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Health, Communities, Disability Services and Domestic
and Family Violence Prevention Committee
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Health, Communities, Disability Services and Domestic and Family Violence Prevention Committee

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Abbreviations

the Act	Pharmacy Business Ownership Act 2001 (Qld)
ACCC	Australian Competition and Consumer Commission
ACP	Australian College of Pharmacy
ACPA	Australian Community Pharmacy Agreement
ACRRM	Australian College of Rural and Remote Medicine
AHPRA	Australian Health Practitioner Regulation Agency
AMAQ	Australian Medical Association Queensland
the Board	Pharmacy Board of Australia
COAG	Council Of Australian Governments
the committee	Health, Communities, Disability Services and Domestic and Family Violence Prevention Committee
the Council	Australian Pharmacy Council
СРА	Community Pharmacy Agreement
the department	Department of Health
GP	General Practitioner
the Guild	The Pharmacy Guild of Australia
Harper Review	Australian Government Competition Policy Review
King Review	Australian Government Review of Pharmacy Remuneration and Regulation
LSA	Legislative Standards Act 1992
Mater	Mater Misericordiae Health Services Brisbane Limited
NCP	National Competition Policy
ОНО	Office of the Health Ombudsman
PBS	Pharmaceutical Benefits Scheme
PSA	Pharmaceutical Society of Australia
QAO	Queensland Audit Office
QCAT	Queensland Civil and Administrative Tribunal

QCPP	Quality Care Pharmacy Program
QPC	Queensland Productivity Commission
QUT	Queensland University of Technology
RACGP	Royal Australian College of General Practitioners
RANZCP	Royal Australian and New Zealand College of Psychiatrists (Queensland Branch)
RDAQ	Rural Doctors Association of Queensland
SHPA	Society of Hospital Pharmacists of Australia
TGA	Therapeutic Goods Administration
UQ	University of Queensland
Wilkinson Review	National Competition Policy Review of Pharmacy

Chair's foreword

This report presents the findings and recommendations of the Health, Communities, Disability Services and Domestic and Family Violence Prevention Committee from our inquiry into the establishment of a pharmacy council and transfer of pharmacy ownership in Queensland.

As Chair of the committee, I am pleased to present this report. The inquiry terms of reference allowed us to consider pharmacy ownership regulation and opportunities to extend the scope of practice for the State's pharmacists and pharmacy assistants.

I thank all submitters to our inquiry, and others from the health sector who shared their passion, knowledge and experience for their roles in helping provide health care in Queensland.

I commend the many community pharmacists who serve their local communities every day in the State's regional and rural areas, and those who participated in our inquiry like Lucy Walker from Terry White Goondiwindi (who travelled to give evidence at our Toowoomba hearing) and Catherine Whalan from Townsville's Cates Chemist. I also thank those pharmacists from the larger franchised pharmacy businesses, such as Chemist Warehouse and Ramsay Pharmacy who also play a valuable role in the pharmacy space, including those embedded in health and hospital services.

We gained invaluable information from organisations such as the Pharmacy Board of Australia, the Pharmacy Guild of Australia, the Australian Pharmaceutical Society, the Australian Medical Association and other medical groups, and inspiring individuals such as Professor Lisa Nissen, Head of the School of Clinical Sciences at the Queensland University of Technology.

I would like to acknowledge the considerable work and assistance provided by the Auditor-General, Mr Brendan Worrall and his team at the Queensland Audit Office (QAO) who reviewed pharmacy business transfers and ownership in Queensland over the last two years and whose audit report resulted in a number of recommendations for the Health Department. I hope that the QAO will continue to play a key role in the pharmacy space in relation to our recommendations.

I would also like to thank the Queensland Productivity Commission (QPC) for their excellent work in reviewing the costs and benefits of establishing a statutory pharmacy authority in Queensland to take over responsibility for administering the provisions of the *Pharmacy Business Ownership Act 2001* from the department. The committee has noted the commission's findings, and recommended not to proceed with a statutory authority. However, given other issues discussed during our inquiry, we see merit in establishing a Pharmacy Advisory Council to provide advice on pharmacy issues to government, at no cost to the Queensland taxpayer.

I thank my committee members for their genuine interest and enthusiasm, and the truly bipartisan approach they adopted to this work – mindful of the very significant role pharmacists and pharmacy assistants play in delivering health care in Queensland. As Chair, I am passionate about affordable health care for all Queenslanders. Having a strong and efficient retail pharmacy industry with pharmacists who are highly professional is absolutely critical. Pharmacists are integral to our health care system.

We see potential for pharmacists to do more that they currently do – with some prescribing of medications in low risk situations and subject to a range of safeguards. In saying that, I note the AMA and other bodies raised concerns during the inquiry about expanding pharmacists' scope of practice.

In framing our recommendations, the committee has sought to allay the concerns of the medical profession about changes to pharmacists' scope of practice by including a number of safeguards as part of a more collaborative approach to prescribing. We heard from many pharmacists they have a

good working relationship with their local GP's, and we hope this will continue and strengthen as pharmacists play a greater role in prescribing certain medicines going forward.

I commend this report to the House.

Aaron Harper MP

Chair

Executive Summary

The inquiry

In May 2018, the Health, Communities, Disability Services and Domestic and Family Violence Prevention Committee was tasked with inquiring into the establishment of a pharmacy council and the transfers of pharmacy ownership in Queensland. For the inquiry the committee:

- published a detailed issues paper inviting written submissions
- accepted and published 210 written submissions
- requested the Auditor-General to conduct an audit of the administration of transfers of pharmacy ownership by the Department of Health for compliance with the *Pharmacy Business* Ownership Act 2001
- wrote to the Deputy Premier requesting that the Queensland Productivity Commission conduct an independent cost benefit analysis of the establishment of a pharmacy council in Queensland
- held five public hearings, including hearings in Toowoomba, Cairns and Townsville to examine the issues raised by submitters
- met with representatives from the Victorian Pharmacy Authority in Melbourne, and
- sought expert advice from the Department of Health.

The committee's inquiry focused on four key issues:

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

Based on 2014-15 financial year, the State's 1,100 pharmacies dispense around \$1.5 billion in prescription medicines annually, equivalent to approximately \$309 per capita. Pharmacies and pharmacists perform a critical role in the health system.

The pharmacy market is undergoing significant structural change. The traditional business model characterised by small, high service pharmacies that offer a range of allied health services is now in heightened competition with large, high-volume, low-margin pharmacies. Despite restrictions on ownership under state and territory legislation, most Australian pharmacies operate under a common brand or name, with the four largest groups in the Australian market accounting for over 70 per cent of industry revenue.

Extending scope of practice for pharmacists

Following the recent success of pharmacists administering vaccinations in Queensland, there are significant potential community health benefits from extending the scope of practice of pharmacists further. These benefits include:

- improved accessibility, convenience and satisfaction for patients
- lower out-of-pocket costs for consumers and lower costs to the health care system
- better health outcomes for patients, and
- improved job satisfaction for health care workers.

Despite the potential benefits, medical practitioners and medical associations raised concerns about extending the scope of practice of pharmacists, suggesting there would be increased risk of negative patient outcomes if pharmacists were permitted to independently prescribe medication because of the increased risk of medication mismanagement and fragmentation of care, amongst other concerns. However, with sufficient safeguards in place, such as establishing consultation through 13HEALTH as per Recommendation 2, and appropriate additional training, these concerns should be allayed.

Many of the issues raised by medical practitioners and medical associations could be addressed by a shared or collaborative prescribing model. It is the committee's understanding that the Pharmacy Board of Australia is exploring options for a collaborative prescribing model in Australia.

Pharmacists, pharmacist organisations, and pharmacy education and training providers put forward many suggestions for where the scope of practice for pharmacists could be extended. While some were within the jurisdiction of the Queensland Government others require action by the Australian Government. For example, the decision to extend continued dispensing (beyond anti-cholesterol medicines and oral contraceptives) is the responsibility of the Australian Government's Department of Human Services. In addition, the decision to allow pharmacists to administer vaccinations on the National Immunisation Program Schedule is the responsibility of the Australian Government's Department of Health. Also, the re-scheduling of medicines is the responsibility of the Therapeutic Goods Administration (which is part of the Australian Government's Department of Health). Changes to administering vaccinations or the prescribing of medicines requires amendments to both state and Commonwealth legislation.

The committee recommends the minimum age for patients for pharmacist-administered vaccinations be lowered to 16 years, and that the Department of Health develop options for pharmacists to provide low-risk emergency and repeat prescriptions (for example, repeats of the contraceptive pill) and low risk vaccinations (including low risk travel vaccinations) through pharmacies subject to a risk-minimisation framework. Any change in scope of practice utilisation should be underpinned by appropriate credentialing and training for the services being delivered.

Administration of vaccines by pharmacists has made a positive impact on health outcomes in Queensland and Australia. However, state and territory health departments have set different requirements for education and training for pharmacists and different scopes of practice in administering vaccinations. There needs to be greater national consistency in both education and training and scope of practice for the administering of vaccinations to ensure the mobility of the pharmacist workforce is not unduly constrained and that access to medicines is not restricted where they can be provided safely. This harmonisation initiative should be progressed through the COAG Health Council which has responsibility for the Health Practitioner Regulation National Law (as in force in participating state and territory jurisdictions).

Extending scope of practice for pharmacy assistants

In contrast to the depth of comment on scope of practice for pharmacists, few submissions commented on extending the scope of practice for pharmacy assistants. Those submissions that did discuss pharmacy assistants were focused on their lack of mandatory qualifications. One area of interest was the handling of dangerous drugs. Some pharmacists wanted legislation changed to enable community pharmacy assistants to handle dangerous drugs in a similar manner to pharmacy assistants who work in hospital settings.

The committee suggests the Department of Health explore the efficacy of aligning the Certificate IV in Community Pharmacy (or Certificate IV in Community Pharmacy Dispensary) and the Certificate IV in Hospital/Health Service Pharmacy Support in relation to the handling of dangerous drugs. This can be achieved by extending the scope of practice of community pharmacy assistants in relation to the handling of dangerous drugs.

Numerous pharmacists, pharmacist organisations and pharmacy education and training providers proposed that pharmacy assistants undertake a minimum level of mandatory training. This is despite

the fact that around 95 per cent of pharmacies are accredited with the Quality Care Community Pharmacy program whereby pharmacy assistants must complete mandatory initial training via a recognised course and ongoing refresher training of at least three hours per year.

It is not clear to the committee that problems with the current training arrangements warrant government intervention. No submission suggested that the current training arrangements for pharmacy assistants are poor or inadequate. Some submitters suggested there were inconsistencies between different training providers. However, if there are no information barriers and no barriers to students choosing the most reputable suppliers of training it appears unnecessary for government to mandate training. Mandating training requirements could be a disincentive for registered training providers to develop new and innovative training techniques and making refinements to the curriculum.

Submitters also complained about the lack of universal qualifications for pharmacy assistants who work in hospital pharmacies and community pharmacies. This is not necessarily a problem if there is justification for the different qualifications in the different pharmacy sectors. It is not clear to the committee that hospital pharmacy assistants and community pharmacy assistants should have the same universal mandatory qualification if their scope of practice is different and this difference is justified. The committee has recommended that the Department of Health should explore the benefits of having the same basic mandatory education and training for assistants working in both sectors.

While there was general support for mandatory qualification requirements several pharmacist organisations and pharmacist proprietors wanted someone other than the employer/employee to pay for the training. It is not clear to the committee why the pharmacy owner should not pay for the training of pharmacy assistants. Under the Pharmacy Board of Australia's, *Guidelines for proprietor pharmacists*, proprietors must ensure that the pharmacy is suitably resourced and that staff members are suitably trained to provide services in accordance with their position descriptions. Pharmacy assistant training costs should be viewed as a normal cost of running a pharmacy business.

Improving the administration of pharmacy ownership regulation

The committee considered the effectiveness of the current systems and processes to regulate pharmacy business ownership and protect Queensland consumers. These pharmacy business ownership requirements are contained in the *Pharmacy Business Ownership Act 2001* (the Act), and are administered by the Department of Health. The committee recommends that the pharmacy ownership requirements contained in the Act be retained. No reason for deregulation has been demonstrated.

The ownership requirements for pharmacies in Queensland as specified in the Act are clear and unambiguous. As long as the restrictions on who can own pharmacies in Queensland remain part of the Act, the committee believe there is a clear expectation from the pharmacy industry and other stakeholders that those requirements are effectively administered and proactively enforced.

For the inquiry, the committee requested the Auditor-General to conduct an audit of how the Department of Health assessed transfers of pharmacy business ownership from 1 January 2016. The committee notes that the Queensland Audit Office found that the Department of Health has not designed processes and controls to ensure transfers of pharmacy ownership comply with all requirements of the (the Act). The Department of Health should improve its processes and controls to effectively administer the Act. The committee supports the audit recommendations with the exception of recommendation 5. The committee has recommended that the department's implementation of this recommendation be limited to testing of commercial arrangements for transfers transacted since 3 May 2016. The committee has also recommended that the department seek a follow-up audit by the Queensland Audit Office, and that the results of that audit be reported to the Legislative Assembly.

The committee recommends the establishment of a Queensland Pharmacy Advisory Council to advise the Department of Health on the Act and the fulfilment of its regulatory responsibilities to monitor and enforce compliance with the Act.

The advisory council would provide expert advice on ownership and pharmacy premises to the department and would enhance the department's capacity to proactively monitor and enforce the state's pharmacy regulatory environment.

The advisory council would comprise members appointed by the Minister with expertise in law, accounting, and business management and members representing the pharmacy sector and consumers. The advisory council would be funded by the pharmacy sector in full (that is, no costs to be borne by government). The advisory council would be consulted by the Department of Health on matters including, but not limited to, managing transfers of pharmacy ownership.

The committee agrees with the recommendation of the Auditor-General for the Act to be amended to strengthen the *Pharmacy Business Ownership Act 2001* to enable the department to more effectively manage the pharmacy ownership notification process.

Establishing a separate statutory authority such as a pharmacy council

The committee found there is no public interest case for establishing a separate statutory authority, such as a pharmacy council, in Queensland with the regulatory functions of ensuring compliance with the pharmacy ownership restrictions and pharmacy premises regulation. This is based on three key findings from the Queensland Productivity Commission's report:

- no evidence that other Australian states with pharmacy councils have better community outcomes
- no evidence that the existing premises regulation is resulting in unsafe conditions in pharmacies in Queensland, and
- no evidence that more intensive enforcement of ownership restrictions would provide greater consumer benefits in Queensland.

The Queensland Productivity Commission undertook a cost—benefit analysis at the request of the committee. That analysis demonstrated that the costs of establishing and operating a separate statutory authority would outweigh the benefits. This is because more intensively regulating the pharmacy ownership restrictions by a pharmacy council would not generate better community outcomes than the status quo. It would simply add to the cost of regulation.

The Queensland Productivity Commission concluded that a separate statutory authority would result in higher prices for consumers (mainly in over-the-counter medicines), lower profits for pharmacy owners, or lower wages/reduced employment for pharmacy employees. The commission also found that more intensive enforcement of the ownership restrictions is likely to reduce competition and discourage innovation.

The committee concludes that the Department of Health should continue to administer pharmacy ownership and premises regulation and drugs and poisons regulation. However, it needs to ensure the professional, safe and competent provision of pharmacy services and maintain public confidence in the pharmacy profession. There is a lack of transparency regarding the compliance of pharmacies and pharmacists with these regulations. This lack of transparency was raised by several submitters and also by witnesses in the public hearings.

The committee also concluded that the Department of Health should publish its compliance audit results, at least annually, and investigate ways to improve communication of the services individual pharmacies provide. The services should be regularly updated. This would make accessing services easier for the general community. It would also be useful for government in times of pandemic, natural disaster and for population health initiatives.

Recommendations

Recommendation 1 39

The committee recommends that the Department of Health lower the minimum patient age requirement for pharmacist-administered vaccinations to 16 years of age.

Minister responsible: Minister for Health and Minister for Ambulance Services

Recommendation 2 39

The committee recommends the Department of Health develop options to provide low-risk emergency and repeat prescriptions (for example, repeats of the contraceptive pill) and low risk vaccinations (including low risk travel vaccinations) through pharmacies subject to a risk-minimisation framework. The framework could include:

- consultation with a GP utilising 13HEALTH
- limitations on the number of times a prescription can be issued within a period of time (eg only once in a six-month period)
- on-site testing, and
- a requirement that the pharmacist consult a 13HEALTH GP or have regard to the patient's medical record via MyHealthRecord.

Any change in pharmacists' scope of practice should be underpinned by appropriate credentialing and training for the services to be delivered.

Minister responsible: Minister for Health and Minister for Ambulance Services

Recommendation 3 40

The committee recommends the Minister for Health seek support through the COAG Health Council for nationally consistent education and training requirements and scope of practice for pharmacists administering vaccinations.

Minister responsible: Minister for Health and Minister for Ambulance Services

Recommendation 4 47

The committee recommends the Department of Health, in conjunction with the Pharmacy Advisory Council (if established), explore the benefits and risks of extending the scope of practice of community pharmacy assistants in relation to the handling of dangerous drugs.

Minister responsible: Minister for Health and Minister for Ambulance Services

Recommendation 5 47

The committee recommends the Department of Health, in conjunction with the Pharmacy Advisory Council (if established), explore whether community pharmacy assistants and hospital pharmacy assistants should undergo the same basic mandatory training, and whether this would provide benefits to the community.

Minister responsible: Minister for Health and Minister for Ambulance Services

Recommendation 6 65

The committee recommends the establishment of a Queensland Pharmacy Advisory Council to advise the Department of Health in its administration of the *Pharmacy Business Ownership Act 2001* and the fulfilment of its regulatory responsibilities.

The Queensland Pharmacy Advisory Council would:

- provide expert advice to the Minister on ownership and premises standards, and would enhance the department's capacity to proactively monitor and enforce the pharmacy regulatory environment
- comprise members appointed by the Minister with expertise in law, accounting, and business management and members representing the pharmacy sector and consumers
- be funded on a cost recovery basis by the pharmacy sector (that is, no costs to be borne by government)
- be consulted by the Department of Health on matters including, but not limited to, managing transfers of pharmacy ownership and changes to scope of practice for pharmacists and pharmacy assistants.

Minister responsible: Minister for Health and Minister for Ambulance Services

Recommendation 7 65

The committee recommends that:

- 1. the Department of Health's development and implementation of a risk-based strategy for testing that existing commercial arrangements for pharmacy ownership in Queensland comply with sections 139B, 139H and 139I of the *Pharmacy Business Ownership Act 2001* be limited to transfers transacted since 3 May 2016, being a period of two years prior to the date the inquiry was referred to the committee
- 2. by 16 October 2019, 12 months from the tabling of this report, the department request a review by the Queensland Audit Office of the implementation of part (1) above of this recommendation together with compliance by the department with the agreed recommendations in the office's *Report No 4: 2017-18 Managing Transfers in Pharmacy Ownership*, and request that the Queensland Audit Office, pursuant to the *Auditor-General Act 2009*, table in the Legislative Assembly the report from its review, and
- 3. within six months of requesting the review recommended in part (2) above of this recommendation, the department provide the committee a written update of the review.

Minister responsible: Minister for Health and Minister for Ambulance Services

Recommendation 8 65

The committee recommends that the *Pharmacy Business Ownership Act 2001* be amended to enable the Department of Health to more effectively manage the pharmacy ownership notification process, including the establishment of offence provisions for breaches of s 139(I).

Minister responsible: Minister for Health and Minister for Ambulance Services

Recommendation 9 65

The committee recommends that the pharmacy ownership requirements of the *Pharmacy Business Ownership Act 2001* be retained.

Minister responsible: Minister for Health and Minister for Ambulance Services

Recommendation 10 83

Based on the findings of the audit by the Queensland Audit Office, the committee recommends that the Department of Health improve transparency regarding the compliance of pharmacists with the *Pharmacy Business Ownership Act 2001*, the Health Regulation 1996 and the Health (Drugs and Poisons) Regulation 1996 by publishing its compliance audit results, at least annually.

Minister responsible: Minister for Health and Minister for Ambulance Services

Recommendation 11 83

The committee recommends that the Department of Health investigate ways to improve communication to consumers about the services individual pharmacies provide such as vaccinations.

Minister responsible: Minister for Health and Minister for Ambulance Services

1 Introduction

1.1 Role of the committee

The Health, Communities, Disability Services and Domestic and Family Violence Prevention Committee (the committee) is a portfolio committee of the Legislative Assembly which commenced on 15 February 2018 under the *Parliament of Queensland Act 2001* and the Standing Rules and Orders of the Legislative Assembly.¹

The committee's primary areas of responsibility include:

- Health and Ambulance Services
- Communities, Women, Youth and Child Safety
- Domestic and Family Violence Prevention, and
- Disability Services and Seniors.

Section 92 of the *Parliament of Queensland Act 2001* provides that a portfolio committee is responsible for dealing with issues referred to it by the Legislative Assembly.

The Inquiry into the establishment of a pharmacy council and transfer of pharmacy ownership in Queensland (the inquiry) was referred to the committee by the Legislative Assembly on 3 May 2018 for report back to the Legislative Assembly by 30 September 2018. On 20 September 2018 the Legislative Assembly extended the reporting date to 16 October 2018.

1.2 Inquiry terms of reference

The committee was required to inquire into and report on:

- a) the establishment of a pharmacy council, and
- b) all transfers of pharmacy ownership in Queensland over the past two years to ensure compliance with existing legislation.

The referral from the legislative Assembly also stated that the committee should consider:

- a) the effectiveness of the current systems and processes in Queensland to regulate pharmacy business ownership in Queensland and protect Queensland consumers
- b) the possible role and scope of responsibility of a pharmacy council, including any powers of enforcement and/or ability to impose penalties; pharmacists' and pharmacy assistants' roles and scope of practice; and interactions with other agencies or individuals involved in regulating pharmacy businesses and practice
- c) models of regulation of pharmacy business ownership in other jurisdictions
- d) a cost-benefit analysis of establishing a pharmacy council
- e) any changes to legislation that would be required to establish a pharmacy council, including, but not limited to, changes to the *Pharmacy Business Ownership Act 2001* (Qld), the *Health Act 1937* (Qld) and subordinate legislation, namely the Health (Drugs and Poisons) Regulation 1996 and the Health Regulation 1996, and
- f) all transfers of pharmacy ownership in Queensland over the past two years.²

Parliament of Queensland Act 2001, section 88 and Standing Order 194.

Legislative Assembly, *Record of Proceedings*, 3 May 2018, p 1000.

1.3 Inquiry process

On 15 May 2018, the committee contacted and invited potential stakeholders to register to receive updates for the inquiry. On 1 June 2018, the committee published an issues paper for the inquiry and invited potential stakeholders to provide written submissions.

The committee accepted and published 210 written submissions. The committee also received 250 copies of form submissions to the inquiry. The submitters are listed at Appendix A. The submissions are available from the inquiry webpage.

For the inquiry the committee received two private briefings in Brisbane from the Department of Health on 6 August 2018 and 12 September 2018. The officers who briefed the committee are listed at Appendix B.

The committee held six public hearings for the inquiry in Brisbane and three regional centres as follows:

- Brisbane 20 August
- Brisbane 3 September
- Toowoomba 7 September
- Townsville 10 September, and
- Cairns 11 September 2018.

The witnesses who gave evidence are listed at Appendix C. The transcripts of the hearings are available on the committee's <u>webpage</u>.

The committee met with representatives of the Victorian Pharmacy Authority in Melbourne. The officers are listed at Appendix D.

2 The pharmacy sector in Queensland

As at 30 June 2015, there were 1,100 pharmacies in Queensland, which accounted for 20 per cent of all pharmacies in Australia at the time.³ Over the 2014-15 financial year, these 1,100 pharmacies in Queensland dispensed prescriptions valued at nearly \$1.5 billion. This equates to expenditure of \$309 per capita or just over \$1.3 million per pharmacy on prescription medicines in Queensland for that year.

The pharmacy industry has evolved significantly over the past 50 years, shifting from a focus on small independent pharmacies in the 1960s, to more sophisticated franchise and banner groups⁴ (both wholesaler-owned and independent) in the 1980s, to the arrival of 'big box' discount pharmacies in more recent years.⁵

According to the Pharmacy Guild of Australia, Australians visit a pharmacy on average 14 times a year.⁶ Pharmacies and pharmacists play an important role in primary health care, most importantly through the delivery of Pharmaceutical Benefits Scheme (PBS) medicines⁷ to the community. Pharmacies also sell over-the-counter medicines⁸ and complementary remedies, health-related products (such as personal care and grooming items) and hire medical devices and equipment.

In recent years some pharmacies have begun moving their focus away from medicine dispensing and front-of-house (non-medicine) sales to a more patient-centred approach, providing services such as:

- wound management
- health checks
- vaccination programs
- methadone programs

- medicines review and reconciliation
- · dose administration aids, and
- supply of diabetes products & advice.

This changing focus has been driven by increased competition from large, high volume, low margin pharmacies that compete mainly on price and declining profitability brought on by the introduction, and subsequent expansion, of the Commonwealth Government's Price Disclosure Regime for PBS

Stephen King, Bill Scott and Jo Watson, *Review of Pharmacy Remuneration and Regulation, Discussion Paper*, July 2016,

http://www.health.gov.au/internet/main/publishing.nsf/content/7E5846EB2D7BA299CA257F5C007C0E21 /\$File/Discussion%20Paper%20-

^{%20}Review%20of%20Pharmacy%20Remuneration%20and%20Regulation.pdf.

Groupings of individually owned stores formed to provide support and undertake joint advertising and promotions.

KordaMentha, *Pharmacy: A challenging and changing outlook*, Publication No 14-01, February 2014, https://www.kordamentha.com/getmedia/9ab7c48d-6d6f-448e-92b7-0ff74b19c4d1/14-01 pharmacy 1.pdf.aspx?ext=.pdf.

The Pharmacy Guild of Australia', 'Vital facts on community pharmacy', May 2018, https://www.guild.org.au/ data/assets/pdf file/0020/12908/Vital-facts-on-community-pharmacy.pdf.

Australian Government scheme that subsidises the cost of most prescription drugs.

Medicines sold without requiring a prescription. These include: Schedule 2 pharmacy medicines (non-prescription medicines that can only be sold in a pharmacy; Schedule 3 pharmacist-only medicines (non-prescription medicines that can only be sold through a pharmacy on the provision of pharmacist advice) and general sales medicines (non-scheduled medicines that can be sold outside of a pharmacy, for example in supermarkets).

medicines. The Pharmacy Guild estimated that in 2014-15 the regime would reduce net profit before tax of an average pharmacy by approximately \$90,000.9

Consumers are also increasingly purchasing general sales medicine from supermarkets. Many supermarkets now stock a range of widely used non-scheduled medicines.

According to the Pharmacy Guild of Australia, most pharmacies derive around 70 per cent of their income from the dispensing of PBS medicines. ¹⁰ However, this proportion can vary quite considerably depending on the pharmacy business model and the size of the pharmacy. For example, where pharmacies have a greater emphasis on front-of-house retail sales, prescriptions can account for as little as 55 per cent of total revenue. ¹¹ According to IBISWorld, from an industry-wide perspective prescription medicines make up 63 per cent of total revenue). ¹²

2.1 Major players in the Australian pharmacy market

Individual operators dominate the industry because state and territory legislation restricts pharmacy ownership to pharmacists and limits the number of pharmacy businesses they may own. However, state and territory legislation still allow for pharmacies owned by different pharmacists to operate under a common brand or banner. According to IBISWorld, the four largest groups in the Australian market, My Chemist Retail Group, Sigma Healthcare Limited, Terry White Group Limited and Australian Pharmaceutical Industries Limited (API Limited) account for over 70 per cent of industry revenue (figure 1).

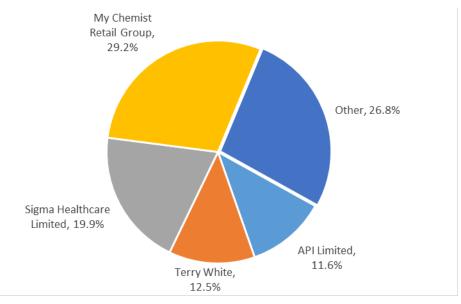


Figure 1: Major players in the Australian pharmacy market (market share)

Source: IBISWorld, *Industry Report G4271a, Pharmacies in Australia*, March 2018.

Australia's largest pharmacy group based on turnover is the **My Chemist Retail Group**, a pharmacist-owned company made up of partnerships and alliances among individual pharmacists. The Group runs two store models: Chemist Warehouse, which has 420 stores across Australia and competes primarily on price; and My Chemist, which has a strong focus on health and beauty. Approximately 60 per cent

4

The Pharmacy Guild of Australia, *Submission in response to the Competition Policy Review Issues Paper*, June 2014, p 30, http://competitionpolicyreview.gov.au/files/2014/07/PGA.pdf.

The Pharmacy Guild of Australia, *Submission in response to the Competition Policy Review Issues Paper*, June 2014, p 30, http://competitionpolicyreview.gov.au/files/2014/07/PGA.pdf.

¹¹ IBISWorld, *Industry report G4271a, Pharmacies in Australia*, March 2018.

¹² IBISWorld, Industry report G4271a, Pharmacies in Australia, March 2018.

of My Chemist Retail Group revenue is derived from the sales of retail products, particularly discounted cosmetics and perfumes. 13

Sigma Healthcare Limited (Sigma) focuses on wholesaling and support services for retail pharmacies since divesting its pharmaceutical manufacturing business in 2011. Sigma has approximately 700 pharmacies in its banner groups, including Amcal, Guardian, PharmaSave, Chemist King and Discount Drug Stores pharmacies, giving it the largest branded retail pharmacy presence in Australia.¹⁴

TerryWhite Group Limited provides franchise services to the TerryWhite Chemmart network in addition to wholesaling products. The group's industry brand names include:

- TerryWhite Chemmart
- · Chemplus, and
- Chemmart.¹⁵

Australian Pharmaceutical Industries Limited (API Limited) is a health and beauty company involved in pharmacy distribution, manufacturing consumer brands and retailing. API Limited operates in the industry through the following banner groups:

- Priceline Pharmacy
- Soul Pattinson, and
- Pharmacist Advice.¹⁶

Ramsay Health Care, a major operator of private hospitals in Australia, is recent large-scale entrant to the retail pharmacy industry. On 14 November 2017 Ramsay Health Care announced that 18 Malouf Pharmacies were now part of its franchise network. Malouf Pharmacies is the largest privately-owned pharmacy group in Queensland, employing more than 450 staff. Its pharmacies are located in the Brisbane metropolitan area and in regional Queensland.¹⁷

Ramsay Health Care is the largest private hospital operator in Australia with 73 facilities located throughout the country. In Queensland, Ramsay Health Care operates 18 hospitals with in excess of 2,500 beds. Ramsay Health Care has been dispensing pharmaceuticals through its hospital pharmacies¹⁸ for over a decade:

In pharmacy, Ramsay Health Care has had more than 10 years' experience in operating dispensaries within the acute hospital setting. Approved under Section 94 of the National Health Act 1953 (Cth) (NHA), Ramsay Health Care dispenses PBS medications and highly specialised drugs to patients treated in or at these facilities either as admitted patients or day patients. On an annual basis, the pharmacies in Ramsay's Health Care's hospitals dispense approximately

15 As above.

¹³ IBISWorld, *Industry report G4271a, Pharmacies in Australia*, March 2018.

¹⁴ As above.

¹⁶ As above.

Ramsay Health Care, 'Malouf Pharmacies joins Ramsay Pharmacy Franchise Network', media release, 14 November 2017, http://www.ramsayhealth.com/News/General-News/Malouf-Pharmacies-joins-Ramsay-Pharmacy-Franchise-Network.

Two types of pharmacy exist in Australia: community pharmacies which are approved to supply PBS medicines under section 90 of the *National Health Act 1953* (Cth) to members of the public; and hospital pharmacies which are approved to supply PBS medicines under section 94 of the *National Health Act 1953* to hospital patients only. Community pharmacies fill most prescriptions and are the focus of this inquiry.

1.2 million prescription medications safely to patients and oversee the clinical ordering of in excess of 100,000 complex chemotherapy doses.'19

Ramsay Health Care is now diversifying into community pharmacy to extend its care continuum to cover patients both pre- and post-hospital admission through the Ramsay Pharmacy franchise network. According to its submission:

In 2013, Ramsay Pharmacy established a franchise network of community pharmacies which are operated by registered pharmacists as franchisees under the Ramsay Pharmacy brand. As at 30 June 2018, Ramsay Pharmacy has 54 franchisees in Australia with 27 in Queensland including two 24/7 pharmacies in Brisbane and on the Gold Coast. Ramsay Pharmacy also owns Pharmacies brand in Queensland, with Malouf Pharmacies also operating under a franchise agreement.²⁰

Ramsay Pharmacy is aiming to achieve 300 community pharmacies in its franchise network by 2020 across Australia.²¹

2.2 Structural changes in the industry

The growing reliance on franchising as a pharmacy business model and the proliferation of big-box pharmacies such as Chemist Warehouse are driving significant structural change in the industry. These recent trends have been reflected in the decline of small, independent pharmacies which are struggling to adapt to the changing operating environment. The industry appears to have divided into those pharmacies that are competing mainly on price and those that are mainly competing on the depth/breadth of services.

These two different business models were succinctly described by Paul Willis of Cate's Chemist, in his evidence at the committee's Toowoomba hearing, when explaining the clientele Cate's Chemist was targeting:

Sadly, we are targeting, in a business sense, people with chronic health conditions that need to be managed over time. For example, I tell a lot of my friends my age that if they have an acute condition, they have a one-off script of antibiotics, they are really good patients for Chemist Warehouse. They are going to save \$1, \$2 or \$3 if they go to Chemist Warehouse. However, if you have diabetes and a cardiovascular disease, come to us because our pharmacists will remember you. The same pharmacist who is there today will be there next week. They will be able to help you manage your condition over time. Also, you are probably going to need dose administration aids. We supply that. We will charge that \$1, \$2 or \$3 extra, but you will get dose administration aids and you will get free delivery. We are going to make this part of your life easier.²²

¹⁹ Submission 151, p 1.

²⁰ Submission 151, p 1.

Heather Saxena, 'Ramsay overcomes regulatory hurdles to expand community pharmacy network, Pharmacy News, 17 November 2017, https://www.pharmacynews.com.au/news/ramsay-overcomes-regulatory-hurdles-expand-community-pharmacy-network.

Public hearing transcript, Townsville, 10 September 2018, p 21.

3 The regulatory framework for pharmacists and pharmacy assistants

The pharmacy sector is heavily regulated in Australia. The conduct of pharmacists and pharmacy assistants is regulated through the Health Practitioner Regulation National Law (the National Law), and a professional registration system administered by the Pharmacy Board of Australia.

3.1 The Health Practitioner Regulation National Law

The purpose of the Health Practitioner Regulation National Law (the National Law), as in force in each state and territory, is to establish the National Registration and Accreditation Scheme (the National Scheme). Pharmacy is a registered profession under the National Law (it appears in the schedule of the *Health Practitioner Regulation National Law Act 2009* (Qld)).

The National Law is comprised of state and territory-based legislation; it is not a single commonwealth law. Queensland is the host jurisdiction for the National Law.

Ultimate accountability to the public for the performance of the National Scheme rests with the parliaments of participating jurisdictions, through the Australian Health Workforce Ministerial Council. Health Ministers from each state and territory and the Commonwealth are members of the Ministerial Council.

The National Scheme has six objectives:

- protect public safety
- facilitate workforce mobility for health practitioners
- facilitate high-quality education and training of health practitioners
- facilitate assessment of overseas-trained health practitioners
- facilitate access to health services, and
- development of a flexible, responsive and sustainable health workforce.

Each of the 15 health professions that are part of the National Scheme are represented by a National Board. In the case of pharmacy, this is the Pharmacy Board of Australia.

The National Boards set the registration standards that practitioners must fulfil to register. Once registered, practitioners must continue to meet the standards and renew their registration yearly with the National Board.

All Boards are supported by the Australian Health Practitioner Regulation Agency (AHPRA) through a Health Profession Agreement.

3.2 Pharmacists registration and accreditation of education providers

3.2.1 Pharmacists

Pharmacists must be registered with the Pharmacy Board of Australia (the board) and meet the board's registration standards in order to practise in Australia.

William Kelly of the Pharmacy Board of Australia, in his evidence at the committee's Cairns hearing, described the workforce mobility, administrative simplicity and transparency benefits of the national scheme:

Workforce mobility, which was one of the aims of the scheme, has certainly improved under the national scheme. Pharmacists register with the board, pay a single registration fee and practise anywhere in Australia, thus reducing administrative burden. There is a national register which is

maintained and accessible online. Anyone can seek the registration status and related information about pharmacists in real time online.²³

Registration standards define the minimum requirements that applicants, registrants or students must meet to be registered. The board has developed seven registration standards:

- pharmacy criminal history
- professional indemnity insurance arrangements
- continuing professional development
- recency of practice
- supervised practice arrangements
- examinations for eligibility for general registration, and
- pharmacy English language skills.

The registration standards support the board to ensure that only suitably trained and qualified individuals are registered to practise as pharmacists.

The board has also developed a code of conduct, six guidelines and a social media policy to provide guidance to the profession and to support the safe delivery of services to the public.

William Kelly of the board provided some examples of the guidelines:

Some examples of these include guidelines for the compounding of medicines, minimum standards for practice and addressing the risks associated with compounding of some medicines, guidelines for the dispensing of medicines, supporting safe dispensing, and guidance on the role of dispensary assistants and pharmacy technicians assisting pharmacists, and guidelines for proprietor pharmacists which focus on the professional responsibilities of proprietor pharmacists and impact the safe and effective delivery of services to the public.²⁴

The code of conduct and guidelines may be used as evidence of what constitutes professional conduct or practice for pharmacy in proceedings under the National Law against a health practitioner.

The code of conduct applies to all registered pharmacists. The code protects public safety irrespective of who owns a pharmacy.

3.2.2 Pharmacy education providers

The National Law defines the accreditation functions that accreditation authorities undertake.

Accreditation authorities exercise the accreditation functions under the National Law. The Australian Pharmacy Council (the Council) is the accreditation authority responsible for accrediting education providers and programs of study for the pharmacy profession—that is pharmacists, not pharmacy assistants.

Accreditation standards are used to assess whether a program of study, and the education provider that provides the program, provides graduates with the knowledge, skills and professional attributes to practise the profession in Australia.

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²³ Public hearing transcript, Cairns, 11 September 2018, p 2.

Public hearing transcript, Cairns, 11 September 2018, p 2.

3.3 Minimum qualifications for pharmacists and pharmacy assistants

3.3.1 Pharmacists

The minimum qualification required to be a pharmacist is the completion of a four-year Bachelor of Pharmacy degree. Graduates then need to register with the board and complete a one-year internship with a registered pharmacist.

Four universities in Queensland have approved programs of study for a Bachelor of Pharmacy degree (some provide Honours/Masters degrees):

- Griffith University
- James Cook University
- Queensland University of Technology, and
- University of Queensland.

3.3.2 Pharmacy assistants

Pharmacy assistants who work within community pharmacies are covered under the Pharmacy Industry Award 2010. There are no minimum qualifications required under the Award, however, certified training courses are available, such as the Certificates II, III and IV in Community Pharmacy and the Certificate IV in Community Pharmacy Dispensary.

Training for pharmacy assistants is provided through the vocational education and training sector by registered training organisations. A range of industry groups and training organisations provide pharmacy assistant training, including the Pharmaceutical Society of Australia and the Pharmacy Guild of Australia.

Pharmacy proprietors ensure that pharmacy assistants are suitably trained to provide services to the public. Despite there being no minimum mandatory qualifications required, the Pharmacy Guild of Australia stated that nearly all community pharmacies are accredited through the Quality Care Community Pharmacy (QCCP) Standard:

In Queensland, approximately 95% of pharmacies are accredited to the AS 85000:2017 Quality Care Community Pharmacy Standard, a formally recognised Australian Standard. A requirement of the Standard is to ensure that all pharmacy employees maintain a training record and development plan that is relevant to the position that they hold.

As per the QCCP requirements, pharmacy assistants that are involved in the support of Schedule 2 and 3 medicines must have received initial training via a Registered Training Organisation and receive ongoing annual refresher training to ensure up to date and relevant knowledge in the interest of patient safety.²⁵

There is also no minimum qualification for pharmacy assistants working at a base grade level in the Department of Health. However, there is a requirement for individuals employed at higher grades to have a Certificate III or IV in Hospital/Health Services Pharmacy Support. For example, there is a requirement for individuals employed as an Advanced Pharmacy Assistant-Patient Care to have a Certificate IV in Hospital/Health Service Pharmacy Support.²⁶

²⁵ Submission 161, p 42.

The Department of Health, private communication, 2 August 2018.

The Technicians Support Services Industry Reference Committee (IRC)²⁷ is currently undertaking public consultation for a review of the Hospital/Health Services Pharmacy support qualifications to meet the needs of the Australian health care system. The IRC is proposing significant changes to the Certificate IV in Hospital/Health Services Pharmacy Support including the addition of new units of competency in compounding medicines, human biology and chemistry, medicines management and medicines for a range of specific conditions. The community pharmacy assistant qualifications are not being considered as part of this review.

3.3.3 Dispensary assistants

Pharmacists may also be assisted in the preparation, dispensing and supply of medicines by dispensary assistants. Pharmacists who are responsible for employing dispensary assistants must engage suitably trained and experienced individuals to perform duties under pharmacist supervision and ensure that the tasks correspond to and are limited to their level of education, training and experience.

Certificate qualifications, competencies and/or workplace training/practical experience can be used to ensure individuals are suitably prepared for their roles as dispensary assistants. Pharmacists who employ dispensary assistants are required to carefully assess the most appropriate options to achieve the level of skilled support required in practice. Pharmacists need to be able to demonstrate the evidence to support their decision.²⁸

3.4 National Code of Conduct for Health Care Workers

The National Code of Conduct for Health Care Workers (the National Code) applies to health care workers who are <u>not</u> required to be registered under the National Law.

The National Code aims to strengthen regulation of unregistered health care workers across all states and territories and provide for mutual recognition of prohibition orders. A nationally accessible webbased register of prohibition orders is being established to enable cross-jurisdiction searching of interim prohibition orders and prohibition orders against health practitioners.²⁹

In Queensland, the National Code is recognised as the National Code for Health Care Workers (Queensland) and is a prescribed conduct document as referred to in section 5 of the Health Ombudsman Regulation 2014. Any concerns in relation to a health care worker's practice under the Queensland Code can be reported as a complaint to the Office of the Health Ombudsman (OHO).

There is no list of health professions or types of health care workers to whom the Queensland Code applies. However, the Queensland Code applies to health care workers 'providing a health service, which is defined in the *Health Ombudsman Act 2013* (Qld) as a service, including any support service that maintains, improves, restores, or manages people's health and wellbeing.' As a consequence, pharmacy assistants are bound by the Queensland Code.

The Technicians Support Services Industry Reference Committee is responsible for national training package qualifications relevant to hospital pharmacies. For further information refer to Australian Industry and Skills Committee, https://www.aisc.net.au/.

²⁸ Pharmacy Board of Australia, Guidelines for Dispensing of Medicines, September 2015.

The Department of Health, *The National Code of Conduct for Health Care Workers (Queensland)*, https://www.health.qld.gov.au/system-governance/policies-standards/national-code-of-conduct.

The Department of Health, *National Code of Conduct for Health Care Workers (Queensland), Frequently asked questions*, p 1, https://www.health.qld.gov.au/ data/assets/pdf file/0021/439212/faq.pdf.

Queensland was deemed to have met the National Code through the establishment of the OHO under the *Health Ombudsman Act 2013* (Qld). This is because the Health Ombudsman has similar powers to regulate unregistered health practitioners as other code-compliant jurisdictions.³¹ Since 1 October 2015, the OHO and the Queensland Civil and Administrative Tribunal (QCAT) may have regard to the Queensland Code when considering what actions to take, including the issuing of interim prohibition orders or prohibition orders, respectively.

³¹ COAG Health Council, *Final Report, A National Code of Conduct for health care workers*, 17 April 2015, p 20, http://www.coaghealthcouncil.gov.au/NationalCodeOfConductForHealthCareWorkers.

4 Should scope of practice be extended for pharmacists?

As part of the inquiry, the committee was tasked with examining whether the scope of practice for pharmacists and pharmacy assistants should be extended.

Extended scope of practice can be defined as a discrete knowledge and skill base additional to the recognised scope of practice of a profession. In Queensland, pharmacists' scope of practice was extended in 2016 to allow pharmacists to administer certain vaccines.

Extension of scope of practice is different to expansion of scope of practice. The two concepts are often used interchangeably but incorrectly, as explained by Dr Lisa Nissen of the QUT School of Clinical Sciences:

It is important to understand that 'expansion of practice' means operating in the full scope of competency that you have, so it is not about adding things; it is about what you actually bring to the table as a health professional. An extension of scope often gets used interchangeably but incorrectly by people: an extension of practice is where you have to add things to your current skill set to be able to practice.³²

This difference between expansion and extension of scope was also highlighted by the Pharmacy Guild of Australia:

When it comes to scope—and I am talking now specifically to pharmacists as opposed to pharmacy assistants—I think we need to differentiate—and no speaker to date has been able to do so—between what is currently within our scope but is forbidden because of some form of anomaly in state government acts or state government regulations and what is not within our scope that may be both of interest to consumers in Queensland to access from a community pharmacy and of interest to community pharmacists being able to provide, and those two things are very different.

There are things that are already within my scope. I already have the skills and knowledge to be able to perform very specific tasks, and those tasks can be put together to help me achieve the role that it is to be a community pharmacist. Unfortunately, I cannot practise to the full scope of my current practice, even though I have the skills and the knowledge to perform those tasks, because there is a degree of anomaly that currently exists in Queensland government regulation that prevents me from doing that.³³

The Pharmacy Board of Australia has overarching responsibility for scope of practice changes for pharmacists, while state and territory governments are responsible for make the legislative changes for implementation to occur. William Kelly from the Pharmacy Board of Australia elaborated on this in evidence at the committee's Cairns hearing:

The board considers any issues in relation to scope of practice changes. We look at it in relation to the safety of the public, the relevant competencies, if they exist or if they are needed, any legislation aspects, any additional training requirements, including continuing professional development, whether there is any other registration standard needed. If the legislation allows that and all those other boxes are ticked, the pharmacists are able to do that. They are meeting their scope of practice, because they are meeting those requirements. ...³⁴

... Generally, the competency side of it is the board's bailiwick to make sure that pharmacists are competent and have sufficient training or identify training requirements. Then it is whether there

Public hearing transcript, Brisbane, 20 August 2018, p 9.

Public hearing transcript, Brisbane, 3 September 2018, p 33.

Public hearing transcript, Cairns, 11 September 2018, p 6.

is appropriate legislation to make it happen, and that is the regulatory model from the jurisdiction side.³⁵

For example, in December 2014, the Pharmacy Board of Australia advised the Department of Health that vaccination was within the current scope of practice of a pharmacist but that further work regarding competencies, standards and training would need to be undertaken.

Following a successful two-year trial, the Queensland Government amended the Health (Drugs and Poisons) Regulation 1996 in March 2016 to allow pharmacists to provide certain vaccination to adults (aged 18 years and over). These included:

- influenza vaccine
- diphtheria-tetanus-acellular-pertussis vaccine
- measles-mumps-rubella vaccine
- adrenalin (for treatment of anaphylaxis only).³⁶

Community pharmacists, under specific circumstances, are also able to dispense an emergency supply of prescription medications under section 194 of the Health (Drugs and Poisons) Regulation 1996. In these cases, the pharmacist must not sell more than three days' supply of the drug or a minimum standard pack if it is a prepacked liquid, cream, ointment or aerosol. This emergency supply is not subsidised by the PBS, and the full cost of the medicine must be met by the patient.

Community pharmacists, under specific circumstances, are also able to dispense a further one-month supply of prescription-only medications (only oral hormonal contraceptives and lipid modifying agents 'statins' which are anti-cholesterol medicines) without a valid prescription. This is known as 'continued dispensing'. Continued dispensing allows community pharmacists to supply eligible PBS medicines when there is an immediate need for the medicine, but it is not practical for the patient to obtain a prescription. A patient cannot receive more than one single full pack (maximum PBS quantity) under the national continued dispensing initiative every 12 months, per eligible medicine. Section 171 of the Health (Drugs and Poisons) Regulation 1996 was amended in 2016 to allow continued dispensing in Queensland.

According to the Department of Health, there are three pharmacy prescribing trials being undertaken in Hospital and Health Service settings (a pre-admission clinic, emergency department and geriatric unit) where pharmacists are working in collaborative prescribing models with medical officers. These trials follow two successful trials (in a pre-admission clinic and a HIV clinic) that were conducted in 2009.

The Brisbane South and Brisbane North Primary Health Networks jointly funded a trial called Reducing Medical Admissions into Hospital through Optimising Medicines (REMAIN HOME) that investigate whether a model of structured GP and pharmacist medication management reduced unplanned hospital readmissions in patients with complex comorbidity. The trial concluded recruitment in May 2018 and is currently in the follow-up phase.

Public hearing transcript, Cairns, 11 September 2018, p 8.

The Department of Health, private communication, 2 August 2018.

Department of Human Services, Education Guide – Continued Dispensing Initiative – PBS requirements, https://www.humanservices.gov.au/organisations/health-professionals/enablers/education-guide-continued-dispensing-initiative-pbs-requirements/31671.

4.1 Arguments for extending the scope of practice of pharmacists

The committee heard a divergence of views on whether scope of practice for pharmacists should be extended. Most pharmacists, pharmacist associations, pharmacy education and training providers and the group representing Queensland Health Consumers supported an extended scope of practice.

The QUT School of Clinical Sciences supported an expansion (to full scope) and an extension of scope (with further training) for pharmacists and indicated that pharmacists were underutilised in Australia:

The expansion (full scope) and extension (beyond current training) of scope for pharmacists in Queensland would be fully supported by the QUT Pharmacy Discipline. The premise that pharmacists play a critical role wherever there is medicine used is testament to this. However, many of the potential models of practice where these key impacts could be felt are not so much issues of competency/training – but more professional boundaries and legislation. As such, it is not that we cannot do it – more the system won't allow it. And often this is on a state-by-state basis. It is clear that the accessibility and skill that pharmacists bring to the health sector is valuable and should be optimized to improve the overall function of the health system.³⁸

The University of Queensland School of Pharmacy shared a similar sentiment, that pharmacists are ready for a broader scope of practice:

The UQ School of Pharmacy contends that for the last 10 years we have been producing pharmacy graduates who, after completing their intern training program, are capable of undertaking an even broader scope of practice than is currently available to them.³⁹

The Australian College of Pharmacy expressed conditional support for an extended of scope of practice:

Although the College supports an extension of scope of practice of pharmacists we support the development of services of extended scope in which there is demonstrated evidence that:

- all undergraduate programs of study across Australia deliver the education which underpins
 the delivery of the extended scope of professional practice (it is recognised that many
 undergraduate pharmacy degree programs will need to be redesigned to cover training new
 pharmacists to address expanded scope of practice); and
- all registered pharmacists are competent to deliver extended scope services. 40

The Grattan Institute suggested that pharmacist should be allowed to provide more health services to reduce pressure on the health system and improve consumer access:

There is good evidence that pharmacists can safely administer vaccinations, provide repeat prescriptions to people with simple, stable conditions, and work with GPs to help patients manage chronic conditions. Allowing them to do so would improve the Australian health system by reducing pressure on the primary care system and improve consumer access to care. 41

Dr Stephen Duckett from the Grattan Institute indicated that extending the scope of practice of pharmacists was important, particularly in rural Australia:

What we did in previous work was look at what doctors do, especially doctors in rural Australia. We found that there is a lot of pressure on general practice in rural Australia because there just are not enough doctors. We looked at the sort of work doctors do and whether that work could be done in cooperation with the GP—not in competition but in cooperation with the GP—by

³⁸ Submission 167, p 3.

Submission 77, p 6.

Submission 92, p 8.

Submission 24, p 7.

pharmacists. There were things that we thought were very clear, and one of them is administration of a broad range of vaccines. I think that is already the case in Queensland. The second was being able to issue simple prescription repeats. Why does a person have to go back to the doctor every time they want a repeat if they have a chronic illness? Obviously they have to go back regularly—maybe every 18 months—to have a check-up and so on, but they do not need to go back to the doctor every time they need a repeat. We think this is something that pharmacists could do in conjunction with the GP. Thirdly, they could assist in chronic disease management. Obviously there are many people with chronic diseases who are on multiple prescriptions and who also need some monitoring on a regular basis. We think pharmacists could do some of that as well, improving access for consumers.⁴²

Health Consumers Queensland supported an extended scope of practice for pharmacists to maximise the impact of Queensland's health workforce:

Geographic challenges to accessing health care, unacceptable inequities in health outcomes for Aboriginal and/or Torres Strait Islander Queenslanders, an ageing population and rising rates of chronic disease mean that Queensland must maximise the impact of our health workforce. In particular nursing, midwifery, allied health and pharmacists must be enabled to work to their full scope, where possible in integrated multidisciplinary place-based models of care.⁴³

This consumer sentiment was reinforced by Dr Shane Jackson of the Pharmaceutical Society of Australia who said consumers wanted a greater availability of pharmacist expertise:

Patients have explained to PSA in a lot of work that we have done with organisations like the Consumers Health Forum that they actually want greater availability of pharmacist expertise. They have described a spectrum of services that could be provided that relate to the accessibility of pharmacists and the pharmacist's skill as a medicines expert and as a primary healthcare provider. It has already been talked about today: access to tests, increased access to vaccinations, the ability to go to the pharmacist for care around common self-limiting illnesses—things like urinary tract infections and migraines—and also activities like pharmacists prescribing.

Examples of pharmacists prescribing, which would mean that a pharmacist would enter into a relationship with a general practice in the care of a person who is taking medicines, are extending the life of a prescription and adjusting doses of a medicine so that the treatment goals are maintained. Only about a quarter of patients treated for high blood pressure actually achieve their treatment targets. It is those types of activities that pharmacists could do in conjunction with the patient's general practitioner. All of these health services fall within the current skill set and competency of a pharmacist but legislation and regulation are often the limiting factors.⁴⁴

The pharmacist regulator, the Pharmacy Board of Australia, was also supportive of extending pharmacists' scope of practice, where it was in the public interest, and at the same time identified that the legal and professional framework may have to change to accommodate an extended scope of practice:

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

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

Public briefing transcript, Brisbane, 20 August 2018, p 23.

Public hearing transcript, Toowoomba, 7 September 2018, p 8.

⁴³ Submission 202, p 11.

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

To support the development of such opportunities, careful assessment of any legislative reform, the need for development of professional practice standards or impact on existing Board registration standards, codes and guidelines is required.⁴⁵

William Kelly of the Pharmacy Board of Australia expanded on extending the scope of practice of pharmacists at a public hearing:

... opportunities for the delivery by pharmacists of additional healthcare services in the public interest are currently being explored. The board held a recent forum with stakeholders including government representatives where it explored the potential role of pharmacists in prescribing in order to support improved access to medicines by the public. This proposal aligns with the objective of the national scheme which are to enable the continuous development of a flexible, responsive, sustainable health workforce and to enable innovation in the education of, and service delivery by, health practitioners. A report outlining discussions of the day and the next steps will be published by the board in the coming week—hopefully this week—and a copy will be provided on its release.

For prescribing by pharmacists to evolve, there will need to be legislative reform—relevant state, territory and Commonwealth legislation. There will need to be further development of the professional framework that pharmacists must practise within including practice standards as well as any regulatory action by the board under the national law including setting registration standards for approval by ministerial council and any codes and guidelines. Successful implementation of such reforms will depend on the effective collaboration of health practitioners responsible for the care of individual patients and effect an efficient service delivery framework. ⁴⁶

Pharmacist associations were also supportive of an expanded scope of practice for pharmacists. For example, the Pharmacy Guild of Australia commented:

An expanded role for the community pharmacy workforce is well aligned with current health reforms and can allow the complete utilisation of the full scope of practice of pharmacists, including preventative health and chronic disease management for the ageing and growing Queensland population.⁴⁷

The focus of the Pharmacy Guild of Australia on an expanded scope of practice (rather than an extended scope of practice) was highlighted by Trent Twomey at the second Brisbane Hearing:

Success for our members would look like a recommendation from the committee which said, 'The committee wishes that all barriers that prevent pharmacists in the state of Queensland from practising to their current scope of practice be removed'—not an increased scope of practice but that which is currently defined by the Pharmacy Board of Australia under the Australian Health Practitioner Regulation Authority, the COAG agreement that the fine doctors who came up and gave evidence before us have said they fully support. Any barriers which prevent pharmacists

⁴⁵ Submission 122, pp 8-9.

Public hearing transcript, Cairns, 11 September 2018, pp 2-3.

⁴⁷ Submission 161, p 38.

from acting to their full scope of practice in the state of Queensland should immediately be removed.⁴⁸

The Pharmaceutical Society of Australia also suggested that pharmacists should be better utilised:

While pharmacists' unique skills and expertise have been historically underutilised, there is a significant opportunity, within the current health reform environment, to ensure that pharmacists' skills are better utilised to contribute to better health outcomes for all Australians.⁴⁹

Peter Giannopoulos of Ramsay Pharmacy saw pharmacists as the medication specialist that should have a greater role in medication management and greater collaboration with doctors in multidisciplinary teams. He suggested there were a lot of missed opportunities that were within pharmacists' current scope of practice:

What is very clear—and I think pharmacists will endorse this—is that pharmacists are the medication specialists. They are the custodians of medicines. They are very well trained in all matters pertaining to medication. From my perspective, the scope of practice, or any extension to the scope of practice, would need to include aspects that pertain to medication management and optimisation of medication management or outcomes as they relate to patients either in a hospital environment or in a community setting. ... From my perspective, I would like to see pharmacists in particular focus on improving their clinical interventions in a way that they clinically provide input as part of that multidisciplinary team.

I think some of the participants in the inquiry have noted that there are some meaningful contributions to be made by pharmacists within a primary healthcare network. GP pharmacists, for example, can make meaningful contributions as part of that. It is important to try to capture some of the prescribing inconsistencies before they occur rather than happening within a community pharmacy setting after the fact. To that end, I think it is very important for pharmacists to be more acutely involved as part of that team. ... I think it is important we retain what is in the area of competency or what is within a scope of practice for pharmacists and optimise that. I think there are a lot of missed opportunities at the moment. ⁵⁰

4.2 Counter arguments

Medical practitioners and medical associations did not generally support extending pharmacists' scope of practice. Most medical stakeholders were adamant that pharmacists should not be allowed to independently prescribe medication.

The Australian Medical Association Queensland suggested that pharmacists would not be competent to undertake the necessary activities that an extended scope would entail:

... pharmacists do not have the education, training or skills to independently formulate medical diagnoses, independently interpret diagnostic tests, prescribe medication, issue repeat prescriptions, or decide on the admission of patients to, and discharge from, hospital.⁵¹

The Rural Doctors Association of Queensland (RDAQ) also thought pharmacists training is inadequate for an extended scope of practice:

Current training for pharmacists ... in medical knowledge including clinical judgment and reasoning skills is currently inadequate to manage general practice type patients.⁵²

⁴⁸ Public hearing transcript, Brisbane, 3 September 2018, p 40.

⁴⁹ Submission 136, p 3.

Public hearing transcript, Brisbane, 3 September 2018, p 26.

⁵¹ Submission 121, p 2.

⁵² Submission 173, p 3.

The Royal Australian College of General Practitioners (RACGP) did not support pharmacists offering the same services as doctors:

The RACGP advocates against multiple health professionals offering the same services. Pharmacists add value when providing services related to the safe, effective and efficient use of medicines. The increasing push to expand the scope of pharmacy beyond this puts patients at risk of poorly coordinated care and wastes valuable health resources.⁵³

The Australian College of Rural and Remote Medicine (ACRRM) did not support extending the scope of practice for pharmacists:

ACRRM fully supports a team-based approach to health care, and this is particularly important in rural and remote communities. The College also supports the concept of work to the full scope of practice to ensure that services are delivered efficiently, effectively and sustainably. However, the extension of pharmacist scope of practice, particularly to include wider prescribing rights, does not fit either of these categories. Prescribing should only be within the scope of practice for fully trained and qualified medical practitioners...⁵⁴

The Royal Australian and New Zealand College of Psychiatrists (RANZCP) was more amenable to an extended scope of practice for pharmacists provided that sufficient safeguards were implemented to address risks to patient safety. For example, the RANZCP was opposed to pharmacists performing independent prescribing in relation to psychotropic medication but was open to pharmacists providing repeat prescriptions if the prescribing doctor provided authorisation.⁵⁵

Dr Dilip Dhupelia from the Australian Medical Association Queensland suggested that if Queensland extended pharmacists' scope of practice unilaterally it would be in contravention of a recently signed Council of Australian Governments (COAG) agreement:

A vital point that I would like to make is that if Queensland were to go it alone and make any changes to the pharmacists' scope of practice it would be in contravention of the COAG agreement developed in 2016. The AHPRA prescribing working group developed a clear national pathway for other health practitioners to prescribe which requires clear steps in determining community need, a comprehensive survey of training standards and accreditation, and a requirement to gain approval at various levels including the AHPRA Scheduled Medicines Expert Committee and then AMAQ before looking at state level approvals. The Pharmacy Board of Australia recently began this process by holding a prescribing forum in Melbourne just a few months ago. In effect, if pharmacists were given approval to prescribe in Queensland this would fly totally in the face of nationally agreed and developed processes which took into account fundamental issues of patient safety ... ⁵⁶

However, if extending the scope of practice of pharmacists went through the COAG agreed process then Dr Dilip Dhupelia said the Australian Medical Association Queensland would support the outcome:

We agree to work very closely with COAG and what has been put through the AHPRA prescribing working group, that there should be a clear national pathway for health practitioners to prescribe. It has to be based on community need, a comprehensive survey of training, a comprehensive survey of standards, accreditation and a requirement to gain approval, including

⁵³ Submission 190, p 2.

Submission 89, p 3.

Submission 97, p 2.

⁵⁶ Public hearing transcript, Brisbane, 3 September 2018, p 2.

the AHPRA Scheduled Medicines Expert Committee and then to AMAQ, before the state should do it. ... As long as it goes through this process, we are happy to work with it.⁵⁷

4.3 Impacts of extending pharmacists' scope of practice

4.3.1 Potential positive community impacts

Submissions from independent public policy analysts, pharmacy education providers, pharmacists' associations and consumer groups identified positive community impacts from extending pharmacists' scope of practice:

- improved accessibility, convenience and satisfaction for patients
- lower out-of-pocket costs for consumers and lower costs to the health care system
- better health outcomes for patients, and
- improved job satisfaction for health care workers.

The Grattan Institute referred to international evidence that community outcomes improved with extended scope of practice for pharmacists in administering vaccinations, issuing repeat prescriptions and managing chronic disease:

Research in Canada and the United States shows that when pharmacists were allowed to provide vaccinations, patients reported improved accessibility, convenience and satisfaction. Successful trials in New Zealand showed that pharmacist vaccinators were far more convenient than seeing a doctor.

Allowing pharmacists to vaccinate improves their incomes while saving the health system money. This is because vaccinating in a pharmacy setting tends to be cheaper and more convenient than in a GP clinic. It may also reduce hospital costs since improved access to immunisations can reduce vaccine-preventable hospital admissions.

Canada, England, the Netherlands, Scotland and the USA have been expanding the scope of their pharmacy practice in regard to prescribing for a number of years. Studies suggest that pharmacist prescribing can improve patient health and access to treatment and is positively regarded by both patients and pharmacists.

Both pharmacists and physicians appear to favour a more collaborative approach to chronic disease management, with agreement on the benefits for patients but uncertainty about the best ways of collaborating in the absence of changes to infrastructure and reimbursement. Evidence found that pharmacist interventions significantly improve blood pressure management, blood glucose and cholesterol levels. They can also improve medication adherence and self-care for patients with chronic conditions, potentially leading to a reduction in hospital cost, with fewer admissions caused by errors in dosage and/or misuse of medication.⁵⁸

The University of Queensland School of Pharmacy outlined a variety of benefits from extending the scope of practice of pharmacists:

Extending the scope of care for pharmacists – subject to education and training – could: improve timeliness of care delivery to patients and access to this care (by releasing more highly skilled clinicians to undertake more complex tasks), resulting in fewer costs from delays and possibly greater client satisfaction; provide a more flexible and responsive workforce while preserving (or even improving) the safety and quality of care; increase work satisfaction for (and retention of)

⁵⁷ Public hearing transcript, Brisbane, 3 September 2018, p 8.

⁵⁸ Submission 24, pp 8-10.

health care workers; decrease costs of service delivery; and lead to greater ability to respond to changes in demand for health services.⁵⁹

According to the Pharmacy Guild of Australia, allowing community pharmacists to practise to their full scope may:

- Free up scarce general practice resources, to allow doctors to provide focussed medical care for patients with serious, complex and chronic conditions;
- Reduce preventable and unnecessary hospitalisations through a greater emphasis on early detection and intervention and ongoing management of chronic conditions.⁶⁰

Some consumers also wanted to extend the scope of practice for pharmacists for reasons of consumer convenience. For example, Desley Hinson stated:

It sometimes frustrates me having to wait to see my doctor just to get a script for a medication that I have been taking for 18 years. I sometimes feel that I am wasting the doctor's and my time just to get a script for something that could have been provided to me through an easier process. I believe my doctor should still be the primary person monitoring my health and medication but if there were an easier way to get my regular scripts when a doctor visit is not necessary, I would be very supportive of this. 61

4.3.2 Potential negative community impacts

Medical groups suggested the following negative impacts from extending the scope of practice of pharmacists:

- less people would visit GPs if pharmacists became prescribers leading to worse health outcomes because they would forego life-saving opportunities
- pharmacist would have conflicts of interest that if they were to become both a prescriber and dispenser that would be to the detriment of consumers
- increased risk of medication misadventure adding cost to the health system through increased hospital admissions
- increased risk of fragmentation of care which could result in dangerous medical conditions being overlooked
- would undermine the Therapeutic Goods Administration risk-based approach, exposing patients to unnecessary risk, and
- would reduce the ability of GP's to de-prescribe medication so patients would take medication longer than required.

The Australian Medical Association Queensland (AMA Queensland) suggested that allowing pharmacists to prescribe repeat medicine would lead to people having less GP consultations leading to worse health outcomes:

AMA Queensland is concerned that allowing pharmacists to become prescribers would see both men and women lose out on vital consultations with their GP as they opt for convenience over better health outcomes. However, convenience when it comes to health is potentially dangerous. Any interaction that occurs between a GP and a patient is an opportunity for that GP to make the patient healthier beyond the initial reason they have presented to the doctor on that

Submission 77, p 6.

⁶⁰ Submission 161, p 38.

Submission 30, p 1.

particular day ... Our GP members have provided numerous instances of where a repeat prescription encounter became a life-saving opportunity. 62

The Royal Australian College of General Practitioners also suggested patients would miss out on important preventative health care services if pharmacists prescribed medicines:

A visit to the doctor is not just about a prescription. A recent analysis of over 1.5 million GP- patient encounters in Australia confirmed that most medications requests to GPs result in additional health care needs being addresses during the same visit. According to the authors, losing this important opportunity for comprehensive and integrated care could be detrimental to patients. ⁶³

The Rural Doctors Association of Queensland had a similar view suggesting that patients would forego the opportunity to obtain a diagnosis for some health issue other than the initial problem on which they sought medical advice:

Repeat prescriptions and simple consultations for problems are used by general practitioners to review the patient holistically and identify emerging problems and plan care, some of these emerging problems are not all immediately apparent but may be serious, this requires medical judgement.⁶⁴

This point was reiterated by Dr Konrad Kangru of the Rural Doctors Association of Queensland in Townsville:

Even in so-called low-value consultations where a diagnosis has already been determined previously and continuing treatment is indicated, general practitioners use these opportunities to undertake the preventative health-care interventions patients seldom would make an individual appointment to assess. Cancer screening, targeted assessments, cardiovascular risk modification and mental health monitoring are all obvious examples of the activities general practitioners incorporate into each consultation often with life-saving consequences.⁶⁵

While some spill-over benefits may arise from a proportion of GP visits, in many cases they do not. In these circumstances it would be more convenient and cheaper for the patient to collect a repeat prescription from the pharmacist without visiting a GP without any additional risk to the patient's safety.

Moreover, while the committee recognises that some people should visit their GP more often, it is somewhat problematic to suggest that people should visit their GP just on the off chance that the GP will identify a life-saving opportunity. The costs of implementing such a precautionary approach on both the consumer and the government would be significant and likely to outweigh the benefits relative to a more risk-based approach.

Several doctors, a vocational training provider and some medical associations⁶⁶ raised concerns about pharmacists being both prescriber and dispenser of medicines. For example, Dr Jade Lee stated:

⁶² Submission 121, pp 6-7.

⁶³ Submission 190, p 3.

⁶⁴ Submission 173, p 3.

Public hearing transcript, Townsville, 10 September 2018, p 7.

Australian College of Rural & Remote Medicine (submission 89), Australian Medical Association Queensland (submission 121), Royal Australian College of General Practitioners (submission 190), AMAQ and RACGP joint submission (submission 139).

If pharmacists are both the prescriber and the dispenser there may be a conflict of interest if pharmacists place their financial or commercial interests above patient's interests by dispensing more medicine than necessary or dispensing a more expensive brand or type of medication.⁶⁷

Dr John Wakefield, Deputy Director-General of the Department of Health's Clinical Excellence Division, voiced similar concerns:

The particular concern—and it is a wide concern—is that, currently, the system separates the role of prescriber and dispenser. At the moment, a prescriber prescribes and has no pecuniary interest in the outcome of that prescription decision. If, as a pharmacist, either as a practising pharmacist or as an owner, you prescribe medication and you receive a financial benefit for doing so, that is a potential conflict of interest. That is not a clinical care safety and quality issue per se; it is more of a structural issue about does that conflict of interest work against the interests of patients.⁶⁸

A pharmacist that is both a prescriber and a dispenser has an inherent conflict of interest. However, the committee suggests this conflict of interest could be resolved by pharmacists being authorised to provide repeat prescriptions with the approval of the patient's GP and the informed consent of the patient. Such a model of shared prescribing was put forward by the Royal Australian and New Zealand College of Psychiatrists (Queensland Branch):

The RANZCP QLD Branch has considered the concept of pharmacists providing repeat prescriptions and is concerned about potential risks. Sufficient safeguards would need to be implemented to address these risks. For example, the prescribing doctor would need to authorise any repeat prescribing by a pharmacist, and the suitability of the patient to receive repeat prescriptions would need to be carefully assessed by the treating doctor. There should be limitations on the number of repeats that can be prescribed, or the time lapsed, before a medical review is required, to ensure that the treatment remains effective and necessary.

We suggest that parameters for any prescribing rights extended to pharmacists will need to be clearly agreed and defined. Guidelines should be developed to assist each practitioner involved in the patient's care to have clear delineation of responsibilities and ensure good communication and coordination. Such collaboration would require shared access to consumer's medical records, such as via My Health Record. Practitioners must obtain the informed consent of the patient before undertaking shared prescribing.⁶⁹

This model of shared prescribing would appear to largely address the conflict of interest because the GP would retain overarching control of the prescribing of medicine.

The Australian Medical Association of Queensland and the Royal Australian College of General Practitioners had concerns about the increased prevalence of medication misadventure if pharmacists were to prescribe medication:

Medication misadventure occurs when specific medications interact adversely with other medications the patient is already taking, and/or when the medication is inappropriate due to a patient's age, co-morbid conditions, family history or a variety of other factors.

In general practice, before medication is prescribed, a GP will examine the patient, consider their medical history (including other medications they might be taking) and discuss symptoms with the patient. GPs will also often take the opportunity to discuss preventative health and non-drug

Submission 1, p 2.

Department of Health, Correspondence, 12 September 2018.

⁶⁹ Submission 97, p 2.

interventions. The more prescribers, the greater the chance of misadventure, particularly if a pharmacist is generating the prescription in a time poor retail environment.⁷⁰

It is unlikely that the prevalence of medication misadventure would increase if a model of shared prescribing was implemented. This is because any repeat prescribing rights extended to pharmacists would require the authorisation of the prescribing doctor.

Doctors and medical associations⁷¹ were also concerned about the increased fragmentation of patient care that could arise if pharmacists were permitted to diagnose and treat patients in a similar manner to doctors. For example, Dr Jade Lee outlined:

... a patient may see multiple providers, with no one overseeing their overall care. Thus, a patient may see one provider for one conditions, another provider for another, and so on. But as no one has the overall picture, dangerous medical conditions can be missed. Diabetes may go undiagnosed. High blood pressure may not be followed up if a person sees a different provider each time.⁷²

Dr Konrad Kangru of the Rural Doctors Association of Queensland was also concerned about pharmacists independently diagnosing patients and leading to fragmentation of care:

The responsibility to make a diagnosis lies with an appropriately qualified medical practitioner and is not taken lightly. It depends on a full patient history taken with the assurance of full privacy and confidentiality. It then requires an appropriate physical examination, consideration of prior mental history or genetic risk factors, further refinement with indicator tests and may even require referral to another colleague.

At every one of these important stages the ability of a pharmacist to reach a proper diagnosis is compromised. Yet, as a trusted health professional, especially in rural communities, a patient is unlikely to understand this complexity and see only the perceived convenience of a quick answer to their concerns. In this manner the fragmentation of care through the pharmacist's interaction could potentially become a risk to proper primary care. Delays in proper diagnosis while several well intentioned pharmacist's suggestions are exhausted, a lack of familiarity with prior medical history or known family history or a bias towards prolonged pharmaceutical interventions when other treatment options would be more appropriate, are all examples of this.⁷³

Fragmentation of care, to some extent, already exists now when patients are unable to obtain an appointment with their usual GP and obtain an appointment with an alternative provider. It is not clear that this problem would be exacerbated under a shared prescribing model — which gives the authorising doctor overarching control. Furthermore, the advent of the My Health Record (where a pharmacist has the potential to access the medical history of the patient) should also reduce fragmentation of care—although this may take some time before it is achieving its potential.

The Australian Medical Association Queensland and the Royal Australia College of General Practitioners were also concerned that if pharmacists were permitted to prescribe medications they could undermine the scheduling process under the Therapeutic Goods Administration (TGA).

The TGA regulates the supply of, import, export, manufacturing and advertising of therapeutic goods. This includes prescription medicines, over-the-counter medicines (OTC) and complementary medicines. Prescription medicines (schedule 4) may only be dispensed by a pharmacist with a doctor's

⁷⁰ Submission 139, p 1.

For example, AMAQ and RACGP joint submission (submission 139), Rural Doctors Association of Queensland (submission 173), Australian College of Rural and Remote Medicine (submission 89).

⁷² Submission 1, p 2.

Public hearing transcript, Townsville, 10 September 2018, p 7.

prescription, OTC medicines may only be sold by a pharmacy (schedule 2) or pharmacist (schedule 3) and other unrestricted general medicines may be sold by any retailer.

According to the Royal Australian College of General Practitioners:

The provision of S4 [schedule 4] medications via pharmacy prescription will result in a de facto s3 [schedule 3] classification, going against the expert, considered advice of the TGA, and exposing patients to unnecessary risk.⁷⁴

As discussed in relation to medication misadventure, it is unlikely that patients would be exposed to any unnecessary risk if a shared prescribing model was implemented. The integrity of the TGA scheduling process would be maintained because schedule 4 (prescription) medications would only be prescribed by pharmacists with the authorisation of the prescribing doctor.

The Royal Australian College of General Practitioners was also concerned that if pharmacists were permitted to prescribe it would reduce the opportunity for GPs to 'de-prescribe' so patients would continue to take medication longer than required:

De-prescribing (reducing the amount of medications) is an active process for GPs, and is increasingly becoming the focus of quality improvement activities within general practice.

De-prescribing requires a thorough knowledge of the often multiple medical conditions a patient is suffering, the likely cause(s) and prognosis, disease/disease interactions, disease/medication interactions, and medication/medication interactions. It also requires an intimate knowledge of the patient's personal and medical circumstances. GPS are therefore best placed to make decisions regarding de-prescribing.

If patients simply present to a pharmacy to get a repeat for a script, there is no opportunity to meaningfully review the medications the patient is on, and de-prescribe medications no longer required.⁷⁵

Again, this concern would be reduced with a shared prescribing model, since the doctor that authorises any prescribing rights to a pharmacist would have control over the number of repeats that can be prescribed, or the time lapsed, before a medical review is required, to ensure that the treatment remains effective and necessary.

The adverse outcomes raised by medical practitioners and medical associations during this inquiry were also raised prior to the Queensland Pharmacy Immunisation Pilot (QPIP) that ran from January 2014 until March 2016. The pilot investigated the benefits of appropriately credentialed pharmacists providing influenza vaccinations in a community pharmacy. In the second phase of that pilot vaccinations were also provided for measles, mumps, rubella and whooping cough. Overall the pilot program demonstrated that appropriately trained pharmacist delivered vaccination for adults is effective and may safely be undertaken in the community pharmacy setting. As Dr Lisa Nissen from QUT School of Clinical Sciences explained in Brisbane, there were many adverse outcomes expected by the medical fraternity, but none eventuated:

We collected outcome information about adverse events. We collected outcome information about adverse events. We were looking for the unintended consequences of adding a poorly skilled workforce. If you looked at the quotes from our good medical colleagues, people would die in the street if pharmacists were available to give vaccinations. They also said that we would be vaccinating people amongst the toilet paper and toothpaste, which was clearly not the case because they were in appropriately kitted out clinical areas. We collected data that showed that that was not the case. We did not have adverse consequences. We did not have people die in the

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⁷⁴ Submission 190, p 7.

⁷⁵ As above.

street. I do not have the exact numbers, but to date hundreds of thousands of people have been vaccinated across the whole country.⁷⁶

Phase 1 of the pilot saw almost 11,000 patients vaccinated in Queensland and resulted in 93 per cent of patients being satisfied with the service. Almost 15 per cent of patients had never been vaccinated before and approximately one-third of patients had previously been vaccinated but not every year (with some not being vaccinated for more than five years). Around 10 per cent of patients were eligible for free vaccinations under the National Immunisation Program (through their GPs), but elected to have the vaccine in their community pharmacy, despite being offered referral to their GPs. 77

4.4 Where should the scope of practice be extended for pharmacists?

The University of Queensland School of Pharmacy maintained that a fixed shopping list of specific activities was not desirable because these are likely to change as people's needs change:

From an education and training perspective, it is not desirable to consider a fixed 'shopping list' of specific activities because these can change from time to time. It is preferable to provide a description of the quality and extent of education and training that we are providing to students and can provide in the future. As a high quality, flexible and responsive education provider we can provide a very high level of education and training, and the community and the pharmacy profession can specify the areas which meet evolving needs of the people of Queensland from time to time.⁷⁸

Despite this, there were many suggestions for extended scope of practice from pharmacists, pharmacist associations, pharmacy education and training providers and consumers. Some of the key suggestions included:

- continued dispensing for chronic diseases such as cardiovascular disease (eg hypertension), skin conditions (eg dermatitis), respiratory conditions (eg asthma) and diabetes
- administering vaccinations on the National Immunisation Program Schedule
- administering travel vaccinations
- prescribing of medicines (both collaboratively and independently)
- dose adjustment and medication management
- health screening and monitoring services, and
- early access to opioid replacement therapy.

4.4.1 Continued dispensing

A number of submissions⁷⁹ claimed that the three-day restriction on continuing supply of chronic disease medications leads to poor outcomes for patients. For example, the proprietor of Good Price Pharmacy Warehouse commented that she was putting her pharmacist's registration at risk by supplying medication for more than three days for the benefit of her patients:

Under the current legislation, continuing the supply of ... [chronic disease] medications is restricted to only three days, with the exception of PBS subsidised oral contraceptives ... and statin therapies to treat high cholesterol. The poor health outcomes of these DAA [dose

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Public hearing transcript, Brisbane, 20 August 2018, p 11.

Lisa Nissen et al, Queensland pharmacists immunisation pilot phase 1 pharmacist vaccination – influenza final report, 2015.

Submission 77, p 6.

For example, Pharmacy Guild of Australia (submission 161), Australian College of Pharmacy (submission 92), Galleon Way Pharmacy (submission 66), and Lucy Walker Pharmacy (submission 9).

administration aid] patients, who often suffer from concurrent chronic conditions, cannot be overstated, should I cease supply of their medications due to a lack of a valid prescription. So, I am most likely putting my registration at risk as a pharmacist and as a business owner when I instruct my team at the pharmacy to continue to supply of medication beyond the three days. ... I urge the Committee to relax the restrictions placed on community pharmacists and allow us to supply full PBS quantities as a continued dispensing of medicines for chronic diseases for those patients who are stabilised in their treatments.⁸⁰

The QUT School of Clinical Sciences also supported extending emergency supply for chronic disease beyond three days to reduce the inconvenience and cost on patients:

Extension of emergency supply is an example where legislation, professional boundaries and cost prevents practice. Currently Pharmacists can only make an appropriate clinical decision to provide a 3-day supply of medicine but not a standard pack or month supply in the case of a chronic disease therapy. The cost of the treatment and the inconvenience to the patient is often significant and the 3 days may not solve the immediate issue. Often leaving the pharmacist to supply a pack and seek an owing script for example. Given the training and knowledge of the pharmacists there would be other possible models of practice, including an expansion of the continuity of supply model – in collaboration with the medical prescriber for these patients.⁸¹

Glaucoma Australia, the peak glaucoma awareness and support organisation, also supported allowing pharmacists to extend emergency supply of medication beyond three days:

Glaucoma Australia supports a change in current regulations to allow pharmacists to properly support patients with the correct healthcare, starting with continuance of medication. Current laws only allow a 3 day emergency supply of medication and mostly does not allow an original pack of medication to be dispensed to a patient who currently uses the medication and is stable on it. For glaucoma, continued use of eye drops is essential, yet cannot by law be issued as an emergency supply due to bottles of eye drops [being] unable to be broken into a 3 day supply. Pharmacists can contribute to ongoing adherence by replacing a bottle of eye drops in case of loss or inappropriate storage including exposure to excessive heat or accidental freezing.

Amending the regulations to enable pharmacists to support continuity of care by supplying essential PBS medications for people with diagnosed glaucoma will assist to improve ... the quality of life for many Queenslanders.⁸²

Karen Brown of TerryWhite Chemmart Samford suggested that a relaxation of the three day restriction on emergency supply of medication would improve community outcomes:

I am very strong in terms of my position about the continuation of repeat prescriptions. I have an example at the moment. I have a GP practice that is closed for 10 days and I have a patient who has come in needing his blood pressure tablets. At the moment, I can only give a three-day emergency supply. I have a five-year history of him being on the same tablets from the same GP. Am I not in the best position to give him that month's supply, as opposed to sending him to a brand-new doctors practice, him going to the emergency department or, worse still, him stopping his tablets until his doctor comes back?

The emergency supply provisions outlined in section 194 of Queensland's Health (Drugs and Poisons) Regulation 1996 permit a pharmacist to supply a small amount of most prescription medicines in the absence of a valid prescription (that is, three days' supply of a drug or the minimum standard pack of

Submission 80, p 3.

⁸¹ Submission 167, p 5.

Submission 37, p 2.

a liquid, cream, ointment or aerosol). As mentioned earlier, this supply is not subsidised by the PBS and the full cost must be met by the patient.

There are national continued dispensing arrangements in place that are designed to complement the existing Queensland emergency supply arrangements. As described earlier, continued dispensing allows the supply of a single standard pack (maximum PBS quantity) of an eligible medicine, currently limited to statins and oral contraceptives, to a patient as a PBS benefit where there is an immediate need but it is not practicable to obtain a prescription—in other words, a follow-up prescription is not required. The purpose of continued dispensing is to improve patient adherence to medicine therapy and ultimately improve health outcomes.

The decision to extend continued dispensing (beyond anti-cholesterol medicines and oral contraceptives) is the responsibility of the Australian Government's Department of Human Services (which includes Medicare).⁸³ Dr Jeannette Young of the Department of Health offered some support for a re-examination of the scope of these national arrangements:

Certainly, at a national level, I think that is something they need to look at—which drugs are captured by that provision—and work that through.⁸⁴

The committee sees merit in the department discussing the extension of continued dispensing to a wider range of medicines with the Department of Human Services. In particular, the committee supports continued dispensing for patients stabilised on medicines used to treat a range of chronic health conditions. For example, such conditions could include: heart conditions, stroke prevention, epilepsy, diabetes, asthma, chronic obstructive pulmonary disease, arthritis and glaucoma.

The supply of a subsidised standard pack through the Australian Government's continued dispensing initiative would be more cost-effective for patients than the cost of a non-subsidised three-day emergency supply. This point was highlighted by Dr Jeannette Young of the department:

You need to do that at a national level, otherwise the person is going to have to pay for them. At the moment, they can get those drugs through Medicare, through PBS funding. It is important that it be done at that level. 85

Lucy Walker of TerryWhite Chemmart Goondiwindi sought an increase in the quantity of medicine able to be supplied (that is, a single standard pack⁸⁶), under the non-subsidised emergency supply provisions controlled by the Queensland Government—rather than through a broadening of the Australian Government's subsidised continued dispensing initiative:

This brings me to my concern that the Queensland drugs and poison regulation's three-day emergency supply is not sufficient to ensure continuous supply of essential medications to my patients or the grey nomads who pass through my town. Farming families usually visit town once a week or fortnightly. It is becoming less often as the drought hits and fuel costs really add up. Say they run out of their antidepressant. To get a script that day they would need to go up to the hospital, and they do not want to clog up the system. They also like seeing their GP who they have a special relationship with. Continuity of care is important to the patient as well. Allowing a PBS quantity of the prescription would give the patients and the healthcare system in Goondiwindi the best outcome for all.⁸⁷

Department of Humans Services, *Education guide – Continued Dispensing Initiative – PBS requirements,* https://www.humanservices.gov.au/organisations/health-professionals/enablers/education-guide-continued-dispensing-initiative-pbs-requirements/31671#a7.

Department of Health, Correspondence, 12 September 2018.

Department of Health, Correspondence, 12 September 2018.

This would be equivalent to a standard PBS quantity, which are generally one month's supply of medicine.

Public hearing transcript, Toowoomba, 7 September 2018, p 21.

Whilst such an initiative would be beneficial for the pharmacist, it would be relatively expensive for patients compared to a broadening of the Australian Government's continued dispensing initiative. This is because, as explained earlier, 'emergency supply' medicines lack a PBS subsidy.

It would also be inconsistent with the definition of 'emergency supply' if more than three days' supply of a restricted drug were to be provided. The unintended consequence is likely to be that more restricted drugs are dispensed (without a prescription) than are necessary to deal with the immediate emergency at hand. This unlikely to be in the community's interest.

4.4.2 Administering vaccinations

Several submissions⁸⁸ suggested pharmacists should be permitted to administer vaccinations on the National Immunisation Program (NIP) Schedule (table 1). The NIP Schedule is a series of immunisations given at specific times throughout a person's life.⁸⁹ The immunisations range from birth through to adulthood.⁹⁰ All vaccines listed in the NIP Schedule are provided free to recipients from their GP and funded by the Australian Government.

The Pharmacy Guild of Australia reiterated its support for community pharmacies to administer vaccinations on the NIP schedule and for the Department of Health to remove any remaining legislative barriers to pharmacists practising to their scope of practice:

I am sure the committee is aware that under the National Immunisation Program community pharmacies do not have access to that essential stockpile which is putting an unfair accessibility burden on Queenslanders because they can only access the government funded program from their GP; they cannot access it from their community pharmacy. Even though that is federally funded, that is an anomaly in the administration by the state in the National Immunisation Program and that should be removed so consumers can have a choice of where they access that program.

All we want, as I said, regarding vaccinations is for this committee to recommend to Queensland Health that all barriers to pharmacists practising within their current scope of practice be removed. We are not asking for an expansion. We are not asking for anything new. If we can do it in another state and territory, if we can do it in another comparable health system, if we can do it working in a nursing home or working in a Queensland hospital, why can we not do it when we are working in our local community pharmacy? ⁹¹

Mr Jamie Dalton expressed his support for pharmacists administering vaccinations on the NIP Schedule:

I would like to see flu vaccinations from pharmacy being administered as part of the national immunisation program – with pharmacists reimbursed the same as nurses – so we can increase vaccination rates and herd immunity. 92

For example, Pharmacy Guild of Australia (submission 161), Galleon Way Pharmacy (submission 66), Wynnum Day and Night Pharmacy (submission 123), and Good Price Pharmacy Warehouse (submission 80).

Australian Government, Department of Health, National Immunisation Program Schedule, https://beta.health.gov.au/health-topics/immunisation/immunisation-throughout-life/national-immunisation-program-schedule

⁹⁰ In Queensland vaccines can only be given by pharmacists to consumers aged 18 years or older.

⁹¹ Public hearing transcript, Cairns, 11 September 2018, p 20.

⁹² Submission 32, p 1.

Table 1: National Immunisation Program Schedule

Age	Disease
Birth	Hepatitis B (usually offered in hospital)
Two months	 Diphtheria, tetanus, pertussis (whooping cough), hepatitis B, polio, <i>Haemophilus influenza type b</i> (Hib) Pneumococcal Rotavirus
Four months	 Diphtheria, tetanus, pertussis (whooping coughing), hepatitis B, polio, <i>Haemophilus influenza type b</i> (Hib) Pneumococcal Rotavirus
Six months Additional vaccines for Aboriginal and Torres Strait Islander children (QLD, NT, WA and SA) and medically at-risk children	 Diphtheria, tetanus, pertussis (whooping coughing), hepatitis B, polio, <i>Haemophilus influenza type b</i> (Hib) Pneumococcal
12 months Additional vaccines for Aboriginal and Torres Strait Islander children (QLD, NT, WA and SA)	 Meningococcal ACWY Measles, mumps, rubella Pneumococcal Hepatitis A
18 months Additional vaccines for Aboriginal and Torres Strait Islander children (QLD, NT, WA and SA)	 Haemophilus influenza type b (Hib) Measles, mumps, rubella, varicella (chickenpox) Diphtheria, tetanus, pertussis (whooping cough) Hepatitis A
Four years Additional vaccines for medically at-risk children.	Diphtheria, tetanus, pertussis (whooping coughing), polio Pneumococcal
10 to 15 years	Human papillomavirus (HPV)Diphtheria, tetanus, pertussis (whooping cough)
15 to 49 years Aboriginal and Torres Strait Islander people with medical risk factors	Pneumococcal
50 years and over Aboriginal and Torres Strait Islander people	Pneumococcal
65 years and over	Pneumococcal
70 to 79 years	Shingles (herpes zoster)
Pregnant women	Pertussis (whooping cough) Influenza

Source: Australian Government Department of Health website, https://beta.health.gov.au/health-topics/immunisation/immunisation-throughout-life/national-immunisation-program-schedule

Similarly, Mr Anthony White of TerryWhite Chemmart stated:

Vaccination services in Australian pharmacies have been very well received by customers who walk through the pharmacies. Expanding these services to cover all of the standard vaccinations, including all of the NIP services, has the potential to dramatically and substantially improve Australia's immunisation status, which would substantially improve and maximise benefits to all Queenslanders. ⁹³

Dr Kos Sclavos from the Pharmacy Guild of Australia also suggested that pharmacists should be able to administer travel vaccinations:

Our best example for an extended scope is travel vaccines. In many countries' jurisdictions and provinces, pharmacists can give travel vaccines. There is no moral hazard because if you are

Public hearing transcript, Brisbane, 20 August 2018, p 1.

going to Peru or some country in South America that is on a register, then you either need that medication or you do not. Generally the rules are: if it is not putting the pharmacist in a position of moral hazard, what is the training that is required? In this case here, generally it is injection technique training, it is the suite of vaccines, how they are sourced, how they are stored and who administers. In a state like Queensland where we are decentralised and access to services is an issue, a very expensive service is travel doctors. Because they are doctors and because it is immediate use, the doctors can dispense those, so they both prescribe and dispense.⁹⁴

On the other hand, Dr Jeannette Young, Chief Health Officer with the Department of Health was more circumspect about pharmacists providing a full suite of travel vaccinations:

Some ... vaccines that you might need for overseas travel are a bit more complicated. It might be a bit difficult to do them in isolation in a pharmacy, without going through all of the other parts. For rabies, for instance, you need a whole course and you need to understand what it would mean if you were bitten by a rabid monkey, dog or other animal. There are those vaccines.

Then you have cholera, which would depend on the country that you are going through. Then your malaria prophylaxis would be medication again. I think you need to understand that it is quite complex. With yellow fever, again, you need it for certain countries and, again, it is quite complex and you can get some significant side effects.

There are certain ones that I think would be very sensible and you can already go to your local pharmacy and do that. Some of the others, I think, you have to take in context with where you are going and what you will be doing when you are going there. For some places, you are going to a tourist resort where there are no mosquitoes. You can work through the risks and what the risks are.

I would prefer myself, in terms of the health outcomes that are then available to the community, to really push some of those very important vaccines that pharmacists have proven to be very good at delivering, such as influenza, rather than go to the more nuanced vaccines. I think that would be a little bit more difficult.⁹⁵

4.4.3 Prescribing medications

Many submissions suggested that pharmacists should be able to prescribe medicines although there were disparate views on whether this should involve independent prescribing or collaborative (shared) prescribing with a general practitioner. For example, the Society of Hospital Pharmacists of Australia (SHPA) stated:

Prescribing rights should be extended to pharmacists ... There are various models of prescribing that could be considered ranging from supplemental through to independent prescribing by pharmacists. It is beneficial to community health outcomes to have pharmacists being able to prescribe PBS items for long-term, stable chronic conditions.⁹⁶

The Pharmaceutical Society of Australia⁹⁷ was open to both collaborative and independent prescribing models, while the Pharmacy Guild of Australia⁹⁸ sought prescribing rights to facilitate continued dispensing, prescription renewal and therapeutic adaption. This was reiterated by Trent Twomey at the Cairns public hearing:

Public hearing transcript, Brisbane, 3 September 2018, p 40.

Department of Health, Correspondence,, 12 September 2018.

⁹⁶ Submission 130, p 2.

⁹⁷ Submission 136, p 16.

⁹⁸ Submission 161, p 38.

What is prescribing? Prescribing by its quintessential definition is a medical professional, whether it be a pharmacist or a GP or a nurse, making a diagnosis and recommending a particular treatment which usually involves a drug. Pharmacists already prescribe. We already prescribe. We prescribe unscheduled medications, we prescribe Schedule 2 medications, we prescribe Schedule 3 medicines and in fact under the continuing dispensing protocols in the emergency supply provisions we already prescribe Schedule 4s. The difficulty is at the moment there are restrictions under the Health (Drugs and Poisons) Regulation and the Medicines Act and the Health Act 1953 which prevent pharmacists from practising to our full scope of practice.

There is a big difference between independently and autonomously initiating treatment of an S4 medication as in, 'We're going to diagnose schizophrenia and provide a drug,' which we heard from the Royal Australasian College of Physicians, to somebody who is already on a chronic medicine, they have run out and we need to ensure a continuity of care.⁹⁹

The Alberta Pharmacists' Association in its submission was supportive of Queensland pharmacists independently prescribing medications. It indicated that appropriately trained pharmacists in Alberta have had independent prescribing rights since 1 April 2007:

Since April 1, 2007, Alberta pharmacists have had included in their scope of practice the authority ... to prescribe prescription drugs. Pharmacists must meet certain criteria established by the Alberta College of Pharmacy (ACP) before being granted ... additional prescribing authorization (APA).

As of March 31, 2018 there were 5,559 pharmacists in Alberta. The number of pharmacists with additional prescribing authorization is 2,181 reflecting 39% of all pharmacists in Alberta. ¹⁰⁰

In Alberta, any pharmacist licensed with the Alberta College of Pharmacy (the provincial regulatory body) has the authority to prescribe an emergency supply, extend prescriptions of alter prescriptions.

The QUT School of Clinical Sciences suggested that allowing pharmacists to prescribe medication in collaboration with GPs, would optimise the use of their existing training, improve medication management and would remove the requirement for a new prescription:

Another opportunity for pharmacists to optimise the use of their existing training would be in the area of script adaption. In these cases, in collaboration with the medical prescriber, the pharmacist would be able to make a therapeutic substitution ...change/adapt drug usage, formulation, regimen, etc (eg swap a tablet for a capsule, adjust the dose where appropriate for optimal delivery). These models exist in Canada and the USA for example already as roles for pharmacists for general practice. This would save the requirement to seek a new prescription/owing script from the prescriber and facilitate utilization of the pharmacists' knowledge and optimize the patient care experience. 101

Some pharmacists wanted prescribing rights so that they could treat uncomplicated urinary tract infections. ¹⁰² In Toowoomba Lucy Walker of TerryWhite Chemmart Goondiwindi outlined the negative consequences that occurred to a patient that received delayed treatment for a urinary tract infection (UTI):

A lady came into the pharmacy late on a Friday afternoon with symptoms of a UTI. I referred her up to the hospital straightaway but she could not go because she had her kids with her and it can take up to four hours to be seen. I told her to call the medical centre the next morning and

¹⁰¹ Submission 167, pp 5-6.

⁹⁹ Public hearing transcript, Cairns, 11 September 2018, p 20.

¹⁰⁰ Submission 109, p 10.

For example, LiveLife Pharmacy Yeppoon (submission 52), Galleon Way Pharmacy (submission 66) and Wynnum Day and Night Pharmacy (submission 123).

get one of the emergency appointments. She didn't because she could not afford the \$40 out- of- pocket expense to see a doctor on a Saturday morning. She did go to the hospital when it got so bad on Sunday afternoon that she required oxycodone, a strong pain reliever, and she was diagnosed with a kidney infection. She was also required to go to the hospital again a few days later. I wonder what would have happened if I was able to supply her three days of Trimethoprim on that Friday afternoon to treat her UTI. 103

Of particular interest to the committee, the Department of Health advised that there were over 28,500 emergency department presentations with UTIs in 2017-18 to Queensland public hospitals. This was an increase of 2,178 UTI presentations, or 8.3 per cent, compared to 2016-17. 104

However, Dr Dilip Dhupelia from the Australian Medical Association warned that allowing pharmacists to prescribe antibiotics for urinary tract infections could just lead to patients being given antibiotics unnecessarily:

Regarding the UTI, a very senior gynaecologist member of the Australian Medical Association has shown the number of people that he sees because of irritable bladder or sensitive bladders where they go to the doctor and say, 'I think I've got a UTI,' yet the urine cultures are always negative and catheter specimens are negative. If these patients just said to the pharmacist, 'I think I've got a UTI,' and have prescribed antibiotics, I think that is wrong, especially where we are now being charged with antimicrobial stewardship. Antibiotics are being abused and the AMA is urging general practitioners to be the keepers of antimicrobial stewardship and show leadership. Without evidence of a UTI, to be prescribing antibiotics I think is fraught. 105

Dr Jeannette Young of the Department of Health raised similar issues and cautioned against professionals prescribing antibiotics for UTIs without being in a position to undertake pathology testing:

... I would not recommend being able to prescribe antibiotics for UTIs. A lot of UTIs are best treated without antibiotics. I think you need to work out the context of the patient as to whether you are going to use an antibiotic. Also—and this is where you would have to think very carefully—I do not think that you should ever allow an individual professional group to prescribe antibiotics that cannot also do the pathology testing. 106

Notwithstanding these concerns regarding the overprescribing of antibiotics, the committee suggests the department consider options to alleviate presentations of UTIs to hospital emergency departments through pharmacists prescribing (under the supervision of a GP or by a structure prescribing arrangement) for low risk, low grade infections.

An alternative to giving prescribing rights to pharmacists for such infections would be to reschedule prescription only medicine (schedule 4) to pharmacist only medicine (schedule 3). 107 Anthony White suggested re-scheduling would improve access to medicine for Queenslanders:

... Queenslanders and Australians actually have some compromised access to certain medicines that can be safely provided by professional pharmacists. The rescheduling of some prescription medicines from schedule 4 medicines to schedule 3 medicines, in association with appropriate and substantial controls over the safe and effective of handling those medicines, would also

Public hearing transcript, Toowoomba, 7 September 2018, p 21.

¹⁰⁴ Department of Health, Correspondence, 9 October 2018.

¹⁰⁵ Public hearing transcript, Brisbane, 3 September 2018, p 3.

Department of Health, Correspondence, 12 September 2018.

See TerryWhite Chemmart (Head Office (submission 135, p 9), which provided examples of medicines that could be re-scheduled from prescription only to pharmacist only medicines without compromising patient safety.

improve care for customers. Medicines for minor ailments to avoid Queenslanders unnecessarily presenting at emergency departments across Australia—that has been indicated in many Queensland Health reports—are a substantial opportunity, and pharmacists certainly have the competency and experience to manage that. 108

Scheduling is a national classification system that controls how medicines and chemicals are made available to the public. Medicines and chemicals are classified into schedules according to the level of regulatory control over the availability of the medicine or chemical, required to protect public health and safety. The Australian Government's Therapeutic Goods Administration (TGA) is responsible for scheduling medicines and makes recommendations to the Secretary of the Department of Health on the level of access required for medicines. Down-scheduling of drugs from schedule 4 to schedule 3 generally happens through the TGA application process.

4.4.4 Dose adjustment and medication management

The QUT School of Clinical Sciences suggested dose adjustment and monitoring of medications were also roles that pharmacists could competently provide. It cited recent evidence from New Zealand that showed pharmacists achieved better results than doctors in anti-coagulant control when using decision support software. However, the ability to undertake this role in Australia would be constrained by pharmacists being prevented from 'adapting a dose' or 'providing an ongoing supply of a different strength tablet':

[There] has been evidence in New Zealand where the Community Pharmacy Anticoagulation Monitoring Services has been implemented and evaluated (Shaw J et al, 2014, Harper P, 2014) demonstrating improved clinical outcomes for patients, including greater time in the therapeutic range and [less] adverse outcomes. However, the ability to implement this service here currently would be potentially impaired by the mechanisms to ensure continuity of supply if pharmacists were unable to 'prescribe' or 'adapt a dose' or provide a 'prescription' or an ongoing supply of a different strength tablet.¹⁰⁹

As Dr Lisa Nissen from the QUT School of Clinical Sciences stated in Brisbane:

The primary outcome of the study was that [patients] had less adverse reactions or outcomes from the Warfarin use—because the problem with Warfarin is that you can get people who bleed—and they got greater timing range, so they got tighter control of the Warfarin monitoring by having the pharmacist do it.¹¹⁰

Greater pharmacist involvement in monitoring of medications, such as warfarin, was supported by Dr Konrad Kangru of the Rural Doctors Association of Queensland:

Once a diagnosis has been made, we then completely acknowledge that the pharmacist is in a great situation to update and to suggest other medications, to be reviewing current evidence and to be providing monitoring. Although I am not familiar with the New Zealand study, I certainly would acknowledge that warfarin is a great example of a medication where close therapeutic monitoring is appropriate. There may be many settings where the pharmacist is well able to more closely monitor those test results and adjust dosages than the GP in that setting. I would be very keen to see where that goes. 111

Public hearing transcript, Brisbane, 20 August 2018, p 14.

¹⁰⁸ Public hearing transcript, Brisbane, 20 August 2018, pp 1-2.

¹⁰⁹ Submission 167, p 6.

Public hearing transcript, Townsville, 10 September 2018, p 9.

4.4.5 Health screening and monitoring services

Several pharmacists and pharmacist organisations also wanted to extend the scope of practice of pharmacists to screening activities. For example, screening for cholesterol (cholesterol monitoring) and diabetes (blood glucose monitoring), skin conditions such as eczema, lung diseases (for example, Chronic Obstructive Pulmonary Disease) and sexually transmitted infections.

Peak bodies of disease sufferers also supported pharmacists being able to undertake further screening. For example, the Eczema Association of Australia stated:

The EEA would be supportive of any extension of screening of skin conditions in pharmacies. We believe that, given that pharmacies are the most visited health destination in Australia, they are best placed to screen for a range of conditions, including skin conditions. While we are supportive of the role medical doctors have to play in the diagnosis and treatment of skin conditions, we believe that screening in pharmacies could ensure that more conditions are picked up sooner, ensuring that Eczema sufferers can get help when they need it. 113

The Lung Foundation Australia was also supportive of extending scope of practice to screening for lung diseases:

With regards to questions of the scope of services which pharmacists can provide, the Lung Foundation would be supportive of any scope which enables pharmacists to take a more active role in screening for lung diseases, particularly COPD [Chronic Obstructive Pulmonary Disease], and educating patients in the appropriate use of their inhaled medications to minimize symptoms, reduce exacerbations and maximize quality of life.¹¹⁴

4.4.6 Early access to opioid replacement therapy

Adnan Gauhar and Dr Andrew Whittaker proposed expanding the role of pharmacists, in collaboration with GPs, to initiate early access to opioid replacement therapy for patients. Rather than wait for a GP to enrol patients on the Queensland Opioid Treatment Program (QOTP) as occurs now, patients could begin daily dosing immediately at the pharmacy following a clinical assessment by the pharmacist using a standardised checklist. Following the assessment the pharmacist would contact the GP by phone to request initiation of treatment. The GP would then issue a prescription after consultation with the pharmacist. Enrolment in the QOTP would only occur following an appointment with the GP. There are 493 pharmacies currently providing the QOTP to patients in Queensland that could facilitate this early access service.

Adnan Gauhar and Dr Andrew Whittaker explained that it is important that people access the program as early as possible so that lives can be saved. However, early access is made difficult by the fact that there are only 12 public medical clinics and 83 private prescribers participating in the program in Queensland. This difficulty of access is compounded by the inherent challenges drug dependent people face in successfully attending doctor's appointments, as described by Dr Andrew Whittaker:

Basically, what Adnan is talking about is that if someone wants to get on the program, as I was saying before, Buprenorphine literally keeps them alive. It is a life-saving drug. If someone gets on the program, they have to first find a GP who prescribes. They have to make an appointment. They have to transport themselves there. That might all sound fairly simple, but for a lot of those people it is not simple.

For example, Pharmaceutical Society of Australia (submission 136), Pharmacy Guild of Australia (submission 161), Terry White Chemmart Head Office (submission 135), Yarraman Pharmacy (submission 14), Wandoan Pharmacy (submission 49), Ian Kinsey Outback Chemist (submission 95), Clermont Pharmacy (submission 33), Bulimba Pharmacy (submission 36) and Terry White Chemmart Arana Hills (submission 61).

Submission 20, p 1.

¹¹⁴ Submission 207, p 1.

Adnan is proposing that essentially he captures these people. They can come to him as their first port of call and say, 'I want to go on the program. I have a problem.' He contacts me. We enrol them in the program. We would not do anything that would not be safe. Until they actually make an appointment to see me, they would go on daily dosing. The difference in this model to a normal model is that Adnan is the first port of call. That is where they go. They do not go looking for a GP. They say, 'This guy does opiate replacement. I will go to him. He will talk to a doctor. He will get me on the program. Then I dose. I build my relationship with him. Then I go and see the doctor at a later date.' My role then comes in. 115

4.5 Training implications

Pharmacists, pharmacist associations, and university education and training providers were generally of the view that no additional training or only minor supplementary training (such as continued professional development or short courses) was necessary to deliver an extended scope of practice.

The University of Queensland suggested pharmacists are well prepared for current and emerging scopes of practice under the current education requirements and would only require minor additional training:

Pharmacy student training at accredited pharmacy schools in Australia well prepares pharmacists for current and emerging scopes of pharmacy practice.

If pharmacists' current training does not prepare them for an extension in their scope of practice, pharmacists also have many opportunities to learn new skills through continuing education sessions, and through further training from a pharmacy school (for example, via a post-graduate certificate or diploma). ¹¹⁶

More specifically, the Queensland University of Technology suggested that it was already including course content for independent prescribing by pharmacists:

While very small 'gaps' in our underlying competencies may exist for 'autonomous/independent' prescribing roles these are actually artefacts of our current scope and practice (Nissen L et al, Pharmacy Board Report 2017). If we are given the ability to operate in some autonomous role pharmacists can be easily 'upskilled' through training — as we have done so for the current AHPOQ pharmacy trials, and as was demonstrated in Hale et al Surgical Pre-admission prescribing trial and HIV trial (Hale et al 2014 and 2015). This upskilling for pharmacy has required some course content but is primarily focused on a period of learning in practice — aligned to the prescribing competencies and similar to that which is offered in the UK. Prospective adaption of the undergraduate programs of study incorporate these skills and competencies would be easily managed, and we have in fact begun this process with our own curriculum at QUT [by] including a final year unit on Pharmacy Prescribing in the course. 117

The Pharmacy Guild of Australia saw the scope of practice of pharmacists evolving in an organic manner over time:

Scope of practice is a time sensitive, dynamic aspect of practice which indicates those professional activities that a pharmacist is educated, competent and authorised to perform and for which they are accountable. They are defined by a regulatory body such as the Pharmacy Board of Australia and the profession after taking into consideration the health professional's training, experience, expertise and demonstrated competency. It includes activities delegated to

 $^{^{115}}$ $\,$ Public hearing transcript, Toowoomba, 7 September 2018, p 3.

¹¹⁶ Submission 77, p 7.

¹¹⁷ Submission 167, p 4.

others and can be expanded at the discretion of the individual practitioner by incorporating into their practice the knowledge, skills and expertise required to deliver a new health service.)

As the role of community pharmacists continues to evolve to meet community health needs, so too will the Pharmacy Board of Australia's definition of scope of practice. The profession will continue to provide evidence-based services, consistent and delivered under the existing robust quality assurance and regulatory frameworks, with the appropriate education, training and qualifications and workforce support mechanisms.¹¹⁸

However, the Australian College of Pharmacy suggested that even if university pharmacy courses were appropriate there needs to be a concerted effort to ensure that existing registered pharmacists were trained where their scope of practice is extended:

Even if undergraduate programs of study are found to consistently produce graduates who are competent to deliver extended scope services, we contend there is a need to upskill existing registered pharmacists to address knowledge and skills gaps such that they can deliver new professional services within an expanded scope of practice. 119

The Royal Australian and New Zealand College of Psychiatrists suggested that if pharmacists are approved to undertake repeat prescribing, independent of doctors, then they would need further training:

If any expanded scope of practice is introduced for pharmacists, appropriate safeguards and supports should be put in place to ensure patient safety is maintained. Pharmacists should be required to undergo appropriate training and supervision in order to obtain repeat prescribing rights. For example, if pharmacists become involved in prescribing repeat psychotropic medication, formal training in mental health care should be a prerequisite. Patients with mental illnesses can present complexities, including comorbid mental health conditions and acute or chronic physical illness that require concurrent treatment. For this patient group, polypharmacy is common and meticulous attention is needed to avoid adverse outcomes.¹²⁰

The Royal Australian and New Zealand College of Psychiatrists (RANZCP) referred the committee to the National Prescribing Service's Prescribing Competencies Framework (PCF) developed in 2012. The PCF describes the competencies required to prescribe medicines safely in the Australian healthcare system. The RANZCP suggested that pharmacist prescribing should be underpinned by a robust national competency framework such as the PCF, where they would be required to demonstrate the prescribing competencies.

Additional education and training for pharmacists should only be required where it is necessary as part of a risk-based approach undertaken by government regulatory authorities. There is also a need for this education and training to be nationally consistent so that the mobility of the pharmacist workforce is not unnecessarily constrained by different requirements in different jurisdictions.

According to the Pharmacy Board of Australia:

State and territory health departments have set requirements for training and education for pharmacists to [administer vaccines].

The education and training is not currently consistent across jurisdictions and this has the potential to impact workforce mobility which is an objective of the National Scheme. To minimise

¹¹⁸ Submission 161, pp 42-43.

¹¹⁹ Submission 92, pp 8-9.

¹²⁰ Submission 97, p 3.

this impact, further efforts are required nationally to ensure that a trained pharmacist can administer vaccines in jurisdictions other than where the training was completed. 121

There are also variations in the range of vaccines that a pharmacist is authorised to administer and differences in minimum age requirements for the patient under state or territory legislation (table 2). The committee recommends these arrangements should be aligned to ensure the benefits of nationally consistent training are maximised (see recommendation 2).

Table 2: Pharmacist administered vaccines in Australia

Jurisdiction	Legislation amended	Vaccines	Minimum age
Queensland	2016	Influenza Measles, mumps, rubella (MMR) Diphtheria, tetanus, pertussis (dTpa)	18
New South Wales	2015	Influenza	18
Victoria	2016	Influenza Diphtheria, tetanus, pertussis (dTpa)	18
Tasmania	2016	Influenza	18
South Australia	2017	Influenza Measles, mumps, rubella (MMR) Diphtheria, tetanus, pertussis (dTpa) Polio (in combination with dTpa)	16
Western Australia	2014	Influenza	18
Australian Capital Territory	2016	Influenza Diphtheria, tetanus, pertussis (dTpa)	18
Northern Territory	2017	Influenza Measles, mumps, rubella (MMR) Diphtheria, tetanus, pertussis (dTpa)	16

Source: Pharmacy Guild of Australia, submission 161, p 40.

Dr Lisa Nissen from the QUT School of Clinical Sciences suggested that there is scope to reduce the minimum age limit to 12 and also increase the number of vaccinations available in Queensland:

We have had some discussion with the Chief Health Officer about reducing the age and also increasing the number of vaccinations that are available. That has continued with the guild and the society having those discussions. My personal view, as has been discussed with the society and the guild, is that that could even be reduced to more than 12. In pharmacy, we consider that for those over 12 the dosing of medicines become adult doses. That would allow us to look at catch-up vaccinations for HPV [Human papillomavirus]. It would allow us to provide flu vaccinations for the super spreaders—that is, then teenagers. It would also allow us to cover a number of other vaccinations for catch-up programs for kids who miss them through immunisation programs. That would be the type of age group that would be most suitable for us to be pitching for. 122

Dr Bruce Willett from the Royal Australian College of General Practitioners was less convinced that there was a justification to reduce the age below 18 for pharmacist administered vaccines because of an increased risk of adverse reaction with younger patients:

¹²¹ Submission 122, p 8.

Public hearing transcript, Brisbane, 20 August 2018, p 11.

I think it is reasonable for uncomplicated adult patients to be vaccinated in pharmacies. As was said earlier this morning, with younger patients they are often live vaccines so there are a lot more contraindications. There is an increased risk of adverse reaction. ¹²³

Dr Jeannette Young of the department suggested that reducing the minimum age limit to 16 for pharmacist administered vaccines was feasible:

We certainly believe that it would make sense to expand it down to the age of 16. There are some things we would have to work through quite carefully under that age in terms of who is providing consent and how it is being done. Certainly, we think down to age 16 would be a reasonable area to work through.¹²⁴

4.6 Conclusions

Following the recent success of pharmacists administering vaccinations in Queensland there are significant potential community health benefits from extending the scope of practice of pharmacists further. These benefits include:

- improved accessibility, convenience and satisfaction for patients
- lower out-of-pocket costs for consumers and lower costs to the health care system
- better health outcomes for patients, and
- improved job satisfaction for health care workers.

The committee recommends the minimum age for patients for pharmacist-administered vaccinations be lowered to 16 years, and that the Department of Health develop options for pharmacists to provide low-risk emergency and repeat prescriptions (for example, repeats of the contraceptive pill) and low risk vaccinations (including low risk travel vaccinations) through pharmacies subject to a risk-minimisation framework. Any change in scope of practice utilisation should be underpinned by appropriate credentialing and training for the services being delivered.

The committee heard a range of concerns during the inquiry, particularly by medical practitioners and medical associations, about extending the scope of practice of pharmacists. These concerns suggested there would be increased risk of negative patient outcomes if pharmacists were permitted to independently prescribe medication because of the increased risk of medication mismanagement and fragmentation of care, amongst other concerns. However, with sufficient safeguards in place and appropriate additional training, these concerns should be allayed. The committee feels the inclusion of 13HEALTH in Recommendation 2 should allay some of the concerns of the AMA in relation to pharmacists' scope of practice.

Many of the issues raised by medical practitioners and medical associations could be addressed by a shared or collaborative prescribing model. Under this model, the prescribing doctor would need to authorise any repeat prescribing by a pharmacist, and the suitability of the patient to receive repeat prescriptions would need to be assessed by the treating doctor. There would need to be limitations on the number of repeats that can be prescribed, or the time lapsed, before a medical review is required, to ensure that the treatment remains effective and necessary. It is the committee's understanding that the Pharmacy Board of Australia is exploring options for a collaborative prescribing model in Australia.

Pharmacists, pharmacist organisations, and pharmacy education and training providers put forward many suggestions for where the scope of practice for pharmacists could be extended. While some were within the jurisdiction of the Queensland Government others require action by the Australian Government. For example, the decision to extend continued dispensing (beyond anti-cholesterol medicines and oral contraceptives) is the responsibility of the Australian Government's Department of

Public hearing transcript, Brisbane, 3 September 2018, p 21.

Department of Health, Correspondence 6 August 2018.

Human Services. In addition, the decision to allow pharmacists to administer vaccinations on the National Immunisation Program Schedule is the responsibility of the Australian Government's Department of Health. Also, the re-scheduling of medicines is the responsibility of the Therapeutic Goods Administration (which is part of the Australian Government's Department of Health). Changes to administering vaccinations or the prescribing of medicines require amendments to both state and Commonwealth legislation.

The committee recommends the Department of Health develop options for pharmacists to provide low-risk emergency and repeat prescriptions (for example, repeats of the contraceptive pill) and low risk vaccinations (including low risk travel vaccinations) through pharmacies subject to a risk-minimisation framework.

The framework could include:

- consultation with a GP utilising 13HEALTH
- limitations on the number of times a prescription can be issued within a period of time (eg only once in a six-month period),
- on-site testing, and
- a requirement that the pharmacist consult a 13HEALTH GP or have regard to the patient's medical record via MyHealthRecord.

Any change in scope of practice utilisation should be underpinned by appropriate credentialing and training for the services being delivered.

Recommendation 1

The committee recommends that the Department of Health lower the minimum patient age requirement for pharmacist-administered vaccinations to 16 years of age.

Minister responsible: Minister for Health and Minister for Ambulance Services

Recommendation 2

The committee recommends the Department of Health develop options to provide low-risk emergency and repeat prescriptions (for example, repeats of the contraceptive pill) and low risk vaccinations (including low risk travel vaccinations) through pharmacies subject to a risk-minimisation framework. The framework could include:

- consultation with a GP utilising 13HEALTH
- limitations on the number of times a prescription can be issued within a period of time (eg only once in a six-month period)
- on-site testing, and
- a requirement that the pharmacist consult a 13HEALTH GP or have regard to the patient's medical record via MyHealthRecord.

Any change in pharmacists' scope of practice should be underpinned by appropriate credentialing and training for the services to be delivered.

Minister responsible: Minister for Health and Minister for Ambulance Services

Administration of vaccines by pharmacists has made a positive impact on health outcomes in Queensland and Australia. However, state and territory health departments have set different requirements for education and training for pharmacists and different scopes of practice in administering vaccinations.

There needs to be greater national consistency in both education and training and scope of practice for the administering of vaccinations to ensure the mobility of the pharmacist workforce is not unduly constrained and that access to medicines is not restricted where they can be provided safely. This initiative should be progressed through the COAG Health Council which has responsibility for the Health Practitioner Regulation National Law (as in force in participating state and territory jurisdictions). ¹²⁵

Recommendation 3

The committee recommends the Minister for Health seek support through the COAG Health Council for nationally consistent education and training requirements and scope of practice for pharmacists administering vaccinations.

Minister responsible: Minister for Health and Minister for Ambulance Services

COAG Health Council, 2014 Terms of Reference,
https://www.coaghealthcouncil.gov.au/Portals/0/Final COAG%20Health%20Council%20Terms%20of%20
Reference 2014.pdf.

5 Should scope of practice be extended for pharmacy assistants?

5.1 Arguments for extending scope of practice for pharmacy assistants

There were few submissions that provided comments on extending the scope of practice for pharmacy assistants. Most submissions that discussed pharmacy assistants were focused on their lack of mandatory qualifications.

The Pharmacy Board of Australia said a range of issues needed to be resolved before governments could consider extending the scope of practice of pharmacy assistants:

- the competence required to safely deliver additional services
- how these competencies can be met
- the financial impact on the business
- the impact on the delivery of other professional services in community pharmacy
- who is held accountable in the event that service delivery is below acceptable standards
- how the public would be adequately protected and whether this requires some type of regulation to achieve this.¹²⁶

As noted earlier, the Pharmacy Board of Australia does not regulate pharmacy assistants or other ancillary staff. This is basically because at this point in time pharmacy assistants are not involved in the clinical area of pharmacy—so there is no need for APHRA registration.

The Queensland University of Technology School of Clinical Sciences saw the extension of pharmacy assistants' scope of practice as helpful in facilitating the extension of pharmacists' scope of practice:

The ability to advance the skill and training development of assistants/technicians to a level which would be comparable to our UK or Canadian colleagues is sometimes seen as a threat to the pharmacists' workforce here – 'what will we do?' if delegation of roles and responsibilities is made for technical and other duties to such a group. This is where the need to offer more scope for pharmacists to participate in the system becomes necessary and the removal of legislative and professional boundaries to make it possible to advance both roles becomes imperative. 127

Dr Lisa Nissen of the QUT School of Clinical Sciences elaborated on this symbiotic relationship between pharmacists and pharmacy assistants in Brisbane:

It is really important that we talk about the technician workforce. If we want pharmacists to do clinical roles and be where medicines are, you need an appropriately trained technician workforce ... If we need to piece those two together, that is, use pharmacists more appropriately paired with an appropriately trained technician workforce—you cannot do them independently; they need to work together—then you can improve access, you can improve skill mix in your health workforce and you can improve medicines management in the community. 128

The Pharmaceutical Society of Australia conveyed similar sentiment:

Better utilisation of appropriately trained and certified pharmacy assistants may allow for better utilisation of pharmacists in taking greater responsibility and accountability for medicines management in the community. This should be seen as an enhancement to pharmacists' practice and not a substitution or role replacement. In addition to enhancing a pharmacists' role,

¹²⁷ Submission 167, p 7.

¹²⁶ Submission 122, p 9.

Public hearing transcript, Brisbane, 20 August 2018, p 10.

appropriately trained pharmacy assistants help to strengthen the pharmacy team's ability to deliver health services according to the needs of the patient and then community. 129

Casey Clark and John Clark wanted an increase in pharmacy assistants' scope of responsibilities so that they could assist in improving workflow efficiencies within pharmacies:

Consideration should be given to the legislation around what pharmacy assistants and dispensary technicians can do, based on them having received training. There is [currently] limitations on their roles [this] does not help with being able to improve workflow efficiencies within a pharmacy. Given their skill set and training a possible increase in their scope of responsibilities should be considered.¹³⁰

5.2 Counter arguments

The Australian Medical Association did not believe there was an evidence-based argument for increasing the scope of practice for pharmacy assistants:

AMA Queensland does not believe that there is a compelling, evidence-based argument for increasing the scope of practice for pharmacists and pharmacy assistants, even in rural and remote areas where anyone with access to the internet can use websites like Doctors on Demand to access prescriptions and have consultations with registered, qualified medical practitioners. ¹³¹

The Rural Doctors Association of Queensland commented that pharmacy assistants lacked the necessary skills to manage medical patients:

Current training for ... Pharmacy Assistants in medical knowledge including clinical judgement and reasoning skills is currently inadequate to manage general practice type patients. ¹³²

5.3 Impacts of extending scope of practice for pharmacy assistants

There was little discussion in submissions of the impacts of extending the scope of practice of pharmacy assistants. The Australian College of Rural and Remote medicine suggested that extending the scope of practice of pharmacy assistants would not increase access to health services in rural and remote areas:

There is no evidence to suggest that expanding the scope of practice of pharmacists and pharmacy assistants will improve access to health care services in rural and remote communities. In the majority of cases, there are no pharmacies located in communities which do not already have a general practice or other access to primary health care services, and it is highly unlikely that a pharmacy would be a viable proposition in those areas. 133

However, this assertion is contested by geospatial evidence provided to the King Review by the Pharmacy Guild of Australia which suggested that community pharmacies are more accessible than medical centres in regional areas:

The findings of MacroPlan Dimasi's comparison of the location of community pharmacy to that of other services are also informative. While there are inevitably some localised variations, it is clear that on balance, consumers are more likely to be close to a community pharmacy than to a supermarket, bank or medical centre. Moreover, the proportion of consumers who are

¹²⁹ Submission 136, p 16.

¹³⁰ Submission 145, p 9.

¹³¹ Submission 121, p 10.

¹³² Submission 173, p 3.

¹³³ Submission 89, p 3.

reasonably close to two or more pharmacies is as high, if not higher, for community pharmacy than it is for the other services that were analysed by MacroPlan Dimasi. 134

5.4 Where should the scope of practice be extended for pharmacy assistants?

Most submissions did not specify where the scope of practice should be extended for pharmacy assistants. However, one area of interest was the handling of dangerous drugs. Some pharmacists wanted legislation changed to enable community pharmacy assistants to handle dangerous drugs in a similar manner to pharmacy assistants who work in a hospital setting. For example, Good Price Pharmacy Warehouse stated that handling dangerous drugs was a technical task that should be delegated:

I also ask the Committee to amend the legislation for pharmacy assistant practice to be universal across the sector, including those working in community and hospital settings. Currently, suitably trained pharmacy assistants working in the public sector in Queensland ... are permitted to handle dangerous drugs, including receiving them from couriers and putting [them] away into the safe. However, when working in community pharmacy in Queensland, the pharmacist must do this. The handling of dangerous drugs is a technical task that should be permitted to be delegated to an assistant by a pharmacist. 135

Pharmacy assistants, such as Kristy Floyd, indicated that being able to handle dangerous drugs would improve workflow:

I'm currently completing my Certificate IV and I understand that pharmacy assistants that hold a Certificate IV qualification and work in a hospital have access to the DD [dangerous drugs] safe. This means Certificate IV qualified pharmacy assistants in a hospital can handle DDs, assisting Pharmacists when dispensing DD scripts. This helps with work flow. Unfortunately, once I complete my Certificate IV I won't be able to help my pharmacist in the same way working in a community pharmacy. There needs to be consistency across the industry with these types of regulations. ¹³⁶

If handling dangerous drugs is a necessary competency in the community pharmacy setting, then the committee would encourage the department to explore the efficacy of aligning the Certificate IV in Community Pharmacy and the Certificate IV in Hospital/Health Service Pharmacy Support in relation to the handling of dangerous drugs. The obvious way to do this would be by extending the scope of practice of community pharmacy assistants in relation to the handling of dangerous drugs.

5.5 Training implications

Numerous pharmacists, pharmacist organisations and pharmacy education and training providers wanted pharmacy assistants to undertake a minimum mandatory training despite 95 per cent of pharmacies being accredited through the Quality Care Pharmacy Program (QCPP), see section 3.3.2. ¹³⁷

Casey Clark and John Clark suggested that the Pharmacy Guild of Australia training program be made mandatory because it sets a great standard:

We believe the current Guild training program for pharmacy assistants sets a great standard for what pharmacy assistants should be trained in. This type of training program should be

Pharmacy Guild of Australia, *Submission to Review of Pharmacy Remuneration and Regulation*, 30 September 2016, p 47, https://www.guild.org.au/ data/assets/pdf file/0024/12957/guild-submission-to-review-of-pharmacy-remuneration-and-regulation-2016.pdf.

¹³⁵ Submission 80, p 3.

¹³⁶ Submission 85, pp 1-2.

Pharmacy staff employed in QCPP accredited pharmacies, who supply pharmacy medicines (schedule 2) and pharmacist only medicines (schedule 3), must complete mandatory initial training via a recognised course in the supply of these products and ongoing refresher training of at least three hours per year.

something that all stores are required to have their staff put through in order to work in a pharmacy.¹³⁸

Paul Jaffar suggested that mandatory qualification would provide a more consistent approach to training across the industry:

Pharmacy assistants play a crucial role within community pharmacy and are often the first point of contact for patients. There are currently a number of training options for pharmacy assistants, however I believe that a more consistent approach and mandatory minimum qualification would be beneficial. Minimum qualifications for pharmacy assistants would help to meet expectations of consumers and would also allow them to better utilise skills and knowledge to assist pharmacists and enable them to provide better health services to patients. 139

The Australian College of Pharmacy wanted a universal minimum qualification to enable workforce mobility:

Pharmacy assistants are bound by the COAG Health Council National Code of Conduct for Health Care Workers that is designed to guide the behaviour of unregistered health care workers providing a health service, and is, or will be enforceable in some jurisdictions. There is no minimum mandatory training for pharmacy assistants in Queensland (with the exception of the delegation frameworks that exist for pharmacy assistants in Queensland hospitals and the requirements of the Quality Care Pharmacy Program).

The College believes a minimum mandatory training requirement should be introduced. The minimum qualification should be universal for all pharmacy assistants, regardless of their area of practice, to enable workforce mobility. 140

The Pharmacy Guild of Australia also wanted a minimum qualification to establish a universal and consistent skill set:

Minimum mandatory vocational training for pharmacy assistants would be a step towards establishing a universal and consistent skill set which includes a range of intellectual, technical and communication skills. Pharmacy assistants should be required within this mandatory training the capacity to demonstrate defined responsibility within an appropriate delegation and supervision framework.¹⁴¹

Dr Shane Jackson from the Pharmaceutical Society of Australia not only wanted a minimum level of training for non-pharmacist staff but also that it be developed through a national competency framework rather than a state-by-state basis:

We also believe that, certainly in the public interest and actually in the public's expectation, there is a minimum level of training for non-pharmacist staff such as pharmacy technicians and pharmacy assistants who are working under the supervision of pharmacists and have responsibilities within that pharmacy. What we believe, however, is that there should be a national competency framework for non-pharmacist staff—so actually identify the roles and functions that we would like pharmacy assistants or non-pharmacist staff to perform in a pharmacy environment and actually map the training and the minimum requirements to that on an ongoing basis. This ideally is done from a national perspective. That framework would guide curricular development and minimum training requirements, as I said, and the framework would

¹³⁸ Submission 145, p 9.

¹³⁹ Submission 148, p 4.

¹⁴⁰ Submission 92, p 10.

¹⁴¹ Submission 161, p 42.

align with the key professional documents that I have tabled today, the professional practice standards, to ensure that they are all in alignment. ¹⁴²

Dr Lisa Nissen also agreed that there was not much consistency in the education of pharmacy assistants in the community pharmacy and hospital pharmacy settings:

We agree that there is not a lot of consistency in what happens with assistants. The highest qualification is a certificate IV. They exist in both the retail and the health packages. That is also an inconsistency currently. Most of the hospital people do a different certificate IV than the people in community practice. ¹⁴³

However, the Society of Hospital Pharmacists of Australia did not support a one-size fits all approach to qualifications because of the inherent differences in the hospital and community pharmacy work setting.

Pharmacy assistants and technicians that work in hospital pharmacies have a much broader and specialised scope of practice compared to their community counterparts.

SHPA believes that a formal qualification designed for pharmacy technicians and assistants wishing to work in hospitals, is a better, standardised, more formal and robust way of ensuring this workforce is fit for purpose.¹⁴⁴

While there was general support for mandatory qualification requirement several pharmacist organisations and pharmacist proprietors wanted someone other than the employer/employee to pay for the cost of provision. For example, the Pharmacy Guild of Australia implied that government would need to provide some financial support to pharmacy owners if minimum qualifications were mandatory:

It should be noted that an introduction of a minimum mandatory level of qualification must be undertaken in a phased approach with consideration of the costs to the employee or employer. Financial support may be required to implement this reform over an agreed reasonable period of time and with recognition of prior learning for employees.¹⁴⁵

Good Price Pharmacy Warehouse also wanted any minimum qualification to be cost neutral for pharmacy owners and employees:

Regarding pharmacy assistants, I would support a recommendation that would see in the future a minimum qualification requirement. However, this should be a cost neutral exercise for both the pharmacy owner and the employee affected, and phased in over a significant time frame, considering the large number of assistants and businesses this would impact. ¹⁴⁶

Similarly, Russell Island Pharmacy was also concerned about any additional burden on business:

I am also broadly supportive of minimum education standards for pharmacy assistants. But government needs to work with pharmacists to make sure this doesn't become too much of a burden on our businesses. We want to ensure our customers receive the highest quality of care, but our businesses have to be sustainable to support this. 147

It is not clear to the committee what the problems are with the current training arrangements. No submission suggested that the current training arrangements for pharmacy assistants were

¹⁴⁵ Submission 161, p 43.

Public hearing transcript, Brisbane, 20 August 2018, p 23.

Public hearing transcript, Brisbane, 20 August 2018, p 10.

¹⁴⁴ Submission 130, p 3.

Submission 80, p 3.

¹⁴⁷ Submission 58, p 1.

inadequate. Some submitters suggested there were inconsistencies between different training providers. If there are no barriers to students choosing the most reputable suppliers of pharmacy assistant training this should not be a significant issue.

Other submitters complained about the different (higher) qualifications for those pharmacy assistants that work in hospital pharmacies compared to those that work in community pharmacies. This is only a problem if there is no justification for the different educational requirements. It is not clear to the committee that hospital pharmacy assistants and community pharmacy assistants should have the same universal qualification if their scope of practice is different and this difference is justified.

Changing the qualification requirements for community pharmacy assistants to align with hospital pharmacy assistants (without justification) could create an unnecessary barrier to entry for those wanting to pursue employment as a community pharmacy assistant. Credentialism for its own sake is not in the community's interest. Mandating higher qualifications for community pharmacy assistants could also increase the cost of providing pharmacy services if this increased community pharmacy assistant wage levels.

It is also not clear to the committee why the pharmacy owner would not pay for the training of pharmacy assistants. Under the Pharmacy Board of Australia's, *Guidelines for proprietor pharmacists*, proprietors must ensure that the pharmacy is suitably resourced and that staff members are suitably trained to provide services in accordance with their position descriptions. Pharmacy assistant training costs should be viewed as a normal cost of running a pharmacy business.

It is also the committee's understanding that pharmacy assistant traineeships can be utilised to offset some of the employer's cost. This process is facilitated via the Australian Apprenticeship Support Network. However, there is a risk to employers of not getting a return on their investment in training if the pharmacy assistant leaves the employer's business before the traineeship is completed. In such cases, no government subsidy would be paid to the employer.

In addition, some students who are eligible for state subsidised training places can already receive reduced course fees. These subsidies are paid to the Registered Training Organisation (for example, the Pharmaceutical Society of Australia, Pharmacy Guild of Australia, etc) and not the employer. ¹⁵⁰

5.6 Conclusions

In contrast to the depth of comment on scope of practice for pharmacists, few submissions commented on extending the scope of practice for pharmacy assistants. Those submissions that did discuss pharmacy assistants were focused on their lack of mandatory qualifications.

Most submissions did not specify where the scope of practice should be extended for pharmacy assistants. However, one area of interest was the handling of dangerous drugs. Some pharmacists wanted legislation changed to enable community pharmacy assistants to handle dangerous drugs in a similar manner to pharmacy assistants who work in a hospital setting.

The committee suggests that the Department of Health explore the efficacy of aligning the Certificate IV in Community Pharmacy (or Certificate IV in Community Pharmacy Dispensary) and the Certificate IV in Hospital/Health Service Pharmacy Support in relation to the handling of dangerous drugs. This can be achieved by extending the scope of practice of community pharmacy assistants in relation to the handling of dangerous drugs.

Pharmacy Board of Australia, *Guidelines for proprietor pharmacists*, https://www.pharmacyboard.gov.au/codes-guidelines.aspx.

Australian Government, Australian Apprenticeships website, https://www.australianapprenticeships.gov.au/employers.

Queensland Government, Subsidised training and incentives, https://training.qld.gov.au/training/incentives

Recommendation 4

The committee recommends the Department of Health, in conjunction with the Pharmacy Advisory Council (if established), explore the benefits and risks of extending the scope of practice of community pharmacy assistants in relation to the handling of dangerous drugs.

Minister responsible: Minister for Health and Minister for Ambulance Services

Numerous pharmacists, pharmacist organisations and pharmacy education and training providers proposed that pharmacy assistants undertake a minimum level of mandatory training. This is despite the fact that around 95 per cent of pharmacies are accredited with the Quality Care Community Pharmacy program whereby pharmacy assistants must complete mandatory initial training via a recognised course and ongoing refresher training of at least three hours per year.

It is not clear to the committee that the problems with the current training arrangements warrant government intervention. No submission suggested that the current training arrangements for pharmacy assistants are poor or inadequate. Some submitters suggested there were inconsistencies between different training providers. However, if there are no information barriers and no barriers to students choosing the most reputable suppliers of training it appears unnecessary for government to mandate training. Mandating training requirements could be a disincentive for registered training providers to develop new and innovative training techniques and making refinements to the curriculum.

Submitters also complained about the lack of universal qualifications for pharmacy assistants who work in hospital pharmacies and community pharmacies. This is not necessarily a problem if there is justification for the different qualifications in the different pharmacy sectors. It is not clear to the committee that hospital pharmacy assistants and community pharmacy assistants should have the same universal mandatory qualification if their scope of practice is different and this difference is justified. The committee has recommended that the Department of Health should explore the benefits of having the same basic mandatory education and training for assistants working in both sectors. This should only occur where there are core competencies applicable to both sectors and where mandatory training would provide benefits to the community. Higher qualifications should be different for community pharmacy assistants and hospital pharmacy assistants if their required competencies diverge.

Recommendation 5

The committee recommends the Department of Health, in conjunction with the Pharmacy Advisory Council (if established), explore whether community pharmacy assistants and hospital pharmacy assistants should undergo the same basic mandatory training, and whether this would provide benefits to the community.

Minister responsible: Minister for Health and Minister for Ambulance Services

While there was general support for mandatory qualification requirements several pharmacist organisations and pharmacist proprietors wanted someone other than the employer/employee to pay for the cost of provision. It is not clear to the committee why the pharmacy owner should not pay for the training of pharmacy assistants. Under the Pharmacy Board of Australia's, *Guidelines for proprietor pharmacists*, proprietors must ensure that the pharmacy is suitably resourced and that staff members are suitably trained to provide services in accordance with their position descriptions. ¹⁵¹ Pharmacy assistant training costs should be viewed as a normal cost of running a pharmacy business.

Pharmacy Board of Australia, *Guidelines for proprietor pharmacists*, p 4, https://www.pharmacyboard.gov.au/codes-guidelines.aspx.

6 Pharmacy ownership requirements in Queensland

6.1 Pharmacy ownership regulation prior to 1 July 2010

Prior to 1 July 2010, provisions in the *Pharmacists Registration Act 2001* (Qld) imposed restrictions on the ownership of pharmacy businesses. In summary, these restrictions limited ownership of pharmacy businesses to:

- registered pharmacists or corporations (consisting of a pharmacist or a combination of pharmacists and their relatives, but with pharmacists holding the controlling interest), who may not own more than five pharmacy businesses, and
- friendly societies and Mater Misericordiae Health Services Brisbane Limited, who may own not more than six pharmacy businesses.

The ownership restrictions applied to the ownership of businesses that operated community pharmacies and not hospital pharmacies.¹⁵² The ownership provisions were administered by the Pharmacist Board of Queensland which was funded by registration fees paid by pharmacists.

6.2 National Registration and Accreditation Scheme for health professions

In March 2008, COAG signed the 'Intergovernmental Agreement for a National Registration and Accreditation Scheme for the Health Professions' (COAG Agreement).

The COAG Agreement provided for a single national registration and accreditation scheme (the National Scheme), initially for ten health professions including pharmacists. However, the National Scheme, also known as NRAS, specified that it did not cover pharmacy ownership restrictions or the registration of pharmacy premises and that these matters would continue to be the responsibility of each state and territory (where applicable). It should be noted that the registration of pharmacy premises has never existed in Queensland.

The National Scheme commenced on 1 July 2010, at which time the Pharmacist Board of Queensland was abolished. Its regulatory functions, excluding those relating to the ownership of pharmacy businesses, were taken over by the Pharmacy Board of Australia.

To coincide with the commencement of the National Scheme, amendments were made to Queensland's Pharmacists Registration Act. These included repealing the provisions unrelated to the pharmacy business ownership restrictions and giving responsibility for administering the ownership restrictions to the department. At the same time, the *Pharmacists Registration Act 2001* (Qld) was renamed the *Pharmacy Business Ownership Act 2001* (Qld) (the Act).

The purpose of the amendments was to establish interim arrangements pending a review by the Department of Health to determine which entity should administer the ownership restrictions in the long term. To facilitate a policy discussion, in January 2012, a review commenced with key stakeholders via the release of a consultation paper titled, 'Pharmacy Regulation Issues'. The paper was distributed to the following stakeholders in a targeted manner (but not made public to the wider community):

- Pharmacy Guild of Australia (Queensland Branch)
- Pharmaceutical Society of Australia (Queensland Branch)
- Society of Hospital Pharmacists of Australia

The definition of 'pharmacy business in the Pharmacists Registration Act excludes a business operated by a State at a public hospital or another business at another hospital (that is, a private hospital) that provides pharmacy services only to patients at the hospital.

¹⁵³ The Department of Health, Pharmacy Regulation Issues, Consultation Paper, unpublished paper, 2012.

- Mater Health Services
- Australian Friendly Societies Pharmacies Association, and
- Pharmacy Board of Australia.

Following the State Election on 24 March 2012 no further action was taken in relation to this Department of Health review. 154

6.3 Pharmacy ownership regulation in Queensland

Pharmacy ownership in Queensland is generally restricted to pharmacists. The Act specifies that:

A person must not own a pharmacy business unless the person is:

- a) a pharmacist; or
- b) a corporation whose directors and shareholders are all pharmacists; or
- c) a corporation:
 - (i) whose directors and shareholders are a combination of pharmacists and relatives of the pharmacist; and
 - (ii) in which the majority of shares are held by pharmacists; and
 - (iii) in which only pharmacists hold voting shares; or
- d) a friendly society; or
- e) Mater Misericordiae Health Services Brisbane Limited. 155

In addition, a pharmacist or eligible corporation must not have a beneficial interest in more than five pharmacy businesses at the same time. Friendly societies and Mater Misericordiae Health Services Brisbane Limited can own up to six pharmacy businesses at the same time. ¹⁵⁶

Table 3 describes pharmacy ownership by the number of pharmacies owned in Queensland. There is only one friendly society in Queensland that has an interest in six pharmacies. Mater Misericordiae Health Services Brisbane Limited ownership profile does not meet its full ownership quota under the Act. 157

Table 3: Pharmacy ownership by number of pharmacies owned as at 5 September 2018

Number of pharmacies owned by pharmacists (and relatives of pharmacists) as sole traders or as directors or shareholders of companies	Proportion of owners
Own a share in one pharmacy	61.21% (655)
Own a share in two pharmacies	19.44% (208)
Own a share in three pharmacies	9.07% (97)
Own a share in four pharmacies	4.39% (47)
Own a share in five pharmacies	5.80% (62)
Own a share in six pharmacies	0.09% (1)

Source: Department of Health, unpublished data as at 5 September 2018.

Department of Health, Correspondence dated 6 June 2018.

¹⁵⁵ Pharmacy Business Ownership Act 2001, s 139B.

Pharmacy Business Ownership Act 2001, s 139H.

Department of Health, Correspondence dated 11 September 2018.

According to the Act these ownership restrictions are deemed necessary 'to promote the professional, safe and competent provision of pharmacy services, and to maintain public confidence in the pharmacy profession'. ¹⁵⁸

6.4 Pharmacy ownership in other Australian jurisdictions

As in Queensland, pharmacy ownership in other Australian states and territories is restricted to pharmacists. Other Australian states also have restrictions on the number of pharmacies a pharmacist may own, while the territories have no such restrictions. The maximum allowable number of pharmacies per pharmacist in each state is:

- Western Australia and Tasmania: four
- Queensland, New South Wales and Victoria: five, and
- South Australia: six. 159

There are minor variations in these ownership restrictions between Australian jurisdictions. According to the department, the main policy rationale for the ownership restrictions is that:

- limiting the controlling interest in the ownership of pharmacy businesses to pharmacists
 promotes the safe and competent provision of pharmacy services and helps maintain public
 confidence in those services, and
- limiting the number of pharmacy businesses that may be owned by a person or entity helps protect the public from market dominance or inappropriate market conduct.¹⁶⁰

6.5 Administration of pharmacy ownership regulation in Queensland

The Department of Health has responsibility for administering the pharmacy ownership restrictions in the Act. 161

A pharmacist must notify the chief executive of the department whenever there is a change of ownership of a pharmacy or a change in business particulars (for example, the name or location of the business, any change in the ownership structure or the equity share of the owners).

These notices must be given in an approved form within 21 days after the change occurs and be accompanied by the fee prescribed by regulation. No fee has been prescribed to date. 162

On receipt of a notification from a pharmacist, the department undertakes checks to ensure that the changes do not result in a breach of the requirements of the Act and writes to the pharmacist to acknowledge their notification or request additional information.

This administrative process was explained to the committee by Bill Loveday of the Department of Health:

The pharmacist will submit a notification form, which is available on our website, which we have formed to try to get as much information from the business ownership arrangements as possible.

¹⁵⁸ Pharmacy Business Ownership Act 2001, s 8.

Laetitia Hattingh, 'The regulation of pharmacy ownership in Australia: The potential impact of changes to the health landscape. *Journal of Law and Medicine*, 2011, vol 19, p 148, https://research-repository.griffith.edu.au/bitstream/handle/10072/41413/73312 1.pdf.

The Department of Health, *Pharmacy Regulation Issues, Consultation Paper*, unpublished paper, 2012, p 2.

The Department of Health informed the Queensland Productivity Commission that it devotes less than one full- time staff to administer the ownership regulation (between 0.4 and 0.8 of an FTE). Contractors are used when an investigation is necessary. See Queensland Productivity Commission, *Cost-benefit analysis of establishing a pharmacy council*, 2018, p 15.

 $^{^{162}}$ $\,$ Pharmacy councils in other jurisdictions charge a change in ownership fee, see chapter 7.

Then our team in the business ownership act area will have a look at that and determine, firstly, that the people involved in that ownership structure are either registered pharmacists or relatives of pharmacists by evidence of the documentation that might be provided and/or if there are those other provisions around friendly societies and the Mater being able to own hospitals.

In looking at an individual pharmacist or a number of pharmacists involved in an application, the first step is to verify on the public register, which is maintained by AHPRA—the Australian Health Practitioner Registration Agency. They will determine if that person is the registrant and identify who they are. The next step is to populate some of that information into our database to determine that all of those pharmacists involved in that structure, or that business arrangement, have a limited number of business interests in Queensland that are under that maximum number of five. Those are the two major checks that we will be doing at that stage to interpret that notification and business arrangements comply with the provisions of the Act.

Once that is completed, the officers will then put that in a verification checklist to me. This is just the administration side of things. They will do up a notice that will go to the pharmacist, or the pharmacists, involved to indicate that the notification has been received and that it complies with the act. That will come to me for a check-off. I will sign that off and that notice will be issued back to the relevant business owners for their records. 163

Table 4: Offences and penalties in the Pharmacy Business Ownership Act 2001

Offence provisions	Maximum penalty 164	
Section 139B Restriction on who may own a pharmacy business	200 penalty units (\$26,110)	
Section 139C Pharmacist whose registration is suspended or cancelled may own pharmacy business for limited period	200 penalty units (\$26,110)	
Section 139H Restriction on number of pharmacy businesses in which a person may have a beneficial interest	200 penalty units (\$26,110)	
Section 141 Pharmacy business to be carried on under supervision of pharmacist	50 penalty units (\$6,527.50)	
Section 141A Notification of change of ownership of a pharmacy business	50 penalty units (\$6,527.50)	
Section 141B Notification of change of ownership particulars of a pharmacy business	50 penalty units (\$6,527.50)	
Section 157 Failure to help inspector	50 penalty units (\$6,527.50)	
Section 158 Failure to give information	50 penalty units (\$6,527.50)	
Section 171 Failure to give name or address	50 penalty units (\$6,527.50)	
Section 173 Failure to produce document	50 penalty units (\$6,527.50)	
Section 177 False or misleading information	50 penalty units (\$6,527.50)	
Section 178 False or misleading documents	50 penalty units (\$6,527.50)	
Section 179 Obstructing an inspector	100 penalty units (\$13,055)	
Section 180 Impersonating an inspector	50 penalty units (\$6,527.50)	

Source: Pharmacy Business Ownership Act 2001 (Qld).

Department of Health, Correspondence, 6 August 2018.

The Penalties and Sentences (Penalty Unit Value) Amendment Regulation 2018 states that the value of a penalty unit is \$130.55 from 1 July 2018.

The Australian Government's Department of Human Services will only approve a pharmacy to dispense medicines in Queensland under the Pharmaceutical Benefits Scheme when the Department of Health confirms that the requirements of the Act have been fulfilled.

The Act provides a range of offences and penalties related to pharmacy ownership restrictions, notification requirements for changes to pharmacy ownership, operating a pharmacy without supervision by a pharmacist, and impeding the work of inspectors who are inspecting apparent breaches of the legislation. These provisions and the maximum penalties that apply are set out in table 4. The maximum penalties prescribed in the Act are the same for individuals and corporations.

6.6 Claims of transfers of pharmacy ownership in breach of the Act

A number of submissions claimed that certain recent ownership transfers have breached the requirements of the Act. For example, the Pharmacy Guild of Australia alleged that Ramsay Health Group ownership transfers had breached the Act:

The Guild has stated in various contexts its belief that acquisitions by the Ramsay Health Group in Queensland may have resulted in a prohibited ownership arrangement which should be forensically audited.

However until that foreshadowed audit is effectively undertaken, like all Queenslanders, the Guild has insufficient visibility of pharmacy ownership transfers over recent years, particularly the last two, to state its position other than on the basis that it is its current considered belief. ¹⁶⁵

LiveLife Pharmacy Airlie Beach, amongst other pharmacists, ¹⁶⁶ had similar concerns about Ramsay Health Care's ownership transactions:

I believe there [are] several transactions which may not have conformed to the Act. In particular, the recent sale of the Malouf group of pharmacies to Ramsay Healthcare involves some suspicious circumstances that a Pharmacy Council with appropriate expertise would see as warning signs:

- The timing of the approvals, during caretaker mode of the state government is more than a coincidence
- All the nominated pharmacists were employees of Ramsay Healthcare. Most, if not all, of these pharmacist do not even [own] their home outright, let alone have enough capital to provision \$120 million in cash, on short notice, for the sale to proceed
- These pharmacists went from being employees in the hospital pharmacy sector, to owning 4-5 community pharmacies in their own right, overnight.
- [Not] a single owner in the Ramsay Pharmacies comes from outside of the employment of Ramsay Health.¹⁶⁷

Other pharmacists¹⁶⁸ raised concerns about the ownership transfers involving Chemist Warehouse. For example, Bayview Pharmacy stated:

I believe the Chemist Warehouse group has circumvented the ownership laws and in doing so has skewed community perception because they find it hard to look past the price on the box and appreciate the expertise behind the recommendation. We have experienced the view that health

¹⁶⁵ Submission 161, p 23.

See also, Owen Pharmacy Group (submission 29), Paul Jaffar (Submission 148), John Clark & Casey Clark (submission 145), and Matthew Doherty (submission 179).

¹⁶⁷ Submission 175, p 6.

See also, Dominic Ward (submission 3) and john Clark & Casey Clark (submission 145).

care providers who are providing high quality services are ripping them off. I am constantly finding myself having to justify to my local community why 'I charge too much'. 169

Mr Matthew Doherty also raised concerns about Chemist Warehouse (and Ramsay Pharmacy) ownership transfers:

Simply put there are pharmacy entities such as Chemist Warehouse and Ramsay that are acquiring pharmacies that contravene state legislation. ... An investigation into the transfer of ownership of the past two to three years of transactions will help to unravel the convoluted schemes used to hide the pecuniary interests involved. They include dodgy franchise agreements, unit trusts, head leasing and subleasing to name a few.

There are clearly owners now such as Gance/Verrochi that have pecuniary interests in more than the allowed number of pharmacies and use a multitude of schemes to hide that. 170

On the other hand, franchisors such as TerryWhite Chemmart and Ramsay Pharmacy were not aware of any illegal transfers. For example, TerryWhite Chemmart Head Office stated:

TerryWhite Chemmart pharmacy owners across Australia satisfy all requirements of the pharmacy ownership approval application process in the State where they carry on business. The franchise system of TerryWhite Chemmart requires the absolute recognition and compliance with the pharmacy ownership restrictions of the Act. 171

Similarly, Ramsay Pharmacy stated that Ramsay Pharmacy was rigorously vetted by the Department of Health and as a consequence Ramsay Pharmacy transfers were compliant with the Act:

Ramsay Pharmacy is not aware of any transfers of pharmacy ownership which have not conformed to the requirements of the Act and does not believe any review of transfers of pharmacy ownership is necessary.

Given the level of scrutiny undertaken by Queensland Health in relation to the acquisition of the Malouf transaction by Ramsay Pharmacy franchisees (not Ramsay Pharmacy or Ramsay Health Care, as has been misleadingly reported), Ramsay Pharmacy is confident that stringent processes are in place to review all transfers of ownership to ensure compliance with the Act prior to their approval. As such, Ramsay Pharmacy has no reason to believe that there have been transfers of ownership that have occurred which did not conform to the Act. 172

Peter Giannopoulos of Ramsay Pharmacy reiterated this position at a public hearing, citing the rigorous process undertaken by the department:

The department took some time to approve the Malouf transaction, and that was on fair reason. They took external counsel around all of the documentation and the fact that it does comply with the requirements of the Act, it does comply with the current ownership rules and it does comply with all the frameworks that oversee the provision of pharmacy within Queensland. That took some time. It took three months, which is a lot longer than it takes typically, but I think it went through the rigorous process to ensure it met the requirements.

... I would strongly say that Queensland Health performed the duties that are required to deliver the object of the act and to ensure that the provision of transfer of ownership was undertaken in a manner that met the requirements of the ownership rules.

...To expand on that, the documents and the advice were given to their external counsel. It was not only administered by members of the department; there was external counsel sought to

¹⁶⁹ Submission 147, pp 1-2.

¹⁷⁰ Submission 179, p 1.

¹⁷¹ Submission 135, p 15.

¹⁷² Submission 151, p 9.

ensure that the appropriate level of comfort was given to the department around the transaction. ¹⁷³

However, the Pharmacy Guild of Australia suggested the resources the Department of Health applied to the implementation and oversight of the Act have been insufficient to provide for compliance with the Act:

We are saying that the resources that have been allocated to the implementation and oversight of the Pharmacy Business Ownership Act—resources being not just finance but also people, systems and processes to ensure that there is enough drilling down of the evidence that is being provided and enough questions being asked about whether or not, at face value, these transactions, whilst they may appear to be consistent with the Act, in fact, if we peeled back the various layers, are not.¹⁷⁴

We are saying that the systems and processes currently being used by Queensland Health are insufficient. They are insufficiently resourced and they have an insufficient skill set to be able to provide informed and accurate advice to the delegate under the Act for him or her to be able to make an informed decision. ¹⁷⁵

On the other hand, Director-General Michael Walsh suggested that the ownership restrictions in Queensland were delivering the same range of pharmacies as those in other states where pharmacy councils had been established and where compliance activity was heavier:

When we have looked at the range of pharmacies that have been approved in Queensland—and some of them franchised pharmacies—and we have looked at that number and distribution and range in other states where there are councils, it is the same. That indicates that Queensland is operating at a similar sort of pharmacy mix and profile as other states. When we look at the number of complaints and issues that have been prosecuted under the act, it is the same—very few, if any, in other states, the same as in Queensland. From that perspective it is the same, although other states do require heavier compliance steps such as annual registration and therefore a contribution which allows them to do more work if they needed to. When you look at the outcome, we have seen that that is about the same.¹⁷⁶

6.7 Transfers of pharmacy ownership in Queensland since 1 January 2016

The terms of reference required the committee to report on all transfers of pharmacy ownership in Queensland over the past two years, to ensure compliance with existing legislation.

On 14 May 2018 the committee requested the Queensland Audit Office (QAO) conduct an independent audit of the transfer of pharmacy ownership since 1 January 2016. The Auditor-General agreed to conduct a reasonable assurance audit as per the Australian Auditing and Assurance Standards. On 5 September 2018 the committee received a confidential copy of the QAO's final proposed report, *Managing transfers in pharmacy ownership.* The QAO's final report, *Managing transfers in pharmacy ownership Report 4: 2018-19*, was tabled on 28 September 2018 and is now available from the QAO website; qao.qld.gov.au.

The objective of the QAO audit was to assess whether the Department of Health had ensured the transfers complied with the requirements of the *Pharmacy Business Ownership Act 2001* (the Act). As discussed in section 6.4, the department has a process for assessing notifications of changes in pharmacy ownership against the requirements of the Act. It requires the pharmacy owner to complete

Public hearing transcript, Brisbane, 3 September 2018, p 31.

Public hearing transcript, Brisbane, 3 September 2018, p 35.

¹⁷⁵ As above, p 44.

Department of Health, Correspondence, 6 August 2018.

a transfer of ownership form (notification) and provide a small number of documents to support it. The department then assesses whether the notification complies with the requirements of the Act.

The QAO was unable to assess the Department of Health's compliance with the Act in administering ownership transfers over the last two years because of gaps in the department's processes and systems. According to the QAO, the department failed to gather sufficient information to make a compliance assessment. As a consequence, this prevented the QAO from having sufficient information about the transfers to make an informed assessment about areas such as:

- the number of pharmacies a person has a beneficial interest in or a corporation owns
- franchise groups having proprietary interests in pharmacies, and
- commercial arrangements allowing non-pharmacists to control a pharmacy.

The QAO noted that the department's compliance monitoring had not kept pace with the complex business structures now in use in the pharmacy sector:

The department has not been effectively administering the Act, as it has not adapted its processes to the more complex business structures and commercial arrangements pharmacy businesses now use.¹⁷⁷

From the committee's investigations it appeared that all Australian jurisdictions were struggling with the complexity of some of the new ownership models, including franchise arrangements—even those jurisdictions with pharmacy councils.

The QAO was also critical of the reactive approach taken by the department in administering the Act:

The department is taking a reactive approach to administering Part 3 of the Act (which addresses monitoring and enforcement), by responding to complaints when and if they are made. This means there is a risk that pharmacies can continue to operate even if they are in breach of the Act. ¹⁷⁸

However, in a written response to the QAO's report, the department argued that its approach to monitoring and enforcement was proportionate to the risk to public health and safety in relation to the activities of pharmacists and the handling of medication:

The Department has taken a risk based approach to assessing notifications of transfers of pharmacy ownership. Given the robust safety net of regulation within which pharmacists operate, the Department has chosen to minimise the administrative burden on pharmacy owners and reduce the red tape associated with pharmacy ownership transfers. The Department assesses notifications to ensure that only those persons prescribed in the Act own pharmacies in Queensland and that ownership is limited to no more than five pharmacies in Queensland. The Department has also taken a reactive approach to administering Part 3 of the Act, which addresses monitoring and enforcement, through responding to complaints when and if they are made. 179

A number of submitters to the inquiry alleged that pharmacies were operating in breach of the Act, but did not provide evidence to substantiate their claims. Moreover, the committee received no evidence that indicated that the department's administration of the Act had resulted in any adverse health outcomes for Queenslanders.

Director-General Walsh suggested to the committee that the QAO report may have benefited from an appreciation of this wider policy context when framing its recommendations:

Queensland Audit Office, Managing transfers in pharmacy ownership, Report 4:2018-19, p 11.

¹⁷⁸ As above, p 10.

¹⁷⁹ Queensland Health, Letter from Director-General to Auditor-General, 27 August 2018, p 2.

I certainly believe that the review as a performance review under the QAO Act has not adequately presented the context in which that is undertaken, and that is the outcomes and that the intent of administering the Act is to ensure the safety and wellbeing of the public and the access to medications.

That is not part of their performance review and certainly I was surprised that that was not in there—that they did not look at comparing Queensland to New South Wales or Victoria and ask, 'What are the outcomes of this approach versus another approach?', and benchmarking those areas against another jurisdiction. When you do analysis of either process or performance you have to know how you compare. What this report does not tell us is are we the same as councils that approach this in other states or are we different to those and how? It does not actually go into that, so I was surprised about that. I thought it should have included that. ¹⁸⁰

The QAO made five recommendations to improve the department's processes and controls to ensure transfers in pharmacy ownership comply with the requirements of the Act. The recommendations are listed at Appendix E. In its response to the audit findings, the Department of Health advised that it accepts recommendations 1-5 that relate to its activities based on a number of assumptions, one being that the committee agrees with the recommendations. Recommendation 6 relates to the committee and is discussed below.

Of particular note for existing pharmacy businesses is Recommendation 5, that the department:

develops and implements a risk-based strategy for testing that existing commercial arrangements comply with sections 139B, 139H and 139I of the Act.¹⁸¹

Sections 139B, 139H and 139I of the Act deal with: restrictions on who may own a pharmacy business; restrictions on the number of pharmacy businesses in which a person may have a beneficial interest; and the circumstances under which commercial arrangements are not legally binding, particularly whether controls by a non-pharmacist exist in franchise businesses. According to the department, the implementation of this recommendation is expected to take up to 24 months.

Depending on the design of the risk-based strategy the department develops, the implementation of this recommendation could see the department reviewing long-standing ownership arrangements for a significant proportion of the State's pharmacies. Alternatively, the strategy could focus on ownership arrangements that have generated complaints from the pharmacy industry, and the increasingly complex arrangements that have evolved in recent years. This was not clear to the committee at the time of writing.

6.8 Strengthening key provisions of the Act

During the audit of transfers of pharmacy ownership, the Auditor-General identified problems with the corporate records and other documents held by the department for pharmacy ownership transfers. The audit also identified that the Act fails to define the legal implications if a commercial arrangement does not meet section 139(I).

The Auditor-General in his report on the audit recommended that the committee recommend that the Minister seeks amendments to the Act to enable the department to more effectively manage the pharmacy ownership notification process.

6.9 Retention of existing ownership requirements

There were a diverse range of views on whether the ownership restrictions are necessary to protect consumers and deliver accessible and affordable medicine. Most independent submitters and new franchise/discount pharmacists considered the ownership restrictions are not required to achieve

Department of Health, Correspondence, 12 September 2018.

¹⁸¹ Queensland Audit Office, Managing transfers in pharmacy ownership - Report 4: 2018.

public health objectives. However, most traditional pharmacy owners and the Pharmacy Guild of Australia believed they are necessary to maintain public health objectives.

For example, Health Consumers Queensland, the peak organisation representing the interests of health consumers in the state, suggested the ownership restrictions are unnecessary because of the significant clinical governance and professional standards governing employee pharmacists (that is, dispensing pharmacists):

The pharmacy ownership restrictions imposed by the Pharmacy Business Ownership Act 2001 are not necessary to protect consumers and deliver accessible and affordable medicines and services.

Health Consumers Queensland believes that deregulating pharmacy ownership and location rules can still ensure the professional, safe and competent provision of pharmacy services, and maintain public confidence in the pharmacy profession through strong clinical governance and professional standards of employee pharmacists. ¹⁸²

The Grattan Institute, an independent public policy think tank, believed there is no public interest in restricting pharmacy ownership to pharmacists:

The only justification for restrictions on ownership of pharmacies is that no one other than a pharmacist can be trusted to run the pharmacy and the risk of allowing doctors, brewers or bakers to own pharmacies is too great. However, it is unclear what these potential risks are, and whether pharmacy ownership controls add any value to other existing controls.¹⁸³

According to Ramsay Pharmacy the current restrictions on ownership only protect pharmacist owners from competition and do nothing for consumers:

The restriction on pharmacy ownership to pharmacists only is an artificial and out-dated model which is self-serving, established only to protect the interests of current pharmacy owners ...

There is no evidence-based relationship between the ownership restrictions and the accessibility and affordability of medicines and services. Accessibility to pharmacies and medicines is determined by the Pharmacy Location Rules which is a Commonwealth responsibility and beyond the scope of this Inquiry. Affordability of medicines is determined by Pharmaceutical Benefits Scheme (PBS) pricing.

There is also no evidence to suggest that the removal of ownership restrictions would be detrimental to patient safety and community wellbeing. Ramsay Pharmacy has been a responsible supplier of PBS medications in a number of its hospitals for over 10 years now, demonstrating that non-pharmacist ownership does not erode patient safety nor community well-being.

Ultimately, there is no basis on which to differentiate pharmacy from other health services such as surgical hospitals, medical centres, pathology services and diagnostic imaging services with respect to ownership. The ownership of the aforementioned services are not confined to doctors, and no one is able to credibly argue that patient safety and community well-being has been compromised as a result.¹⁸⁴

Damien Gance from Chemist Warehouse suggested the ownership restrictions were unnecessary because they were not required to deliver safe and responsible access to medicines:

Whilst I can appreciate the historical context and at least fathom the rationale for the introduction of these laws, I contend wholeheartedly that they have no place in a modern

¹⁸⁴ Submission 151, pp 4-5.

¹⁸² Submission 202, pp 5-6.

¹⁸³ Submission 24, p 3.

Australia. When these laws were introduced, times were different. At times legislators may have been led to believe that these laws were necessary to ensure an equitable, universal, safe and responsible access to medicines. Whilst these ownership laws may have been well intentioned, what we have learned over time is that they are unnecessary and do little, if anything, to achieve these desired ends.

We have observed over the years that ownership laws in reality act to raise costs to consumers, prevent innovation in our industry and undermine the value of industry-wide investment. Restrictions on who can own pharmacies are unnecessary and constitute damaging regulations that should be reformed as a matter of urgency. I commend the committee for reviewing and considering the appropriateness or otherwise of these laws. 185

Pharmacists who own pharmacy businesses do not have to be, and are often not, involved in the delivery of pharmacy services at their own pharmacy business. According to Queensland Health, many business owners live in other jurisdictions or have ownership interests in pharmacies at locations far removed from where they reside. 186

Dr Stephen King from the Productivity Commission characterised many pharmacy owners as 'absentee landlords':

... there are a large number of pharmacy owners who may best be categorised as absentee landlords. To the degree that the ownership rules are meant to bring the owners to have skin in the game, it seemed to be a very loose connection in the sense of talking to shopfloor pharmacists. At a large number of chemists, I would ask quite often, 'Who are the proprietors? How often do see them?' An answer of 'never' or 'perhaps once every three months' or 'perhaps a couple of times a year' was a fairly common answer.¹⁸⁷

Data from Queensland Health show only about 50 per cent of proprietor pharmacists reside in the same location as at least one of their pharmacy businesses (as defined by the SA4¹⁸⁸ statistical area). On the other hand, nearly 50 per cent of business owners live in other jurisdictions (either interstate or overseas) or have ownership interests far removed from where they reside in Queensland (table 5).

Table 5: Location of pharmacy owners' residence relative to their pharmacy business/businesses

Location of pharmacy owners' residence	Proportion of owners
Owners who reside in the same geographic location as at least one of their pharmacy businesses in Queensland	50.98%
Owners who reside in a different geographic location to any of their pharmacy businesses but live in Queensland	33.64%
Owners who reside interstate	14.82%
Owners who reside overseas	0.09%
Owners whose residence could not be determined	0.47%
Total	100.00%

Source: Queensland Health, unpublished data.

Public hearing transcript, Brisbane, 20 August 2018, p 27.

Queensland Health, private communication, 2 August 2018.

Public hearing transcript, Brisbane, 20 August 2018, p 16.

The SA4 statistical area usually contains a minimum of 100,000 persons. In regional areas, SA4s tend to have a population closer to the minimum. In metropolitan areas, SA4s tend to have larger populations (300,000-500,000). The Australian Bureau of Statistics provides further information on the SA4 statistical area,

 $[\]frac{\text{http://www.abs.gov.au/ausstats/abs@.nsf/Lookup/by\%20Subject/1270.0.55.001^July\%202016^Main\%20}{\text{Features}^\text{Statistical\%20Area\%20Level\%204\%20(SA4)}^\text{10016}.}$

In describing the current ownership laws, Dr Stephen King alluded to the fact that it is the professionalism and ethics of dispensing pharmacists (which are incentivised by the regulatory framework) that drive public health benefits not the ownership structure of the pharmacy:

I think the current ownership rules are ineffective. I do not think there is any evidence that I saw that an absentee pharmacy owner would be any different from an absentee shareholder, a cooperative owner or any other form of ownership structure. I think the ethical and professional role has to come back onto the pharmacist who is running the dispensary and overseeing the dispensary. That is the relevant point, to make sure that the ethics are there. That view is simply that the current ownership laws are leading to absentee owners at the moment who are interested in profit maximising; they just happen to be limited to people who also happen to have pharmacy degrees or be registered pharmacists. It would be better to focus back in on the professionalism at the correct point, which is the point of dispensing. 189

Dr Jeannette Young of Queensland Health also supported the essential role of the dispensing pharmacist (rather than the pharmacy ownership structure):

My point is that you have to have a qualified pharmacist in that pharmacy at all times. That is essential. Whether or not the pharmacy needs to be owned by a pharmacist I think is a different issue, especially as one pharmacist can own five pharmacies in Queensland then another five in another state, six in another and four in another.¹⁹⁰

On the other hand, the Pharmaceutical Society of Australia suggested that the ownership restrictions are necessary to promote patient safety and protect the public from market dominance.

The main policy rationale and justification for the pharmacy ownership restrictions is that limiting the controlling interest in the ownership of pharmacy businesses to pharmacists promotes patient safety and competent provision of high quality pharmacy services and helps maintain public confidence in those services; and limiting the number of pharmacy businesses that may be owned by a person or entity helps protect the public from market dominance or inappropriate market conduct.¹⁹¹

The Pharmacy Guild of Australia also suggested that the ownership restrictions are necessary to ensure a decentralised and diverse ownership structure:

The ownership requirements, which require pharmacies to be owned by pharmacists and which limit the number of pharmacies each pharmacist can own, ensure a decentralised and diverse ownership structure which is essential to providing access to Queenslanders, wherever they are throughout the state. Further, they ensure that pharmacies are owned by registered pharmacists, who are health care professionals first and foremost and are patient-focused through their professional autonomy. 192

Submissions from pharmacist associations and traditional pharmacy owners highlighted negative, and at times particularly dire consequences, if ownership restrictions were relaxed. These included:

- non-pharmacist owners would place commercial considerations over patient welfare
- reduced access to medicines
- reduced access to services

Public hearing transcript, Brisbane, 20 August 2018, p 20.

Department of Health, Correspondence, 6 August 2018.

¹⁹¹ Submission 136, p 4.

¹⁹² Submission 161, p 7.

- rural and remote pharmacies would close, and clustering of pharmacies would occur in metropolitan regions
- increased competition from supermarket pharmacies would price traditional pharmacies out of the market, and
- non-pharmacist owners would have conflicts of interest that would be to the detriment of consumers.

Many submissions ¹⁹³ indicated that a cost of relaxing pharmacy ownership would be that a proprietor who is not a pharmacist was more likely to place commercial considerations before professional judgements than a proprietor pharmacist. In many submissions this was expressed as 'putting profits before people'. This belief assumes that a proprietor who is not a pharmacist is prepared to sell or provide a given medicine or service to a consumer, despite the professional judgement of the dispensing pharmacist that the sale would be unwise or unnecessary.

For example, LiveLife Pharmacy Airlie Beach stated:

Currently, every pharmacist every day makes decisions in the best interests of their patients, without regard for profit. This is the small business mentality – hoping and believing that patients will appreciate the care and service continue to be loyal. Large corporations do not display that level of dedication to the best interests of the patient. Their primary concern is to the shareholder and generating a profit.¹⁹⁴

The Pharmacy Guild of Australia shared a similar view:

The corporate pharmacy structure would see a fundamental change to the provision of pharmacy services to the Australian public from primarily a patient-centric structure of the community pharmacy sector to a corporate pharmacy model with a shareholder-centric focus on maximising shareholder value. 195

Chris Owen of Owen Pharmacy Group indicated that under a corporate model, poor customers would no longer be able to access 'buy now pay later' arrangements with their local pharmacist:

I pack Webster packs. I work in the valley and I do have a fair number of lower socio-economic customers. Last week a patient came to me and said, 'I don't have any money. Can you pack my medication but I cannot pay you until next week?' I do not know any Coles or Woolworths or any company like that who would allow you to take your milk and come back and pay for it next week, but I do that because I see the patient benefit. That is a personal experience that I have that may not exist in an otherwise corporatised world. 196

Karen Brown of TerryWhite Chemmart Samford also suggested that local pharmacists put patients first (not profit):

You can see the value in locally owned or pharmacist owned [pharmacies] because we put the patient first. It is not about the profit, which it would be if it was deregulated. It would be the sweatshop out the back with the pharmacist just churning out scripts. The majority of our value now is out the front. At Samford we actually have three pharmacists on every single day so we are accessible and available. We are one of the most trusted health professionals ... We go over

For example, Priceline Pharmacy Riverlink (submission 170), ConNetica Consulting (submission 4), Wulguru Pharmacy/Aitkenvale Medical Centre Pharmacy (submission 22), Owen Pharmacy Group (submission 29).

¹⁹⁴ Submission 175, p 2.

¹⁹⁵ Submission 161, p 16.

Public hearing transcript, Toowoomba, 7 September 2018, p 15.

and above, outside those four walls, and absolutely make a difference to our patients' lives. I do not think you would ever get that in a corporate [setting]. 197

Some submissions¹⁹⁸ also maintained that if the ownership restrictions were relaxed there would be reduced access to certain medicines and services because non-pharmacist owners would not provide these medicines and services to patients because of their low or zero profit margins. On the other hand, proprietor pharmacists would continue to supply them because of their professional and ethical obligations.

For example, Peter Kolb Amcal Pharmacy stated:

Pharmacies are often the first point of contact for patients seeking health advice, referral and support. A lot of this is provided at low or no cost which provides a massive saving for taxpayers as it frees up hospital and general practitioner time. I employ approximately 25 staff across my two pharmacies and provide many free services to my local community such as free delivery (5 days a week to patients who would otherwise go without as they are homebound), subsidised medication packing (to improve patient adherence), free diabetes and blood pressure screening, free medication advice, free shop accounts for those who struggle to afford their medications etc. ... There is no way that big corporations answering to shareholders will provide the same level of patient centred care that the current system offers. ¹⁹⁹

Similarly, Broadwater Pharmacy stated:

Under a corporate structure, the sole obligation of a company – particularly a listed company – conducting a pharmacy business is to return a profit to shareholders. There are many activities and services that my pharmacy does that perform an essential public service but would not be provided if returning a profit to shareholders was the primary concern of my business. However, my professional and ethical obligations as a registered pharmacist allow me to provide these services because my duty to uphold these obligations as a registered pharmacist allow me to override the profit motive, which would not be possible to do were the business not owned by other pharmacists who have the same professional and ethical obligations.²⁰⁰

Several peak bodies for ailments and diseases were concerned that if pharmacy ownership restrictions were relaxed non-pharmacist owners would reduce services to their constituents. For example, the Eczema Association of Australasia stated:

We fear that a big business takeover of community pharmacies would see the services they provide to eczema patients, in screening, consultation and treatment, diminish. We believe that a pharmacy driven to deliver returns to corporate shareholders would see little value in educating its staff about eczema, or in encouraging its pharmacists to have conversations with their customers about Eczema and other health conditions.²⁰¹

Similarly, Vision Australia stated:

We are concerned that under a corporate model, pharmacists would no longer provide the sort of care that our constituents need, given that this service is not in itself profitable for pharmacies. Our experience with community pharmacy makes us confident that pharmacists who own their

¹⁹⁷ Public hearing transcript, Brisbane, 20 August 2018, p 3.

¹⁹⁸ For example, Owen Pharmacy Group (submission 29), LiveLife Pharmacy Airlie Beach (submission 175).

¹⁹⁹ Submission 27, p 1.

²⁰⁰ Submission 178, p 2.

²⁰¹ Submission 20, p 1.

own pharmacies understand the importance of supporting members of their community with disability including vision impairment.²⁰²

Some submissions from pharmacy owners suggested that if the ownership restrictions were relaxed there would be a hollowing out of pharmacies in the regions that would reduce competition. These submissions also suggested an increased concentration of pharmacies in the metropolitan areas of Queensland. For example, LiveLife Pharmacy Airlie Beach stated:

Relaxing of ownership restrictions would create clustering in city areas where pharmacies would be more profitable and the loss of small pharmacies in one pharmacy towns, where the pharmacy would no longer be viable. If ownership restrictions were relaxed, the competitive environment that currently exists would cease to exist as the major players would crush competition and then raise prices once they have market share.²⁰³

Owen Pharmacy Group had the same sentiment:

With Queensland being a decentralised state, relaxing of ownership restrictions would create clustering in city areas where pharmacies would be more profitable. However, this approach would come at the expense of small and rural pharmacies, in particular small towns where the pharmacy would no longer be viable.²⁰⁴

Many submissions from pharmacy owners and pharmacist associations were concerned about increased competition from supermarkets operating pharmacies from within the confines of the supermarket or owning pharmacies and operating them as a separate shopfront, as currently occurs with supermarket owned liquor stores. For example, Tony Norton stated the industry cannot sustain any further increase in competition and many small traditional pharmacies would close:

The industry has become more competitive in the last 10 years. Between the advent of 'big box' pharmacies and changes to the PBS many pharmacies are now struggling. If the industry was deregulated and large retailers such as Coles and Woolworths were able to compete it would inevitably lead to the closure of many small community pharmacies.²⁰⁵

In a similar assessment, Cate's Chemist Townsville stated:

As an owner of a community pharmacy, I am concerned about a takeover of community pharmacies in Queensland from 'profit-focused' businesses and the impact this would have on my patients. I know the Return on Assets of my pharmacy is not attractive to corporates like Coles or Ramsay, but my market share is. Under these circumstances any interested corporate would either:

- Price me out of the market until I closed, or
- Buy my pharmacy and then close the site.²⁰⁶

The Pharmaceutical Society of Australia was also concerned about increased market concentration in the pharmacy sector if supermarkets could own pharmacies:

PSA is also concerned that, given the degree of concentration in Australia's supermarket sector (approximately 80 per cent of supermarkets are owned by Coles and Woolworths), if the

Submission 26, p 1.

²⁰³ Submission 175, p 9.

²⁰⁴ Submission 29, p 9.

²⁰⁵ Submission 155, p 1.

²⁰⁶ Submission 185, p 1.

ownership was opened up to non-pharmacist run corporations, then the supermarkets could gain and wield substantial power in the pharmacy market to the detriment of health consumers. ²⁰⁷

Several pharmacy owners raised concerns about the conflicts of interest that would be created if certain non-pharmacist were able to own pharmacies.²⁰⁸ For example, Giant Chemist Pacific Fair suggested that if doctors owned pharmacies it would create a conflict of interest between prescribing and dispensing with poor outcomes for patients:

Under the current system doctors prescribe purely based on which medication/treatment would provide the best outcome for the patient. If doctors were to own pharmacies one would question whether the financial gain made by selecting certain products to prescribe might sway the decision making in any way.²⁰⁹

Pharmacy owners were also concerned about drug manufacturers owning pharmacies and reducing access to medicines.²¹⁰ This might be a valid concern. Drug manufacturers owning pharmacies could lead to vertically integrated companies which might be incentivised to align their pharmacy product range to their own manufactured products. This could reduce accessibility of certain medicines.

After examining the evidence provided through submissions, in particular from pharmacy owners and the Pharmacy Guild of Australia during the public hearings, the committee assessed, on balance, that the objectives of the Act are best achieved by maintaining the restrictions on who may own a pharmacy business. The committee remained concerned that any removal or relaxation of the ownership restrictions would result in reduced access to medicines and quality of services, particularly in rural and regional areas of Queensland. It was concerned that heightened competition from large corporates would force many small, independent pharmacies to close and it was not clear that they would be replaced by a corporate pharmacy. The committee was also unconvinced that the Australian Competition and Consumer Commission would be able to prevent an increased concentration of ownership in the pharmacy market that would ultimately see Queensland consumers paying more for their medicines in the longer term.

6.10 Conclusions

The committee considered the effectiveness of the current systems and processes to regulate pharmacy business ownership and protect consumers in Queensland. These pharmacy business ownership requirements are contained in the *Pharmacy Business Ownership Act 2001* (the Act). The ownership requirements for pharmacies in Queensland as specified in the *Pharmacy Business Ownership Act 2001* are clear and unambiguous. No reason for deregulation has been demonstrated. As long as the restrictions on who can own pharmacies in Queensland remain part of the Act, the committee believe there is a clear expectation from the pharmacy industry and other stakeholders that those requirements are effectively administered and proactively enforced.

For the inquiry, the committee requested the Auditor-General to conduct an audit of how the Department of Health assessed transfers of pharmacy business ownership from 1 January 2016. The committee notes that the Queensland Audit Office found that the Department of Health has not designed processes and controls to ensure transfers of pharmacy ownership comply with all requirements of the *Pharmacy Business Ownership Act 2001* (the Act). The Department of Health should improve its processes and controls to effectively administer the Act. The committee supports the audit recommendations with the exception of recommendation 5. The committee has

Calanna Whole Health Pharmacy (submission 7), Blooms the Chemist (submission 10), Wulguru Pharmacy and Aitkenvale Medical Centre Pharmacy (submission 22).

²⁰⁷ Submission 136, p 5.

²⁰⁹ Submission 57, p 1.

²¹⁰ Calanna Whole Health Pharmacy (submission 7), Wulguru Pharmacy and Aitkenvale Medical Centre Pharmacy (submission 22), Warner Dakin (submission 56).

recommended that the department's implementation of this recommendation be limited to testing of commercial arrangements for transfers transacted since 3 May 2016.

The committee has also recommended that the department seek a follow-up audit by the Queensland Audit Office, and that the results of that audit be reported to the Legislative Assembly.

The recommendations of the Queensland Audit Office report will have a significant bearing on the future operations of the Department of Health in relation to the pharmacy industry. In the department's response to the audit report, it has advised that implementation of the recommendations will take a significant period to complete. Given the problems identified by the audit, the committee believes the Auditor-General should conduct a follow-up review of the implementation of agreed audit recommendations.

The committee supports the recommendations of the audit report with the exception of recommendation 5. This recommendation requires the department to develop and implement a risk-based strategy for testing that existing commercial arrangements comply with key sections of the Act. While the intent of the recommendation is clear, the committee is concerned at the potential for its implementation by the department to have significant ramifications for the retail pharmacy industry. If the viability of existing pharmacy businesses is jeopardised, the committee sees potential for flow-on impacts on the availability of pharmaceutical medicines and services to consumers, particularly in remote and regional areas. For this reason, the committee believes any review of existing pharmacy ownership transfers by the department, in accordance with the recommendation, should be restricted to recent ownership transfers up to two years prior to the committee's inquiry. This is consistent with the terms of reference for the committee's inquiry.

Through the inquiry, the committee has identified a range of issues where the interests of the pharmacy industry and the health outcomes for Queensland health consumers would be better served by a closer working arrangements between the pharmacy industry, the Department of Health and other medical stakeholder groups. The committee recommends the establishment of a Queensland Pharmacy Advisory Council to support the Department of Health in its administration of the Act and the fulfilment of its regulatory responsibilities to monitor and enforce compliance with the Act.

The committee envisages that this advisory council would provide expert advice to the Minister on pharmacy ownership, and standards for pharmacy premises and the proactive monitoring and enforcement of all pharmacy regulations, including ownership requirements and all issues affecting the pharmacy sector, including changes to scope of practice for pharmacists and pharmacy assistants.

The advisory council would comprise members appointed by the Minister with expertise in law, accounting, and business management, as well as members representing the pharmacy sector and health consumers.

The costs of establishing and operating the advisory council would be met by the Department of Health and funded by the pharmacy sector in full (that is, no costs to be borne by government).

The committee agrees with the recommendation of the Auditor-General for the Act to be amended to strengthen the *Pharmacy Business Ownership Act 2001* to enable the department to more effectively manage the pharmacy ownership notification process.

Recommendation 6

The committee recommends the establishment of a Queensland Pharmacy Advisory Council to advise the Department of Health in its administration of the *Pharmacy Business Ownership Act 2001* and the fulfilment of its regulatory responsibilities.

The Queensland Pharmacy Advisory Council would:

- provide expert advice to the Minister on ownership and premises standards, and would enhance the department's capacity to proactively monitor and enforce the pharmacy regulatory environment
- comprise members appointed by the Minister with expertise in law, accounting, and business management and members representing the pharmacy sector and consumers
- be funded on a cost recovery basis by the pharmacy sector (that is, no costs to be borne by government)
- be consulted by the Department of Health on matters including, but not limited to, managing transfers of pharmacy ownership and changes to scope of practice for pharmacists and pharmacy assistants.

Minister responsible: Minister for Health and Minister for Ambulance Services

Recommendation 7

The committee recommends that:

- the Department of Health's development and implementation of a risk-based strategy for testing that existing commercial arrangements for pharmacy ownership in Queensland comply with sections 139B, 139H and 139I of the *Pharmacy Business Ownership Act 2001* be limited to transfers transacted since 3 May 2016, being a period of two years prior to the date the inquiry was referred to the committee
- 2. by 16 October 2019, 12 months from the tabling of this report, the department request a review by the Queensland Audit Office of the implementation of part (1) above of this recommendation together with compliance by the department with the agreed recommendations in the office's Report No 4: 2017-18 Managing Transfers in Pharmacy Ownership, and request that the Queensland Audit Office, pursuant to the Auditor-General Act 2009, table in the Legislative Assembly the report from its review, and
- 3. within six months of requesting the review recommended in part (2) above of this recommendation, the department provide the committee a written update of the review.

Minister responsible: Minister for Health and Minister for Ambulance Services

Recommendation 8

The committee recommends that the *Pharmacy Business Ownership Act 2001* be amended to enable the Department of Health to more effectively manage the pharmacy ownership notification process, including the establishment of offence provisions for breaches of s 139(I).

Minister responsible: Minister for Health and Minister for Ambulance Services

Recommendation 9

The committee recommends that the pharmacy ownership requirements of the *Pharmacy Business Ownership Act 2001* be retained.

Minister responsible: Minister for Health and Minister for Ambulance Services

7 Should a Queensland pharmacy authority be established?

As part of the inquiry, the committee was tasked with considering whether a Queensland pharmacy council should be established.

Most jurisdictions have established a separate statutory entity to administer the pharmacy ownership restrictions. Except for the Queensland and territory health departments, these entities also exercise the function of registering or approving pharmacy premises (table 6).

Table 6: Entities administering pharmacy ownership (and premises) restrictions by jurisdiction

Jurisdiction	Entity	Legislation	Entity responsibilities
Queensland	Department of Health	Pharmacy Business Ownership Act 2001 (Qld) Health Regulation 1996	Administer ownership restrictions Administer obligations that dispensaries must comply with standards
New South Wales	Pharmacy Council of NSW	Health Practitioner Regulation National Law (NSW) No 86a, Schedule 5F Pharmacies (NSW) Health Practitioner Regulation (New South Wales) Regulation 2016	Administer ownership restrictions Approve pharmacy premises
Victoria	Victorian Pharmacy Authority	Pharmacy Regulation Act 2010 (Vic)	Administer ownership restrictions Register pharmacy premises
Tasmania	Tasmanian Pharmacy Authority	Pharmacy Control Act 2001 (Tas)	Administer ownership restrictions Register pharmacy premises
South Australia	Pharmacy Regulation Authority SA	Health Practitioner Regulation National Law (South Australia) Act 2010 (SA), part 4 (pharmacy practice) Health Practitioner Regulation National Law (South Australia) Regulations 2010	Administer ownership restrictions Register pharmacy premises
Western Australia	Pharmacy Registration Board of WA	Pharmacy Act 2010 (WA) Pharmacy Regulations 2010	Administer ownership restrictions Register pharmacy premises
Australian Capital Territory	ACT Health	Public Health Act 1997 (ACT) Public Health (Community Pharmacy) Code of Practice 2016 (No 1)	Administer ownership restrictions Administer obligations on pharmacists to comply with premises requirements
Northern Territory	Pharmacy Premises Committee (part of Department of Health)	Health Practitioners Act (NT)	Administer ownership restrictions Administer obligations on pharmacists to comply with premises standards`

Source: Department of Health, *Pharmacy Regulation Issues, Consultation Paper*, unpublished paper, 2012.

The primary functions of the separate entities (such as pharmacy councils, authorities and boards) in other jurisdictions is in regard to the regulation of pharmacy premises and ownership. A secondary function of these entities that emanates from these primary functions is the handling of complaints, investigations and inspections. A minor function of these entities is education, policy and research.

In 2016-17, it cost between \$0.076 million and \$2.7 million per annum to operate the statutory entities in other states depending on the respective jurisdiction (table 7). These entities are funded by registration fees. No information is publicly available for the costs of operating the respective functions

in the Queensland, Australian Capital Territory and Northern Territory government health departments.

All jurisdictions have penalties for pharmacy ownership offences. There is a large degree of variability in the magnitude of fines for ownership offences among jurisdictions. Some jurisdictions specify different penalties for individuals and corporations for the same offence, they include: Victoria, Western Australia, the Australian Capital Territory and the Northern Territory.

Table 7: Annual ongoing costs and sources of funding of administering entity

Jurisdiction	Entity	Annual ongoing costs and sources of funding
Queensland	Department of Health	No relevant cost information was located in the Department of Health Service Delivery Statement 2017-18 or Annual Report 2016-17 Funding sourced from the Consolidated Fund
New South Wales	Pharmacy Council of NSW	\$2.66 million (2016-17) ²¹¹ Funding sourced from registration fees, interest revenue and 'other revenue'
Victoria	Victorian Pharmacy Authority	\$1.16 million (2016-17) ²¹² Funding sourced from application, licence and registration fees, fines and penalties and income from investments
Tasmania	Tasmanian Pharmacy Authority	\$76,079 (2016-17) ²¹³ Funding sourced from initial application fees, renewal fees and other miscellaneous fees and bank interest
South Australia	Pharmacy Regulation Authority SA	\$428,162 (2016-17) ²¹⁴ Funding sourced from the payment of registration fees, required notification of changes to the registers and sundry revenue
Western Australia	Pharmacy Registration Board of WA	\$530, 763 (2016-17) ²¹⁵ Funding sourced from licence fees, application fees, interest received and grants (if any) from the State—government funding was nil in 2016-17
Australian Capital Territory	ACT Health	No relevant cost information was located Funding sourced from the Consolidated Fund
Northern Territory	Pharmacy Premises Committee	No relevant cost information was located Funding sourced from the Consolidated Fund

Source: Various jurisdictional administering entity 2016-17 annual reports.

7.1 Pharmacy premises regulation in Queensland

Pharmacy premises are not, and have never been, licensed/registered or approved in Queensland. However, pharmacy premises are regulated in Queensland.

Pharmacy premises are regulated under Part 4 of the Health Regulation 1996. This regulation imposes various obligations about standards for dispensaries and other matters relating to dispensing. According to the department, these obligations require occupiers of dispensaries to ensure that:

²¹¹ Pharmacy Council of New South Wales, *Annual Report 2016-17*, p 183.

²¹² Victorian Pharmacy Authority, *Annual Report 2016-17*, p 23.

²¹³ Tasmanian Pharmacy Authority, *Annual Report 2016-17*, p 11.

²¹⁴ Pharmacy Regulation Authority SA, *Annual Report 2016-17*, pp 9 and 15.

²¹⁵ Pharmacy Registration Board of WA, Annual Report for the year ended 30 June 2017, p 15.

- the dispensary meets specific physical standards (for example, is adequately enclosed, ventilated and lit, has lined walls and ceilings; stainless steel sink, separate dispensing bench)
- the dispensary, dispensing equipment and containers are kept clean and in good condition
- specified items (for example, refrigerator, dispensing measures, tablet counting tray, copy of the Health (Drugs and Poisons) Regulation 1996) and additional items for extemporaneous dispensing are available at the dispensary
- specific measures are in place for the sterile dispensing of therapeutic drugs, written policies and procedures about sterile dispensing and sterile dispensing equipment regularly maintained, and
- specific requirements are met for the dispensing of antineoplastic drugs (for example, vertical laminar flow cabinets, separate air supply for compounding room). ²¹⁶

The Health (Drugs and Poisons) Regulation 1996 also contain provisions about the storage of medicines that apply to pharmacy premises. These provisions require medicines to be stored in a safe or in another secure place.

According to Bill Loveday of the department, Queensland hospital and health services have officers conducting inspections of pharmacies in relation to scheduled medicines:

Throughout the broader Queensland environment, the hospital and health services have public health units that have appointed inspectors under the Health (Drugs and Poisons) Regulation and those are the officers who do the on-the-ground inspections of pharmacies around the regulation of their access and use to scheduled medicines. They will go and inspect a safe or they will go and inspect the records of a pharmacy. When complaints arise across Queensland, they are the point of call to go and actively deal with those complaints and look at the actual activities of a pharmacist.

We have an agreed compliance plan with the public health units, so their goal is to every three years attend to the total number of pharmacies within their region or their area, with the idea that they try to achieve a third of the pharmacies in their patch each year. That of course is an aspirational goal. Those officers often are attending to a range of other public health acts as well.

... they have a complete checklist—a pharmacy audit tool—that they do and sometimes that can take half a day sitting in a pharmacy going through everything from records to wholesale records. They are looking over the controls that a pharmacist might exercise to manage their use of those scheduled drugs. They do have a particular emphasis on looking over Schedule 8 drugs because of their misuse and diversion in the community, so that is a high-priority area.²¹⁷

7.2 Pharmacy premises regulation in other jurisdictions

In New South Wales, pharmacy premises are required to be approved (this involves similar processes and criteria as for registration in the other states). Pharmacy premises are required to be registered in Victoria, Tasmania, South Australia and Western Australia (table 7).

According to the department, the main policy objectives of the approval or registration regimes for pharmacy premises in the other states are to:

 provide a means to ensure compliance with the pharmacy ownership restrictions (for example, by requiring owners of pharmacy businesses to demonstrate, when applying for

The Department of Health, *Pharmacy Regulation Issues, Consultation Paper*, unpublished paper, 2012, p 6.

Department of Health, Correspondence, 12 September 2018.

registration of premises, they are permitted to own the pharmacy business operated from the premises)

- ensure the premises are suitable for the safe and competent provision of pharmacy services, and
- prevent pharmacy premises being located where they are accessible from within a supermarket.²¹⁸²¹⁹

It should be noted that state and territory regulations preventing supermarkets from operating a pharmacy business duplicate the Australian Government's pharmacy location rules. ²²⁰ The pharmacy location rules are described in further detail in appendix F. The only jurisdictions that do not have legislated prohibitions on pharmacy premises being located within or accessed through supermarkets are Queensland, Victoria and the Northern Territory (table 8).

Table 8: Regulation of pharmacy premises by jurisdiction

Jurisdiction	Premises approved	Premises registered	Premises meet standards	Supermarket restriction
Queensland			✓	×
New South Wales	✓			✓
Victoria		✓		×
Tasmania		✓		✓
South Australia		✓		✓
Western Australia		✓		✓
Australian Capital Territory			✓	✓
Northern Territory			✓	×

Source: Department of Health, Pharmacy Regulation Issues, Consultation Paper, unpublished paper, 2012.

For premises to be approved or registered, an application (accompanied by the relevant fee) must be made to the approval/registration authority by the owner of the pharmacy business operated from the premises. As part of the registration process, the owner must satisfy the ownership provisions that apply in the state.

The approval/registration authority must also be satisfied the premises are suitable for the safe and competent provision of pharmacy services. According to the department, suitability is assessed on whether the premises meet specified physical standards, including, for example, that:

- the premises have appropriate public access
- the dispensing area must exceed a specified minimum floor area
- the premises have an area that permits the pharmacist to provide confidential counselling to members of the public
- the premises are hygienic, adequately lit and ventilated and equipped with specified equipment and publications, and

The Department of Health, *Pharmacy Regulation Issues, Consultation Paper*, unpublished paper, 2012, p 7.

The only jurisdictions that do not have legislated prohibitions on pharmacy premises being located within, or accessed through, supermarkets are Queensland, Victoria and the Northern Territory.

The rules are legislated in the National Health (Australian Community Pharmacy Authority Rules)
Determination 2011 (PB 65 of 2011) made under subsection 99L(1) of the *National Health Act 1953*.

• the premises have provision for temperature control of medicines and adequate provision for the safe and secure storage of medicines and confidential or sensitive information.²²¹

Pharmacy premises are not required to be licensed, registered or approved in the Australian Capital Territory and the Northern Territory. But similar to the situation in Queensland, pharmacy premises must still comply with specified physical requirements or standards which are comparable to those found in the states that approve or register premises.

For example, in the Australian Capital Territory, pharmacists must comply with the premises requirements outlined in the Public Health (Community Pharmacy) Code of Practice 2016 (No 1). There are 10 premise requirements in the Australian Capital Territory.

In the Northern Territory, a person must not conduct a pharmacy business from premises unless the premises comply with the standards prescribed by the Pharmacy Premises Committee. There are 11 pharmacy standards in the Northern Territory and pharmacy businesses are audited and inspected at least every two years against the minimum prescribed standards.

William Kelly of the Pharmacy Board of Australia suggested that either harmonisation of pharmacy premises regulations across jurisdictions or a national regulator of pharmacy premises would be a useful reform because of the lack of consistency in different jurisdictions which leads to complexity for pharmacy owners (who can own pharmacies in every Australian jurisdiction):

The board deals with each of these authorities, but we deal at different levels because of the different requirements and the different legislation involved. Anything towards harmonisation is certainly welcomed. Non-harmonisation just leads to complexity, which is what we should probably try to avoid ...

[The pharmacy premises regulatory framework] varies between jurisdictions. In some you need to grant/revoke licences that establish a business; grant/revoke approval of premises; different powers to inspect premises to ensure minimum standards; power to take action; and power to audit premises. That is the harmonisation of the types of activities that need to be consistent across this part of the regulatory framework ...

... something like a national regulator of pharmacy premises would probably be of assistance ... ²²²

7.3 Wilkinson Review recommended registration of pharmacy premises be removed

The 2000 Wilkinson Review concluded that so long as pharmacy premises are accessible and conform to any requirements laid down to facilitate the safe and competent practice of pharmacy there is no need to register either the premises or the business entities that operate them.

Registration of premises was deemed to be unnecessary given that owners can face disciplinary action as responsible professionals for incompetence, recklessness and wilful disregard of proper practice in their professional duties. The Wilkinson Review recommended that:

- Legislative requirements for the registration of pharmacy premises be removed provided that:
 - Acts, regulations and related guidelines can continue to require pharmacy proprietors and managers to ensure that their premises are of a minimum standard of fitness for the safe and competent delivery of pharmacy services
 - The responsibilities of pharmacy proprietors and managers, and of registered pharmacists, under State and Territory drugs and poisons legislation are not compromised

The Department of Health, *Pharmacy Regulation Issues, Consultation Paper*, unpublished paper, 2012, p 7.

²²² Public hearing transcript, Cairns, 11 September 2018, pp 3-4.

- o Acts or regulations may require the proprietor of a pharmacy to notify a regulatory authority, in writing, of the location or relocation of a pharmacy, and
- o Regulatory authorities, their employees or agents may enter and inspect pharmacy premises to investigate complaints, conduct spot checks, or act on the reasonable suspicion of guidelines being breached; and
- Regulations requiring the registration of pharmacy businesses by regulatory authorities are removed, given that pharmacists are already registered in each State and Territory, and that business registration is not connected to the safe and competent practice of pharmacy.²²³

In accepting these recommendations in 2002 the COAG Senior Officials Working Group commented:

It is notable that Queensland and the Territories have no requirements for premises or business registration, there is no clear evidence that this lack of registration has affected pharmacy or pharmacist standards in those jurisdictions. 224

7.4 Support for a separate statutory authority

Numerous proprietor pharmacists and the Pharmacy Guild of Australia raised concerns in submissions about the administration of the Pharmacy Business Ownership Act 2001 (Act) by the Department of Health as being the primary rationale for establishing a pharmacy council. For example, the Owen Pharmacy Group, suggested the administration of the Act by the department is the problem, not the Act itself:

The Queensland Health 'tick and flick' exercise is being abused by groups and corporates using complex accounting and legal structures. An independent body with industry expertise needs to administer the Act to ensure all applicants comply with the intent of the Act – for this, a QPC [Queensland Pharmacy Council] with industry specific knowledge of the issues should be put in place. Compliance to the Act is paramount and this structure works effectively in other jurisdictions. Although some jurisdictions are better than others, all are superior to Queensland in this aspect.²²⁵

Chris Owen from Owen Pharmacy Group reiterated this point:

I have concerns about how the department, without sufficient resourcing, has been able to achieve this legislative intent. I am not convinced that in Queensland this could be achieved without a pharmacy council as it is in other jurisdictions with a dedicated regulator. A council would have the expertise and the capability to properly scrutinise ownership structures. The nominated pharmacist must maintain proprietary and pecuniary interests of the business at all times. In recent times it is my belief that the legislation has been open to being gamed by nominating a pharmacist's proxy to pass the current approval processes of Queensland Health while they do not contain any true proprietary or pecuniary control in the running of their business.²²⁶

Public hearing transcript, Toowoomba, 7 September 2018, p 12.

²²³ Warwick Wilkinson, National Competition Policy Review of Pharmacy, Part A, Final Report Of The Review, 8 February 2000, p 68, https://www.health.gov.au/internet/main/publishing.nsf/Content/3FC1206410A83FBDCA257BF0001DAD 71/\$File/finalparta.pdf.

COAG (Council of Australian Governments), COAG Senior Officials Working Group Commentary On The National Competition Policy Review Of Pharmacy, 2002, p 23, https://www.health.gov.au/internet/main/publishing.nsf/Content/73C2DF272686DEB2CA257BF0001B5D D2/\$File/coag sowg.pdf.

Submission 29, p 3.

Similar sentiments were expressed by LiveLife Pharmacy Airlie Beach:

The current Queensland Health administration of the [Act] has failed to uphold the legislative instrument of the PBOA [Pharmacy Business Ownership Act] by not clearly establishing who holds the true and financial and managerial control of the pharmacy.²²⁷

The Queensland Health tick and flick form is being abused by groups and corporates using complex accounting and legal structures. An independent body with industry expertise needs to administer the Act to ensure all applicants comply with the intent of the Act – for this, a Queensland Pharmacy Council with industry specific knowledge of the issues [should be] put in place. Compliance of the Act is paramount, and this structure works effectively in other jurisdictions. ²²⁸

The Pharmacy Guild of Australia also supported this rationale for a pharmacy council:

The ownership requirements as they stand are sufficient but could be improved to ensure that there is greater transparency regarding the regulation of pharmacy ownership. ... To assist with this, the Guild submits that there should be a regulatory authority established (such as a Pharmacy Council) so that, on the sale of a pharmacy, the Pharmacy Council can undertake a forensic analysis to ensure that the purchaser is ... in accordance with section 139B of the Pharmacy Business Ownership Act 2001 (Qld).²²⁹

Galleon Way Pharmacy suggested a pharmacy council would ensure that pharmacy remains in the hands of pharmacists and that illegal ownership of pharmacies is prevented:

We need a Queensland Pharmacy Council to ensure pharmacy remains in the hands of pharmacists and to ensure practice remains patient focused. Queensland is the only state not to have this in place.

Also, it is vital the current ownership and location laws are adhered to [to] protect the public from illegal ownership practices. It is imperative that Queensland follows suit with every other state and territory to ensure current ownership laws, location rules and monitoring of pharmacies is upheld.²³⁰

Similarly, Matthew Brosnan, who has an interest in four pharmacies, sought better policing of the Act—without it, the new franchise models would continue to grow and young pharmacists would not be able to own a pharmacy:

It is too important not to act. There is a feeling of disenchantment and cynicism amongst our young pharmacists coming through in relation to ownership. I personally believe that the opportunity that many others have had in this profession to attain ownership provides an incentive to stay in the profession. The disillusionment of our young towards attaining ownership and the angst of those who have taken the leap have led to an exodus of good people from our profession, and it is a waste of a health resource. We cannot afford to maintain the status quo. If we do, three things will happen: the likes of Chemist Warehouse will continue to grow, other corporates like Ramsay will enter the market and existing groups will continue to acquire independence using existing loopholes.

This inertia in pharmacy regulation is a strategy for those who argue that we have reached a critical point which is too difficult to wind back. I often hear the comment that we should be deregulated, corporates are already at play, no-one abides by the rules anyway. There are groups

²²⁷ Submission 175, p 2.

²²⁸ Submission 175, p 4.

²²⁹ Submission 161, p 12

²³⁰ Submission 66, pp 1-2.

that are currently buying pharmacies with the intention of selling them if and when deregulation occurs. This is a defeatist view and community pharmacy is worth fighting for. It just needs resolve and leadership, and we can do it only with your help.²³¹

7.5 Experience with statutory authorities in other jurisdictions

There was little evidence provided in submissions that demonstrated that establishing a pharmacy council/authority in other Australian jurisdictions has led to better community outcomes in those jurisdictions (relative to Queensland). Most submissions were not aware of evidence that pharmacy councils in other jurisdictions had improved outcomes:

For example, the Pharmaceutical Society of Australia (PSA) commented:

PSA is not aware of any evidence to indicate that Australians in any other jurisdiction have better community outcomes compared to Queensland. ²³²

In a similar fashion, Ramsay Pharmacy, which has 54 franchises across Australia (that is, in those jurisdictions with and without a pharmacy council), commented:

Ramsay Pharmacy is not aware of any reliable evidence to suggest that additional pharmacy ownership regulation in other Australian jurisdictions (such as approval and registration of pharmacy premises in New South Wales and Victoria) has improved community outcomes (relative to Queensland).²³³

Indeed, the department was also not aware of any evidence that Queensland consumers of pharmacy services are disadvantaged compared to consumers in state or territories where pharmacy ownership and premises regulations are administered by pharmacy councils or other authorities. As Michael Walsh from the department commented:

What we are saying is that when you look at the safety and access that people have in terms of pharmacies and medications the outcomes in Queensland are similar to the outcomes in New South Wales and Victoria.²³⁴

When you look at the outcomes of pharmacy business ownership decisions in Queensland versus the pharmacy business ownership decisions in, let's say, New South Wales and Victoria—we have the same franchise chains operating, including Ramsay. We have pharmacies that are accessible to the public in rural locations. We have the same levels of safe handling of medications whether or not there are inspections in terms of those outcomes. Therefore, the processes to achieve those outcomes may be different in terms of a council or the department, but we believe in asking what has been achieved in terms of that.

...In answering your question, I would say the real question is: what is it that is currently operating that we see we need to fix in terms of the outcomes, given that the outcomes appear to be the equivalent to New South Wales and Victoria?²³⁵

Dr Lisa Nissen from the QUT School of Clinical Sciences also had no evidence to suggest that pharmacy practice was better in those states that had a pharmacy council:

I think the current system as it stands is fine. This is my impression, given an observation of other states that have a council and what happens in Queensland. The fact is that there is no difference

²³³ Submission 151, p 11.

²³¹ Public hearing transcript, Townsville, 10 September 2018, p 23.

²³² Submission 136, p 9.

Department of Health, Correspondence, 12 September 2018.

Department of Health, Correspondence 12 September 2018.

in how practice happens in those states and this state and the way that pharmacies are operated. I do not see any difference. 236

On the other hand, Anthony White of TerryWhite Chemmart had anecdotal evidence that pharmacy ownership transfers were slower in those states with pharmacy councils:

I know that in other states where councils have been established the processing of transfers of ownership has been substantially delayed and for pharmacists who are wanting to sell their pharmacy it is taking an enormously long time. Other than that, I am unsure of whether they are successful in the other states or not.²³⁷

However, the Pharmacy Guild of Australia believe that jurisdictions with a pharmacy council improve community outcomes by providing regular reports of their activities, including by monitoring and investigating the operation of pharmacy premises. The Pharmacy Guild of Australia described three recent investigations undertaken by the Victorian Pharmacy Authority, where licensees were reprimanded, and a condition inserted into their licences that quarterly self-assessments be conducted.²³⁸

Such activities undertaken by pharmacy councils in other jurisdictions are not evidence of improved community outcomes emanating from the existence of a pharmacy council. Evidence could include, for example, outcomes such as lower hospital admission rates from medication errors, or less complaints/prosecutions for breaches of relevant health legislation.

There could be greater transparency about regulatory outcomes for pharmacy premises across all jurisdictions—not just Queensland. Most pharmacy councils do not publicly report premises compliance outcomes. In Queensland, pharmacy premises are audited by authorised officers of the Public Health Units of the Hospital and Health Services for compliance with the Health (Drugs and Poisons) Regulation 1996 and the Health Regulation 1996. But the audit results are not published.

According to the Queensland Productivity Commission (QPC) the rate of premises' inspection in Queensland is less than in most other jurisdictions with a pharmacy council:

Queensland Health inspected 161 pharmacies in 2017-18. At this rate of inspection pharmacies would be inspected every 7.3 years. This is less regularly than some other states—for example in New South Wales, Victoria and South Australia every pharmacy is inspected every 1.5, 2 and 3 years, respectively, but more pharmacies than in Western Australia (where 15 inspections were conducted in 2016-17. Between 2013-14 and 2017-18, an average of 246 inspections were carried out per year in Queensland—on average pharmacies were inspected approximately every 4.6 years.²³⁹

Table 9: Outcomes of Queensland Health inspections of audit of pharmacies in relation to the Health (Drugs and Poisons) Regulation, 2013-14 to 2017-18

•		
	Number	Proportion
Compliant	514	41.8%
Non-compliant	450	36.6%
Undetermined	238	19.3%
Non-applicable	29	2.4%

Source: QPC, Cost-benefit analysis of establishing a pharmacy council, report, 2018, p 20.

²³⁹ Queensland Productivity Commission, *Cost–benefit analysis of establishing a pharmacy council*, 2018, p 19.

²³⁶ Public hearing transcript, Brisbane, 20 August 2018, p 12.

Public hearing transcript, Brisbane, 20 August 2018, p 4.

²³⁸ Submission 161, pp 27.

The Queensland Productivity Commission (QPC) sourced unpublished data from the Department of health which showed slightly more pharmacies were compliant than non-compliant (table 9).

According to the QPC most pharmacy premises' failures represented lower-level non-compliance:

The data does not detail what proportion of failures are serious (for example exposure of hazardous substances or drug theft) – however, consultation with Queensland Health indicates that most failures represent lower-level non-compliance. Inspectors aim to rectify failures, by following up non-compliance with a range of tools of graduating severity to achieve enforcement.²⁴⁰

Some pharmacists, such as Catherine Whalan from Cate's Chemist, wanted more intensive regulation of their pharmacy premises and no announcement of an imminent inspection by the department:

At my last inspection, which was a number of years ago, they rang me the day before the inspection to say that they were coming. I was shocked. I have never been given notice of an inspection, so that was the first time ever. I queried the staff why. I asked, 'Why would you give me notice that I am being inspected?' Their response to me was that if they gave notice things went a lot more smoothly and there was a lot less paperwork to do. In the Queensland department's annual report for 2016-17—the department report—they maintained confidence in the controls around community pharmacy businesses. I disagree. I do not think they do and, on the balance of the 200-odd submissions to this inquiry, I know I am not alone in thinking this.²⁴¹

While pharmacy premises' regulatory outcomes are not transparent across all jurisdictions, pharmacist practice outcomes are publicly disclosed by the national occupational licensing regulator. In relation to professional standards, the QPC found no evidence that Queensland pharmacists breach standards²⁴² more frequently than those in other states (table 10):

The percentage of Queensland registrant pharmacists who received notifications (complaints or concerns lodged to AHPRA) was at or lower than the Australian average in each of the last three years. In contrast, in New South Wales, which has a pharmacy council model, the percentage of pharmacists who received notifications from AHPRA was above the national average in each year.²⁴³

Table 10: Percentage of registered pharmacists who received notifications from AHPRA, by state

	2014-15	2015-16	2016-17
Queensland	0.7%	1.2%	1.8%
New South Wales	2.8%	2.8%	1.9%
Victoria	1.3%	1.8%	2.0%
Western Australia	1.1%	0.9%	1.1%
South Australia	1.8%	1.5%	1.6%
Tasmania	2.0%	3.0%	3.0%
Australia	1.7%	1.9%	1.8%

Source: QPC, Cost-benefit analysis of establishing a pharmacy council, report, 2018, p 21.

²⁴⁰ Queensland Productivity Commission, *Cost–benefit analysis of establishing a pharmacy council*, 2018, p 20.

Public hearing transcript, Townsville, 10 September 2018, p 14.

As described under the Health Practitioner Regulation National Law, as in force in each state and territory.

²⁴³ Queensland Productivity Commission, Cost-benefit analysis of establishing a pharmacy council, 2018, p 21.

7.6 Submitter expectations for a Queensland pharmacy authority

Numerous submissions from a wide variety of organisations indicated there would be no benefits in establishing a pharmacy council in Queensland because there was no evidence that a pharmacy council would do a better job of regulating ownership (and premises) than the Department of Health.

For example, Health Consumers Queensland did not have any evidence that a pharmacy council would improve community outcomes (relative to the department):

Given that Queensland Health currently oversees the regulation of medicines and drugs, maintain a register of pharmacy ownership and what is being dispensed (e.g. opioid treatment programs, medicinal cannabis distribution, etc.), it is unclear whether health consumers and the community would be assured that a new pharmacy council in Queensland would provide greater performance, safety & quality than current monitoring and regulation through Queensland Health.²⁴⁴

Peter Giannopoulos of Ramsay Pharmacy did not believe a pharmacy council would improve community outcomes and also raised concerns about the composition of any proposed pharmacy council:

In terms of the establishment of community pharmacy, our view is that we do not believe it is a necessary requirement to establish a pharmacy council, nor would a pharmacy council improve community outcomes. Queensland Health has shown that it has been able to apply in an impartial way and competently and comprehensively administer the intent of the current regulatory regime. However, should a pharmacy council be established it should have representatives from a broad stakeholder group, not necessarily those who might be perceived to have a conflict of interest.²⁴⁵

Mater Misericordiae Limited stated that there is no public health risk in Queensland that requires an additional layer of regulation:

Given Queensland has never licensed or [registered] pharmacy premises and that there is no definitive evidence of any particular risk to the public from the current situation where there is no premises [registration], Mater does not believe there are any significant gaps in the above regulatory framework that place the public at risk and that would be addressed by the establishment of another layer of regulation (and cost), namely a pharmacy council with a likely focus on physical infrastructure such as dispensary standards and pharmacy premises.²⁴⁶

Dr Stephen King of the Productivity Commission was unclear about the benefits that could be gained by establishing a pharmacy council in Queensland:

... it was not clear exactly what a pharmacy council would achieve or do compared to what the state department is able to do. If its base aim is to ensure or help ensure that the relevant ownership rules are complied with—whether they are the current rules, tightened rules or loosened rules—that is fine, except that it is not obvious to me why that cannot be done efficiently within the department.

My situation is that I really [can't] see what the objective of a pharmacy council would be or what the benefits would be compared to just retaining the relevant enforcement role of the ownership rules within the department context.²⁴⁷

²⁴⁴ Submission 202, p 9.

Public hearing transcript, Brisbane, 3 September 2018, p 25.

²⁴⁶ Submission 146, p 5.

Public hearing transcript, Brisbane, 20 August 2018, p 18.

The Australian Medical Association indicated that establishing a pharmacy council would duplicate the regulatory functions of the department for little perceived benefit and that it may lead to added risks for the community because of the likelihood that a pharmacy council executive would be composed mainly of pharmacy industry representatives:

AMA Queensland does not support the establishment of a pharmacy council in Queensland. Based on the issues paper from the committee, it would appear most of its proposed functions and powers are already vested in legislation and the Pharmacy Board of Australia, thus duplicating processes that already exist for what may be very little benefit.

It is the view of AMA Queensland that the current arrangements have been serving patients and the broader health system extremely well and that the move to an 'independent' body whose secretariat and executive could potentially be stacked with pharmacy industry representatives presents a serious threat to stability.²⁴⁸

Following the release of the Queensland Productivity Commission report, *Cost–benefit analysis of establishing a pharmacy council*, Dr Dilip Dhupelia from the Australian Medical Association Queensland reiterated its opposition to the establishment of a pharmacy council:

We note in the Queensland Productivity Commission's report, which aligns with AMA Queensland's position, that a pharmacy council would not deliver better outcomes to industry or consumers in Queensland, is unlikely to produce a material benefit, would cost Queensland taxpayers money that does not need to be spent and will dampen innovation and competition. The report goes on to say that it seems redundant and short-sighted to establish a new body. We already have a system in Queensland that works—a system that AMA Queensland believes can be further improved by greater transparency and reporting but one that does not require the establishment of a new body. ²⁴⁹

Dr Shane Jackson of the Pharmaceutical Society of Australia also referred to concerns with duplication of functions and governance of a pharmacy council.

... if a council was to be formed, any duplication in the function of other agencies involved in pharmacy business and pharmacy practice should be avoided. Previous reference has been made today to national frameworks and national organisations, and we highlight that duplication is something to be avoided. From a governance point of view, we would need to make sure that there is a diverse range of industry and independent health governance experts involved in the membership of a council to ensure that appropriate and contemporary understanding of the pharmacy landscape is reflected.²⁵⁰

It could be expected that if a pharmacy council was established in Queensland that some of the functions of the department would be transferred to the pharmacy council— if this were to occur duplication would be minimised. However, there would remain an obvious community concern if a pharmacy council was largely composed of people or organisations closely affiliated with those it was supposed to be regulating. The pharmacy councils established in other jurisdictions all have a majority of members that are pharmacists (table 11):

²⁴⁸ Submission 121, p 4.

Public hearing transcript, Brisbane, 3 September 2018, p 2.

Public hearing transcript, Brisbane, 20 August 2018, p 23.

Table 11: Pharmacy council member composition of members and staff

State	Members and staff
New South Wales	Ten members:
	Nominated by Minister for Health – two local pharmacists, two non-pharmacist community representatives, one lawyer
	Local pharmacists elected by local pharmacists
	Has an executive officer and supporting staff
Victoria	Five members:
	Registered pharmacists
	One lawyer
	One person who is not a registered pharmacist
	Also employs a Registrar and other staff necessary to administer the Act
Tasmania	Three members nominated by the Secretary of the Department of Health and Human Services and appointed by the Minister for Health:
	Two pharmacists
	One non-pharmacist
	Must also appoint a Registrar. May establish committees in support of its functions
South Australia	Five members appointed by the Governor on the nomination of the Minister for Health:
	An officer of the Department of Health who has responsibility in relation to the administration of pharmacy services
	A person selected from a panel of three pharmacists nominated by the Pharmacy Guild of Australia
	A person selected from a panel of three pharmacists nominated by the Pharmaceutical Society of Australia
	A person selected from a panel of three pharmacists involved in the operation of pharmacies in South Australia, nominated by the Australian Friendly Societies Pharmacies Association
	A person qualified by reason of their expertise and experience to represent the interests of the public
	A general manager and other staff are also employed
Western Australia	Four members appointed by the Minister for Health:
	Pharmacists
	One person who has knowledge and experience in representing the interests of consumers
	Also employs a registrar and other staff

Source: Queensland Productivity Commission, unpublished research.

The industry association of pharmacy proprietors, the Pharmacy Guild of Australia suggested that an independent organisation from government would be more effective at enforcing the *Pharmacy Business Ownership Act 2001* than the current arrangements:

An independent authority would have the advantage of being able to secure and maintain the confidence of pharmacists, particularly if it included representation from the pharmacy profession. Further an independent body with appropriate specialist professional and business expertise and consumer representation, supported by an appropriate secretariat, would be in the best position to respond with independence to enforce the legislation.²⁵¹

While such an entity may be independent of government, it is not clear that if would be sufficiently independent from the pharmacy businesses it would be responsible for regulating. There could be significant conflicts of interest if the proposed pharmacy authority had significant representation from proprietor pharmacists. This issue was highlighted by the Queensland Productivity Commission:

²⁵¹ Submission 161, p 29.

Depending on the members selected for a pharmacy council, independence might be reduced. There would be a potential conflict of interest if the pharmacy council members were also pharmacy owners and were tasked with enforcing pharmacy ownership regulation.²⁵²

The Owen Pharmacy Group also saw better enforcement of the Act, through better governance, would improve the Queensland community's perception of safety:

The way to enforce the intent of the PBOA is to have a body which has the industry expertise and knowledge to ask the right questions of applicants and to study the evidence on a forensic level to ensure proprietary and pecuniary interest remains, at all times, with the pharmacist applicant. The current standards of practice employed by Queensland Health in administering this instrument is alarming. Queensland Health processes do not have the ability, industry expertise or resourcing to properly administer the legislation. A Queensland Pharmacy Council with industry representation, adequate resourcing and transparency will allow Queenslanders to be safe in the knowledge that the legislation is being upheld.²⁵³

The Society of Hospital Pharmacists of Australia believed that a pharmacy council would improve the professionalism of community pharmacy:

Establishing a formal pharmacy council in Queensland will improve the performance and professionalism of community pharmacy by improving standards and links with other professional and regulatory bodies. This will foster a more robust review system of pharmacy services that are offered in the community setting, ensuring the delivery of the highest quality of care to the community, and complimenting services by the hospital pharmacy setting.

The committee has not been made aware of any evidence that demonstrates that community pharmacy in Queensland is less professional (or less focused on patient safety) than community pharmacy in those jurisdictions with a pharmacy council. Moreover, improving professionalism in community pharmacy is a means to improving community outcomes but it is not evidence of improved community outcomes.

7.7 Costs and benefits to the community

Numerous submissions highlighted a pharmacy council will add to costs without adding to benefits, therefore the community will be worse off. For example, the Pharmaceutical Society of Australia stated:

If a council was to be established, it is likely that there would be an administrative cost, of which a significant proportion ... would likely be passed onto the community sector to pay for. And to PSA's knowledge, there has yet to be any benefits determined.²⁵⁴

TerryWhite Chemmart had a similar sentiment, but focused on the administrative burden on proprietor pharmacists without providing any additional benefits:

An additional layer of external regulation which involves a time consuming fee based application process at a cost to the pharmacist and causing unnecessary delays and time constraints on transactional matters where people, being pharmacist owners, pharmacy staff, suppliers, service providers and patients, are intrinsically reliant on the outcome, is costly, particularly in circumstances where a professional pharmacist is making a conscientious declaration of truth about their ownership interests.²⁵⁵

Health, Communities, Disability Services and Domestic and Family Violence Prevention Committee

²⁵² Queensland Productivity Commission, Cost-benefit analysis of establishing a pharmacy council, 2018, p 22.

²⁵³ Submission 29, p 2.

²⁵⁴ Submission 136, p 10.

²⁵⁵ Submission 135, pp 16-17.

Anthony White of TerryWhite Chemmart reiterated these concerns about the administrative burden of a pharmacy council at the public hearings. He suggested it should not have a regulatory role but instead should solely focus on implementing an expansion of pharmacists' scope of practice:

I think that support for a pharmacy council would be very much encouraged, particularly if its charter and direction were focused around facilitating and fast-tracking some of the expansion of scope that Queenslanders are looking for. If it is a council that is bogged down in a lot of administrative processes that add a layer of bureaucracy over and above the current system unnecessarily with no benefit to the system, I would ask why there is a need for that to be considered.²⁵⁶

Mater Misericordiae Limited was concerned about the unintended consequences of establishing a pharmacy council that may arise, particularly for its own activities, given its unique standing under sections 139B and 139H of the *Pharmacy Business Ownership Act 2001*.

... Mater is ... particularly concerned about the risk of many unintended but significant adverse consequences and scenarios for patients, health outcomes and our operations from any new regulatory regime for pharmacy operations and/or premises. Any regulatory change brings this risk but rushed, unplanned or poorly defined changes can create major disruptions to care and compromise patient safety.

The establishment of a new pharmacy council (i.e. with no experience or historical context) and which would likely be heavily focussed on the community pharmacy sector (i.e. limited focus on hospital settings) would bring considerably more risk for hospitals (both public and private) and in particular Mater.²⁵⁷

On the other hand, the Pharmacy Board of Australia suggested the costs of registration would be offset by the benefits:

Setting mandatory fees similar to those imposed in other states and territories by relevant authorities would mean additional costs to proprietors, however, these would be offset by the benefits to the public who can be provided assurance through routine inspection that minimum pharmacy business and premises standards are maintained and action taken when standards fall below minimum requirements.²⁵⁸

While there would be additional costs, there would not necessarily be additional benefits of a more intensive regulatory approach. Pharmacies are audited by authorised officers of the Public Health Units of the Hospital and Health Services for compliance with the Health (Drugs and Poisons) Regulation 1996 and the Health Regulation 1996. An increase in the rate of audit inspections would only generate additional benefits if the inspections were risk-based: increasing inspections on compliant pharmacy businesses would provide no additional benefits.

The Pharmacy Guild of Australia went further asserting that there would be little or no costs to the government (as opposed to the community) and that these would be offset by the benefit of better enforcement:

Establishing a Pharmacy Council in Queensland would not result in any significant additional costs to the Government, as it may be self-funded by fees from pharmacy ownership and pharmacy premises registration. The benefits would be a guarantee that the legislative intent of the Pharmacy Business Ownership Act 2001 was being enforced to protect the public.²⁵⁹

²⁵⁶ Public hearing transcript, Brisbane, 20 August 2018, p 2.

²⁵⁷ Submission 146, p 5.

²⁵⁸ Submission 122, p 6.

²⁵⁹ Submission 161, p 33.

There would be no cost to the government if the council was funded by proprietor pharmacists through the collection of registration fees on an annual basis, as well as application fees for certain activities such as new pharmacies, or changes of ownership. However, it is likely that the additional costs on proprietor pharmacists would be passed on to consumers in the form of higher prices for pharmacy goods and services, reduced wages for pharmacy employees or reduced pharmacy staffing levels.

On the other hand, Chris Owen of Owen Pharmacy Group suggested that the funding of a pharmacy council should be shared between industry and the taxpayer:

To ensure cost-effectiveness, the majority of this would be industry funded, with the government contributing no more than the existing budget that is allocated to Queensland Health for this exercise. The balance would be covered by an annual licensing fee to ensure that each year these pharmacies satisfy the requirements of the Act. ²⁶⁰

7.8 Cost-benefit analysis of establishing a separate statutory authority

On 26 May 2018 the Treasurer requested the Queensland Productivity Commission (QPC) undertake a cost—benefit analysis of establishing a pharmacy council (or other viable alternatives). On the 14 August the committee received a copy of the QPC's report, *Cost—benefit analysis of establishing a pharmacy council*, via the Treasurer. The QPC's report is available from the QPC website; qpc.qld.gov.au.

A revenue source would be required to meet the costs of establishing and operating a pharmacy council. The QPC indicated that any new fee levied on the pharmacy industry would be expected to work in a similar way to an additional tax which would negatively affect either consumers, pharmacy owners or their employees:

While a pharmacy council funded through industry fees may appear 'cost neutral' to the government, this is an additional cost [to the community], which will ultimately be paid for by either the pharmacy owners, pharmacists or pharmacy staff (through lower profits and wages) and/or consumers (through higher prices).²⁶¹

The QPC's cost—benefit analysis found there would be a net cost from forming a pharmacy council in Queensland. The cost to Queensland of establishing a pharmacy council was estimated to be in the range of \$7.7 million to \$11.1 million over a 10-year period. This range depended on the extent of the functions of the pharmacy council: whether it had a regulatory role (\$7.7 million), or whether it had an advisory and educational role in addition to a regulatory role (\$11.1 million).

The QPC found no evidence that other Australian states with pharmacy councils have better outcomes for producers and consumers than Queensland. This is because:

... safety and quality of services and products are addressed through the more direct regulation of pharmacists and medicines.

The Commission has not been able to identify evidence that pharmacist-owned pharmacies in aggregate have a greater focus on consumers/less focus on profit than other professions owning a business or different corporate structures.²⁶²

The QPC found no evidence the existing premises regulation is resulting in unsafe conditions in pharmacies or that enforcement of premises regulation through a pharmacy council provides better health and safety outcomes in pharmacies in other states.

The QPC found that forming a pharmacy council was unlikely to produce any material benefits because there are more direct regulations already operating to achieve the objectives sought from the

²⁶⁰ Public hearing transcript, Toowoomba, 7 September 2018, p 13.

²⁶¹ Queensland Productivity Commission, Cost–benefit analysis of establishing a pharmacy council, 2018, p 16.

²⁶² Queensland Productivity Commission, Cost-benefit analysis of establishing a pharmacy council, 2018, p 18.

ownership regulations. Consequently, administering the ownership regulations more intensively, as proposed by creating a pharmacy council, was unlikely to generate any additional benefits. Rather, it would simply add to the general cost of regulation on the Queensland community.

The QPC concluded that:

Overall, the results suggest the Queensland community will be unambiguously worse off with the transfer of the functions from Queensland Health.²⁶³

7.9 Conclusions

The committee found there is no public interest case for establishing a separate statutory authority, such as a pharmacy council, in Queensland to assume the regulatory functions of ensuring compliance with the pharmacy ownership restrictions and pharmacy premises regulation. This is based on three key findings:

- no evidence that other Australian states with pharmacy councils have better community outcomes
- no evidence that the existing premises regulation is resulting in unsafe conditions in pharmacies in Queensland
- no evidence that more intensive enforcement of ownership restrictions would provide greater consumer benefits in Queensland.

The Queensland Productivity Commission undertook an analysis at the request of the committee. That analysis demonstrated that the costs of establishing and operating a separate statutory authority would outweigh the benefits. This is because more intensively regulating the pharmacy ownership restrictions by a pharmacy council would not generate better community outcomes than the status quo. It would simply add to the cost of pharmacy regulation in Queensland.

The Queensland Productivity Commission concluded that a separate statutory authority would just add to costs in the form of higher prices for consumers (mainly in over-the-counter medicines), lower profits for pharmacy owners, or lower wages/reduced employment for pharmacy employees. Also, more intensive enforcement of the ownership restrictions is likely to reduce competition and discourage innovation. If this prevents innovative pharmacy groups from entering or expanding their offerings to consumers in terms of services and products or achieving economies of scale in their business, it would have a detrimental cost on Queensland consumers.

It is the committee's assessment that the Department of Health should continue to administer pharmacy ownership and premises regulation and drugs and poisons regulation. However, it needs to ensure the professional, safe and competent provision of pharmacy services and maintain public confidence in the pharmacy profession. There is a lack of transparency regarding the compliance of pharmacies and pharmacists with these regulations. This lack of transparency was raised by several submitters²⁶⁴ and also by witnesses in the public hearings. For example, Dr Dilip Dupelia from the Australian Medical Association Queensland stated:

To the best of our knowledge there is no publicly available information from the department on how they are administering the Pharmacy Business Ownership Act. Greater transparency in this regard could help improve enforcement of the Act and improve compliance where there are requirements without establishing a pharmacy council.²⁶⁵

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Queensland Productivity Commission, Cost-benefit analysis of establishing a pharmacy council, 2018, p 27.

For example, Pharmacy Guild of Australia (submission 161), Health Consumers Queensland (submission 202), Fiona Watson (submission 140), Owen Pharmacy Group (submission 29) and TerryWhite Chemmart Arana Hills (submission 61).

²⁶⁵ Public hearing transcript, Brisbane, 3 September 2018, p 2.

The Department of Health should publish its compliance audit results, at least annually.

Recommendation 10

Based on the findings of the audit by the Queensland Audit Office, the committee recommends that the Department of Health improve transparency regarding the compliance of pharmacists with the *Pharmacy Business Ownership Act 2001*, the Health Regulation 1996 and the Health (Drugs and Poisons) Regulation 1996 by publishing its compliance audit results, at least annually.

Minister responsible: Minister for Health and Minister for Ambulance Services

The Department of Health should also investigate ways to improve communication of the services individual pharmacies provide. The services should be regularly updated. This would make accessing services easier for the general community. It would also be useful for government in times of pandemic, natural disaster and for population health initiatives.

Recommendation 11

The committee recommends that the Department of Health investigate ways to improve communication to consumers about the services individual pharmacies provide such as vaccinations.

Minister responsible: Minister for Health and Minister for Ambulance Services

Appendix A – Submitters

Sub#	Submitter
001	Dr Jade Lee
002	Jadin Chemist – Caboolture
003	Dominic Ward
004	ConNetica Consulting Pty Ltd
005	Bravehearts Foundation Ltd
006	Coorparoo Discount Pharmacy
007	Calanna Whole Health Pharmacy Group
800	Form Submission Type 1
009	Lucy Walker Pharmacy
010	Blooms the Chemist – The Gap
011	Queensland Positive People
012	Douglas Chemists
013	LiveLife Pharmacy – Cannonvale
014	Yarraman Pharmacy
015	TerryWhite Chemmart – Pacific Pines
016	Carina Day and Night Pharmacy
017	Terry White Chemmart – Mt Gravatt Plaza
018	Greg Sexton
019	Chemist Warehouse
020	Eczema Association Australasia
021	Civic Fair Pharmacy – Mt Gravatt
022	Wulguru Pharmacy and Aitken Vale Medical Centre Pharmacy
023	Number not allocated
024	Grattan Institute
025	Number not allocated

026	Vision Australia
027	Peter Kolb Amcal Pharmacy
028	HealthSave Everton Park Pharmacy
029	Owen Pharmacy Group
030	Desley Hinson
031	Direct Chemist Outlet Brisbane Airport
032	LiveLife Pharmacy – Mission Beach
033	Clermont Pharmacy
034	J.P. Barsi
035	Good Price Pharmacy Warehouse – Robina
036	Number not allocated
037	Glaucoma Australia
038	Atrium Plaza Pharmacy
039	Scott Street Pharmacy
040	Wesley Pharmacy and Associated Pharmacies
041	Gladstone Road Pharmacy
042	Number not allocated
043	TerryWhite Chemmart – Samford
044	Wallumbilla Pharmacy
045	Number not allocated
046	Tufnell Road Pharmacy
047	LiveLife Pharmacy – Tully
048	Joshua Thorburn
049	Wandoan Pharmacy
050	Thrive Pharmacy – Annandale
051	Amanda McIntosh
052	LiveLife Pharmacy – Keppel Plaza

053	Costigans Pharmacy – Maryborough
054	Thuy Le
055	Leukemia Foundation
056	Warner Dakin
057	Giant Chemist – Pacific Fair
058	Russell Island Pharmacy
059	Kidney Health Australia
060	Form Submission Type 2
061	TerryWhite Chemmart – Arana Hills
062	Amanda Maguire
063	Deanna Jackson
064	Tracy-ann Jarman
065	Liz Howland
066	Galleon Way Pharmacy
067	Glenda Lord
068	Albany Creek Day & Night Chemist
069	Number not allocated
070	Cate's Chemist Hyde Park
071	Spinal Life Australia
072	Maree Mathews
073	United Chemist Oxenford
074	Number not allocated
075	TerryWhite Chemmart Day & Night Pharmacy – Rockhampton
076	Craig and Linda Young
077	University of Queensland School of Pharmacy
078	LiveLife Pharmacy Goodchap St
079	JG Whalan

080	Good Price Pharmacy Warehouse – Ashmore and Carrara
081	Noosa Heads Pharmacy
082	Parkinson's Queensland Inc
083	Michelle Stone
084	Daphne Anderson
085	Kristy Floyd
086	Queensland Alliance for Mental Health
087	McDonaldtown Pharmacy
088	Trevor and Julia Branch
089	Australian College of Rural and Remote Medicine
090	Simon Sponza
091	Diabetes Queensland
092	Australian College of Pharmacy
093	Dale Hennessy
094	Bamaga Pharmacy
095	Ian Kinsey Outback Pharmacy
096	Sadleirs Pharmacy
097	The Royal Australian & New Zealand College of Psychiatrists
098	Priceline Pharmacy – Albany Creek
099	Foote's Pharmacy
100	True Relationships & Reproductive Health
101	Sue Sharpe
102	Alive Pharmacy Warehouse – Innisfail
103	Number not allocated
104	Lenore Young
105	TerryWhite Chemmart – Ayr and West End
106	Asthma Australia

107	Stephen Winnett
108	Alistair Cook
109	Alberta Pharmacists' Association
110	Landsborough Chemist
111	Gatton Plaza Discount Drug Store
112	Good Price Pharmacy Gympie
113	Tufnell Road Pharmacy – Banyo
114	Manly West Pharmacy
115	Joy Bush
116	Medicross Pharmacy – Ipswich
117	Anne Kelly
118	Scarness Beachside Pharmacy
119	Peter Mayne
120	Priceline Pharmacy – Noosa Civic
121	Australian Medical Association Queensland
122	Pharmacy Board of Australia
123	Wynnum Day & Night Pharmacy
124	TerryWhite Chemmart – Karalee Village
125	SuperPharmacy Plus – Stafford
126	TerryWhite Chemmart – Keperra
127	Carmel Russell
128	Joel Watson
129	Good Price Pharmacy Warehouse – Mackay
130	Society of Hospital Pharmacists of Australia
131	Pharmacy Council of New South Wales
132	Ross and Lorraine Valinoti
133	Kirsty Harris

134	Capital Chemist Palmwoods
135	TerryWhite Chemmart – Head Office
136	Pharmaceutical Society of Australia
137	TerryWhite Chemmart – Clifford Gardens
138	Griffiths Pharmacy – Charters Towers
139	Joint Submission – Australian Medical Association Queensland and Royal Australian College of General Practitioners
140	Redland Bay Discount Drug Store
141	Stephanie Carsley
142	Confidential submission
143	Number not allocated
144	Marlin Coast Amcal Pharmacy – Smithfield
145	John Clark & Casey Clark
146	Mater Misericordiae Limited
147	Bayview Pharmacy
148	Paul Jaffar
149	Nick Doan
150	Clare Stone
151	Ramsay Pharmacy
152	Brigid Davey
153	Epilepsy Queensland
154	Number not allocated
155	Riverlink Medical Centre Pharmacy
156	Peter Jones
157	Amy Ford
158	LiveLife Pharmacy Group – Noosaville
159	Form Submission Type 3
160	TerryWhite Chemmart – Clifton Beach

Pharmacy Guild of Australia – Queensland Branch
Clinton Ford
Ormeau Day and Night Pharmacy
Keith Rand
Logan Central Pharmacy
Busiko's Pharmacy
Queensland University of Technology School of Clinical Sciences
Number not allocated
RSM Australia
Priceline Pharmacy – Riverlink
Sunny Park Discount Drug Store
TerryWhite Chemmart – Keperra
Rural Doctors Association of Queensland
Thursday Island Pharmacy
LiveLife Pharmacy – Airlie Beach
Matthew Brosnan
Joy McAllister
Broadwater Pharmacy
Matthew Doherty
Jan McNulty
Larry Vine
Linda Kohle
Sue Smith
Paul Willis
Cate's Chemist – Townsville
Greg Higgins
Henry & Jennifer Slaney

188	Number not allocated
189	Kallangur Day & Night Amcal Pharmacy
190	Royal Australian College of General Practitioners
191	Confidential submission
192	Confidential submission
193	John Ward
194	Number not allocated
195	Jake McIntosh
196	Kathryn Shaw
197	Number not allocated
198	Yeppoon Family Practice
199	Bianca Olsen
200	Priceline Pharmacy Fairfield Central
201	Brassall Pharmacy
202	Health Consumers Queensland
203	Pharmasave – Clontarf Bridge
204	Confidential submission
205	Discount Pharmacy Retail Group
206	Jadin Chemist group
207	Lung Foundation Australia
208	Number not allocated
209	Number not allocated
210	Chempro (Qld) Pty Ltd

Appendix B – Officials at private departmental briefings

Brisbane, Monday 6 August 2018

Department of Health

- Mr Michael Walsh, Director-General
- Dr Jeannette Young, Chief Health Officer and Deputy Director-General, Prevention Division
- Mr Peter Farley, Acting Chief Legal Counsel, Legal Branch, Corporate Services Division
- Ms Dorothy Vicenzino, Executive Director, Chief Medical Officer and Healthcare Regulation Branch, Prevention Division
- Mr Bill Loveday, Director, Medicines Regulation and Quality, Chief Medical Officer and Healthcare Regulation Branch, Prevention Division

Brisbane, Wednesday 12 September 2018

Department of Health

- Mr Michael Walsh, Director-General
- Dr Jeannette Young, Chief Health Officer and Deputy Director-General, Prevention Division
- Dr John Wakefield, Deputy Director-General, Clinical Excellence Division
- Mr Bill Loveday, Director, Medicines Regulation and Quality, Chief Medical Officer and Healthcare Regulation Branch, Prevention Division

Appendix C – Witnesses at public hearings

Brisbane Hearing, Monday 20 August 2018

TerryWhite Chemmart

- Mr Anthony White, Chief Executive Officer, TerryWhite Chemmart
- Ms Karen Brown, Managing Partner, TerryWhite Chemmart, Samford

School of Clinical Sciences, Queensland University of Technology

• Dr Lisa Nissen, Professor (Head), School of Clinical Sciences,

Productivity Commission

• Dr Stephen King, Commissioner

Pharmaceutical Society of Australia

- Dr Shane Jackson, National President
- Ms Jacqueline Meyer, Queensland Branch President
- Mr Mark Lock, State Manager

Chemist Warehouse

• Mr Damien Gance, Group Commercial Manager

Brisbane Hearing, Monday 3 September 2018

Australian Medical Association

• Dr Dilip Dhupelia, President AMA Queensland

Royal Australian & New Zealand College of Psychiatrists

· Associate Professor Dan Siskind

Health Consumers Queensland

• Ms Melissa Fox, Chief Executive Officer

Royal Australian College of General Practitioners

- Dr Bruce Willett, Chair RACGP Queensland
- Mr James Flynn, State Manager RACGP Queensland

Ramsay Pharmacy

Mr Peter Giannopoulos, Chief Executive Officer

Toowoomba Hearing, Friday 7 September 2018

Just Pharmacy Toowoomba

- Mr Adnan Gauhar, Consultant Pharmacist
- Dr Andrew Whittaker

Grattan Institute

• Dr Stephen Duckett, Director, Health Program

Owen Pharmacy Group

• Mr Chris Owen, Managing Director

TerryWhite Chemmart Goondiwindi

• Ms Lucy Walker, Pharmacist Proprietor

Townsville Hearing, Monday 10 September 2018

LiveLife Pharmacy Group, Airlie Beach

• Mr Allan Milostic, Pharmacist Proprietor

Rural Doctors Association of Queensland

• Dr Konrad Kangru, Immediate Past President

Cate's Chemist

- Ms Catherin Whalan, Director
- Mr Paul Willis, General Manager

Mr Matthew Brosnan, Pharmacist

Cairns Hearing, Tuesday 11 September 2018

Pharmacy Board of Australia

• Mr William Kelly, Chair

Pharmacy Guild of Australia

- Mr Trent Twomey, Queensland Branch President
- Professor Khory McCormick, Bartley Cohen Litigation Lawyers
- Mr Peter Saccasan, National Director of Pharmacy Services, RSM Australia

Alive Pharmacy Warehouse, Innisfail

• Ms Georgina Twomey, Pharmacist Proprietor

Appendix D - Private meeting

Melbourne, Thursday 13 September 2018

Victorian Pharmacy Authority

- Mr Aaron Bawden, Registrar
- Mr David Thirlwall, Senior Pharmacist

Appendix E - Audit report recommendations

Department of Health

We recommend that the Department of Health (the department):

- clarifies its role and obligations in the administration of the *Pharmacy Business Ownership Act* 2001 (the Act) and the skills and resources it needs to fulfil its functions effectively
- 2 re-designs its internal controls so it can effectively administer the Act

This should include:

- revising the *Pharmacy Ownership Business Rules* document and the notification checklist to include all relevant information relating to the notification process
- determining whether decision support tools such as the Monitoring of Drugs of Dependence System (MODDS) database can be modified to better support its notification process or if new tools are required
- defining checks to detect whether pharmacists have undeclared ownership interests in a pharmacy through a corporation.
- 3 better defines the type of documents pharmacy owners need to provide to support the notification process

This should include:

- requiring owners to provide documents that allow the department to thoroughly test all
 ownership requirements of the Act, including circumstances under which ownership of
 pharmacies can be made not legally binding due to control issues(139I)
- requesting all relevant documentation at the time of the notification submission, including information to validate an individual's identity such as date of birth
- keeping sufficient records to enable process validation.
- 4 implements a process to monitor pharmacies' ongoing compliance with the Act
 - This should include establishing a monitoring and compliance program to review pharmacy ownership at regular intervals, for example, conducting random inspections of pharmacies at the department's discretion.
- develops and implements a risk-based strategy for testing that existing commercial arrangements comply with sections 139B, 139H and 139I of the Act.

Note: These recommendations assume the Health, Communities, Disability Services and Domestic and Family Violence Prevention Committee's inquiry does not result in any changes to the legislation or governance arrangements. If changes are made, the accountable parties will need to revisit these recommendations.

The Health, Communities, Disability Services and Domestic and Family Violence Prevention Committee

We recommend that the Health, Communities, Disability Services and Domestic and Family Violence Prevention Committee (the committee):

- recommends to the Minister for Health to seek amendments to the Act to enable the department to more effectively manage the pharmacy ownership notification process.
 - This should include defining the legal implication if a commercial arrangement does not meet section 139I of the Act (Certain arrangements about control of pharmacy business void).

Appendix F – Pharmacy location rules

The Australian Government limits the number and location of pharmacies using the pharmacy location rules (the rules). The rules set location-based criteria that are designed to encourage pharmacies to locate in areas of 'community need' (as long as they are a minimum distance from existing pharmacies). The rules affect where an individual pharmacy can be established/relocated and therefore the overall geographic spread of the industry.

History of the pharmacy location rules

The pharmacy location rules were originally designed as a regulatory mechanism to:

- ensure that the distribution of community pharmacies broadly reflects the requirement for the Australian population
- limit the cost of maintaining the pharmacy network (as a means of distributing PBS subsidised medicines)
- reinforce service quality requirements, and
- encourage investment in community pharmacy infrastructure facilities. 266

In 1988, an inquiry conducted by the Commonwealth Pharmaceutical Benefits Remuneration Tribunal found that there were marked inconsistency in the location of pharmacies and the national network of pharmacies supplying PBS medicines.

The inquiry found that many pharmacies in urban areas were clustered together with rural and remote areas having significantly poorer access. Some rural and remote communities experienced distance barriers to access community pharmacies, which made it difficult or expensive to access PBS medicines. This contributed to poorer health outcomes for rural and remote Australians than for those in urban areas. In addition, the overall pharmacy to population ratio in Australia was considered high compared to other developed countries. In 1988 there were 5,609 pharmacies with a population to pharmacy ratio of 2,974:1.²⁶⁷

At that time, remuneration arrangements for community pharmacy included an 'economy of scale factor' which meant that if prescription volumes decreased, the remuneration per prescription for an individual pharmacy business increased. This arrangement was designed to support small pharmacies but had the unintended consequence of serving as a disincentive to pursuing efficiencies through economies of scale.²⁶⁸

In July 1990, the Australian Government and the Pharmacy Guild of Australia agreed to set out a new remuneration framework for community pharmacy which was reflected in the First Community

/\$File/Discussion%20Paper%20-

Stephen King, Bill Scott and Jo Watson, Review of Pharmacy Remuneration and Regulation, Interim Report, June 2017.

http://www.health.gov.au/internet/main/publishing.nsf/content/7E5846EB2D7BA299CA257F5C007C0E21 /\$File/interim-report-final.pdf.

Stephen King, Bill Scott and Jo Watson, Review of Pharmacy Remuneration and Regulation, Discussion paper, July 2016, http://www.health.gov.au/internet/main/publishing.nsf/content/7E5846EB2D7BA299CA257F5C007C0E21

^{%20}Review%20of%20Pharmacy%20Remuneration%20and%20Regulation.pdf.

Department of Health (Australian Government), Senate Inquiry On The Effects Of Red Tape On Pharmacy Rules, Submission by the Department of Health, October 2017, https://www.aph.gov.au/Parliamentary Business/Committees/Senate/Red Tape/Pharmacyrules/Submissions.

Pharmacy Agreement (CPA). This was coupled with the introduction of the pharmacy location rules in 1991.

These changes resulted in industry restructuring that lowered pharmacy numbers and encouraged greater efficiency, profitability and economies of scale in individual pharmacy businesses. Between 1990 and 1995 there were 630 pharmacy closures and 64 amalgamations resulting in less than 5,000 pharmacies across Australia.²⁶⁹

Despite the significant increase in Australia's population since that time, the growth in the number of approved pharmacies²⁷⁰ has not kept pace with population growth. The number of pharmacies in 2016 was 5,588, giving a population to pharmacy ratio of 4,188:1 (figure 2). This is significantly higher than the 1988 ratio (2,974:1).²⁷¹

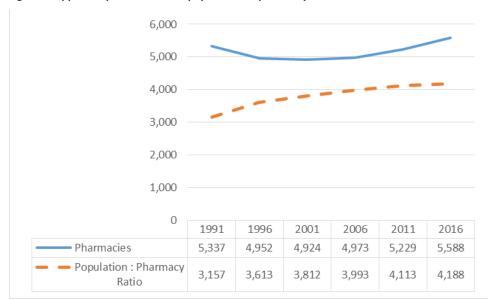


Figure 2: Approved pharmacies and population to pharmacy ratio from 1991 to 2016

Department of Health (Australian Government), Senate Inquiry On The Effects Of Red Tape On Pharmacy Rules, Submission by the Department of Health, October 2017.

Current environment

The rules have been a key component of successive five-year CPAs between the Australian Government and the Pharmacy Guild of Australia. There have been six CPAs to date.

The rules set out the location-based criteria which must be met in order for the Australian Community Pharmacy Authority (ACPA) to recommend approval of a pharmacist to supply PBS medicines. However, at the same time they limit the potential for new pharmacies to open and existing pharmacies to relocate:

- new pharmacies can only be established where both the 'community need' criteria and distance requirements of the rules are satisfied, and
- existing pharmacies can only relocate within the local area for which they are approved (up to one kilometre from the existing premises) provided they have been at those premises for at least two years.²⁷²

²⁶⁹ As above.

²⁷⁰ Pharmacies authorised to supply PBS medicine under section 90 of the National Health Act 1953.

²⁷¹ As above.

The two year restriction does not apply if the pharmacy is relocating within the same town, or within a small shopping centre, large shopping centre, large medical centre or large private hospital.

The rules are legislated in the National Health (Australian Community Pharmacy Authority Rules) Determination 2011 (PB 65 of 2011) made under subsection 99L(1) of the *National Health Act 1953*. Applicants wishing to lodge an application under the rules are asked to consult the 50 page 'Applicant's Handbook'.

The 11 rules are divided into two general types:

- those that apply to the relocation of an existing pharmacy (four rules, rule 121 to rule 124), and
- those that apply to the establishment of a new pharmacy (seven rules, rule 130 to rule136).

The rules are highly technical in nature. For example, under rule 130, used for the establishment of a new pharmacy:

- the proposed premises must be at least 1.5 km, by straight line, from the nearest approved pharmacy, and
- the ACPA must be satisfied that there is:
 - o within 500m, in a straight line from the proposed premises: at least one full time prescribing medical practitioner and a supermarket with a gross leasable area of at least 1,000m², or
 - o within 500m, in a straight line, from the proposed premises a supermarket with a gross leasable area of at least 2,500m².

It is important to note that the current rules require that a community pharmacy is 'not directly accessible by the public from within a supermarket'.²⁷³ This restriction prevents the operation of pharmacies by supermarkets.

Harper Review of competition policy

In 2015, the Competition Policy Review ('Harper Review') concluded that governments do not need anti-competitive regulation to ensure pharmacies meet community expectations of safety access and standard of care:

The Panel considers that current restrictions on ownership and location of pharmacies are not needed to ensure the quality of advice and care provided to patients. Such restrictions limit the ability of consumers to choose where to obtain pharmacy products and services, and the ability of providers to meet consumers' preferences.

The Panel considers that the pharmacy ownership and location rules should be removed in the long-term interests of consumers. They should be replaced with regulations to ensure access to medicines and quality of advice regarding their use that do not unduly restrict competition.²⁷⁴

The Harper Review recognised that competition between pharmacies in rural and remote regions would not be sufficient on its own to meet access objectives. However, it suggested there were a range of less anti-competitive alternatives (to the pharmacy location rules), including:

- imposing obligations directly on pharmacies as a condition of their licensing and/or remuneration
- tendering for the provision of pharmacy services in certain underserved rural or remote areas,
 or

National Health (Australian Community Pharmacy Authority Rules) Determination 2011 (PB 65 of 2011) made under subsection 99L(1) of the National Health Act 1953., item 212(b), https://www.legislation.gov.au/Details/F2015C00957

lan Harper et al, Competition Policy Review, Final report, March 2015, p 49, http://competitionpolicyreview.gov.au/final-report/

 funding through a community service obligation, as currently applies to pharmacy wholesaling.²⁷⁵

The Australian Government's response to the Harper Review noted this recommendation and stated:

... the Government recognises the need for competition in the pharmacy sector, including that the location rules should be examined closely. The Government recognises the original intention of the location rules was to create a suitable geographic spread of pharmacies to ensure dependable and timely access to Pharmaceutical Benefit Scheme medicines, including in rural and remote regions.

While the location rules have been extended for another five years under the Sixth Community Pharmacy Agreement, the Government and the Pharmacy Guild have agreed that an independent public review of pharmacy remuneration and regulation will also be conducted. The review will examine whether the location rules should remain in their current form or be updated in the future, with a final report by March 2017.²⁷⁶

King Review of pharmacy remuneration and regulation

In September 2017, the Australian Government Review of Pharmacy Remuneration and Regulation ('King Review') final report noted:

There are clearly aspects of the existing Rules that require reform to address unintended consequences to consumer access and affordability ... Even staunch advocates of the Rules acknowledge that their operation in some instances, such as relocating existing pharmacies, are not optimal and require amendment.

In reforming the Rules, the Panel considers that it is the viability of the overall network of pharmacies, rather than individual pharmacists that is critical and provides the most value to the government and consumers. In addition, emphasis should be placed on ensuring that any regulatory mechanism is responsive to innovation and positive change in the sector and does not place an unnecessary burden on the public or pharmacy.²⁷⁷

The final report included the following recommendation to reform the rules:

The Australian Government should:

- reform the rules to remove barriers to community access and competition between pharmacies, and to ensure they continue to support equitable and affordable access to medicines for all Australians, in accord with the National Medicines Policy,
- establish a working group with the Pharmacy Guild of Australia or other representative of Approved Pharmacists with the aim of reforming the rules to ensure that they remain responsive to the evolving needs of the community while also supporting innovation through competition between pharmacies, and
- ensure that any reform of the rules is subject to a suitable transition period. 278

Australian Government, *Australian Government Response to the Competition Policy Review*, 24 November 2015, p 14, https://static.treasury.gov.au/uploads/sites/1/2017/06/Govt_response_CPR.pdf.

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²⁷⁵ As above.

²⁷⁷ Stephen King, Bill Scott and Jo Watson, *Review of Pharmacy Remuneration and Regulation, Final Report*, September 2017, p 76, http://www.health.gov.au/internet/main/publishing.nsf/content/7E5846EB2D7BA299CA257F5C007C0E21/

²⁷⁸ As above, p 76.

In response, the Australian Government noted this recommendation.²⁷⁹ Moreover, PBS legislation passed by the Australian Parliament on 13 February 2018 repealed the sunset clause that would have seen the location rules expire on 30 June 2020 (the end of the sixth CPA).

In relation to the co-location of community pharmacies within supermarkets, the Review Panel assessed that the current restrictions on accessing a pharmacy from within a supermarket is not appropriate. The final report did not include an explicit recommendation, however it concluded:

The current restrictions on the accessibility by the public to a community pharmacy from within a supermarket should be discontinued, provided that any pharmacy located within a supermarket is required to operate in accord with all relevant practice requirements for an Approved Pharmacy.²⁸⁰

Since 2000 there have been seven reviews that have considered the location rules. According to the Grattan Institute, pharmacy regulation is an area of 'policy purgatory' in which the Australian Government chooses not to implement change:

Independent reviews of pharmacy regulation have been ignored by successive governments. This policy purgatory now houses a plethora of independent reviews, Grattan Institute research and national audits. Report after report disappears, with the only explanation being that the pharmacy industry has far too great an influence on its own regulation.²⁸¹

\$File/review-of-pharmacy-remuneration-and-regulation-final-report.pdf.

²⁷⁹ Australian Government, Australian Government Response To The Review Of Pharmacy Remuneration And Regulation, May 2018, http://www.health.gov.au/internet/main/publishing.nsf/content/7E5846EB2D7BA299CA257F5C007C0E21/

^{\$}File/Pharmacy-Review-Aus-Gov-Response-3-May-2018.pdf. ²⁸⁰ Stephen King, Bill Scott and Jo Watson, Review of Pharmacy Remuneration and Regulation, Final Report, September 2017, p 78, http://www.health.gov.au/internet/main/publishing.nsf/content/7E5846EB2D7BA299CA257F5C007C0E21/

²⁸¹ Grattan Institute, The effect of red tape on pharmacy rules, Grattan Institute submission to the Senate Select Committee o Red Tape, October 2017, p 7, https://www.aph.gov.au/Parliamentary Business/Committees/Senate/Red Tape/Pharmacyrules/Submiss ions.