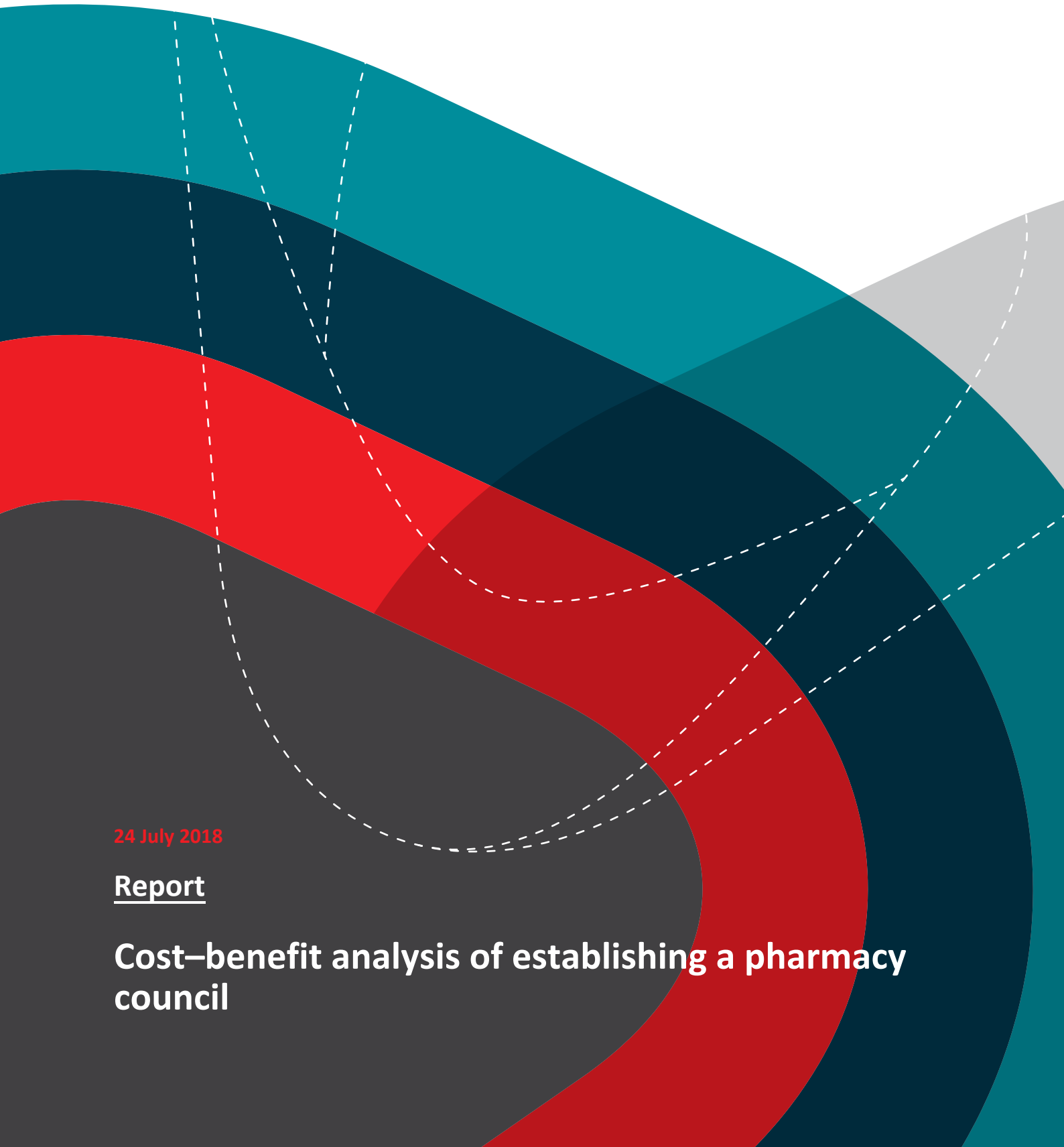
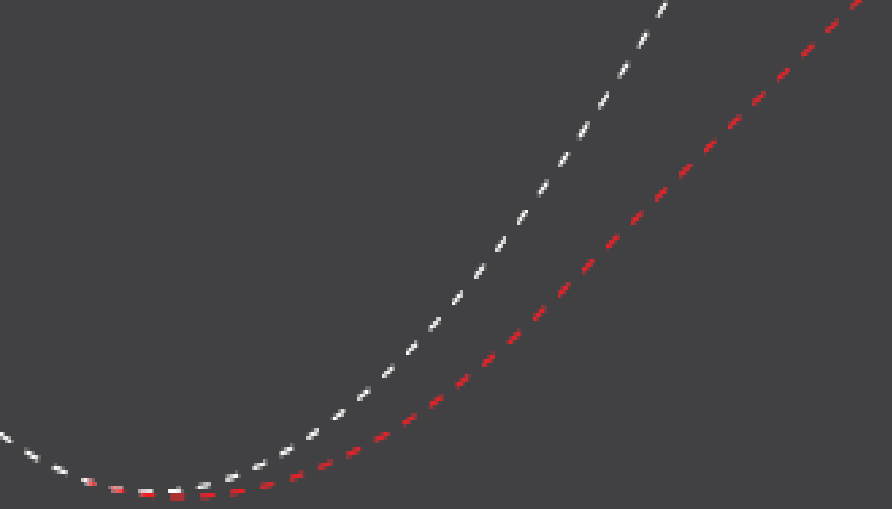


24 July 2018

Report

Cost–benefit analysis of establishing a pharmacy council



Contents

Key points

- In May 2018, the Commission was asked to undertake a cost–benefit analysis of establishing a pharmacy council in Queensland to inform the Parliamentary Inquiry into pharmacy regulation.
- The central issue under review is whether establishing a pharmacy council to more intensively enforce the ownership restrictions—that only pharmacists can own a pharmacy—would provide a net benefit to the Queensland community.
- Government objectives for consumers may be achieved in several ways—such as reforming the regulatory framework, or through non-regulatory and deregulatory options—the Commission has analysed the specific option of establishing of a pharmacy council (and directly related alternatives).
- Three options were assessed:
  - Option 1: Continued regulation by Queensland Health.
  - Option 2: Establish a pharmacy council with a regulatory role.
  - Option 3: Establish a pharmacy council with a regulatory, advisory and educational role.
- The costs of establishing a pharmacy council primarily comprise the direct institutional costs. There may also be other costs in terms of consumer choice and prices.
- The Commission considered a range of possible benefits, from service quality and availability through to improved policy advice and education and training.
- The Commission assessed the impact of increasing the resources used to enforce the ownership restrictions against the available evidence on the impact of ownership restrictions—taking account of the wide range of other regulations and arrangements directed at protecting consumer wellbeing.
- Based on the available data, the Commission found no evidence that:
  - other Australian states with pharmacy councils have better outcomes for producers and consumers than Queensland
  - the existing premises regulation is resulting in unsafe conditions in pharmacies
  - more intensive enforcement of the ownership restrictions would provide greater consumer benefits.
- The cost–benefit analysis compares the difference between the total costs and benefits of Options 2 and 3 with the status quo (Option 1). The analysis found there would be a net cost to the community from establishing a pharmacy council. The net cost of Option 2 is $7.7 million. The net cost of Option 3 is $11.1 million.

1.0 Introduction

1.1 Background

This report provides an economic evaluation of the establishment of a pharmacy council in Queensland.

On 3 May 2018, the Legislative Assembly referred an inquiry to the Health, Communities, Disability Services and Domestic and Family Violence Prevention Committee (the Committee). The Committee is to inquire into the establishment of a pharmacy council and all transfers of pharmacy ownership in Queensland over the past two years to ensure compliance with the existing legislation.

The Committee has been asked to report on:

- the effectiveness of the current systems and processes in Queensland to regulate pharmacy business ownership in Queensland and protect Queensland customers
- 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 business and practice
- models of regulation of pharmacy business ownership in other jurisdictions
- a cost–benefit analysis of establishing a pharmacy council
- 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*, the *Health Act 1937*, and subordinate legislation, namely the *Health (Drugs and Poisons) Regulation 1996* and the *Health Regulation 1996*
- all transfers of pharmacy ownership in Queensland over the past two years.

The Inquiry was initiated in response to industry concerns that the ownership restrictions embodied in the *Pharmacy Business Ownership Act 2001* (Act)—that only a pharmacist can own a pharmacy—are not preventing market entry of certain pharmacy groups.

Specifically, the Pharmacy Guild of Australia, which is the national peak body representing community pharmacy owners, stated that, in order to enhance public safety, transparency and accountability for the services delivered through the network of pharmacies in Queensland, the Inquiry is needed to consider:

- the establishment of a pharmacy council
- appropriate oversight of pharmacy business ownership regulation considering models of control in other jurisdictions
- all transfers of pharmacy ownership in Queensland over the past two years to determine compliance with the legislation in the contemporary pharmacy ownership environment (The Pharmacy Guild of Australia 2018).

Following a request from the Committee, on 26 May 2018, the Deputy Premier, Treasurer and Minister for Aboriginal and Torres Strait Islander Partnerships directed the Commission to undertake a cost–benefit analysis into the establishment of a pharmacy council (or other viable alternatives) in Queensland. The terms of reference (Appendix A) states that the Commission should consider and report upon 'potential direct and indirect costs and benefits, including impacts on Queensland consumers, business and the wider community'.

1.2 Our approach

Cost–benefit analysis is a method of evaluation that uses economic concepts to estimate and compare the total benefits and costs of a particular policy proposal against other options for addressing a policy issue. It calculates the dollar value of the benefits and costs incurred by a community affected by the policy problem. If the sum of all benefits less costs is positive, then the community is said to be better off by introducing the proposed change.

The goal is to identify the option that provides the largest net benefit to the community. In some cases, doing nothing (the business as usual option) may be the best option available. Cost–benefit analysis can also inform policy makers on how the benefits and costs are shared in the community, which can assist in decision-making.

By monetising impacts, cost–benefit analysis provides an objective framework to compare different impacts, including those that occur in different time periods. Whenever possible, impacts are measured in present day dollar values. Box 1.1 lists the key steps in conducting a cost–benefit analysis.

Box 1.1 Steps in cost–benefit analysis

Step 1	Specify the set of options.
Step 2	Decide which costs and benefits 'count' (e.g. state, national or international impacts).
Step 3	Identify the impacts and select measurement indicators.
Step 4	Predict the impacts over the life of the proposed regulation.
Step 5	Monetise (place dollar values on) the impacts.
Step 6	Discount future costs and benefits to obtain present values.
Step 7	Compute the net present value of each option.
Step 8	Perform sensitivity and distributional analysis.
Step 9	Formulate a conclusion.

A key issue in this cost–benefit analysis is isolating the impact of a pharmacy council from the many other forces affecting outcomes. The most notable are the broad regulatory framework at the Commonwealth and state levels as well as market factors driving outcomes beyond regulation.

In addition, the Commission has been asked to advise on one element of the Parliamentary Inquiry, and as such, it has confined its assessment to the regulatory proposal identified in the direction. That is, while there may be many options to achieve government objectives for Queensland consumers, such as reforming the regulatory framework, as well as non-regulatory or deregulatory options, the Commission has considered only those options relating to the establishment of a pharmacy council. The Commission has undertaken targeted consultation with parties to inform this cost–benefit analysis, including the Pharmacy Guild, Queensland Health and the Pharmaceutical Society of Australia.

The Parliamentary Inquiry's terms of reference cover a wider range of issues and options that do not form part of this analysis. The Parliamentary Inquiry will also undertake a full public consultation process, which had not been completed when this advice was provided.

1.3 Structure of this report

This report is set out as follows:

Chapter 2	Regulatory framework and market
Chapter 3	Issue and options
Chapter 4	Identifying the benefits and costs
Chapter 5	Quantifying the benefits and costs
Chapter 6	Results
Chapter 7	Summary of findings.

2.0 Regulatory framework and market

A key challenge in determining the costs and benefits of establishing a pharmacy council is separating the impact of any proposed council from the broader regulatory and market factors that affect outcomes. This chapter provides an overview of the key regulatory and market conditions.

2.1 Regulatory framework

The pharmacy industry is regulated by both Commonwealth and state laws. The regulation of the industry pursues multiple objectives, such as to:

- uphold patient and community safety
- ensure pharmacists provide consumers with appropriate information and advice about their medication
- provide equitable access to medication
- ensure accountability for appropriate standards and behaviour by pharmacists
- manage costs to patients and government (Australian Government 2015a, p. 178).

The Australian Government regulates location of pharmacies that have been approved to dispense subsidised medicines under the Pharmaceutical Benefits Scheme (PBS) (Productivity Commission 2015, p. 50), with the aim of maintaining broad access to pharmacies across Australia.

The Australian Government enters into Community Pharmacy Agreements (CPAs), with the Pharmacy Guild of Australia (the Guild), for dispensing medicines covered by the PBS to the public. The CPAs include:

- pharmacy remuneration, or the fees pharmacies are paid to dispense PBS medicines
- funding of various programs to improve the use of PBS medicines in the community
- a community service obligation—to be drawn on by pharmaceutical wholesalers that can meet the PBS service standards for supplying pharmacies (Australian Government 2015a, pp. 180–182).

The Therapeutic Goods Administration (TGA) regulates the supply, import, export, manufacturing and advertising of therapeutic goods. This includes prescription medicines, over the counter (OTC) and complementary medicines. Prescription medicines (schedule 4) may only be dispensed by a pharmacist with a prescription, OTC medicines may only be sold by a pharmacy (schedule 2) or pharmacist (schedule 3) and other unrestricted general medicines, which may be sold by any retailer (TGA 2018).

Pharmacists are regulated under the National Registration and Accreditation Scheme, which governs pharmacists' standards of practice.[1] Under the standards, pharmacists must meet a minimum level of education, undertake continual professional training, maintain recency of practice, and comply with professional standards of conduct and discipline, among other requirements.

[1] Before 2010, both the occupational licensing of pharmacists and ownership regulations were administered by the Pharmacists Board of Queensland. Following the establishment of the national scheme, the Pharmacists Board of Queensland was abolished and its residual function (oversight of the ownership regulation) was transferred to Queensland Health.

Queensland's pharmacy ownership regulation

In Queensland, the *Pharmacy Business Ownership Act 2001*:

- limits ownership[2] of community pharmacies to pharmacists
- limits the number of pharmacies that may be owned by a person
- provides for compliance with the Act to be monitored and enforced.

The main policy objectives for ownership restrictions are that:

- limiting the controlling interest in the ownership of pharmacy business to pharmacists promotes the safe and competent provision of pharmacy services and helps maintain public confidence in those services
- 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 (Queensland Health 2012, p. 2).

Table 2.1 summaries the pharmacy ownership rules outlined in the Act.

Table 2.1 Ownership rules under the Act

Who may own a pharmacy in Queensland	How many pharmacies may be owned in Queensland
Pharmacist	Must not have beneficial interest in more than five pharmacies.[3]
A corporation whose directors and shareholders are all pharmacists.	Must not own more than five pharmacies at the same time.
A corporation— • whose directors and shareholders are a combination of pharmacists and relatives of the pharmacists, and • in which the majority of shares are held by pharmacists, and • in which only pharmacists hold voting shares.	Must not own more than five pharmacies at the same time.
A friendly society that operates a pharmacy business in the State, or another state.	Must not own more than six pharmacies at the same time.
A friendly society that is an amalgamation of two or more friendly societies.	Must not own more than six pharmacies at the same time.
Mater Misericordiae Health Services Brisbane Ltd.[4]	Must not own more than six pharmacies at the same time.

Note: For the purposes of the Act, a pharmacy business is defined as 'a business providing pharmacy services' but does not include a business operated by the State at a public sector hospital, or another business at a hospital that provides pharmacy services only to patients at the hospital.

[2] To 'own' a pharmacy business means having a proprietary interest in the pharmacy business. The definition of 'own' in the Act does not include having an interest in the pharmacy business arising under a bill of sale, mortgage or other form of security.
[3] Beneficial interest for a pharmacist means the pharmacist owns the pharmacy business; or is a director of (or shareholder in) a corporation that owns the pharmacy business.
[4] Mater Misericordiae Health Services Brisbane is a privately owned hospital network located in Brisbane, which provides both public and private health services.

Queensland Health regulates pharmacy business ownership, including investigation of compliance with obligations and enforcement of the Act. At present, Queensland Health does not charge fees.

Pharmacy premises regulation

Certain aspects of pharmacy premises are regulated under the *Health Regulation 1996.* Regulation includes:

- **the physical standards of a dispensary**—for instance, it is enclosed, ventilated, painted, lit; it has lined walls and ceilings
- **the cleanliness of the dispensary**—including the equipment and containers
- **items that must be in a dispensary**—for instance, a refrigerator fitted with a device capable of registering the minimum and maximum temperature
- **sterile dispensing**—of drugs or poisons for therapeutic use
- **specific requirements**—to be met for the dispensing of specific drugs.

Queensland Health administers the *Health Regulation 1996*. Queensland Health also administers provisions in the *Health (Drugs and Poisons) Regulation 1996*, which:

- authorise pharmacists to administer, dispense, sell and supply scheduled medicines
- enable pharmacists to obtain approval to operate a facility for administration of controlled drugs
- impose obligations on pharmacists relating to dispensing medicines (for instance: quality standards, conditions of dispensing), record-keeping and storage of scheduled medicines (Queensland Health 2012, Appendix 1, p. 4).

At present, pharmacy premises are not required to be licensed in Queensland. The policy objectives for registration or approval regimes (for other Australian jurisdictions) include:

- providing a means to ensure compliance with pharmacy ownership restrictions
- ensuring the premises are suitable for the safe and competent provision of pharmacy services (Queensland Health 2012, p. 7).

The *Health Act 1937* (sections 132 (w), (za), (zb)) contains a head of power that allows regulations to be made about:

> *…the siting, construction, layout, condition and registration of licensee's premises*
>
> *...the registration by the chief executive of premises in which medicines, mixtures, compounds and drugs are dispensed …*
>
> *…the siting, construction, layout and condition of such premises.*

To date, no such regulations have been made.

Jurisdictional comparison

All state governments and territories restrict ownership of pharmacies to pharmacists (with some jurisdictions making exceptions for non-profit friendly societies).

Ownership restrictions extend to the number of pharmacies a pharmacist can own or have a financial interest in (the maximum ranges from four to six in each state, but there is no maximum in the territories. These regulations do not prevent pharmacies (owned by different pharmacists) from operating under a common name and brand (Productivity Commission 2015, p. 51).

In terms of pharmacy registration, all Australian jurisdictions (apart from Queensland, the Australian Capital Territory, and the Northern Territory) require mandatory registration of pharmacies.

Each Australian state (other than Queensland) has a body separate from a government department that is responsible for administering ownership restrictions or mandatory registration (or both functions). Both territories regulate out of the respective departments of health.

A table comparing the jurisdictions is in **Appendix B**.

2.2 Queensland's pharmacy industry

The pharmacy market has evolved in recent decades, from services delivered by small independent pharmacies to more sophisticated franchise and banner group models. Recent trends indicate pharmacies are changing their business models to focus more on retail and non-PBS revenue streams amongst increasing industry competition and ongoing PBS reforms, which have reduced prices for prescription medicines (IBIS World 2018). The dominant business models are small, high-service pharmacies that may offer allied health services, and large high-volume, low-margin pharmacies (IBIS World 2018). The franchise pharmacy model is widespread, with the four largest groups accounting for 73 per cent of the Australian market. In 2016-17 there were 1139 pharmacies in Queensland (IBIS World 2018).

Table 2.2 shows that entry rates into the Australian pharmacy industry are low relative to both businesses in all industries and retail. Exit rates are also low, suggesting incumbent businesses have a relatively high survival rate.

Table 2.2 Business entry and exit rates, June 2013 to June 2017

	Industry	Number of businesses (% change)	Entry rate	Exit rate
Queensland	All businesses	2.7%	15.0%	12.3%
	All retail	–0.5%	13.7%	14.2%
	Pharmaceutical, Cosmetic and Toiletry Goods Retailing	1.3%	11.6%	10.5%
Australia	All businesses	3.1%	15.1%	12.0%
	All retail	–0.6%	13.2%	13.8%
	Pharmaceutical, Cosmetic and Toiletry Goods Retailing	0.6%	10.4%	9.8%

Notes: Entry and exit rates are the number of new businesses established or existing businesses closing as a proportion of the number of businesses.
Source: ABS 2018c

The pharmacy market in Australia has an annual turnover of around $16 billion (on a population share basis it would be over $3 billion in Queensland) (ABS 2018a; IBIS World 2018). IBIS World reports an average annual revenue per pharmacy of $2.8 million. Australian pharmacy revenue has declined on average by 0.25 per cent per annum between 2012–13 and 2017–18. This decline is related to Australian Government measures to curb PBS expenditures. IBIS World forecasts the industry to return to a growth rate of 1.1 per cent over the next five years—derived primarily from an aging population and growth in real household disposable income.

Profit as a proportion of industry costs is 8.7 per cent in the pharmacy industry compared to 5 per cent in all industries (IBIS World 2018).[5] Despite declining revenue, profit margins have increased over the last five years, due to non-PBS medicines.

2.3 Summary

Commonwealth laws regulate the pharmacy industry for:

- quality and safety—via the TGA and AHPRA occupational licensing
- accessibility and price—via the PBS and location rules.

Queensland legislation regulates who may own a pharmacy, certain physical aspects of pharmacy premises and provides operating approval for pharmacists to administer, dispense, sell and supply scheduled medicines.

The trends in the Queensland pharmacy market are broadly consistent with trends in other retail markets with a shift towards varied consumer offerings and larger banner group models. However, pharmacy profit and survival rates appear higher than the broader retail sector.

[5] The profit estimates include wages paid to proprietors, which can be 4% to 5% of costs—excluding these wages would result in a lower profitability proportion.

3.0 Issue and options

This chapter sets out the issue that a pharmacy council would aim to address and identifies three options for assessment.

3.1 Issue to be addressed

Some pharmacy owners have expressed concerns that in the absence of the pharmacy ownership laws, or without sufficient enforcement of the existing ownership laws, there will be increasing ownership and market concentration of pharmacy activities by non-pharmacists.

Representatives of the community pharmacy industry have expressed concern that the ownership regulations in Queensland are not being enforced as effectively as in other states. The Pharmacy Guild of Australia stated that a return to supervision of pharmacy ownership laws by a regulatory agency at arms-length from Queensland Health would improve regulatory outcomes by:

- ensuring compliance and strengthening the *Pharmacy Business Ownership Act 2001*
- ensuring the physical premises of pharmacies are suitable for safe and competent provision of services
- providing regulatory independence (The Pharmacy Guild of Australia 2018).

The key issue for this analysis is how the benefits and costs of regulation change with different models of regulatory enforcement.

3.2 Options

A cost–benefit analysis would typically examine the nature and extent of the problem (such as the need to ensure quality products and services for consumers) and then consider a range of regulatory and non-regulatory scenarios to address any identified problem. However, given the scope of the direction, the Commission has not included non-regulatory or deregulatory options, nor scenarios to improve the efficiency of the broader regulatory framework. Rather, options have been selected in line with the pharmacy council proposal.

The options assessed are:

Option 1: Continued regulation by Queensland Health (base case)

Option 2: Establish a pharmacy council with a regulatory role

Option 3: Establish a pharmacy council with a regulatory, advisory and educational role

The functions under each of the options have been specified at a high level, as detailed functions would depend on specific information regarding staff levels and skills, frequency and type of compliance/enforcement activities, and office location, among other considerations.

Option 1 Continued regulation by Queensland Health (base case)

Under this option, Queensland Health would continue to administer *the Pharmacy Business Ownership Act 2001*. A change in ownership of a pharmacy must be notified to Queensland Health. The notification must provide documentary evidence that a proposed ownership complies with the requirements of the legislation. Queensland Health will investigate and enforce contraventions of the Act.

It is assumed that administration costs and enforcement activity will remain at its current level.

Option 2 Establish a pharmacy council with a regulatory role

Under this option, a pharmacy council would be established to enforce the *Pharmacy Business Ownership Act 2001*. The council would be a statutory body and carry out the following functions:

- investigating pharmacies for breaches of the *Pharmacy Business Ownership Act 2001*
- registering and regulating the premises of pharmacy businesses
- when so requested by the Minister, providing information or advice related to its functions or as reasonably required by the Minister
- keeping a public register.

The council is likely to increase the intensity of regulatory compliance activity compared to Option 1, including investigating changes of ownership and responding to complaints.

It is assumed that the additional costs would be recovered by regulatory charges levied on pharmacies.

Option 3 Establish a pharmacy council with a regulatory, advisory and educational role

This option is similar to Option 2, with the council having responsibility for the following additional functions:

- promoting education and research for pharmacists
- providing policy advice on public health issues relating to pharmacies.

The key difference between Option 2 and Option 3 is an advisory and education function of the council in Option 3, which is likely to require additional resources.

It is assumed that the additional costs would be recovered by regulatory charges levied on pharmacies.

4.0 Identified costs and benefits

The direct costs of establishing a pharmacy council will depend on its functions and enforcement strategy. Identifying the benefits is much more challenging because the outcomes of the ownership regulations are not independent of the impacts from other regulations or the market.

A cost–benefit analysis assesses options against a baseline. Costs and benefits of introducing a pharmacy council are assessed relative to the base case, Option 1. Where benefits or costs do not change relative to how pharmacies are currently regulated, there is no net impact.

4.1 Costs

Possible costs identified are:

- establishment costs
- operational costs
- economic efficiency from additional fees paid by the industry (deadweight costs)
- competition and innovation impacts.

4.2 Benefits

Possible benefits identified are:

- improved safety and quality of services
- increased health and safety of pharmacy premises
- preventing pharmacy ownership being concentrated in a small number of corporations or individuals
- greater transparency and independence of regulation
- improved pharmacist education and training
- improved quality and timeliness of policy advice resulting in better regulation in the future.

Each of the benefits and costs are discussed and their impacts are assessed in Chapter 5.

5.0 Quantifying the costs and benefits

5.1 Cost estimates

Direct costs

Option 1: Continued regulation by Queensland Health (base case)

The benchmark cost was estimated using full-time-equivalent (FTE) estimates for the Queensland public sector and Queensland Health. Queensland Health informed the Commission that it currently devotes less than one full-time staff member to administer the ownership regulation (between 0.4 and 0.8 of an FTE). Contractors are used when an investigation is necessary.

In addition, the Medicines Regulation and Quality area has 25 staff regulating several health Acts and regulations. It is expected that most or all of these staff would be required even if some aspects of the state's pharmacy regulation were devolved to a pharmacy council, because these regulations apply to a range of health services.

A benchmark cost of $88,600 plus on-costs of 30 per cent (indexed for inflation) per annum has been used in the analysis. On-costs include an allowance for the indirect costs of employment (taxes, insurance, etc.).

Option 2: Establish a pharmacy council with a regulatory role

Cost estimates are based on financial information provided in annual reports of bodies which administer the ownership regulations in other Australian jurisdictions.

No establishment costs have been included. These costs include all the upfront capital expenditure necessary to establish a council, such as IT and accommodation fit-out. The establishment costs could be low in some operating models. For example, a full leasing model with a pharmacy council owning no capital could reduce the establishment cost to close to zero. Ideally, any establishment costs would be included in year one of the analysis. The Commission has no information on which to base an estimate of establishment costs. There is information on the depreciation expense of similar bodies in other jurisdictions. The Commission has used this information to account for capital costs, albeit imperfectly, in its cost estimate.

Operating costs were estimated using the average of New South Wales (NSW), Victoria, and Western Australia per capita operational expenditure for 2016–17. This has been multiplied by the Queensland population and indexed to 2017–18 dollars using an indexing factor equal to the upper range of the Reserve Bank of Australia inflation target. Note these costs include depreciation which accounts for the annualised cost of fixed capital that partially offsets the exclusion of establishment costs.[6]

A revenue source will be required to meet the cost of establishing and operating a pharmacy council. A fee levied on the industry has been assumed as the revenue source (this is consistent with the regulatory models used in other jurisdictions). Any new fee to the industry is likely to work in a similar way as an additional tax on

[6] Depreciation is an estimate of the annual cost of capital. It will understate the cost of fixed costs associated with establishing a council as the depreciation payments do not allow for the fact that a dollar in the future is worth less than a dollar today.

the industry. These costs are eventually passed through to consumers and/or borne by pharmacy owners or their employees. Introducing new costs on business will result in higher costs than the existing regulatory model.

Option 3: Establish a pharmacy council with a regulatory, advisory and educational role

The cost of Option 3 is greater than Option 2 because of the additional functions to be discharged by the council. The Pharmacy Council of NSW has functions that are similar to the functions proposed for the council in Option 3. Costs were estimated using per capita operational expenditure in NSW in 2016–17 and multiplying that by the Queensland population. In Options 2 and 3, the cost of operating the council is assumed not to grow above the rate of inflation.

Table 5.1 Annual cost of each option

	Option 1	Option 2	Option 3
Operational costs	$117,542	$1,218,692	$1,699,400
Additional expenditure to Option 1	$0	$1,101,150	$1,581,857

Source: ABS 2018a, 2018b, 2018c; IBIS World 2018; Pharmacy Council of New South Wales 2015, 2016, 2017; Pharmacy Registration Board of Western Australia 2016; Pharmacy Regulation Authority SA 2017; Queensland Health 2018a, 2018b; Tasmanian Pharmacy Authority 2016; Victorian Pharmacy Authority 2015, 2016, 2017.

Table 5.2 shows the annual costs per Queensland pharmacy.

Table 5.2 Estimated cost of each option per pharmacy

	Option 1	Option 2	Option 3
Operational costs	$103.2	$1,069.97	$1,492.01
Additional cost to Option 1	$0	$966.77	$1,388.81

Note: Based on 1139 Queensland pharmacies in 2016-17.
Source: ABS 2018a, 2018b, 2018c; IBIS World 2018; Pharmacy Council of New South Wales 2015, 2016, 2017; Pharmacy Registration Board of Western Australia 2016; Pharmacy Regulation Authority SA 2017; Queensland Health 2018a, 2018b; Tasmanian Pharmacy Authority 2016; Victorian Pharmacy Authority 2015, 2016, 2017.

While a pharmacy council funded through industry fees may appear 'cost neutral' to the government, this is an additional cost, 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). The Commission has not determined the potential incidence of the costs between these groups. However, given that pharmacies have a limited ability to raise prices for PBS medicines—80 per cent of medicines sold in Australia (IBIS World 2018)—or general retail goods, the costs are likely to either be borne by pharmacists through lower wages or, where possible, passed on to consumers through higher prices for pharmacy-only non-PBS medicines.

These fees are additional to the costs imposed on pharmacies, pharmacists and consumers through complying with other existing regulation and enforcement activities. This cost–benefit analysis does not evaluate those existing costs or related benefits.

For both Option 2 and 3, establishment costs, economic costs of fees and impacts on competition and innovation have not been quantified.

Other costs

There is the potential that greater enforcement of the ownership restrictions may affect competition in the industry by discouraging innovation in ownership and entry.

More intensive enforcement of ownership regulations is likely to be designed to prevent market entry. If this prevents innovation, economies of scale and product service offerings, it will likely come at a cost to Queensland consumers.

Consumers' preferences are changing. Diversifying and expanding product and service offerings provide customers with greater choice, convenience, and at times, reduced prices.

Some supply chain and process innovations are only made possible through large scale investments, which are achievable through access to capital and knowledge sharing of larger organisations.

Although the industry is heavily regulated and its core offering—PBS medicines—is managed through the operation of the National Pharmacy Agreement, ownership restrictions may dampen incentives for price competition, particularly for non-PBS pharmacy-only medicines.

It is not possible to quantify the potential cost of restricting market entry, given the overlay and impact of Commonwealth PBS and location rules. However, even small changes in business models that improve efficiency and reduce prices can bring large benefits to consumers.

5.2 Benefits

This section discusses the potential benefits of Options 2 and 3, relative to the status quo (Option 1). There are three preliminary considerations overlaying this analysis.

First, any proposed pharmacy council would need to be assessed under the Queensland Government's Public Interest Map policy (PIM). Under the PIM, a proposed new body must meet the threshold test (Appendix C). To meet the threshold test, three questions must be answered with 'yes':

- Does the activity need to be done?
- Should the government undertake the proposed activity?
- Is there a compelling reason why a government department, cannot, or should not, undertake the proposed activity?

A second, and related issue, is whether benefits (or costs) arise from *institutional arrangements* or *functions* or the *regulation*. That is, the possible benefits of a pharmacy council may not be the result of a pharmacy council per se, but the function assigned to it, which could equally be assigned to Queensland Health (unless separation or independence is required to effectively fulfil the function).

Finally, at a conceptual level, the impact of a pharmacy council will depend on the current level of non-compliance with regulation. The Queensland Audit Office (2018) at the time of this analysis was undertaking an audit to assess whether Queensland Health ensures that transfers in pharmacy ownerships comply with the requirements of the *Pharmacy Business Ownership Act 2001*. That said, the relevant issue for assessing costs and benefits is the *impacts* of compliance or non-compliance, rather than whether the *process* of compliance is, or has been, sufficiently administered.

Improved safety and quality of services

The ownership regulations are intended to promote the safe and competent provision of pharmacy services.

Restricting pharmacy ownership to pharmacists is based on the supposition that only a pharmacist owner can ensure that patient safety is not suborned by commercial motives.

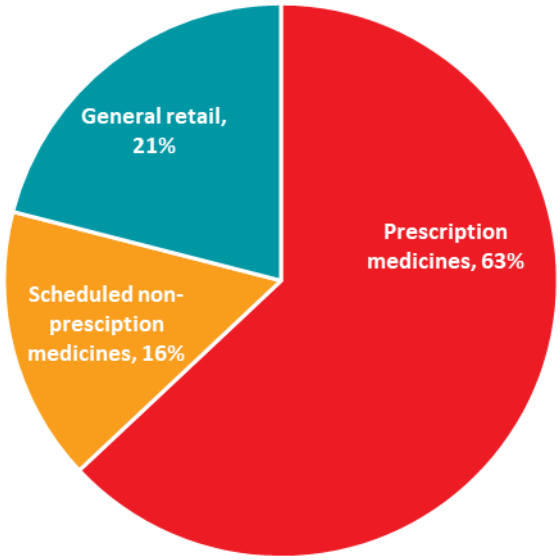
The Pharmacy Guild stated:

> *[O]wnership rules encourage efficiency in the provision of community pharmacy services while ensuring that these services are provided to an appropriate quality standard. … by placing the pharmacist and his or her professional reputation at the centre of the distribution relationship, a position that the pharmacist stands to lose if quality standards are not met, the Government effectively 'raises the stakes' for poor quality performance. (The Pharmacy Guild in Australian Government 2015a, p. 179)*

The Commission is not required to assess the case for ownership restrictions, only whether more intensive regulation would generate additional benefits to producers and consumers.

The Commission has not been able to identify evidence that those states with a pharmacy council have better outcomes for producers or consumers than in Queensland. This is primarily because safety and quality of services and products are addressed through the more direct regulation of pharmacists and medicines. For example, Figure 5.1 illustrates that most (79 per cent) of pharmacy revenue comes from TGA regulated products.

Figure 5.1 Pharmacy revenue, Australia, 2017–18



Source: IBIS World 2018.

A pharmacist is a licensed profession with requirements for minimum professional education, continuing education, and professional standards of conduct and discipline. Pharmacists' practices and standards are regulated by the Australian Health Practitioner Regulation Agency (AHPRA).

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.[7] Based on available market information (see Chapter 2), while revenue has declined in recent years, profitability is relatively high and has increased.

[7] Profit motives appear to exist for pharmacies regardless of the type of owner. A recent study of Queensland pharmacies posits that consumers face information barriers, and as a result, their purchasing decisions are strongly influenced by pharmacist sellers, and often they cannot assess whether the treatment was needed even after the fact (Smith et al. 2018). The research found significant rates of overselling of medicines relative to recommended treatment in TGA guidelines in Queensland pharmacies—with overtreatment rates between 23 and 31 per cent for three symptoms tested.

This type of ownership regulation does not apply to other medical services or any other types of business in Queensland. For example, non-practitioners may own a medical centre or a hospital. There are many examples of pharmacies owned by non-pharmacists that operate effectively. Friendly Society dispensaries have operated pharmacies in Australia since the 1840s without detrimental impacts on consumer outcomes (Australian Friendly Societies Pharmacies Association nd).

The Commission also reviewed available domestic and international reviews to identify possible benefits from more intensive enforcement of ownership regulation. The international literature (Vogler et al. 2012; Vogler 2014; Rudholm 2007) does not identify a link between ownership regulation and better consumer outcomes. Rather, occupational licensing of pharmacists provides for safety and professional conduct. Vogler et al. (2012, p. 198) concluded:

> *The quality of pharmacy services appears to be appropriate in all countries regardless of the extent of regulation. This is due to a high professional standard within the pharmacists' profession.*

Similarly, domestic reviews have found that ownership restrictions may not benefit the community, and they recommended easing or removing ownership regulation:

- The 2000 National Competition Policy Review of Pharmacy, headed by pharmacist Wilkinson, did not recommend removing the restrictions of pharmacy ownership to pharmacists. However, it did recommend lifting the limits on the number of pharmacies owned (COAG 2000, p. 5).
- The 2005 Productivity Commission Review of National Competition Policy Reforms found that 'there seems little doubt that whatever the benefits, pharmacy restrictions potentially impose large costs on consumers, taxpayers and the wider community' (Productivity Commission 2005, p. 264). It recommended that the restrictions on competition be reviewed.
- In 2015 the Productivity Commission in its Efficiency in Health paper said that 'all regulations should be reviewed over time to ensure they remain relevant, proportionate and cost effective', and that pharmacy ownership restrictions did not meet these conditions. It also said that 'separate arrangements for preventing the abuse of market power in the pharmacy sector are not necessary' (Productivity Commission 2015, p. 54–55).
- The 2014 National Commission of Audit considered that '[a]llowing a wide range of new competitors to enter the market would provide greater access and choice for consumers and, over time, place greater downward pressure on pharmaceutical prices' (National Commission of Audit 2014, p. 229).
- The 2015 Harper Review found that 'restrictions limit both consumers' ability to choose where to obtain pharmacy services and suppliers' ability to meet consumers' demands' (Australian Government 2015a, p. 48). It recommended states remove all restrictions.

Regulation of pharmacy premises

The Queensland Government does not regulate the approval of pharmacy premises. However, the *Health Act 1937* and the *Health (Drugs and Poisons) Regulation 1996* has the effect of regulating the health and safety of pharmacy premises.

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) (Pharmacy Council of New South Wales 2017; Pharmacy Registration Board of Western Australia 2017; Pharmacy Regulation Authority SA 2015, 2017; Victorian Pharmacy Authority 2017). 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.

Most pharmacy councils do not publicly report premises compliance outcomes. In Queensland, slightly more pharmacies inspected were compliant (41.8 per cent) than non-compliant (36.6 per cent). In South Australia, 84 per cent of pharmacies inspected were compliant between 2012 and 2017 (Pharmacy Regulation Authority SA 2015 & 2017).

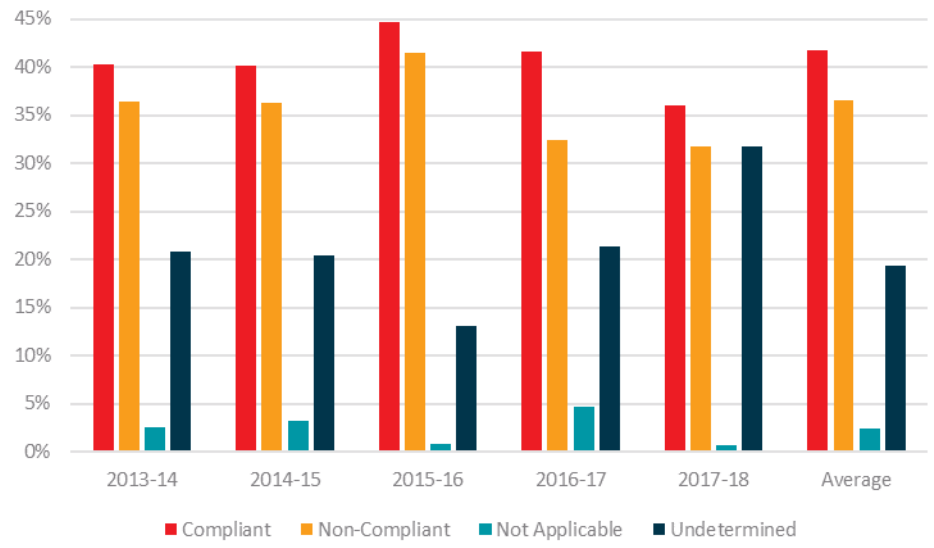
Table 5.3 Outcomes of Queensland health inspections or audits of pharmacies in relation to the Health (Drugs and Poisons) Regulation, 2013–14 to 2017–18

	Number	Proportion
Compliant	514	41.8%
Non-compliant	450	36.6%
Undetermined	238	19.3%
Non-applicable	29	2.4%

Note: Undetermined may mean that the inspection officer has sought more information or is following up with another inspection. Inspection outcomes are sometimes classified as non-applicable because not all checklist items were assessed. Inspectors do not consistently enter data, which limits further analysis of the reasons for non-compliance.
Source: Queensland Health unpublished data.

The rate of non-compliance in pharmacies was similar across years—between 31.7 and 41.5 per cent. 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.

Figure 5.2 Proportion of outcomes from pharmacy inspections, Queensland



Note: Undetermined may mean that the inspection officer has sought more information or is following up with another inspection. Inspection outcomes are sometimes classified as non-applicable because not all checklist items were assessed. Inspectors do not consistently enter data, which limits further analysis of the reasons for non-compliance.
Source: Queensland Health unpublished data.

More frequent inspection of premises would provide a benefit to consumers if there was evidence to suggest that the design and fit-out of pharmacies in Queensland is resulting in unsafe outcomes for consumers. The Commission does not have evidence that there is such a problem. Further, there is no evidence available to the

Commission that shows that enforcement of ownership and premises regulation through a pharmacy council provides better health and safety outcomes in pharmacies in other states.

While premises' regulatory outcomes are not transparent across all jurisdictions, pharmacist practices outcomes are disclosed. In relation to professional standards, there is no evidence that Queensland pharmacists breach standards more frequently than those in other states. The percentage of Queensland registrant pharmacists who received notifications (complaints or concerns lodged to the 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 (like Option 3), the percentage of pharmacists who received notifications from AHPRA was above the national average in each year.

Table 5.4 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: AHPRA 2016, 2017.

The pharmacy market is regulated and managed, and pharmacies compete for customers. The safe storage and dispensing of medicines are fundamental to remaining competitive. Both the process of competition and the existing regulation provide strong incentives to operate and maintain a safe pharmacy.

Preventing market concentration

One of the stated aims of ownership regulation is to prevent economically harmful pharmacy market concentration. Pharmacists are not permitted to own more than five pharmacies in Queensland. Presumably the cap represents a view on the limit of effective control of an owner. The ownership cap has been cited as a benefit because it may limit market concentration.

This is an indirect method of pursuing competitive markets. Competition laws exist to address the potential for economically harmful market concentration. The Australian Competition and Consumer Commission (ACCC) is responsible for regulating competition, including in medical industries. Its powers were enhanced in 2017 when the Australian Parliament amended the *Competition and Consumer Act 2010 (Cth)* (ACCC 2017).

The amendment contained broad amendments to cartels, price signalling and concerted practices, exclusionary provisions, third line forcing, resale price maintenance, merger authorisation and non-merger authorisations, access and evidentiary provisions. The misuse of market power test was also strengthened to prohibit a 'corporation with a substantial degree of market power from engaging in conduct with the 'purpose, effect or likely effect' of substantially lessening competition' (ACCC 2017).

The goal of preventing pharmacy market concentration through ownership limits can have unintended consequences. An owner could own a larger number of pharmacies without affecting competition in some markets. Restrictions on the number of pharmacies could prevent pharmacies from achieving lower costs through scale economies and the spread of innovative practices.

The Pharmacy Guild has stated that without ownership rules pharmacies would cluster in urban areas and leave rural and regional communities underserved. Governments can more directly encourage pharmacies to open in underserved rural and remote areas with direct subsidies—for example the Australian Government committed to providing $120 million of rural support programs in the Sixth CPA (Australian Government 2015b, p. 29). The location rules also aim to maintain broad community access and are more likely to impact business location decisions. It is unlikely, given the lack of targeting of location decisions, that ownership rules provide any spatial benefit for remote and regional Queenslanders.

In Europe, countries that deregulated their pharmaceutical sectors generally saw an increase in the number of pharmacies and a corresponding increase in the number of pharmacies per inhabitant (Vogler 2014). In some countries (Norway, Iceland and Sweden), opening hours increased on average (from 42 to 53 hours) per week. While new pharmacy entry was generally found to cluster in urban areas, there was no evidence of a reduction of services in rural areas (Vogler 2014).

Overall, there is no evidence that more intensive ownership regulation restrictions will provide additional consumer benefit beyond the existing competition laws and operating requirements that apply to pharmacy markets and pharmacies.

Other benefits

Regulatory independence and transparency

Establishing a pharmacy council may provide greater independence from government as well as greater transparency of regulatory outcomes than current arrangements.

There is limited disclosure of the activities of Queensland Health, the current regulator. Details of the number and outcome of investigations are not made public. The regulator operates a complaints-based enforcement strategy. There do not appear to be any material conflicts of interest between Queensland Health's regulatory role and any of its other duties.

Depending on the members selected for the 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.

There are instances where public health and safety could be improved by a publicly available list of pharmacies and the services they provide. To support public confidence in pharmacies and policy-making, regulatory outcomes could also be disclosed, as in some other jurisdictions. Providing such information transparently would be virtually costless. Such changes could be undertaken by a pharmacy council in any form, but equally by Queensland Health in its current form.

Improving pharmacist education and training

Several professional bodies already exist, which collect fees from member pharmacists and provide education material as one of the services they provide to members.

The policy decision for a national system of professional regulation was made just over a decade ago. The Pharmaceutical Society of Australia is the largest pharmaceutical education provider in Australia. It is also contracted by the Australian Government to deliver practices education (Pharmaceutical Society of Australia 2018b). Guidance resources are provided to both members and non-members.

The Commission did not find any evidence of educational gaps that would best be met by a new pharmacy body. There is no evidence available to the Commission that the oversight of the profession by AHPRA needs to be supplemented or complemented by a state-based authority.

Improving the quality and timeliness of policy advice

The benefit of having a pharmacy council with an advisory function may be its ability to provide specialist advice faster than a department. However, given the ownership rules are simply constructed, it is unlikely that policy advice would be sought frequently.

In other jurisdictions, the composition of pharmacy councils is dominated by members of the profession. A weighted membership in favour of the profession creates a perception against objectivity of policy advice on business ownership. Pharmacists do not usually have the skills required to determine whether a business ownership structure is compliant with the Act.

Discussions with stakeholders revealed there were instances where changes to health regulation or scope of practice could result in better patient outcomes and/or lower health expenditure. The Pharmacy Guild indicated that a council would help drive these beneficial changes. It indicated that Queensland lagged other states and territories in making the necessary legislative changes to allow continued dispensing (The Pharmacy Guild of Australia 2017).

Although policy advice is primarily provided by Queensland Health, other pharmacist bodies such as the Pharmacy Guild and Pharmacy Society of Australia can and do give policy advice to government. Dedicated pharmacists also work within Queensland Health. There is the possibility that bureaucratic complexities impede efficient advice to government and expedient policy changes. However, it would be more effective to address these issues at the cause rather than establishing this function for a pharmacy council.

6.0 Results

A cost–benefit analysis compares the difference between the total costs and total benefits of various options, valued in present day dollars. Although several possible benefits of intensifying the administration of ownership regulations were assessed, the Commission does not consider they will produce any material change in the regulated outcomes. There are also some costs the Commission has not quantified, because they are unlikely to be material, or their impact is too uncertain to assign a value.

In these circumstances, the quantification reduces to a comparison of the costs of each option. As mentioned the net benefits are the incremental costs to the base case. The main assumptions used in the calculation are:

- a 10-year assessment period (consistent with life-cycle of regulation)
- all values are in real terms, that is model inputs are not indexed for inflation
- a real discount rate of 7 per cent, which is widely recommended in CBA Guidelines in Australia
- the net present value of the cost streams is used to compare the options.

The results are shown in Table 6.1.

Table 6.1 Cost–benefit analysis results

Option	NPV ($)
Option 2 Establish a pharmacy council with a regulatory role	–$7,734,014
Option 3 Establish a pharmacy council with a regulatory, advisory and educational role	–$11,110,302

The results show that the net cost of Option 2 is $7.7 million over a 10-year period. The net cost of Option 3 is $11.1 million, because it requires additional resources, without offsetting benefits.

Normally, a sensitivity analysis is performed as part of a cost–benefit analysis to test whether the results are sensitive to changes in the assumptions. There is no need to perform sensitivity analysis for this cost–benefit analysis, as Options 2 and 3 do not deliver benefits relative to the base case and therefore the results will always be negative.

7.0
Summary of findings

The cost–benefit analysis has estimated there would be a net cost from forming a pharmacy council in Queensland.

The cost of a pharmacy council ranges from $7.7 million to $11.1 million over a 10-year period. The Commission has taken a conservative approach to estimating costs, and has not included the efficiency costs of the fees necessary to fund a pharmacy council.

The Commission has found that any of the possible impacts it has identified from forming a pharmacy council are unlikely to produce a material benefit. The absence of benefits from a pharmacy council stems from the fact that more direct regulations are already operating to achieve the objectives sought from the ownership regulations. In this context, administering the ownership regulations more intensively, as proposed by creating a pharmacy council, is unlikely to produce material benefits. Rather, it simply adds to the general cost of regulation.

Of more concern, is that an industry-dominated institution, such as the proposed pharmacy council, may dampen innovation and competition in the industry at a cost to Queensland consumers.

Overall, the results suggest the Queensland community will be unambiguously worse off with the transfer of the functions from Queensland Health.

Appendix A Terms of reference

TERMS OF REFERENCE

Background

The Health, Communities, Disability Services and Domestic and Family Violence Prevention Committee is undertaking an inquiry on the establishment of a pharmacy council. The Committee has been asked to report on:

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;
f) all transfers of pharmacy ownership in Queensland over the past two years.

The Committee is to report to the Legislative Assembly by 30 September 2018.

The Committee is seeking the Commission's advice on item d) of the terms of reference.

Scope

The Commission should undertake a cost–benefit analysis of establishing a pharmacy council (or other viable alternatives). The analysis should consider and report upon:

- potential direct and indirect costs and benefits, including impacts on Queensland consumers, business and the wider community.

Consultation

The Commission should consult with relevant parties and subject matter experts on a targeted basis. However, no public consultation is required.

Reporting

The Commission should provide a final report to Government by 24 July 2018. There is no requirement for a draft or other form of report.

Appendix B Jurisdictional comparison

Australian Comparison

State/Territory	Regulatory body	Regulatory functions	Enforcement powers?	Ownership restrictions?	Mandatory premises registration?
New South Wales	Pharmacy Council of New South Wales	Premises registration, ownership restrictions, complaints, enforcement, education and research.	Yes	Yes	Yes
Victoria	Victorian Pharmacy Authority	Premises registration, complaints about premises or owner, provides ministerial advice.	Yes	Yes	Yes
Queensland	Queensland Health	Ownership restrictions.	Yes	Yes	No
Western Australia	Pharmacy Registration Board of Western Australia	Premises registration, ownership restriction, and provides ministerial advice.	Yes	Yes	Yes
South Australia	Pharmacy Regulation Authority SA	Premises registration and ownership restrictions and complaints.	Yes	Yes	Yes
Tasmania	Tasmanian Pharmacy Authority	Premises registration and ownership restrictions.	Yes	Yes	Yes
Australian Capital Territory	ACT Health	Undertakes routine inspections of premises.	Yes	Yes	No[a]
Northern Territory	Pharmacy Premises Committee	Pharmacy premises standards, ownership restrictions.	Yes	Yes	No

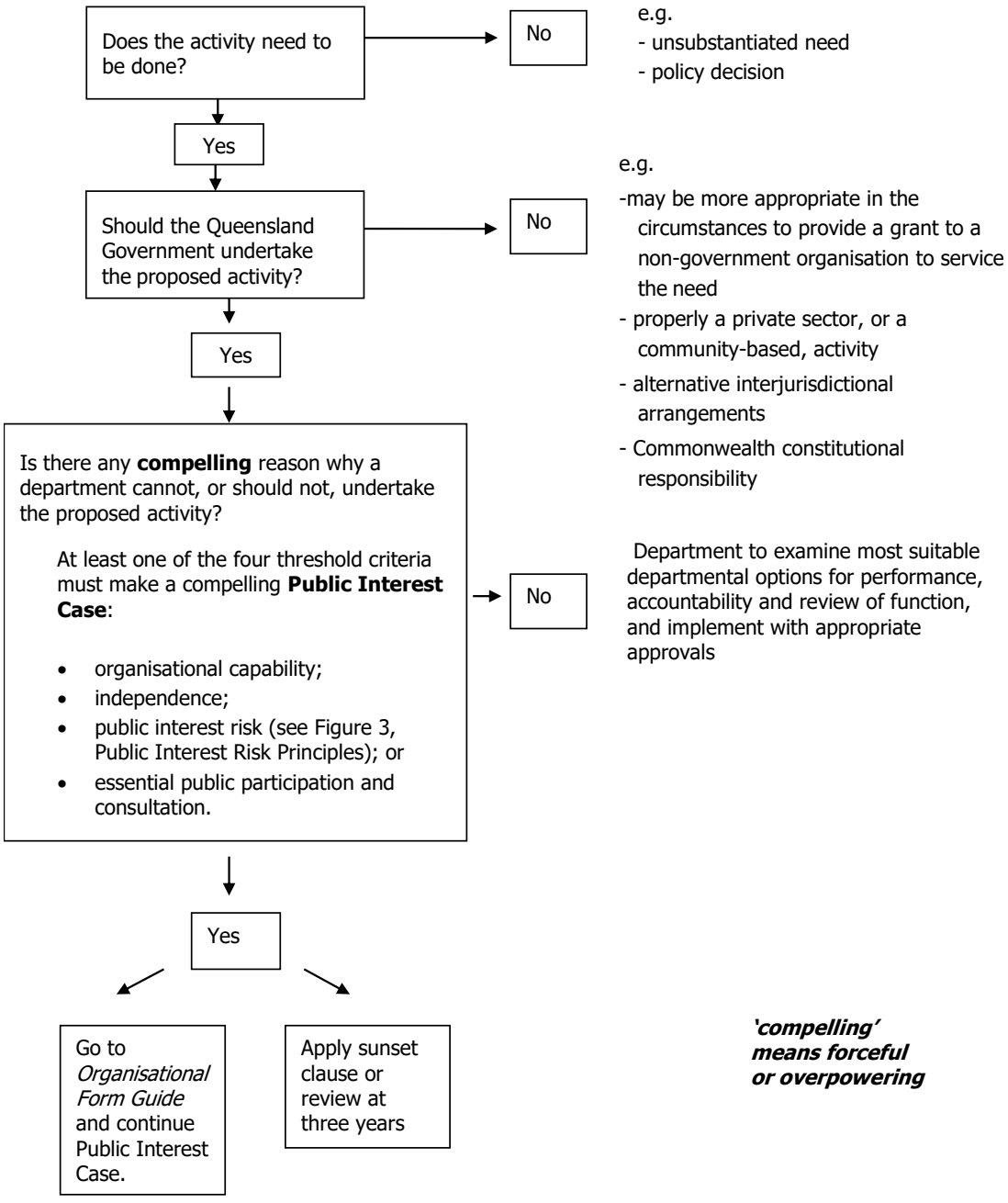
Notes: a. The ACT licences pharmacy owners but does not have mandatory premises registration.
Source: Pharmacy Council of New South Wales 2015, 2016, 2017; Pharmacy Registration Board of Western Australia 2016; Pharmacy Regulation Authority SA 2017; Queensland Health 2018a, 2018b; Tasmanian Pharmacy Authority 2016; Victorian Pharmacy Authority 2015, 2016, 2017; Pharmaceutical Society of Australia 2018a; ACT Health 2018.

Appendix C Public Interest Map policy

The Public Interest Map is the Queensland Government's public sector governance model for improving the relevance, economy, efficiency, effectiveness and accountability for non-departmental government bodies in Queensland (excluding companies and government owned corporations).

The first threshold question to be answered is: why have a non-departmental government body? Under the policy, the portfolio department is the first choice for government (when it comes to organisational form). The threshold test is detailed in Figure 1 below.

Figure 1 Public Interest Map policy's threshold test



Source: Department of the Premier and Cabinet 2016.

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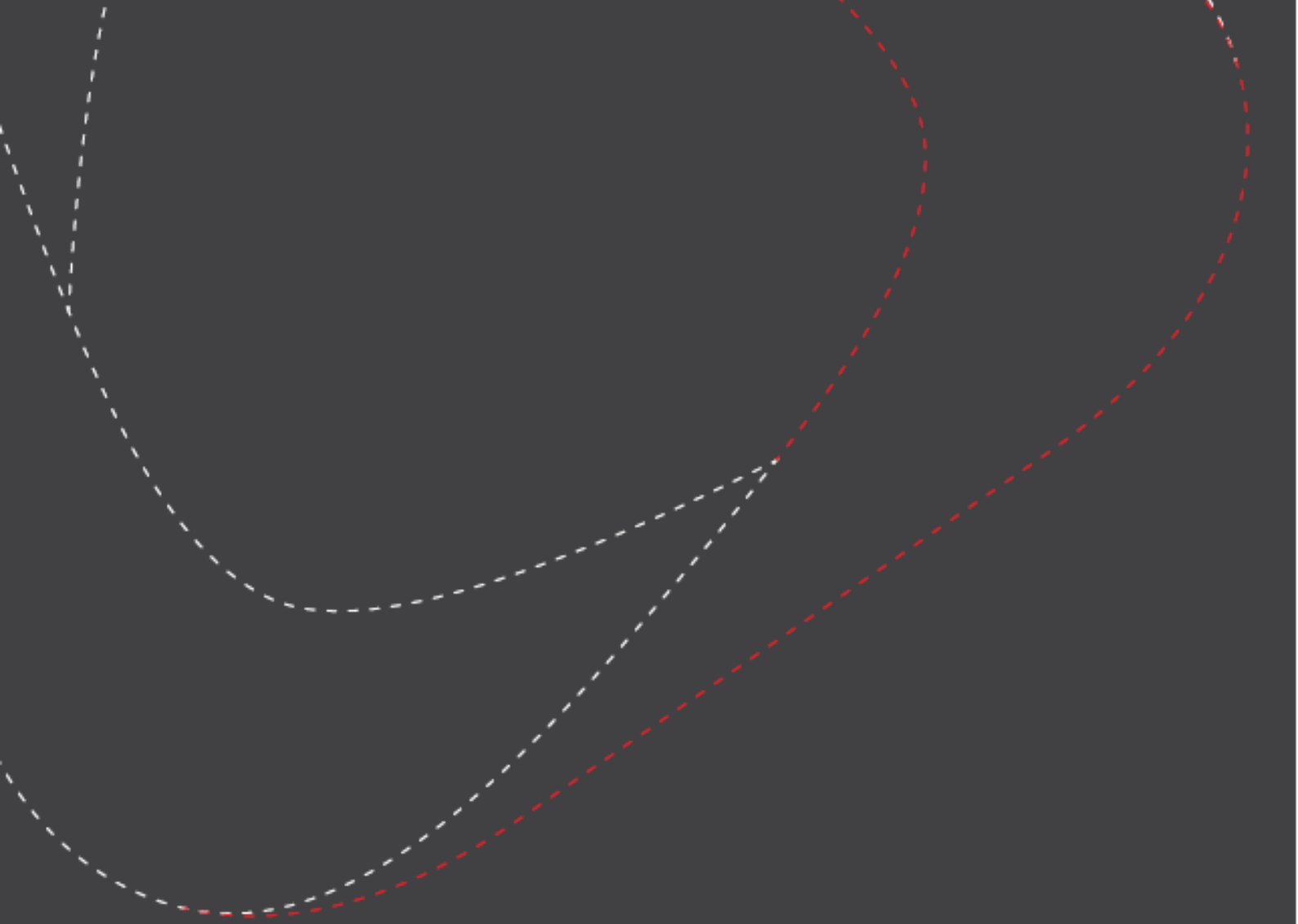


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