally.<sup>4</sup> As at July 2017, there were 633 registered pharmacies in WA<sup>5</sup>, or about 11% of the national total.<sup>3</sup>

## 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* and 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.<sup>7</sup> 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.<sup>8</sup>

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 to be little dispute that individual pharmacists should be appropriately qualified and meet minimum standards of competency.

Medicines are not seen to be ordinary items of commerce<sup>6</sup> 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 a 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 Australian 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.<sup>9</sup>

### **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 Review<sup>6</sup> 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.”*<sup>3</sup>

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:

**[communitypharmacyownershippreview@health.wa.gov.au](mailto:communitypharmacyownershippreview@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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## APPENDIX 2: Application requirements for pharmacy registration around Australia

Information required	WA	VIC	NSW	ACT	NT	QLD*	SA	TAS
Plans	✓	✓	✓	✓	✓		✓	✓
Bill of sale over any fittings or equipment	✓							
Lease	✓		✓					✓
Security interests documentation	✓							
Finance/guarantee documentation	✓		✓					
Partnership agreement/company constitution or memorandum of articles/trust deed	✓	✓	✓	✓	✓	✓	✓	✓
ASIC business name registration	✓		✓		✓			
ASIC company extract	✓	✓	✓	✓	✓	✓		
Australian Business Number Registration					✓			
Franchise/banner group agreement	✓	✓	✓					✓
Service agreement	✓	✓	✓					✓
Sale agreement	✓							
Evidence to support relationship to beneficiaries declared to be close relatives				✓		✓		
Proof of identification		✓		✓				
Person with overall responsibility specified	✓	✓						
Planning permit restrictions on what can be sold from the premises	✓	✓						
Services to be provided from the premises		✓						
Persons other than the licensee that will conduct any business or activity in the premises		✓						✓
List of other pharmacy businesses applicant has a proprietary interest in		✓				✓	✓	
Declaration	✓	✓	✓	✓	✓	✓	✓	✓
<b>TOTAL ITEMS</b>	<b>14</b>	<b>12</b>	<b>9</b>	<b>6</b>	<b>6</b>	<b>5</b>	<b>4</b>	<b>7</b>

\* Queensland operates a notification system

### APPENDIX 3: Summary of pharmacy regulation around Australia

	WA	VIC	NSW	ACT	NT	QLD	SA	TAS
Legislation	<i>Pharmacy Act 2010</i>	<i>Pharmacy Regulation Act 2010 (Vic)</i>	<i>Health Practitioner Regulation National Law (NSW) No 86a</i>	<i>Public Health Act 1997</i>	<i>Schedule 7 of the Health Practitioners Act</i>	<i>Pharmacy Business Ownership Act 2001</i>	<i>Health Practitioner Regulation National Law (SA) Act 2010</i>	<i>Pharmacy Control Act 2001</i>
Governing body	Pharmacy Registration Board of WA (PRBWA)	Victorian Pharmacy Authority (VPA)	Pharmacy Council of NSW (PCNSW)	ACT Health	Pharmacy Premises Committee (PCC) - NT Government Department of Health	QLD Department of Health	Pharmacy Regulation Authority South Australia (PRASA)	Tasmanian Pharmacy Authority
Registration requirements	Register with the PRBWA	Licence from VPA	Register with the PCNSW	Licence from ACT Health	Certificate of compliance issued by the PCC	Notification to QLD Department of Health	1. Register pharmacy premises with PRASA 2. Register Corporate/Trustee pharmacy services providers with PRASA	Registration requirements
Pharmacy ownership limit	4	5	5	No limit	No limit	5	6	4

	WA	VIC	NSW	ACT	NT	QLD	SA	TAS
Persons allowed to have a proprietary interest in a pharmacy	<ol style="list-style-type: none"> <li>1. registered pharmacist</li> <li>2. close family member of a registered pharmacist who also owns a stake in the pharmacy</li> <li>3. 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</li> <li>4. friendly society</li> <li>5. preserved company</li> </ol>	<ol style="list-style-type: none"> <li>1. registered pharmacist</li> <li>2. company registered under the Corporations Act whose directors are all registered pharmacists</li> <li>3. company registered under the Corporations Act that immediately before 1 July 1999 was registered or incorporated as a friendly society</li> <li>4. person approved by the Authority to carry on a pharmacy business in an area that the authority determines needs a pharmacy business but in which there is no person that fits the criteria to be authorised to own a pharmacy</li> </ol>	<ol style="list-style-type: none"> <li>1. registered pharmacist</li> <li>2. partnership of registered pharmacists</li> <li>3. pharmacists' body corporate</li> </ol>	<ol style="list-style-type: none"> <li>1. registered pharmacist</li> <li>2. complying pharmacy corporation</li> <li>3. former corporate pharmacist (grandfathered provision)</li> </ol>	<ol style="list-style-type: none"> <li>1. registered pharmacist</li> <li>2. a partnership of which all the partners are pharmacists</li> <li>3. a corporation of which all shareholders and directors are pharmacists</li> <li>4. Aboriginal health service or friendly society that has been granted an exemption by the Minister</li> </ol>	<ol style="list-style-type: none"> <li>1. registered pharmacist</li> <li>2. corporation whose directors and shareholders are all pharmacists or relatives of the pharmacists</li> </ol>	<ol style="list-style-type: none"> <li>1. registered pharmacist</li> <li>2. pharmacist controlled company</li> <li>3. pharmacist controlled trust</li> </ol>	<ol style="list-style-type: none"> <li>1. registered pharmacist</li> <li>2. a partnership of which all the partners are registered pharmacists</li> <li>3. a body corporate where the controlling interest is held by one or more registered pharmacists and all the other members of the body corporate are close relatives of the pharmacist(s)</li> <li>4. an individual or body corporate as trustee of a trust where all beneficiaries are registered pharmacists or close relatives of the pharmacist(s)</li> </ol>

#### APPENDIX 4: Pharmacy registration fees around Australia (2016-2017)

	WA	VIC	NSW	ACT	NT	QLD	SA	TAS
New pharmacy application fee	\$850	\$547.90 - \$622.90 (registration of pharmacy business) + \$478.70 - \$749.90 (licence to carry on a pharmacy business)	\$480 + \$550 per financial interest	\$578	\$0	\$0	\$450	\$480.50 (registration of pharmacy premise) + (\$54.25 - \$1395) (eligibility certificate)
Change of ownership application fee	\$850	\$478.70 - \$749.9	\$550 (for each new financial interest)	\$346	\$0	\$0	\$450	\$54.25 - \$1395
Relocation of existing pharmacy application fee	\$850	\$547.90 - \$622.90 (registration of pharmacy business) + \$478.70 - \$749.90 (licence to carry on a pharmacy business)	\$480	\$578	\$0	\$0	\$450	\$480.50
Alterations to existing pharmacy application fee	\$500	\$328.80	\$480	No fee	\$0	\$0	\$150	\$0
Renewal fee	\$650	\$219.10 (registration) + \$219.15 - \$490.35 (licence)	\$320	\$578	\$0	\$0	\$500	\$387.50 (registration) + \$108.50 - \$217.00 (eligibility certificate)
Number of pharmacies	634	1381 (plus 75 pharmacy departments and 22 pharmacy depots)	1969	78	38	1100	482	159
Registration fee revenue (2016-17)	\$511,940	\$1,036,697	\$2,684,059	not available	\$0	\$0	\$476,050	\$98,263



## APPENDIX 5: Selected responses from online submissions

The examples below are provided to provide a qualitative sense of the type of submissions received. They have been grouped into general themes for each Review question.

For some themes, multiple responses were provided, including a large number of similar answers in some cases. For brevity, those judged to best represent the opinions of stakeholders, have been reproduced here - the number for responses under a specific theme below is not indicative of the total number of similar responses received.

### Question 1: What are the lessons on pharmacy ownership from other States and Territories, and what trends should we be aware of?

#### Improved competition

- *"The overall trend is that retail pharmacy is now more competitive which is good for consumers."*
- *"... do acknowledge that the 'big box' discounters have made some drugs available at more affordable prices to the Australian community."*

#### General trends

- *"...rapid growth of the very aggressive 'big-box' discount chains."*

#### Emergence of 'corporatization' and 'big box' discounters

- *"Evidence of 'corporatisation' of pharmacy ownership in other States and Territories."*
- *"Health is being commoditized by the discounters and professionalism is at risk. The pharmacist's ability to put in the extra time and effort with patients that require it most, the frail and elderly, is being eroded as margins fall."*
- *"Having practiced in the community pharmacy space for the last 25 years, I have seen many changes. The most concerning is the growth of large warehouse style pharmacies that focus on price only, and owners have little control over day to day management."*
- *"The existing ownership structure in Western Australia needs to ensure a dispersed ownership structure with low levels of ownership concentration otherwise the distribution of many local pharmacies will be lost to a few large warehouse style pharmacies."*

#### Conflicts of Interest occurring

- *In the UK, pharmacy ownership and management is not restricted to pharmacists. This has created countless stories of inappropriate use and supply of medication - (e.g. 'I'm your boss, do it or you will be out of a job')."*
- *"I was registered in the UK... I was also warned against unethical working practices that would be expected of me by the larger corporately owned businesses."*
- *"I believe ownership rules are important to protect consumers, and to provide/drive high quality care. I believe that a breakdown will lead to a compromising of standards and the industry being reduced to the lowest common denominator which is driven by price in priority over outcomes."*

#### Ownership being concentrated to a small number

- *"A more recent and worrying trend though has been the concentration of ownership."*

- *"There is a great deal of vertical and horizontal integration in the community pharmacy sector. This compromises professional standards with the reduction in the individual owner responsibility and accountability."*
- *"Concentration of pharmacy ownership creates an unfair playing field and a situation where government cannot meet its objectives as easily as it can now due to these operators being solely interested in price and profit rather than the community health outcomes."*

#### Market dominance by some groups

- *"Allowing a pharmacist or group of pharmacists to own more than 4 pharmacies allow these people (e.g. X Pharmacy) to dominate areas. The more they own, the stronger they become. This doesn't allow new pharmacists a chance to own a pharmacy."*
- *"Trends that have happened overseas where deregulation has occurred show duopolies with reduced product ranges and no pricing benefit to the consumer."*

#### Price being more important than service

- *"Pharmacies are not becoming health destinations that are evidence based and pushing the marketing of products with dubious efficacy such as supplements and homeopathy to supplement their low cost medicines."*
- *"Don't be bullied into changing rules to suit the agenda of 'big box' pharmacies, these are organisations whose main agenda is expansion and increasing revenue, not patient care like my pharmacy and the many others like it."*

#### Corporate drivers being more important than professional drivers

- *"...non-pharmacist owned corporation which has a duty to act in the best interest of its shareholders (to increase profits) and not in the best interests of the community or its patients."*
- *"As an individual owner and pharmacist I have a professional responsibility to provide safe and high quality care. Every day I face situations where I forgo profit but provide my community with vital primary health care and improved quality health outcomes which maximises my professional and business goodwill."*

#### Improved professional focus needed

- *"The regulations need to be strengthened so that community pharmacy is owned by individuals who have the care of their patients as number 1 priority. It is this reason the public has such a strong relationship with community pharmacy and consistently rate it as the second most trusted profession behind nurses."*
- *"There are dangers in not having Pharmacists owning Pharmacies and in the current situation having silent partners making global decisions without understanding the local environment."*

#### Loss of service occurring or likely

- *"Price wars mean that services such as home deliveries, dose administration aids which are all costly to the pharmacy will be reduced or cease."*
- *"They won't offer the late night and weekend services that we do as it is unprofitable and their management is miles away from the coalface of retail pharmacy and the community."*
- *"The first thing to suffer is wages which in turn hits local families and in the pharmacy reduces the quality of service pharmacy are able provide to the community."*

- *"It is now becoming an increasing event in my pharmacy that an X Pharmacy regular customer will come to see me for primary care advice, because such advice is not available at X Pharmacy. And as usual, I provide this service for free, often not selling the patient anything at all"*
- *"...in X State and has now completely dominated that state. The result of this is that traditional Pharmacies have been squeezed, and have had to reduce their costs of operation, which in turn has resulted in a reduced service offering"*

#### Workforce effects

- *"This has left little chance for young pharmacists to enter the market and own their own family owned pharmacy."*
- *"Corporations would reduce the already low wages paid to pharmacists (and have already done so) and in time this would become an unattractive profession to go into for generations to follow. Reduced service to the community would promptly follow."*

#### Concerns about holding owners responsible for standards

- *"I believe the intent of pharmacy ownership rules is to ensure the pharmacist proprietor has direct responsibility and involvement in the running of the pharmacy."*
- *"The pharmacist proprietor in my view needs to spend time in the pharmacy to ensure that all professional obligations are met and that patients receive a high level of service and care."*

#### Variation of rules between states and territories

- *"Inconsistent number of pharmacies a pharmacist can own and different jurisdictional rules."*

#### Legislation not being enforced

- *"Ensuring that the Pharmacy Registration Board has the expertise and funding to uphold the intent of the legislation... is important."*
- *"I believe there needs to be uniformity and robustness in reviewing all applications for Pharmacy ownership by Registered Pharmacists to ensure there is not a corporate takeover by 'stealth'."*

#### Cases of inappropriate ownership

- *"...there are worrying signs that the intent of the legislation is not being upheld."*
- *"In other States, the laws on pharmacy ownership have been unable to prevent significant horizontal integration in community pharmacy. This is leading to a greater concentration of ownership in a fewer number of owners."*

#### Opinions on numbers that can be owned

- *"I would find it difficult to understand how anyone could make sure that their business is operating at the ethical standards required by Pharmacy Registration Board of WA if they had an interest in more than 4 pharmacies."*

#### Miscellaneous comments

- *"The first lesson is to be learnt from Victoria. The Victorian Government has strengthened the regulations to protect community pharmacy from being obliterated by the corporates, but it has made the decision far too late."*

## Question 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?

### The laws are adequate

- *“The current laws in Western Australia help to preserve the diverse ownership of pharmacies. This gives great competition among pharmacies in respect of price and service levels.”*
- *“We believe current ownership laws are sufficient in protecting the sector in this state, with the current trend of discount models moving throughout Australia, we see this as a way to prevent the sector from becoming monopolised.”*

### The laws are inadequate

- *“The current ownership laws are either not sufficient or they are not being administered properly, as they have allowed the establishment of chains that are clearly centrally owned.”*

### Increase the ownership number

- *“The limit of pharmacies owned by a pharmacist in WA can be increased to six.”*

### Decrease the ownership number

- *“I believe that a pharmacist can only have a meaningful impact upon the operations of 2 pharmacies at any one time. To be directly responsible, and aware of what happens, requires you to actually be there.”*
- *“I would actually prefer this number to be lower as it is easy to miss things if you are trying to oversee so many separate pharmacies.”*

### Do not change ownership number

- *“I believe limiting pharmacists to owning a total of 4 pharmacies strikes the right balance between ensuring owners are personally responsible and accountable for standards and service provided by their pharmacies, and allowing owners to pass on knowledge and give opportunities to younger pharmacists through partners in new pharmacies.”*
- *“Limiting ownership to 4 or 5 ensures Pharmacy remains a small business. Small business owners are more in tune with their communities, more inclined to employ local people and provide a wider variety of services as opposed to a corporate model that will provide exactly the same service (or lack of) throughout the country, predicated by profit and not individual community need.”*

### Better alignment with other States and Territories

- *“Perhaps increasing from 4 to 5 may bring WA more into line with Vic, NSW and QLD which would seem more logical.”*

### Increase powers of the law or penalties for offences

- *“The laws are sufficient but I believe there needs to be more stringent examination of compliance to the rules. There are many anecdotal accounts of people/groups flaunting the rules via service agreements that sit outside the required documentation for registration. There needs to be stronger penalties for breaching the pecuniary interest rules and there should be mandatory examination of all payments from pharmacies to "external" service providers with strict penalties imposed on pharmacists/lawyers/accountants that facilitate the breaches that currently occur.”*

- *“The WA Pharmacy Registration Board needs sufficient resources to investigate suspicious commercial arrangements. It should also have the power to de-register Pharmacies that have been untruthful in their application.”*

#### Make the legislation clearer

- *“... there are so many variations of ‘ownership’ that it appears impossible to regulate the ownership of pharmacies. The model whereby a ‘management company’ is set up to provide services to individual pharmacies means that ultimately the ‘control’ of the pharmacy is held within the management company which may be owned and operated by a few individuals who control the operation of many (at least more than 4 and sometimes more than 30) pharmacies. These management companies also control the sale and purchase of these pharmacies and it means that individual ownership is difficult to achieve without the support from these management companies.”*

#### Enforce the current rules better

- *“Current WA pharmacy ownership laws are sufficient ... if they are enforced by the pharmacy regulatory authorities.”*
- *“I believe that the laws that are in place should be enforced. There should be more done to curb silent partnerships where a Pharmacist is paid a fee for their name on the door or are given a small share. I also believe that corporates... should be limited in their activity in our state, it is not in the best interests of the community to have huge groups or corporates monopolise the sector.”*

#### Increase the resources of the Pharmacy Registration Board

- *“The WA Pharmacy Board should be given the funding and resources to investigate suspicious commercial arrangements and given the ability to deregister pharmacies that have been shown to have used false information in their applications.”*
- *“The Pharmacy Registration Board needs to be provided with adequate resources to fully investigate those that would seek to avoid compliance with the rules via questionable commercial arrangements. The Board has to not only police the rules, but also have the power to adequately punish those that have misled the Board in their application.”*

#### The Pharmacy Registration Board operates effectively

- *“I believe that the WA Pharmacy Registration Board does a fantastic job of overseeing the current regulations, if they were provided even better funding, they would be able to ensure that WA doesn't become like some of the other states that can't effectively regulate ownership laws.”*

#### The current rules are being broken

- *It is well known that the rules only stop the honest people. Many skirt the laws and are known to have "an interest" in more than 4 pharmacies.*
- *“However there are a number of pharmacy chains that exploit the ownership laws & circumvent this legislation!”*

#### Owners should be resident in WA

- *“The current ownership laws allow any pharmacist, regardless of their geographic residential location in Australia, to own 4 pharmacies in WA.”*
- *“Keeping the theme of wanting pharmacists held accountable and to have a focus on professionalism is supported by having the numbers restricted. Having to have the proprietor*



*living within the state is a good way of ensuring that the owners are relatively local, in the same time zone, available and focused.”*

#### More accountability / owner responsibility

- *“My concern is that some of these pharmacist owners are so remote from the pharmacies they "own" that they cannot possibly take responsibility for what goes on in "their" pharmacy. Physically stepping foot in the pharmacy once a year is not conducive to good pharmacy practice.”*

#### Miscellaneous comments

- *“The professionalism and ethics of an employed pharmacist should be independent of ownership as is with corporate dentistry, medicine, etc.”*
- *“Retail pharmacy is not a 'utility' owned by the government as community pharmacies are owned by us and profit feeds our families and pays the bills.”*

### **Question 3: What role can pharmacies play in an integrated health care model in WA, and how does the current pharmacy regulatory model support this?**

#### Value of the community pharmacy network

- *“We have coverage of the whole state of WA either directly for most or using delivery modes for others. We are accessible by anybody, no appointments required. We see 140,000 patients daily spread over 619 locations and have 2,500 highly trained pharmacists...”*
- *“Pharmacy is ideally positioned to take on more roles in health delivery. The infrastructure is privately funded, distributed incredibly well across the state and open an incredibly long number of hours. Over the last 3 years most pharmacies have invested in having consulting rooms.”*
- *“Pharmacy is already locally distributed and working collaboratively with a range of health professionals, so it makes sense to include pharmacy at the centre of any integrated health care model.”*
- *“Pharmacies in WA are an opportunity for the State to utilise, for health initiatives, without the barrier of capital investment. They already exist, they are already staffed, and they are willing and able to be part of the solution for increasing health literacy and health outcomes for West Australians.”*

#### Support for expanded scope of practice

- *“Pharmacists can contribute a lot more to community health outcomes if allowed to practice with an increased scope. Also, Government health programmes could be rolled out across the network efficiently and quickly and cost effectively e.g. the recent increased scope to allow influenza vaccination through community pharmacy”*
- *“Pharmacists can contribute to community outcomes if allowed to work to the top of their scope.”*
- *“No doubt our abilities are being underutilised, so anything from vaccinations, screening, health assessments, diabetes programmes, education and the like, are well within our scope.”*

#### Support for enhanced role in immunisation

- *“Injections by the pharmacist needs to be expanded, as per in other countries, such as the US and Canada.”*

### Support for greater involvement in hospital discharge

- *“One area where community pharmacies can assist hospitals is become more involved with patient discharge. On discharge a patient nominates their pharmacy just like they would their GP.”*
- *“Patients returning to their local community pharmacy following discharge would ensure continuity of care, better communication and health outcomes for patients, GP's and allied health teams.”*

### Support for continued dispensing

- *“...a regulatory and policy change to enable a continued dispensing model and introduction of prescription renewal for stable, long-term conditions.”*

### Support for assisting with prescribing

- *“If a pharmacist was able to prescribe medications needed for the ongoing care of some chronic illnesses including hypertension, diabetes and asthma, the burden on the medical system would be reduced.”*
- *“Our role can include a wider scope of vaccinations, the ability to directly refer patients to other healthcare professionals, and a wider net of products that we can supply for primary care situations. For example, topical antibiotics, some simple antibiotics for urinary tract infections.”*

### Supporting for roles in mental health

- *“Pharmacists should have an opportunity to work with community to target early intervention in mental health, improve the training of pharmacist to better manage patients with common mental health issues including depression and anxiety.”*

### Support for roles in health screening

- *“There are certain triaging services which may be adequately managed by the pharmacist including BP and BSL measurement, minor wound care and assessment for further investigation by a doctor.”*

### Support for roles in public health programs

- *“There is also the ability to provide certain prescription only medications for specific conditions under a regulated framework e.g. azithromycin for chlamydia, enabling more effective treatment of sexually transmitted diseases.”*

### Support for a role in health promotion

- *“Use the access community pharmacy provides for public health awareness and prevention campaigns.”*

### Support for assisting manage chronic diseases

- *“One simple example of how pharmacy can help is when a patient is started on a new blood pressure medication, or an altered dosage. This service can easily be provided in a community pharmacy, where we could be paid a lower value... to see the patient 2, 3 or 4 times on follow-up, at potentially different times of the day. We can feed this information back to the GP, to keep them informed of the outcomes of the results.”*

### Multiple extensions of scope and miscellaneous services

- *“Some of the things that I believe can be done... pharmacies can contribute to are: a seat at the table with the government in the Department of Health and Mental Health Commission; minor ailment services; continued dispensing model; hospital discharge programs to reduce*



*falls and medicine misadventure; collaborative mental health intervention program; expand vaccination capabilities; implement self-managed chronic pain programs; new technologies such as self-worn devices; health prevention and promotion initiatives;*

- *“Some examples include early intervention mental health screening, peer-lead pain management programmes, screening for diabetes, cardiovascular disease or sleep apnoea, increased scope of vaccinations and post hospitalisation discharge management.”*
- *“Community pharmacies can play an integral role in: quality use of medicines, patient education and follow up; patient health screening; vaccinations; asthma / COPD; wound care, mental health; diabetes; hospital discharge; be part of the shared care / chronic care team via team care arrangements; collaboration with General Practice through improvements in information sharing.”*
- *“I believe pharmacy can play a role in to improve and maintain the health of Western Australians and reduce the financial strain on the health sector... minor ailment service... hospital discharge program... appropriate medicines management services to reduce falls and prevent readmission within 28 days... program with a focus on medicines management for seniors living in residential aged care facilities and at home...”*

#### More funding is required

- *“Medicare provider numbers for pharmacists when managing chronic diseases, e.g. type 2 diabetes, chronic pain management”*
- *“I think pharmacies are perfectly placed within their communities to play a greater part in an integrated health care system however we are expected to provide many of our services free of charge and this is unsustainable.”*
- *“The challenge is to get the funding right, so that only those that are actually delivering upon it receive any funding from it.”*

#### Comments on regulatory barriers

- *“The ownership structure of pharmacies does not really come into play here in my opinion.”*
- *“The current pharmacy ownership regulations have presented the WA government with a ready-made network of health professionals that if integrated into the primary healthcare system can keep people out of hospital at massive savings to government and a healthier community.”*

#### Comments regarding the Sustainable Health Review

- *“The Pharmacy Guild's recent submission to the WA sustainable Health Review made 16 recommendations that are worth looking into to integrate pharmacy into the health care model, reducing the burden on the budget.”*

#### Involvement in health planning and Government engagement

- *“I believe the pharmacy industry is often left out of integrated health discussions and can add great strategic support and value.”*

#### Miscellaneous comments

- *“Any community pharmacists including myself get to have real and raw conversations with doctors who are passionate about making a difference in those that want to get better with their health. The truth is that we can work together beautifully.”*
- *“Pharmacies should be used to co-ordinate health care services and ensure that information is properly shared and patients are referred to correct and available services.”*

- "... we must embrace the need to change the current model. We have to be seen as the place to go for good information about your health and convince the public to pay for it as every other health professional does."
- "Pharmacy's traditional role of dispensing medications and ensuring correct usage of those medications keeps people out of hospital. However there are many other programmes that can be rolled out, cost effectively, through community pharmacy that can also keep people out of hospital."
- "There are significant opportunities for pharmacies that genuinely understand their patients and are able to meet their needs by working collaboratively with other health providers in an integrated and technology-enabled, outcomes-focussed approach to health care."
- "The successful future of community pharmacies and the pharmacist profession are intrinsically linked to their ability to integrate with the broader primary health care system."

#### Negative comments

- "Pharmacies are criticized for selling vitamins, tissues, lollies, fragrances, etc."
- Pharmacists give us information on our medication that doctors often don't expand on. They also do medication reviews, make up Webster packs etc. They also can write sick certificates and freely give over the counter health advice. They could be a bit more private at times."

#### Question 4: What changes, if any, could the WA Government make to see the pharmacy role in the WA health system protected?

##### Less regulation desired

- "We should be asking how we protect the customer not the retailer. We protect the customer by an open market place and competition. You protect the customer by having the right regulations in place and monitoring these."

##### More regulation desired

- "More robustness when reviewing a pharmacist's suitability to own a pharmacy".
- "Not allow the companies licensed to run the public/private hospitals or their employees to own the pharmacies within the hospitals."
- "Community needs are constantly changing, and legislation must keep up. Any gaps that allowed the concentration of ownership into a few hands would be disastrous for patient care in this State."
- "Look to bring in local residency as a requirement for pharmacy ownership in WA. This could be phased in as a requirement over a 2 year period, so as to not adversely affect any current owners of WA pharmacies who are not WA residents."

##### Do not make any regulatory changes

- "Leave location and ownership rules alone. Many of us have made a significant investment in the industry and meddling with them could have serious financial impact and will be a step backwards for health outcomes"
- "The WA Government needs to ensure that ownership remains with individual pharmacists owning a maximum of four pharmacies. The government and industry regulators can then apply and enforce all relevant regulatory requirements and professional standards."

- *"The current ownership rules that only pharmacists can own pharmacies, and limiting the number of pharmacies a pharmacist can own, were put in place to protect the public from undue commercial interests taking priority over patient care."*
- *"Maintain and protect ownership. This will give the certainty that we require to embrace new roles."*

### Increase the resources available to the Pharmacy Registration Board

- *"The legislation that upholds these principles must be maintained, but also the statutory body that is entrusted to ensure the legislation is complied with must be given adequate resources and the power to not only uphold the spirit of the legislation, but also to take punitive action on those that seek to circumvent the legislation for their own personal gain. The Pharmacy Act needs to be strengthened to continue to provide the safety it was designed to provide and the WA Pharmacy Registration Board must be given the necessary authority, funding and support to take a stronger role in regulating professional pharmacy practice in the public interest."*
- *"The Government must allocate the resources required to make sure the ownership laws are actually implemented and not side-stepped by clever business structures invented by big business."*

### Better enforcement of existing rules

- *"Uphold the current Pharmacy ownership laws and do more to enforce them. Audit business structures to ensure that ultimately it is the Pharmacist whose name is on the door that owns the pharmacy. Make sure that the Pharmacy Registration Board has the backing of the Government to enforce the laws."*
- *"Strengthen the adherence to the rules that are in place. At a state level, ensure if possible, continuation of existing rules so that investment can be made with full knowledge that a return can be made without the constant threat of changes to the playing field. Our industry is very progressive and has a wealth of talent that is sadly being eroded. Lack of certainty is causing the best to leave our industry due to conditions and lack of clear career pathways including ownership."*
- *"Enforce the current ownership laws - this is not happening currently in my view."*

### Harsher penalties for breaching the legislation

- *"Harsh penalties for any group or person found to be in breach of the ownership laws. Permanent disqualification and huge fines may help. Look to stop models where groups sell stock to stores at a price above normal cost prices to enable them to effectively share the profit."*

### Fund more health services through pharmacy

- *"Assist pharmacists in lobbying the Federal Government for pharmacists to obtain Medicare provider numbers."*
- *"Move towards a model where professional services are government funded and acknowledge the new and existing roles of community pharmacy. In this way, more pharmacies could opt for a professional service based model. This further increases the ways in which pharmacies can serve the community (supporting Medicare rebates for key services), encouraging inter-professional liaising to bring the pharmacist into the conversations surrounding patient care."*

- *“Start identifying further areas of poorly implemented health care delivery and start the process of having local pharmacies and pharmacists help to improve service delivery.”*

#### Improve standards in community pharmacy

- *“Make Pharmacists personally responsible and accountable for the service their business provides, prevent external forces from compromising the professionalism of the sector and reduce conflicts of interest including horizontal or vertical supply chains.*

#### Seek a consistent approach to State and Territory laws

- *“The State Government should also play a proactive role with the Federal Government to make sure that changes to pharmacy ownership and location rules are not changed to accommodate corporates.”*

#### Cease reviews of the community pharmacy sector

- *“Competition reviews and the King review have shrouded our profession with uncertainty and stress.”*
- *“While this review has good intentions, it is again providing a level of uncertainty to pharmacy owners and I am not sure what the WA Government seeks to achieve. If it wishes to lower the number of pharmacies owned by an individual, what happens to those who have more than the current number? Will they be forced to sell and on what terms?”*

#### Improve awareness of legislation

- *“Government regulators should ensure that community pharmacies and pharmacists are made fully aware of their regulatory obligations and that there are avenues for redress in the event of breaches.”*

#### Comments on non-Pharmaceutical Benefits Scheme Pharmacies

- *“In order to ensure the ongoing viability of PBS pharmacies there needs to be tightening regulations around the opening and location of non-PBS pharmacies.”*

#### Miscellaneous comments

- *“I welcome this review as pharmacy in WA can still be saved.”*
- *“Increased transparency in regards to ownership pathways and education opportunities for young pharmacists in regards to ownership pathways could help to motivate young pharmacists to move into ownership, which in turn would lead to the protection of the pharmacy role.*

## APPENDIX 6: Proposed WA Pharmacy registration fees

Regulation	Registration provision	Current fee	Proposed fee
<b>Application fees</b>			
r.4	Grant of registration of premises as a pharmacy owner	\$850	\$926.00
	<i>Additional fees</i>		
	Each additional individual (other than as trustee)		\$50.00
	Each and every additional individual (as trustee)		\$450.00
	Each and every body corporate (other than as trustee)		\$200.00
	Each and every body corporate (as trustee)		\$650.00
	“Complex Licence Application” premium		\$2000.00
r. 6	Renewal of registration of premises as a pharmacy	\$650	\$708.00
r. 14	Significant alteration to a pharmacy	\$500	\$544.00
<b>Other fees</b>			
r. 7	Replacement of certificate of registration	\$30	\$100.00
r. 9	Change to information recorded in the register	\$30	\$150.00
r. 10	Certified copy of the register or a particular entry in the register	\$30	\$300.00
r. 18	Copy of minutes of the Board (per meeting)	\$30	\$150.00

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