

Proposed Regulatory Fees and Licensing Framework for Pharmacy Ownership in Queensland

Consultation Regulatory Impact Statement



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Executive summary

The objective of the *Pharmacy Business Ownership Act 2001* (PBO Act) is to provide for the promotion of safe and competent provision of pharmacy services to maintain public confidence in the profession. The PBO Act does this by placing restrictions on the ownership of pharmacy businesses. Queensland Health is responsible for administering the PBO Act. The PBO Act sets out the regulatory framework for pharmacy ownership in Queensland.

In May 2018, the Health, Communities, Disability Services and Domestic and Family Violence Prevention Committee (Committee) was asked to inquire into the establishment of a pharmacy council and the transfer of pharmacy ownership in Queensland. The Committee made 11 recommendations relating to: the establishment of a pharmacy council; regulation of pharmacy ownership; changes to pharmacy ownership legislation; improved transparency of compliance outcomes in the pharmacy industry and that with any proposed legislative amendments that the pharmacy ownership requirements of the PBO Act be retained. In making their recommendations, the Committee considered the Queensland Audit Office: Report No. 4: 2018/19 – *Managing transfers in pharmacy ownership*¹ (QAO Audit Report), the Queensland Productivity Commission Report: *Cost-benefit analysis of establishing a pharmacy council* and the 210 public submissions to the Inquiry and testimonies from public hearings held in Brisbane, Toowoomba, Townsville and Cairns. The Government Response to the Committee Report was tabled in Parliament on 16 April 2019. All of the recommendations made by the Committee were accepted in full or in-principle, the Government Response also proposed amendment to the PBO Act to introduce a new licensing scheme.

This Consultation Regulatory Impact Statement (Consultation RIS) has been prepared by the Queensland Department of Health to assess impacts of options arising from the Government Response to the Committee *Report No. 12 – Inquiry into the establishment of a pharmacy council and transfer of pharmacy ownership in Queensland*² (Committee Report).

The Consultation RIS discusses whether to:

- establish a new licensing framework to monitor, and where necessary, enforce compliance with the ownership requirements in the PBO Act;
- prescribe licensing fees as part of the new licensing framework;
- prescribe a fee to fund the Queensland Pharmacy Council (Council) as an advisory body to provide advice to the Deputy Premier, Minister for Health and Minister for Ambulance Services (the Deputy Premier) and Queensland Health about the administration and enforcement of compliance with the PBO Act, and to make recommendations to Queensland Health about the transfers of pharmacy businesses, as required; and

¹ https://www.qao.qld.gov.au/sites/default/files/reports/podcast_script-managing_transfers_of_pharmacy_ownership.pdf

² <https://www.parliament.qld.gov.au/documents/tableOffice/TabledPapers/2018/5618T1639.pdf>

- publish a register containing information about the ownership and location of pharmacy businesses.

Identification of the problem

The current regulatory environment does not provide for the ongoing monitoring of compliance with the PBO Act. This is a consequence of deficiencies within the PBO Act and may result in pharmacy owners, that may be operating in breach of the pharmacy ownership requirements, to remain non-compliant without regulatory intervention.

Queensland Health does not have express authority under the PBO Act to require information to fully assess compliance. This means that once a pharmacy owner has notified Queensland Health of a transfer of pharmacy ownership, there is no further requirement for the owner to demonstrate whether they continue to maintain compliance with other provisions under the PBO Act.

Equally, Queensland Health lacks the authority to enforce compliance with the PBO Act as there are no operative provisions which enables Queensland Health to proactively monitor compliance. The PBO Act limits Queensland Health's ability to enforce and monitor compliance to instances where an Inspector appointed under the PBO Act 'reasonably believes'³ an offence against the PBO Act has been committed. This being the only available enforcement provision is not conducive to proactive monitoring of compliance with the PBO Act.

The Committee Report also noted that these were barriers in effectively administering, monitoring and reporting compliance outcomes. Further, the Report stated that ownership requirements for pharmacies in Queensland as specified in the PBO Act are clear and unambiguous. As long as the restrictions on who can own pharmacies in Queensland remain part of the PBO 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 by Queensland Health⁴.

Currently, community pharmacy enjoys very high levels of public trust and support. Empirical evidence suggests there is strong support that community pharmacy regulation meets the Federal Government's and the public health objectives⁵ in relation to safety and equity of access to medicines and services through community pharmacies. This is assisted by the ownership rules requiring pharmacies to be owned by pharmacists who are trained in the appropriate use of medicines and who act in the best interests of the patient⁶. Practical consequences of non-compliance with the PBO Act may mean that a person who is not a pharmacist owns a pharmacy. Not only could this lead to public trust issues and therefore loss of confidence in the pharmacy profession, but, in the most adverse of circumstances,

³ <https://www.legislation.qld.gov.au/view/html/inforce/current/act-2001-012#sec.174>

⁴ <https://www.parliament.qld.gov.au/documents/tableOffice/TabledPapers/2018/5618T1639.pdf>

⁵ <https://www1.health.gov.au/internet/publications/publishing.nsf/Content/NPHC-Strategic-Framework-priorities-and-objectives>

⁶ https://www.guild.org.au/_data/assets/pdf_file/0019/6157/pgoa-submission-to-competition-policy-review-draft-report-november-2014-fv.pdf 1

advice on medications or the administration of vaccines may be provided by non-qualified personnel. In turn, this could lead to patient and / or community safety issues.

Objectives of government action

This Consultation RIS considers options that would allow Queensland Health to efficiently and effectively assess, monitor, investigate, enforce and report on compliance with the pharmacy ownership requirements in Queensland. This includes introducing mechanisms for penalising non-compliance and giving Queensland Health the authority to compel the provision of relevant documentation. In addition, Queensland Health is seeking more complete information about community pharmacies in Queensland in the form of a register and the ability to utilise this information to:

- benefit the pharmacy industry and consumers; and
- leverage community pharmacies in the event of an emergency, such as a natural disaster or pandemic, to support government responses to such events.

Queensland Health seeks to increase transparency around pharmacy industry compliance with relevant legislation, including pharmacy ownership legislation. This could be achieved by publicly reporting compliance activities undertaken by the department and reporting on the outcomes of these activities.

The Government Response included the development of a compliance strategy and framework. The Department will implement a risk-based strategy, which will enable Queensland Health to make informed choices regarding its compliance and enforcement activity. Implemented effectively, such a strategy will enhance the efficiency and consistency of the department's compliance and enforcement program in relation to community pharmacy. This approach will enable Queensland Health to tailor its compliance and enforcement activities so that they are commensurate with the relevant risks. The benefits of taking a risk-based approach will mean where the risk associated with non-compliance is relatively low, less intrusive enforcement tools and lighter enforcement responses are justified. Additionally, the Committee's assessment was that Queensland Health should continue to administer pharmacy ownership (and if necessary, premises) regulation, as Queensland Health needs to ensure the professional, safe and competent provision of pharmacy services and maintain public confidence in the pharmacy profession. There are clear benefits in taking this approach to proactive compliance, over the long term. Regulatory intervention will underpin longer term pharmacy stewardship.

In developing and evaluating the options presented in this Consultation RIS, Queensland Health considered the following objectives:

- Efficient administration – administration of pharmacy ownership legislation must be practical, transparent and streamlined;
- Efficient cost recovery – costs of administration should be recovered on a fee for service arrangement at a cost to industry equal to the costs of administering the legislation;
- Transparency – the basis for any fee framework should be clear and readily accessible to industry stakeholders. Additionally, there must be a clear link between the cost of pharmacy business ownership activities the charges imposed for those activities; and

- Equity – The cost of activities should be recovered directly from the industry to which the activities apply.

Government Response to Committee recommendations

The Government Response to the Committee proposed to introduce a licensing scheme to support the regulation of pharmacy ownership, as is common in other jurisdictions. The Committee recommended that the pharmacy ownership requirements of the PBO Act be retained. The QAO report recommended Queensland Health re-designs its internal controls so it can effectively administer the PBO Act (QAO recommendation 2) and implements a process to monitor pharmacies' ongoing compliance with the PBO Act (QAO recommendation 4).

In order to effectively address the recommendations, Queensland Health must provide a mechanism that:

- Provides clarity to the industry about what is required from pharmacy owners and how compliance is assessed;
- Allows for ongoing monitoring and regular review of compliance status; and
- Provides effective enforcement options, including the ability to apply conditions.

In addition, other recommendations made by the Committee require that Queensland Health:

- Ensure that details that the department holds about pharmacies is correct and current; and
- Have the authority to publish information about compliance activities undertaken and the outcomes of those activities (Recommendation 10).

While these objectives could be achieved by making changes to the legislation and increasing the department's compliance activities, this would represent a significant cost to government in the form of additional resources to monitor and enforce ongoing compliance.

The introduction of a licensing system would allow the department to recover the cost of these activities through a licensing fee.

In addition, the use of a licensing system to implement the above activities allows:

- transparency of processes for the pharmacy sector, in that pharmacy owners would have full awareness of what is required of them, how they will be assessed and what the cost will be;
- currency and accuracy of information about a pharmacy business due to regular review by pharmacy owners and/or the department as a part of licence renewal or declarations;
- improved efficiency through automating processes and validation, which will assist in keeping costs to government (and therefore, cost of licences) to a minimum;
- regular review of compliance through fixed licensing terms;
- the use of conditions to apply closer monitoring of a pharmacy business where concerns are identified;

- the option to refuse or revoke a licence to address instances of significant or repeated non-compliance;
- recovery of costs associated with increased regulatory activities; and
- a mechanism for recovering the costs of maintaining the Queensland Pharmacy Council (in whatever form) as recommended by the Committee (Recommendation 6).

Without the formality of a licensing framework, enforcement and monitoring is likely to be more ad hoc and less efficient, there is no incentive for pharmacy owners to be proactive in notifying Queensland Health of changes, and there is no opportunity to recover costs. Financial penalties for non-compliance may be seen by pharmacy owners as a cost of doing business, and hence may not result in increased compliance across the sector.

If a licensing framework is adopted, Queensland Health will change its processes to collect sufficient information about the commercial structures and arrangements for each pharmacy business every 3 years, require pharmacy owners to provide an annual compliance statement and carry out random audits as deemed appropriate. The collection of this information will also support improving communication to consumers about pharmacy business ownership matters, including public reporting about pharmacies' and pharmacists' compliance with relevant legislation.

Any proposed licensing framework for pharmacy ownership in Queensland will align with existing guidelines and legislation, such as the Australian Government Cost Recovery Guidelines and Queensland Treasury's Principles for Fees and Charges.

Offences are proposed for breaches of the licensing scheme, including introducing a penalty for breaching the existing pharmacy control provision in section 139I, which states that a commercial arrangement for a pharmacy business is void to the extent that the arrangement provides for external control over the business.

Queensland Health proposes to impose licensing fees to offset the cost of administering the licensing scheme and increased compliance activities, including the cost of the Council. The proposed fees are set out in Appendix 1. Appendix 2 provides a summary of the proposed legislative amendments. Appendix 3 summaries the current legislative instruments across all jurisdictions and Appendix 4 provides a summary of fees in Victoria, New South Wales and Tasmania for comparative purposes. Appendix 5 is the proposed draft Terms of Reference for the Council and Appendix 6 is an extract of section 139I of the PBO Act.

Consideration of options and impact analysis

A number of options have been considered in order to address these problems – focusing on a regulatory package that establishes a framework for licensing the pharmacy industry to monitor and enforce compliance with ownership requirements. These have been split into two parts, being:

- Part A – Monitoring and enforcement of pharmacy ownership legislation; and
- Part B – Establish a Queensland Pharmacy Council, funded by community pharmacy owners, through an annual administration fee.

The options for Parts A and B are summarised in the Table 1 below. A synopsis providing a general overview of each option follows.

Table 1. Options for Part A and Part B.

Part A - Monitoring and enforcement of pharmacy ownership legislation	
Option 1	Maintain the status quo.
Option 2	Retain the current notification approach and make minor amendments to the existing PBO Act to improve compliance processes and establish the Council.
Option 3	Establish a licensing framework for pharmacy businesses. A number of fees structures have been presented as part of this Consultation RIS.
Part B - Establish a Queensland Pharmacy Council, funded by community pharmacy owners, through an annual administration fee	
Option 1	Maintain the status quo.
Option 2	Establish an advisory Queensland Pharmacy Council funded by an annual administration fee by community pharmacy owners.
Option 3	Establish a voluntary advisory Pharmacy Round Table.
Option 4	Establish a Queensland Pharmacy Council as a Regulatory Authority.

Part A – Monitoring and enforcement of pharmacy ownership legislation

The policy objectives of Part A are to ensure efficient and equitable administration of the PBO Act and to improve transparency through public reporting of compliance activities undertaken by Queensland Health in relation to the legislation.

These policy objectives aim to address the gaps within the current PBO Act which does not provide for effective scrutiny of the commercial agreements and business structures related to pharmacy ownership for elements of control. In addition, the lack of a penalty for breaching section 139I (external control of pharmacy businesses void) does not promote compliance with the existing legislation. Further, there is no express mechanism to provide for public reporting of compliance activities undertaken by Queensland Health in relation to pharmacy ownership legislation.

The Committee recommended that Queensland Health improve transparency regarding the compliance of pharmacists with the PBO Act. This will require the collection and maintenance of relevant information about pharmacy businesses to enable the publication of Queensland Health compliance / audit results.

Part A consists of three policy options being:

- Option 1 - Maintaining the status quo;
- Option 2 – Retain the current notification approach and make minor amendments to the existing PBO Act to improve compliance processes and establish the Council; and
- Option 3 – Establish a licensing framework for pharmacy businesses

Option 1 – Maintain the status quo

Under this option, legislation would not be updated, nor would a Council and a licensing framework be established. This option does not address the QAO recommendation to address the gaps identified in the PBO Act to effectively manage the pharmacy ownership notification

process. This option also does not address the requirement for Queensland Health to increase its ability to effectively monitor and enforce compliance with the PBO Act. Option 1 is found not to be appropriate on the basis that it does not address either the QAO Report or the Committee's recommendations. This option does not meet the required policy objectives.

Option 2 - Retain the current notification approach and make minor amendments to the existing PBO Act to improve compliance processes and establish the Council

Under this option, the current notification approach would be retained however minor technical amendments to the PBO Act would be carried out to improve Queensland Health's ability to obtain information to monitor and enforce compliance. This would include amendments to the current section 139I by establishing an offence for entering into certain commercial arrangements, which provide for the pharmacy business to be controlled by a third party and minor amendment to an existing provision which would allow Queensland Health to compel the provision of relevant document to assess or monitor compliance with the PBO Act. Queensland Health will ensure any penalties proposed are consistent with other offences in the PBO Act for breaches of ownership restrictions and in other legislation / jurisdictions. Other amendments proposed aim to improve the ability of Queensland Health to have complete and up-to-date information to monitor and manage transfers of pharmacy ownership. This option addresses some of the gaps identified in the QAO Report in the current legislation. However, it does not provide solutions to improve the notification systems so that there is clear expectation from the pharmacy industry and other stakeholders that the PBO Act is proactively enforced and monitored against transparent compliance outcomes. The underlying rationale for this option will address the establishment of the Council and go some way toward improving controls to effectively administer the PBO Act, however, it does not meet all the objectives of government action.

Option 3 – Establish a licensing framework for pharmacy businesses

This option aims to provide a regulatory reform package that addresses all the gaps identified in the QAO Report and implement a system wide change that addresses the Recommendations handed down by the Committee. This will be achieved through the implementation of a licensing framework, underpinned by updated legislation and will include the establishment of the Council. This option also seeks to improve transparency of pharmacists with the PBO Act, across Queensland through the establishment of a register. It is proposed Queensland Health establish and maintain a public register of information about:

- Details of pharmacists owning pharmacy businesses; and
- Changes to the ownership of a pharmacy business.

This option seeks to ensure results of monitoring and enforcement of the PBO Act, is published annually to improve transparency regarding the compliance with the PBO Act.

In relation to the licensing framework, Queensland Health seeks stakeholder feedback on the type of fee framework proposed to be implemented.

This option suggests three different types of fee frameworks. These are:

- a) Establishing a one size fits all fee structure (flat fee scheme);
- b) Establishing a tiered fee scheme based on complexity of business structure; and

- c) Establishing a fee framework that includes fees per application related to pharmacy businesses as well as additional fees based on business complexity and the number of financial interests' persons (including body corporates) hold in a pharmacy business.

The impact analysis suggests this option will efficiently increase transparency in monitoring and compliance with the PBO Act and overall streamline pharmacy ownership requirements. Option 3 most aligns with the policy objectives.

Part B – Establish a Queensland Pharmacy Council, funded by community pharmacy owners, through an annual administration fee

The policy objective of Part B is to address the requirement for Queensland Health to implement a mechanism, underpinned by legislation, that will support Queensland Health in fulfilling its regulatory responsibilities to proactively monitor and enforce compliance with the PBO Act. Part B consisted of four policy options; these are:

- Option 1 – Maintain the status quo;
- Option 2 – Establish an advisory Queensland Pharmacy Council funded by an annual administration fee by community pharmacy owners;
- Option 3 – Establish a voluntary advisory Pharmacy Round Table; and
- Option 4 - Establish a Queensland Pharmacy Council as a Regulatory Authority.

Option 1 – Maintain the status quo

Under this option the Queensland Pharmacy Council would not be established. This is due to the legislation requiring an update to underpin the establishment of the Council. This option represents no immediate impact to existing stakeholders and does not address the Committee's recommendation to establish a Ministerial advisory body to support Queensland Health in pharmacy ownership matters.

This option does not meet the policy objectives and therefore is not considered a viable option.

Option 2 – Establish an advisory Queensland Pharmacy Council funded by an annual administration fee by community pharmacy owners

This option will establish the Council and apply an annual flat fee of \$265.00 to all pharmacies across Queensland. The purpose of the Council is to provide expert advice to the Deputy Premier on ownership and any relevant standards, enhancing the department capacity to proactively monitor and enforce the regulatory environments across the pharmacy industry. The members would be appointed by the Deputy Premier and comprise of experts in law, accounting, business management and representatives from the pharmacy industry as well as health consumers. This option most aligns to the policy objectives and meets the Committees recommendation to establish a Council to support Queensland Health in its administration of the PBO Act. The costs to determine the flat fee were based on cost recovery principles. The annual flat fee represents payment for the actual cost of the Council. Under this model, the proposed Council is similar to other established Councils in Queensland Health, such as the Radiation Advisory Council. This option most aligns to the policy objectives.

Option 3 – Establish a voluntary Pharmacy Round Table

Under this option a voluntary Pharmacy Round Table (PRT) will provide advice on the recommendations from the Committee, including the proposed amendments to the legislative framework and the establishment of the proposed licencing framework. The PRT may have up to eight members with expertise in law, business management, community pharmacy, hospital pharmacy as well as consumer representatives. The PRT would be informally established to support Queensland Health in implementing the Committee’s recommendation to amend the PBO Act, however the PRT cannot be remunerated. Typically, Round Tables are time limited which would only provide Queensland Health with an interim advisory group to support the early stages of implementing the Committee’s recommendations. This option would not provide for ongoing advice to support the compliance monitoring stages and ‘business as usual’.

Under this option it may be difficult to retain members to the PRT. The investment of the members’ time and expertise is significant, and a voluntary status does not recognise this investment. A voluntary advisory body is not considered a feasible option because of the level of clinical, legal, financial and business management expertise required. The Committee recommended the establishment of the Queensland Pharmacy Council to advise Queensland Health on regulatory and compliance matters that include, but are not limited to, transfers of pharmacy ownership and reviews of complex commercial arrangements.

This option will not meet the policy objectives of government and therefore is not considered to be a viable option.

Option 4 – Establish a Queensland Pharmacy Council as a Regulatory Authority

The administration of pharmacy ownership and premises varies across jurisdictions. Most have established independent pharmacy authorities to replace the abolished State / Territory pharmacy / Pharmacists Boards post 2010. Only Queensland and Northern Territory do not have independent pharmacy administration authorities. Also, pharmacy premises and / or pharmacy owners are currently registered/licensed in all jurisdictions except Queensland and the Northern Territory. This option proposes to establish a Queensland Pharmacy Council as an independent regulatory authority.

While a pharmacy council funded through industry fees may appear 'cost neutral' to the government, the cost of establishing and maintaining an independent statutory authority to administer pharmacy ownership legislation in Queensland will ultimately be paid for by either the pharmacy owners, pharmacists or pharmacy staff (through lower profits and / or wages), and / or consumers (through higher prices). In addition, depending on membership composition, there is likely to be potential conflict of interest, where pharmacy council members are also pharmacy owners and are tasked with enforcing pharmacy ownership regulation.

In the recent Inquiry into the establishment of a pharmacy council in Queensland, the Committee found there is no public interest case for establishing a separate statutory authority, such as a Council, in Queensland with the regulation functions of ensuring compliance with the pharmacy ownership restrictions and pharmacy premises regulation. Queensland Health considers this option will therefore not meet the policy objectives of government and therefore is not considered to be a viable option.

Recommended option/s

The recommended option is to combine both Part A Option 3 and Part B Option 2. These two options together will address the concerns of the QAO Report about the lack of information given to Queensland Health about pharmacy ownership and inadequate compliance monitoring. It will also support the Government in retaining the requirements of the PBO Act by maintaining community confidence in the pharmacy profession through transparent reporting of compliance outcomes.

The recommended option will provide for a new licensing scheme to be established which will enable Queensland Health to gather and assess information about the ownership arrangements of pharmacy businesses and determine their compliance with the pharmacy ownership requirements. It will also establish the Council and a register of pharmacy businesses that will ensure the commitments made in the Government Response to the Committee are delivered.

The proposed licensing framework will require a licence application to be made for each premises at which a pharmacy business is carried out and / or owned by a relevant person. Licences will be assessed by the chief executive against the following matters:

- whether each applicant for the licence is a fit and proper person, including whether they have been charged or convicted of an indictable offence, been bankrupt, or disqualified from managing corporations under the *Corporations Act 2001* (Cwth). If the person is a qualified pharmacist, information about their registration and any conditions placed on their registration;
- whether each applicant for the licence has previously held a pharmacy licence under the PBO Act, had any conditions placed on their licence, or had a licence cancelled or suspended;
- sufficient evidence to demonstrate compliance with the pharmacy ownership requirements, such as not owning more than five pharmacies and not being in a commercial arrangement that allows an external party to exercise control over the pharmacy business; and
- any other matter that the chief executive considers relevant to determining whether each applicant for the licence is a fit and proper person to carry on a pharmacy business.

This combined option is recommended as, of all the options investigated, it best addresses the identified issues with the current framework and achieves the objectives of government action.

Have your say

Submissions are open until **5:00pm Friday 4 September 2020** and can be made by email or post. Feedback will be used to inform the Regulatory Impact Statement process, and provide an informed, objective and transparent basis for decision making.

Electronic submissions:

pharmacy.governance@health.qld.gov.au

Written submissions:

Queensland Health
Chief Medical Officer & Healthcare Regulation Branch
Prevention Division
Pharmacy Inquiry Response Program
GPO Box 48 Brisbane, Queensland 4001

1. Background

The objective of the *Pharmacy Business Ownership Act 2001* (PBO Act)⁷ is to provide for the promotion of safe and competent provision of pharmacy services to maintain public confidence in the profession. The PBO Act does this by placing restrictions on the ownership of pharmacy businesses. Queensland Health is responsible for administering the PBO Act. The PBO Act sets out the regulatory framework for pharmacy ownership in Queensland.

These objects are achieved by prescribing restrictions on pharmacy business ownership including that:

- a pharmacy business must be owned by a pharmacist, or a corporation whose directors and shareholders are all pharmacists or a combination of pharmacists and relatives of pharmacists;
- a pharmacist must not have a beneficial interest in more than five pharmacy businesses at the same time; and
- a pharmacy business should not be subject to external control by third parties.

As the administering agency for the PBO Act, Queensland Health is responsible for monitoring and enforcing compliance with the PBO Act.

In May 2018, the Legislative Assembly referred an inquiry into the establishment of a pharmacy council and transfer for pharmacy ownership in Queensland (the Inquiry) to the Health, Communities, Disability Services and Domestic and Family Violence Prevention Committee (the Committee). The referral fulfilled a 2017 Government Election commitment to 'ask the relevant Parliamentary Committee to investigate the establishment of a Pharmacy Council and investigate all transfers of pharmacy ownership in Queensland over the past two years'. The commitment was given in response to concerns of some pharmacy owners that some emerging franchising models may be in breach the PBO Act.

As part of its inquiry, the Committee requested:

- the QAO conduct an audit of the administration of transfers of pharmacy ownership by Queensland Health; and
- Queensland Productivity Commission conduct an independent cost benefit analysis of the establishment of a pharmacy Council in Queensland.

The Committee delivered Report No. 12 – Inquiry into the establishment of a pharmacy Council and transfer of pharmacy ownership in Queensland (the Report). The Report referenced QAO's Report No. 4: 2018-19 – *Managing transfer in pharmacy ownership* and the Queensland Productivity's Report – *Cost-benefit analysis of establishing a pharmacy council*. The Committee endorsed the QAO's Report and made 11 recommendations.

⁷ <https://www.legislation.qld.gov.au/view/pdf/2012-07-01/act-2001-012>

In April 2019, the Government Response to the Committee Report, which accepted all 11 recommendations, in full or in principle, was tabled in the Legislative Assembly and included that:

- the minimum patient age requirement for pharmacist-administered vaccinations be lowered to 16 years of age;
- options be developed to provide low-risk emergency and repeat prescriptions, and low risk vaccinations through pharmacies, subject to a risk-minimisation framework and any necessary credentialing;
- support be sought for nationally consistent education and training requirements and scope of practice for pharmacists administering vaccinations;
- the benefits and risks of allowing community pharmacy assistants to handle dangerous drugs be explored;
- the benefit of community pharmacy assistants and hospital pharmacy assistants undergoing the same basic mandatory training be explored;
- a Queensland Pharmacy Advisory Council be established to advise the Queensland Department of Health in administration of the PBO Act and other relevant legislation;
- the Queensland Department of Health develop and implement a risk-based strategy for testing arrangements for pharmacy ownership that comply with the PBO Act;
- the PBO Act be amended to more effectively manage the pharmacy ownership notification process, including offence provisions for breaches;
- pharmacy ownership requirements of the PBO Act be retained; and
- there be improved transparency regarding the compliance of pharmacists with the PBO Act.

2. Introduction

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

The pharmacy profession is considered to be heavily regulated; however, the reasons that drove the original regulation of pharmacists and pharmacies in 1894 are largely still present today. There appears to be little dispute that individual pharmacists should be appropriately qualified and meet minimum standards of competency. Medicines are not seen to be ordinary items of commerce and pharmacies are unique amongst health practitioner businesses, in that they carry very large quantities of medicines, including significant stockholdings of drugs

with a high potential for misuse and abuse, or illicit value⁸. Refer Figure 1 below regulatory environment in Australia.

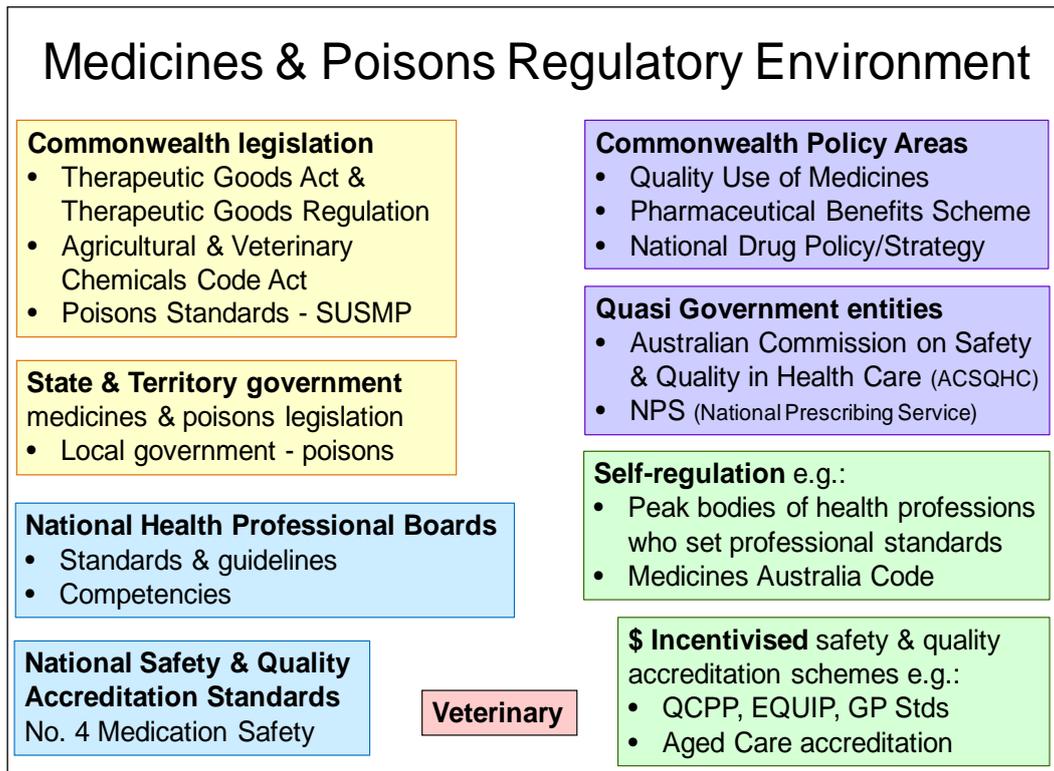


Figure 1: Medicines and Poisons Regulatory Environment in Australia

There are good reasons for pharmacies and pharmacists to meet the regulatory requirements for pharmacy ownership, given that pharmacies keep regulated substances in their possession and must prevent unauthorised access to these substances. They also need to be safe places for patients to enter and suitable to delivery of the type of care they offer.

Queensland Health is the sole regulator of pharmacy ownership in Queensland.

The QAO Report stated that Queensland Health is not taking all reasonable steps to ensure the objectives of the PBO Act are being met. However, gaps in the PBO Act itself, have resulted in Queensland Health not having sufficient information about pharmacy ownership transfers to ensure appropriate systems and processes are in place to proactively manage compliance monitoring and reporting.

Table 2 below is a summary of the results of the QAO compliance test on Queensland Health administration of the PBO Act.

⁸ https://ww2.health.wa.gov.au/~/_media/Files/Corporate/general%20documents/Pharmacy%20review/Review-of-Community-Pharmacy-Ownership-Discussion-Paper-v2.pdf

Table 2. Findings of the QAO Audit

Section of the PBO Act	# of notifications form tested	Findings
139B Restriction on who may own a pharmacy business	333*	<p>We did not find any instances of non-compliance in our sample of pharmacies in the non-franchise group. All pharmacy owners were registered pharmacists.</p> <p>However, s.139A of the Act defines ‘own’ to include proprietary interest (full or part interest that entitles the owner to a share in the profits). We were unable to determine whether franchise groups had a proprietary interest in those pharmacies because there were insufficient documents in the department’s files.</p>
139H Restriction on number of pharmacy businesses in which a person may have beneficial interest (that is, they benefit from the pharmacy’s profitability)	816 (for 316 changes in pharmacy ownership)	<p>We did not find any individual pharmacists listed in the department’s Monitoring of Drugs of Dependence System (MODDS) database owning more than five pharmacies in Queensland. But we identified the potential for non-compliance with the ownership rules, specifically, the potential for some pharmacists to have undeclared beneficial interests in more than five pharmacies.</p> <p>The department has not thoroughly tested whether pharmacists have ownership interests in more pharmacies than the Act allows through corporate structures. According to s.139H(2), a pharmacy owner may have a beneficial interest in a pharmacy if they are a director of or shareholder in a corporation that owns a pharmacy.</p> <p>The department does not record sufficient information in its database about entities or individuals such as Australian Company Numbers (ACN) and Australian Business Numbers (ABN) and individuals’ dates of birth. This limits the department’s ability to detect if pharmacists have ownership interests through corporations.</p>
139I Certain arrangements about control of pharmacy business void (circumstances under which commercial arrangements are not legally binding)	374**	<p>We found 70 instances where a pharmacy file either:</p> <ul style="list-style-type: none"> • did not contain the required corporate documents (Australian Securities & Investment Commission extract, certification of corporation, the corporate’s constitution), or • the documents were not certified, or • some documents were missing, and some were not certified. We were unable to determine whether the franchise pharmacy transfers complied with section 139I because there were insufficient documents (such as franchise agreements) in the department’s pharmacy file to confirm whether controls by a non-pharmacist exist in the franchise business.

Notes:

* This is the number of notification forms we tested (on a sample basis) in the categories of buying as a pharmacist, buying as an entity and opening a new pharmacy. There were 418 notification forms in these groups during the audit period 1 January 2016 to 31 July 2018.

** This is the number of notification forms we tested (mostly all) in the categories of buying as an entity and opening a new pharmacy (where the pharmacy is an entity). We tested all notification forms in these groups. There were 394 notification forms in these groups during the audit period 1 January 2016 to 31 July 2018. (Source: Queensland Audit Office).

As a result, the QAO Report recommended several changes to improve the compliance and enforcement processes of Queensland Health, including recommending the Committee seeks amendments to the PBO Act to enable Queensland Health to more effectively manage the pharmacy ownership notification process and defining the legal implications if a commercial arrangement breaches the PBO Act.

The Committee agreed with the recommendations of the Auditor-General in the QAO Report for the PBO Act to be amended to strengthen the PBO Act overall, enabling Queensland Health to more effectively manage the pharmacy ownership notification process.

The Committee's recommendations included to:

- establish a Council to advise Queensland Health in its administration of the PBO Act and provide expert advice on ownership and premises matters (recommendation 6);
- make amendments to improve compliance with the PBO Act including new offences for breaches of the ownership provisions (recommendation 8);
- retain the existing pharmacy ownership requirements (recommendation 9); and
- investigate ways to improve transparency regarding the compliance of pharmacists with the PBO Act (recommendation 10).

Therefore, the purpose of this Consultation Regulatory Impact Statement (Consultation RIS) responds to recommendations 6, 8, 9 and 10 of the Committee Report by proposing regulatory options to increase Queensland Health's ability to monitor and enforce compliance with the pharmacy ownership requirements. Additionally, the regulatory reform will provide a mechanism for funding the administration of the Council.

The Consultation RIS presents the proposed regulatory reforms in two parts:

- Part A – Monitoring and enforcement of pharmacy ownership requirements of the PBO Act; and
- Part B – Establish a Queensland Pharmacy Council, funded by community pharmacy owners, through an annual administration fee.

Queensland Health is seeking feedback from the community and affected stakeholders on the proposed options in Part A and Part B, including the proposed fees in option 3 of Part A.

Out of Scope

- Pharmacy businesses 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 (e.g. in-patients) are not included in any proposals as part of this Consultation RIS. This is because they are not regulated under the PBO Act as a pharmacy business, as they do not provide pharmacy services to the general public / community.
- The Commonwealth Pharmacy Location Rules legislated under the National Health (Australian Community Pharmacy Authority Rules) Determination 2018⁹ (PB 45 of 2018) made under section 99L of the *National Health Act 1953* have not been considered as part of any impact assessment within this Consultation RIS. This is because most medicines supplied in the primary care (community) setting in Australia today are subsidised by the Commonwealth Government as part of the Pharmaceutical Benefits Scheme (PBS). To supply PBS medicines, pharmacies must be approved under the *National Health Act 1953*. The Community Pharmacy Agreement (noted above) between the Commonwealth Government and the Pharmacy Guild of Australia contains rules that govern the location of an approved new pharmacy or the relocation of an existing pharmacy. The location rules are intended to ensure that the objectives of the National Medicines Policy are met, specifically that there is “timely access to medicines that Australians need, at a cost to individuals, that the community can afford”. Approvals are considered by a statutory body, named the Australian Community Pharmacy Authority. The Queensland Government has no role in PBS-pharmacy location rules, which are distinct from State and Territory ownership laws. For this reason, they are out of scope as part of this Consultation RIS.

Identification of the problems requiring action

Queensland Health has identified two key policy problem areas that require action:

1. *Monitoring and enforcement of pharmacy ownership legislation; and*
2. *Establish a Queensland Pharmacy Council, funded by community pharmacy owners, through an annual administration fee.*

These are discussed in detail below.

Monitoring and enforcement of compliance with the PBO Act, including a register of pharmacy businesses

Under the PBO Act, a person who owns a pharmacy business is required to notify Queensland Health within 21 days of a change in ownership or ownership particulars. This includes a change in the ownership structure or ownership proportion for pharmacies owned by a corporation or partnership (section 141A) or a change to the name or location of the pharmacy (section 141B). Penalties apply for a breach of these provisions.

⁹ <https://www.legislation.gov.au/Details/F2018L01321>

The current PBO Act was enacted 18 years ago and is based on legislation designed for a different purpose that has been significantly amended, including the repeal of a large number of provisions. Queensland Health believes the current regulatory framework does not provide for the ongoing monitoring of compliance with the PBO Act. This limitation exists because once a pharmacy owner has notified Queensland Health of a transfer of pharmacy ownership, there is no further requirement for the owner to demonstrate compliance with the PBO Act. This includes whether a pharmacy owner continues to maintain their Australian Health Practitioner Regulation Agency (AHPRA) registration, as a relevant person, defined under the PBO Act. For example, where a pharmacist's registration has been cancelled or suspended, as an individual, the pharmacist must not personally provide a pharmacy service. However, there is no current requirement in the PBO Act for the pharmacist, having been suspended or their registration cancelled, to notify Queensland Health as the regulator. While AHPRA do have public searchable registers including a register of practitioners who can practise within the scope of their registration and a register of cancelled practitioners and a list of practitioners who have given an undertaking not to practice, there is no mechanism at either Commonwealth or State levels that compels release of this information to the various regulatory bodies¹⁰. Additionally, the PBO Act does not provide for effective scrutiny of the commercial agreements and business structures related to pharmacy ownership for elements of control. The lack of a penalty for breaching section 139I (external control of pharmacy businesses void) does not promote compliance with the existing legislation. In addition, there is no express mechanism to provide for public reporting of compliance activities undertaken by Queensland Health in relation to pharmacy ownership legislation. This is primarily a result of the current gaps within the PBO Act that do not support Queensland Health requesting relevant information to confirm ongoing compliance with the legislation.

Queensland Health does publicly provide departmental reports, annually, which include regulatory performance reports. These reports outline regulatory performance against the five regulatory model practices and principles included in the Queensland Government's recently introduced Regulatory Performance Framework. The reports outline the extent to which Queensland Health has implemented the five model practices included in the framework and outlines Queensland Health's plans for future improvements of regulatory practices. The Regulatory Performance Reports contain health legislation enforcement action. However, the reports do not contain compliance and enforcement activities undertaken across pharmacy ownership as Queensland Health has relied upon voluntary compliance by the industry to date. The Committee Report noted these were barriers in effectively administering, monitoring and reporting compliance outcomes.

The Committee recommended that Queensland Health improve transparency of compliance of pharmacists with the PBO Act, this will require the collection and maintenance of relevant information about pharmacy businesses to enable the publication of compliance data. There is currently no mechanism to allow for the collection of this information to support this activity.

¹⁰ Queensland Health is currently liaising with AHPRA regarding possible notification systems. This is likely to be in the form of a subscription.

These gaps have a significant impact on the regulation of the pharmacy ownership requirements in Queensland and Queensland Health's ability to effectively monitor and enforce compliance with the PBO Act, including providing public reporting of compliance activities undertaken.

The Committee Report further stated that ownership requirements for pharmacies in Queensland as specified in the PBO Act are clear and unambiguous. As long as the restrictions on who can own pharmacies in Queensland remain part of the PBO 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.

Establish a Queensland Pharmacy Council, funded by community pharmacy owners, through an annual administration fee

The Committee recommend that Queensland Health establishes a Council, funded by the pharmacy industry. There is little perceived benefit for the Council (as identified by the Committee Report) to have duplicate regulatory or a quasi-regulatory framework to underpin Council functions. Therefore, the Council will be established as an independent Queensland Government advisory body. The Council would be comprised of members appointed by the Deputy Premier for their expertise in relevant specialty areas to provide advice and support to Queensland Health as the regulator. The Council would be governed by its Terms of Reference (see Appendix 5. Proposed draft Terms of Reference, Queensland Pharmacy Council) which outlines the its functions, appointment, membership, reporting and communication.

Given the ongoing nature of the Council's functions and diversified expertise required to deliver the intended outcomes, the Council will be established under legislation and remunerated in line with the 'Remuneration Procedures for Part-time Chairs and members of Queensland Government Bodies'¹¹.

The Council members would be able to apply their industry expertise and knowledge to enhance performance of Queensland Health's regulatory responsibilities, while providing for potential improvement in the professionalism of community pharmacy through links with other professional bodies.

The Council's functions, as noted in the draft Terms of Reference (Appendix 5), would include the provision of non-binding strategic advice to the Deputy Premier and the chief executive on pharmacy ownership matters, standards for pharmacy premises and the proactive monitoring and enforcement of all pharmacy regulations, including pharmacy ownership requirements and other issues, if / when they arise, affecting the pharmacy sector. The Council will not duplicate any regulatory functions as they will not act in a regulatory capacity. They may provide recommendations to Queensland health on regulatory matters by providing advice on more complex or unusual ownership matters, including advice in responding to, or reviewing complaints, atypical business arrangements or decisions related to licences or proposed conditions.

Establishing a Council will provide an opportunity to foster closer working arrangements between the pharmacy industry, health consumers and Queensland Health through its diverse

¹¹ https://www.qld.gov.au/__data/assets/pdf_file/0025/39481/remuneration-procedures.pdf

membership. The Council will have a key role in advising Queensland Health in any pharmacy ownership reforms, making it more transparent for industry stakeholder and consumers. In Queensland, within pharmacy ownership, there is currently no such pharmacy advisory body to facilitate this approach as industry peak bodies and the pharmacy profession do not typically possess the skillset required to review or provide advice in relation to the legality of business structures or commercial arrangements surrounding pharmacy businesses. In addition, there is no professional body that represents the interests of all pharmacy owners in Queensland.

The Health Portfolio includes a range of non-departmental government entities, such as boards, foundations and committees known collectively as health statutory agencies. These agencies are established under legislation to meet a specific state or public purpose. Each have representative guiding legislation and includes, but is not limited to:

- Hospital and Health Services;
- Hospital foundations;
- Mental health authorities;
- Ministerial advisory councils; and,
- QIMR Berghofer Medical Research Institute Council.

There are a number of other informal working groups, roundtables and others under the auspice of various memorandum of understanding across the Health Portfolio. These seek to address health challenges through pro-active, integrated and coordinated approaches to healthcare solutions for all Queenslanders. Establishing an advisory council under the Health Portfolio is not innovative as such, however, establishing a pharmacy council under legislation provides an opportunity to meet state specific objectives, in particular, stewardship of pharmacy ownership.

Queensland Health suggests this is the most appropriate mechanism as the proposed pharmacy council will be remunerated. Remuneration may only be paid to members of an advisory body in limited instances, where the members of that body essentially provide an expert service to the Government through the relevant professional, scientific or technical experience or expertise the member applies to the specific tasks required. This is distinct from any general advisory brief, informal working group, or time limited roundtable arrangements.

3. Objective of Government Action

The objective of government action is to better achieve the objects of the PBO Act by improving monitoring and enforcement of pharmacy ownership legislation. To support this outcome a Consultation RIS has been developed. The Consultation RIS has been presented in two parts (as previously mentioned) being Part A - Monitoring and enforcement of pharmacy ownership legislation and Part B – Establish a Queensland Pharmacy Council, funded by community pharmacy owners, through an annual administration fee. This is to address key outcomes of the Inquiry.

Part A – Monitoring and enforcement of pharmacy ownership legislation

The Government Response to the Committee Report proposed to introduce a licensing scheme to support the regulation of pharmacy ownership, as is common in other jurisdictions. If adopted, Queensland Health will change its processes to collect sufficient information about the commercial structures for each pharmacy business every 3 years (as part of the licensing / renewal process), require pharmacy owners to provide an annual compliance statement, and carry out random audits as deemed appropriate.

Policy objectives

In developing and evaluating the options presented in this Consultation RIS, Queensland Health considered the following objectives:

- Efficient administration – administration to establish and deliver the licensing framework must be practical, such that the cost of implementing the fee should not exceed the benefit of doing so;
- Efficient cost recovery – costs should be recovered on a fee for service arrangement at a cost to industry equal to the costs of the assessment and processing of an application;
- Transparency – the basis for the fee framework should be clear and readily accessible to industry stakeholders. Additionally, there must be a clear link between the cost of pharmacy business ownership activities associated with the licensing framework and the charges imposed for those activities; and
- Equity – The cost of activities should be recovered directly from the industry in which the licensing framework is applicable.

In addition to meeting the policy objectives, Queensland Health seeks also to address the Committee's recommendations as they relate to the administration and regulation of pharmacy ownership in Queensland and the QAO Report recommendations to improve the efficacy of the processes and systems used to administer the PBO Act.

The Government Response also included the development of a compliance strategy and framework. The Department will implement a risk-based strategy, which will enable Queensland Health to make informed choices regarding its compliance and enforcement activity. Implemented effectively, such a strategy will enhance the efficiency and consistency of the department's compliance and enforcement program in relation to community pharmacy. This approach will enable Queensland Health to tailor its compliance and enforcement activities so that they are commensurate with the relevant risks. The benefits of taking a risk-based approach will mean where the risk associated with non-compliance is relatively low, less intrusive enforcement tools and lighter enforcement responses are justified. There are clear benefits in taking this approach to proactive compliance, over the long term. Regulatory intervention will underpin longer term pharmacy stewardship.

Any proposed licensing framework for pharmacy ownership in Queensland will align with existing guidelines and legislation, such as the Australian Government Cost Recovery Guidelines and Queensland Treasury's Principles for Fees and Charges.

Consideration of options

This section presents options generated to deliver a regulatory reform package to improve the assessment, monitoring and enforcement of compliance with pharmacy ownership legislation in Queensland. These options have been developed based on the recommendations by the Committee and / or solutions proposed within the Government Response to the Committee. The options have been evaluated against the stated policy objectives above and are the subject of impact assessment considering the potential economic (business and industry impacts), social and government impacts. The options are not likely to lead to environmental impacts as any proposed licensing framework only affects the pharmacy ownership industry. Any proposed licensing framework option is considered equitable as Queensland taxpayers would not be subsidising the costs of pharmacy owners being required to obtain a licence. However, the introduction of a licensing scheme may result in increased costs to consumers should pharmacy owners seek to recoup at least some of their licence costs by increasing their prices.

Option 1 – Maintain status quo

Option 1 is to maintain the current status. There are no current fee arrangements in place as part of Queensland Health's notification process. Pharmacy businesses are not licensed, approved, registered or otherwise endorsed by the department under the PBO Act. However, pharmacists (including owners) must operate the pharmacy business in compliance with the PBO Act and all other relevant legislation and professional standards.

Assessment of Option 1

Currently pharmacy business owners are required to notify the department within 21 days of a change of ownership or change of pharmacy business details only. A public list or register of pharmacy businesses is unavailable in Queensland. This is primarily a result of gaps within the current legislation. The PBO Act does not currently have a mechanism for requesting necessary information to establish if pharmacy owners are compliant with the legislation, nor a head of power to annually publish the results of any monitoring and enforcement of compliance with the PBO Act. Additionally, this option does not address issues raised by the Committee regarding strengthening the PBO Act to enable Queensland Health to more effectively manage the pharmacy ownership notification process or address concerns regarding transparency of compliance. This option also does not address the Committee's recommendation to improve transparency of compliance / audit results regarding the compliance of community pharmacies in Queensland.

Under this option, maintaining the status quo will not address either the QAO Report or the Committee's recommendations to enable Queensland Health to more effectively manage the pharmacy ownership notification process. This option does not provide Queensland Health the ability to monitor pharmacy ownership for compliance with the PBO Act. Further, this option is not equitable. While many pharmacy owners strive to ensure compliance with the PBO Act, there are also a number of pharmacy owners who potentially may not be compliant with the PBO Act, particularly in relation to section 139I of the PBO Act.

Section 139I is important in relation to being able to obtain sufficient evidence to demonstrate compliance with the pharmacy ownership requirements, such as not having a beneficial interest in more than five pharmacies, and not being in a commercial arrangement that allows an external party to exercise control over the pharmacy business.

As a result of the current gaps within the PBO Act, which do not allow Queensland Health to compel provision of additional information to ensure compliance, Queensland Health as a regulator is not able to ascertain compliance with ownership requirements. For example, franchise and other third-party agreements may be written in a way that gives a person, other than the owner of the business the right to control in whole or part the way in which the business is conducted, and if not provided as part of notification requirements, Queensland Health is not able to compel pharmacy owners to provide them. Additionally, breaches of section 139I under the current PBO Act do not carry any penalties.

There are no new financial cost implications for business or industry in maintaining the status quo. However, Table 3 below highlights the current inconsistencies of regulation, combined with the limited flexibility within the current framework, associated with maintaining the status quo.

Table 3. Issues of maintaining the current regulatory framework

Stakeholder	Issues
Industry / Business	<ul style="list-style-type: none"> • Does not achieve the objectives of the PBO Act as many franchise arrangements and other commercial agreements contain clauses that Queensland Health deem as potentially void under section 139I • Pharmacy owners cannot be confident they are compliant with the PBO Act • Lack of confidence in government’s ability to effectively manage pharmacy ownership compliance • Does not achieve the objectives of the PBO Act, for providing a level of public confidence through appropriate monitoring and enforcement mechanisms
State Government	<ul style="list-style-type: none"> • Does not achieve the objectives of the PBO Act as many franchise arrangements and other commercial agreements contain clauses that are void under section 139I for which no penalties apply • Difficulties in applying penalties for breaches within the PBO Act due to lack of visibility of current ownership structures / models • Governance of the pharmacy business ownership scheme is only partly regulated due to deficiencies in the current PBO Act • No visible assurance (industry and community) that government is effectively managing pharmacy ownership compliance
Community	<ul style="list-style-type: none"> • As there is no mechanism to compel documentation from pharmacy owners to confirm compliance with the PBO Act, Queensland Health as the regulator is not able ensure the objects of the PBO Act are being met. This may lead to a potential lack of confidence in the pharmacy profession for the safe and competent provision of pharmacy services • Lack of confidence in government’s ability to effectively manage pharmacy ownership compliance • Does not achieve the objectives of the PBO Act, for providing a level of public confidence through appropriate monitoring and enforcement mechanisms

As there will be no changes to the current legislative environment under this option, no further impact assessment has been undertaken.

Option 2 – Retain the current notification approach and make minor amendments to the existing PBO Act to improve compliance processes and establish the Council

Option 2 is to retain the current notification approach and make minor technical amendments to the PBO Act to improve Queensland Health's ability to obtain information to monitor and enforce compliance. This will include offences for breaches of the current section 139I. Technical amendments to the PBO Act will include provisions to:

- retain the pharmacy ownership requirements in the current PBO Act;
- increase and / or introduce penalties for non-compliance with the pharmacy ownership requirements, such as failing to notify the chief executive when a change in ownership particulars occurs and where control is granted to a person other than the owner of the business. Any penalties imposed will require consultation with relevant government departments and industry representative bodies;
- modernise the framework for inspectors, powers of entry, warrants, delegations and other provisions to reflect current drafting standards; and
- establish the Council (including the ability to apply a fee).

These are discussed in more detail below.

Assessment of Option 2

Under this option the existing notification approach will require technical amendments to the PBO Act to support improved ability for Queensland Health to administer compliance of the PBO Act, including where relevant, penalties for breaches. It will also address the recommendations of the Committee to establish a Council. More information about the role, functions and membership of the Council and its proposed operation is available in Appendix 5. This option will address minor technical inconsistencies with the current legislation; however, it will not address systems or policy objectives. This option will provide for general improvements, in that it will provide for improved processes to administer the PBO Act. It will not provide a solution to improve the management of pharmacy ownership transfers and the necessary compliance information that is required. It is a clear expectation from the pharmacy industry and other stakeholders that the requirements of the PBO Act are proactively enforced and monitored against transparent compliance outcomes.

The cost implications for business or industry in option 2 is the introduction of a fee to cover the cost of the Council and, where non-compliance is identified under this option, new penalties for breaches of the PBO Act will be applicable. Under this option there is the likelihood that some compliance costs as part of business as usual activities may increase due to the additional requirements under an updated PBO Act. Refer to Table 4 below.

Table 4. Costs and benefits of retaining the current notification approach and make minor amendments to the existing PBO Act to improve compliance and establish the Council.

Stakeholder	Costs	Benefits
Industry / Business	<ul style="list-style-type: none"> • Prescribed fee (\$265.00 per annum, per pharmacy) to establish and administer the Council • Increase and / or introduce penalties for non-compliance with the PBO Act 	<ul style="list-style-type: none"> • Increased confidence in Queensland governments ability to manage and enforce compliance with the PBO Act
State Government	<ul style="list-style-type: none"> • Increased costs to inspect / review compliance with updated legislation of all community pharmacies 	<ul style="list-style-type: none"> • Coordinated / integrated approach to pharmacy ownership with the establishment of the Council who provide expert advice on complex ownership matters • Improved monitoring, assessment and compliance via improved notification processes will reduce unnecessary administration
Community	<ul style="list-style-type: none"> • Potential for any associated fees and / or increased compliance costs to be passed on by industry to health consumers via higher costs of medicines* 	<ul style="list-style-type: none"> • Advocacy of interests through the consumer representative member on the Council

*In relation to costs being passed on by industry to health consumers via higher costs of medicines, by law, community pharmacies must not charge more than the applicable Pharmaceutical Benefits Scheme (PBS) co-payment. This includes any brand price premium, therapeutic group premium or special patient contribution that apply under the conditions of PBS listing for a particular drug or brand.

In summary, this option will go some way toward increasing transparency including updating the current notification approach to better manage and respond to compliance processes and establish the Council. However, this option does not meet all of the objectives of government action

Option 3 – Establish a licensing framework for pharmacy businesses (preferred)

Option 3 is to provide a regulatory reform package that establishes a licensing framework for pharmacy businesses including the establishment and administration of the Council. This option also reflects the commitments made in the Government Response to the Committee to introduce a licensing scheme to support the regulation of pharmacy ownership in Queensland as is common in other jurisdictions. This option also seeks to improve transparency regarding compliance of pharmacists across Queensland. For this option, Queensland Health proposes three licensing fee schemes for consideration.

These are:

- a) Establishing a one size fits all fee structure (flat fee scheme);
- b) Establishing a tiered fee scheme based on complexity of business structure; and,
- c) Establishing a fee framework that includes fees per application related to pharmacy businesses as well as additional fees based on the number of financial interests' individuals hold in a pharmacy business.

Assessment of Option 3

Under this option, a licensing framework incorporating fees to administer the Council will be established to improve monitoring and enforcement of compliance with the PBO Act. This option underpins the intent of the Government's response to the Committee that enables Queensland Health (as the regulator) to more effectively manage the pharmacy ownership notification process. This includes implementing reform measures and establish mechanisms, seeking to improve transparency and compliance by the regulator and through the role of the Council (as a Ministerial advisory body).

The preferred option will address the concerns of the QAO about the lack of information given to Queensland Health about pharmacy ownership and compliance monitoring, through implementing a licensing scheme. The new licensing scheme to be established will enable Queensland Health to gather and assess information about the ownership arrangements of pharmacy businesses and determine their compliance with the pharmacy ownership requirements. In addition, a new licensing scheme will be able to implement a fit and proper person tests to maintain integrity within the community pharmacy industry. It will also address the recommendations of the Committee to establish a pharmacy Council to provide expert advice to the Deputy Premier and the chief executive of Queensland Health about ownership of pharmacy businesses and other matters as required, and how Queensland Health can achieve its regulatory responsibilities. Additionally, the Council will be required to publish annual reports on the performance of its functions on Queensland Health's website. Option 3 will improve transparency through improved reporting of compliance matters with the PBO Act.

To provide consistency in the type of matters referred to the Council, Queensland Health will develop a policy outlining the key triggers for the chief executive to refer a matter to the Council. Examples may include matters where an applicant seeks to operate under a complex franchise agreement or has conditions on their Australian Health Practitioner Regulation Agency licence.

The proposed scheme will require a licence application to be made for each premises at which a pharmacy business is carried on that is owned by the relevant person. Licences will be

assessed by the chief executive, Queensland Health (as the regulator), against the following matters:

- whether each applicant for the licence is a fit and proper person, including whether they have been charged or convicted of an indictable offence, been bankrupt, or disqualified from managing corporations under the *Corporations Act 2001* (Cwth). If the person is a qualified pharmacist, information about their registration and any conditions placed on their registration will also be considered;
- whether each applicant for the licence has previously held a pharmacy licence under the PBO Act, had any conditions placed on their licence, or had a licence cancelled or suspended;
- sufficient evidence to demonstrate compliance with the pharmacy ownership requirements, such as not owning more than five pharmacies and not being in a commercial arrangement that allows an external party to exercise control over the pharmacy business; and
- any other matter that the chief executive considers relevant to determining whether each applicant for the licence is a fit and proper person to carry on a pharmacy business.

Refer to Figure 2 for high level processes for applications and renewal of a licence. The ‘Impact analysis of a licensing framework’ section of this Consultation RIS discusses assessment time and costs associated with the application / approval pathways proposed under the pharmacy licensing scheme.

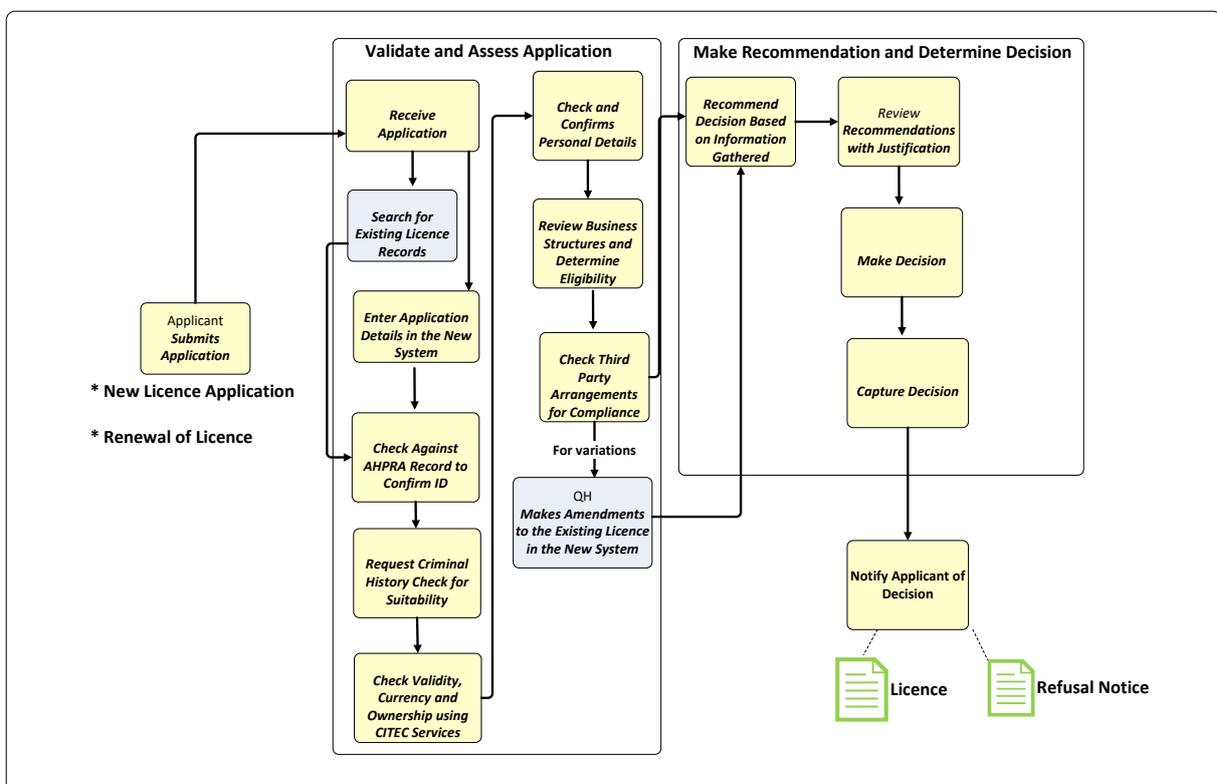


Figure 2. High level processes for applications and renewal for a licence – pharmacy licensing and ownership

The chief executive may grant or refuse a licence or impose conditions on the grant of a licence. A licence may be granted for a term of up to three years and a licensee must make an application to renew their licence before it expires. A maximum three-year licence term provides a balance between the administrative burden in considering and issuing licences and oversight to ensure that licence holders are compliant. A maximum three-year licence also provides a pharmacy business owner with a level of certainty for business continuity.

A licence holder will be required to notify Queensland Health of changes in the ownership structure of the pharmacy business and to seek approval to amend the licence where the change results in a transfer in the ownership of the pharmacy business. Provisions will be included about suspending, cancelling or renewing licences, and offences for operating a pharmacy without a licence.

The proposed approach will also require a licence holder to provide an annual compliance statement within one month of the anniversary of the date they were granted a licence. The annual compliance statement will require a person to provide a declaration, which confirms that their business:

- has not changed their ownership structure or particulars within the relevant 12-month period; and
- remains compliant with all of the relevant legislative requirements under the proposed legislation, including that they have not entered into any agreements that would divest control of the pharmacy business to a third party, such as under a franchise arrangement or other commercial agreement.

These annual compliance statements will allow pharmacy ownership to be regulated by Queensland Health in accordance with a self-assessment compliance model. This will also assist Queensland Health to confirm the accuracy of the information it has been provided by licence holders on at least an annual basis. If a licence holder fails to provide an annual compliance statement to the chief executive, in accordance with the requirements of the proposed PBO Act, their licence may be suspended or cancelled.

The information provided under the licensing scheme will support the establishment of a register of pharmacy businesses. To assist in keeping the proposed register up-to-date, the chief executive may require a person who holds a pharmacy business licence to give information or documents relating to a person's ownership and the person's interest in a pharmacy business. The ability to request information and maintain a register, will also improve transparency regarding compliance of pharmacists through publishing compliance audit results annually.

Collecting relevant data in this manner occurs across a number of programs within Queensland Health currently that aim to provide effective health responses, minimise transmissibility, morbidity and mortality associated with outbreaks of infectious diseases such as influenza, measles among others. Without a database of information, Queensland Health would not be able to mobilise the workforce, for example primary care facilities to manage and mitigate the public health risk.

For example, Queensland Health currently collects data to ensure the achievement of objectives as part of the Queensland Health Disaster and Emergency Incident Plan

(QHDISPLAN)¹² which describe the Queensland Health arrangements for the response to a disaster or emergency incident.

Another example is the regulatory framework to support and deliver the provision of the Queensland Opioid Treatment Program. Queensland regulation requires certain persons to obtain an approval or licence to perform certain regulated activities with Schedule 8 medicines (drugs of dependence) in Queensland. Patients must also be registered as part of the program requirements. The registration supports transitioning patients across Queensland regionally as well as inter-jurisdictionally, safely and supports continuity of care.

Appendix 2 provides a summary of changes proposed to the existing regulation of ownership of pharmacy business as part of the assessment of this option.

Impact analysis of a licensing framework

The proposed new licensing scheme will allow Queensland Health to more proactively assess, monitor and investigate pharmacy ownership compliance. It will also allow for better enforcement of compliance through the introduction of offences. All matters under an updated PBO Act, where / if a breach is identified are civil matters. Licence applications must contain relevant details of the owners, the type of ownership structure and the applicable commercial arrangements applying to the pharmacy.

The new licensing framework will allow a licence application to be assessed by the chief executive against the following matters:

- whether the person is a fit and proper person, including whether they have been charged or convicted of an indictable offence, been bankrupt, or disqualified from managing corporations under the *Corporations Act 2001 (Cwth)*, and, if the person is a qualified pharmacist, information about their registration and any conditions placed on their registration;
- whether the person has previously held a pharmacy licence under the PBO Act, had any conditions placed on their licence, or had a licence cancelled or suspended;
- whether the premises at which the pharmacy services are being provided comply with relevant requirements;
- sufficient evidence to demonstrate compliance with the PBO Act, such as not having a beneficial interest in more than five pharmacies, and not being in a commercial arrangement that allows an external party to exercise control over the pharmacy business; and
- any other matter that the chief executive considers relevant to determining whether the person is a fit and proper person to carry on a pharmacy business.

As Option 3 is the only option proposing fees, this section provides an impact assessment of the three different types of fee frameworks including the costs associated with each fee framework proposed.

¹² https://www.health.qld.gov.au/__data/assets/pdf_file/0031/628267/disaster-emergency-incident-plan.pdf

Queensland Health seeks your feedback on the type of fee framework to be implemented. To help inform industry, Queensland Health has completed analyses of the anticipated costs of each of the proposed the licensing frameworks. All fee options proposed within Option 3 have been based on government cost recovery principles and includes only the administrative costs associated with the administration of each different licensing fee framework. The licensing fees for each option will include the costs of the establishing the Council.

Summary of fees / costs

A summary of the fee for each proposed option relating to an initial licence application and renewal licence for each proposed license fee framework is below, refer Table 5.

Table 5. Pharmacy licensing fee framework costings

Task	Fee option 3 - A	Fee option 3 - B	Fee option 3 - C
Recurrent fees			
Application for a Licence (3-year licence)	\$2130.00	Tier 1 - \$1290.00	Indicative application fee = \$2499.00 (Base application \$1499.00 + Two corporations \$360.00 + Trust \$365.00 + 1 x Extra natural person \$275.00)
		Tier 2 - \$1935.00	
		Tier 3 - \$4225.00	
Renewal of a Licence (3-year licence)	\$1270.00	Tier 1 - \$730.00	Indicative renewal fee = \$1580.00 (Base renewal \$580.00 + Two corporations \$360.00 + Trust \$365.00 + 1 x Extra natural person \$275.00)
		Tier 2 - \$1225.00	
		Tier 3 - \$2250.00	
Annual Compliance Declaration (off licence years only)	\$105.00	\$105.00	\$105.00
Pharmacy Council Levy/Fee (per annum)	\$265.00	\$265.00	\$265.00
Non-recurrent fees (only applicable in certain circumstances)			
Notice of Change of Ownership Particulars / Licence Variation – removal of a financial interest, change in business details	\$135.00	\$135.00	\$135.00
Notice of Change of Ownership Particulars / Licence Variation – change in material commercial arrangements (not resulting in a change of ownership)	\$455.00	\$455.00	\$455.00
Notice of Change of Ownership Particulars / Licence Variation - Special circumstances	\$250.00	\$250.00	\$250.00

Assumptions: For option 3, the indicative fee has been calculated based on the assumption that an ownership structure involves two corporations (one of which is a Trustee of a discretionary trust) in an informal partnership. Further, the entire structure includes two pharmacists (relevant persons). This assumption is based on the average of the current range of ownership structures / models, and estimated occurrence of each model type. The average model is likely to move over time as the pharmacy industry and therefore, pharmacy ownership structures continue to change. Table 6 below itemises each cost associated with option 3.

Table 6. Option 3 - C fee breakdown

Task	Base Fee
Recurrent fees	
Application for a License (3-year licence) – Base fee	\$1499.00
Additional cost per natural person’s beneficial interest	\$275.00
Additional cost per corporation’s beneficial interest	\$180.00
Additional cost per trust	\$365.00
Renewal of a License (3-year licence) – Base fee	\$580.00
Additional cost per natural person’s beneficial interest	\$275.00
Additional cost per corporation’s beneficial interest	\$170.00
Additional cost per trust	\$90.00

Current estimated assessment costs

For each option within the licensing fee scheme, the costs of implementation have been estimated based on the time and effort for the department to assess individual licence applications and / or associated renewal licences, annual compliance statement and other associated activities. The average assessment time and cost per license fee framework contains the same base assumption. Table 7 identifies the estimated assessment costs for licences. These estimates are based on the number of hours departmental officers spend, on average, assessing each type of licence application.

Table 7. Average assessment time and cost per licence type by fee option

Fee Option 3	Licence type	Estimated Assessment hours	Cost (at \$/hr)
A	Initial	21	\$93.00
	Renewal	13	\$80.00
B	Initial	17 (Tier 1)	\$94.00
		29.5 (Tier 2)	\$94.00
		40 (Tier 3)	\$94.00
	Renewal	9.5 (Tier 1)	\$80.00
		17 (Tier 2)	\$80.00
		22.5 (Tier 3)	\$80.00
C	Initial	23	\$95.00
	Renewal	15	\$80.00

This means fees only differ in cost based on assessment hours to complete each activity across each of the fee frameworks proposed. The process time, end to end, ranged from approx. 9.5 hours to 40 hours. This time was estimated dependant on how much legal review would be required for simple commercial agreements to complex commercial agreements / ownership structures when initial and / or renewal of a licence is required. Additionally, all licence fees

include fees for corporation statutory fees and fit and proper persons tests which also vary in accordance with relevant commercial agreements / ownership structure complexity.

Estimated revenue from licence fee

Under a full-cost recovery fee model, the cost to government of the administration of the new licensing framework, and the costs of the Council, would be covered by the revenue received through fees paid as part of the licensing scheme implemented. Initially, approximately 1200 pharmacies will be required to submit a new licence application, if the licensing framework is adopted. Based on normal distribution of the total number of pharmacies, for each fee option, the costs associated over the three options proposed are approximately \$6 million for the initial three-year period. Costs associated with licence renewals after the initial three-year licensing period reduces to approximately \$1.3 million. This is a result of the stabilisation of cyclical three-year licensing renewals, new market entrants (at a growth rate of 1.6% per annum) and transfers in ownership resulting in a new licence (estimated at 10% per annum). Refer Option 3 - A example in Table 8 below.

Table 8. Option 3 – A: Example approx. # activities and costs over first three years

Activity Type	Option A						
	Avg Cost	Est No.	Y1	No.	Y2	No.	Y3
Initial Licence	\$2130	1343	\$2,861,267	153	\$325,890	155	\$330,150
Renewal of licence	\$1270	0	\$0	0	\$0	1064	\$1,351,280
Annual Compliance Declaration Fee	\$105	0	\$0	1047	\$109,935	136	\$14,298
Notice of Change of Ownership Particulars / Licence Variation – removal of a financial interest, change in business details	\$135	107	\$14,495	109	\$14,727	111	\$14,962
Notice of Change of Ownership Particulars / Licence Variation – change in material commercial arrangements (not resulting in a change of ownership)	\$455	19	\$8,685	19	\$8,824	20	\$8,965
Notice of Change of Ownership Particulars / Licence Variation - Special circumstances	\$250	5	\$1,193	5	\$1,212	5	\$1,231
Pharmacy Council Levy/Fee	\$265	1193	\$316,145	1212	\$321,203	1231	\$326,343
Total per annum			\$3,201,785		\$781,791		\$2,047,229

Baseline Assumption	<p>2.6% annual growth of new pharmacy businesses</p> <p>1% annual negative growth of pharmacy business closures</p> <p>Net annual growth = 1.6%</p> <p>10% of existing pharmacy business will require a new licence (due to a change of ownership)</p> <p>9% of existing pharmacy businesses will notify a removal of a financial interest and/or change in business details</p> <p>1.6% of existing pharmacy businesses will notify of a change in material commercial arrangement (indicative numbers from comparable jurisdictions)</p> <p>0.4% of existing pharmacy businesses will be notify a Notice of Change of Ownership Particulars / Licence Variation - Special circumstances</p>
<u>Year 1</u>	<p>Baseline: 1193 existing</p> <p>31 new businesses (2.6%) of baseline (rounded)</p> <p>119 subject to significant change resulting in new licence (10%)</p> <p>Total: 1343 applications for a licence</p> <p>Total Pharmacies: 1224</p> <p>1% closure rate = 12 closures (rounded) Pharmacy Count: 1212</p>
<u>Year 2</u>	<p>Baseline: 1212</p> <p>31 new businesses (2.6%) of baseline (rounded)</p> <p>121 subject to significant change resulting in new licence (10%)</p> <p>Totals: 152 applications for a licence</p> <p>Total Pharmacies: 1243</p> <p>1% closure rate = 12 closures (rounded) Pharmacy Count: 1231</p> <p>Total Pharmacies that require an annual compliance declaration: 1079 (1231 pharmacies, less 152 subject to new licence)</p>
<u>Year 3</u>	<p>Baseline: 1231</p> <p>32 new businesses (2.6%) of baseline (rounded)</p> <p>123 subject to significant change resulting in new licence</p> <p>Totals: 155 applications for a licence</p> <p>Total Pharmacies: 1263</p> <p>1% closure rate = 13 closures (rounded) Pharmacy Count = 1250</p> <p>Total Pharmacies that require an annual compliance declaration: 32 (new pharmacies from last year)</p> <p>Total Pharmacies that require a licence renewal: 1063 (baseline and new pharmacies, less 155 applications for a licence and 32 licences issued previous year (though are subject to compliance declaration))</p>

Other benefits / costs

Additional potential benefits and associated costs, should the regulatory reform option for licensing be adopted, have been listed in Table 9 below.

Table 9. Anticipated costs and benefits

Stakeholder	Costs	Potential Benefits
Industry / Business	<ul style="list-style-type: none"> • The implementation of a new licensing scheme will contain upfront costs to industry via fees for an initial licence application and then each 3 years for renewal of licence • Recurrent annual fees 	<ul style="list-style-type: none"> • Improved transparency with compliance of the PBO Act with the establishment of public reporting. • Pharmacy ownership compliance will be streamlined under desktop audit process when applying for a license, renewing a license or through the annual compliance notification process • Streamlining may save legal costs to industry as full disclosure enables the regulator to assess compliance with the PBO Act • Business and industry will benefit over time with improved reliability of the regulatory requirements – fostering enhanced understanding leading to improved compliance
State Government	<ul style="list-style-type: none"> • Implementation of a new licensing scheme will increase administration / compliance with pharmacy ownership requirements initially. However, government anticipate decrease in administration over time as increasingly industry will come into higher levels of compliance through annual reporting requirements 	<ul style="list-style-type: none"> • Improved transparency with compliance of the PBO Act to establish public reporting • Implementation of risk-based compliance monitoring plans to support ongoing monitoring of compliance with the PBO Act • Improved quality and timeliness of policy advice resulting in better regulation in the future • Increased and enhanced pro-active compliance approach and identification of state-wide compliance trends • Improving pharmacy business ownership transfer process will support the implementation of pro-active compliance desktop auditing • Simplifying the systems including improved notification processes, establishment of suitable electronic decision support tools and amended notification form/s will streamline administrative processes overtime

Stakeholder	Costs	Potential Benefits
Community	<ul style="list-style-type: none"> • Potential for any associated fees and / or increased compliance costs to be passed on by industry to health consumers via higher costs of medicines 	<ul style="list-style-type: none"> • Promotes the professional, safe and competent provision of pharmacy services through improved mechanisms to monitor and enforce the requirements with the PBO Act • Improved access to information • Improved confidence due to transparent compliance outcomes

The baseline assumptions (in relation to Table 9 above) relate to streamlining administrative burden over-time through achieving administrative efficiencies relating to compliance with the PBO Act being realised. This is primarily the result of desktop audits conducted to ensure any license application is correct at time of application. Further, annual compliance statements will ensure ongoing annual reviews are carried out as part of proactive compliance monitoring to meet the objectives of the PBO Act. To determine direct costs, a full cost assessment will be carried out within five years of implementation as part of an in-depth review of the effectiveness and efficiency of any proposed implementation of the new licensing framework.

It is important to highlight that all other States and Territories across Australia, other than Queensland (Qld) and the Northern Territory (NT), impose fees on pharmacy owners through registration and / or licensing arrangements. All States other than Qld, Australian Capital Territory (ACT) and NT have established pharmacy councils. Qld, ACT and NT are all regulated by their state health departments (Refer section 4 – Jurisdictional comparison below).

Part B – Establish a Queensland Pharmacy Council, funded by community pharmacy owners, through an annual administration fee

Background

Following a request from the Committee, on 26 May 2018, the then Deputy Premier, Treasurer and Minister for Aboriginal and Torres Strait Islander Partnerships directed the Queensland Productivity Commission (QPC) to undertake a cost-benefit analysis into the establishment of a pharmacy council (or other viable alternatives) in Queensland. On the 24 July 2018, the QPC provided its report: *Cost-benefit analysis of establishing a pharmacy council* (QPC Report). The QPC report found that there was no benefit to establishing a pharmacy council to regulate pharmacy ownership in Queensland, and that the Queensland community will be unambiguously worse off if regulatory functions were transferred from Queensland Health. However, the Committee recommended that a Queensland Pharmacy Council be established as an advisory body (Recommendation 6). This section discusses the following options:

- Maintaining the status quo;
- Establish an advisory Queensland Pharmacy Council, underpinned by legislation and funded by the pharmacy industry;
- Establish a Pharmacy Round Table; and
- Establishing the Queensland Pharmacy Council as an independent regulatory body.

Policy objectives

The policy objectives of Part B are to better serve the interests of the pharmacy industry and other stakeholders on a range of issues and to support Queensland Health in fulfilling its regulatory responsibilities to proactively monitor and enforce compliance with the PBO Act.

The Committee recommended that this objective would be achieved by the establishment of an advisory council to advise the department in its administration of the PBO Act and the fulfilment of its regulatory responsibilities. Queensland Health proposes regulatory amendments to the PBO Act to establish the Council as an advisory body.

Consideration of options

Option 1 – Maintain status quo

This option will mean that the Council will not be established. This is due to the legislation requiring an update to underpin the establishment of the Council. Under this option, Queensland Health would continue to administer the PBO Act and carry out investigations and enforcement (where applicable) if contraventions of the PBO Act occur. This option assumes that the administration costs and enforcement activity will remain at its current level.

Currently, 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. However, the current gaps within the PBO Act, do not allow Queensland Health to manage compliance effectively enough for Queensland Health to fulfil its regulatory responsibilities. This is due to the PBO Act having no mechanisms that compel the provision of information under a request from the regulator.

The Committee recommended the PBO Act be amended to enable Queensland Health to more effectively manage the pharmacy ownership notification process, including the establishment of offence provisions for breaches relating to control of pharmacy businesses by external parties: making this option non-viable.

Assessment of Option 1

Under this option, maintaining the status quo will not address either the QAO Report or the Committee's recommendations to increase Queensland Health's capacity to proactively monitor and enforce the regulatory environment. The QAO Report found that in assessing a sample of high-risk transfers, a portion of the transfers did not contain sufficient documentation to determine compliance with 'the right to control' element of the PBO Act. For example, QAO found that that Queensland Health did not request sufficient information to allow it to determine if:

- Franchise groups have a proprietary interest in individual pharmacies, that is, the franchise group has a complete or partial ownership in the pharmacy business; or
- Undeclared pharmacy ownership exists, for example, people may own multiple pharmacies through different business structures such as having a share in an entity that owns a pharmacy.

The gaps in the current PBO Act, do not compel pharmacy owners to provide additional information if the regulator requests it to ascertain compliance. This is a fundamental flaw in the current regulatory environment, making it challenging to carry out monitoring and compliance activities.

This option will not meet the policy objectives of government and therefore is not considered to be a viable option. Further, this option represents no immediate impact to existing stakeholders/industry, community or government and therefore, no impact assessment has been undertaken. A costs and benefits analysis was not undertaken as this option represents no change to the current state.

Option 2 – Establish a Queensland Pharmacy Council, funded by community pharmacy owners, through an annual administration fee (preferred)

This option will establish the Council and introduce a new fee paid by pharmacy owners to fund the operations of the Council. The key purpose of the Council is to provide expert advice to the Deputy Premier on ownership and any relevant standards, enhancing the departments capacity to proactively monitor and enforce the pharmacy regulatory environment (Appendix 5 details a proposed draft Terms of Reference for the Council). This option meets the recommendation of the Committee, for the Deputy Premier to appoint members to the Council.

The Council would comprise members appointed by the Deputy Premier with expertise in law, accounting, and business management and members representing the pharmacy sector and health consumers (see Appendix 5). This combination of expertise would inform regulatory policy and activities as they relate to the often complex business ownership structures and detailed commercial arrangements that pharmacies operate under in the current environment. The Council would be funded by the pharmacy industry in full (that is, no costs to be borne by government). The Council would be consulted by the Department of Health on matters including, but not limited to, managing transfers of pharmacy ownership. The Committee recommended the establishment of the Council, to support Queensland Health in its administration of the PBO Act and the fulfilment of its regulatory responsibilities to monitor and enforce compliance with the PBO Act.

Assessment of Option 2

Under this option the Council will provide expert advice about ownership arrangements. However, decisions about a licence application or transfer of pharmacy ownership will remain solely with the chief executive or delegate of Queensland Health as the regulator. A fee for the administration costs of the Council, on a cost recovery basis will apply.

Costs of operating the Council

The Committee recommended that the Council will be funded by the pharmacy industry, on a cost recovery basis. This means that no costs are to be borne by government. Costs for administration of the Council has been estimated at \$265.00 per pharmacy business per annum. The fee has been estimated on the assumption that the cost of the Council per annum will be in the vicinity of \$320,000.00 a breakdown of which is contained in Table 10 below. As there are approximately 1200 pharmacies in Queensland the fee has been equally attributed to each pharmacy.

Table 10. Annual cost estimation of Queensland Pharmacy Council

Expense type	Cost per year
Payment to Council Chair	\$7,500.00
Payment to members (\$6,000 per member)	\$48,000.00
Travel (incl. airfares, accommodation, taxis, meal allowances)	\$89,100.00
Meeting costs (incl. catering, printing, room bookings)	\$4,800.00
Secretariat support (1.1 FTE incl. 'on costs')	\$170,200.00
TOTAL	\$319,600.00

Assumptions:

- (1) 12 meetings will be held per year
- (2) As membership is not known, all members were allocated travel expenses

It is not proposed to set any fees and charges above or below cost recovery. Further, it is proposed that indexation of the fees will occur in line with the current government indexation policy, which provides for the annual indexation of fees and charges by applying the Government-endorsed indexation factor. This is consistent with the obligations and principles of the *Financial Accountability Act 2009*, *Financial and Performance Management Standard 2009*, Queensland Government Full Cost Pricing Policy (2010) and Queensland Treasury Principles for Fees and Charges (January 2018).

Council functions

Throughout the Inquiry, the Committee identified a range of issues where the interests of the pharmacy industry and health outcomes for Queensland Health consumers would be better served by closer working arrangements between the pharmacy industry, Queensland Health and other medical stakeholder groups and recommended the establishment of a Council.

As a result, the Council will have functions that include advising the Deputy Premier and the chief executive of Queensland Health about the ownership of pharmacy businesses and standards for pharmacy premises as required. They will also facilitate the proactive monitoring of pharmacy premises and enforcement activities carried out by Queensland Health by advising Queensland Health on how they can achieve its regulatory responsibilities. This support and advice will enhance Queensland Health's capacity to monitor and enforce the PBO Act. To provide for consistency in the type of matters referred to the Council, Queensland Health will develop a policy outlining the key triggers for the chief executive to refer a matter to the Council, for example, complex franchise arrangements or where an applicant has conditions on their AHPRA registration.

Further, establishing an advisory body who can be consulted and involved as a central stakeholder, in primary health care matters, such as community pharmacy, will ensure other State and Federal initiatives that involve tackling the burden of chronic disease (e.g. diabetes, asthma) and medications mismanagement can be discussed and integrated at the highest level (if required). The Council, as an advisory body, provides the opportunity for a panel of experts, having a voice, assisting to shape health policy and / or discussions about integrated approaches to health care needs.

Should the option proposing to establish the Council not be adopted, as is current state, this will not provide an opportunity to address the identified deficiencies. This may mean the

current deficiencies in the system existing between government and the community pharmacy stakeholders may not be overcome. Refer Table 11 below regarding costs / benefits of establishing a Council.

Table 11. Costs / benefits of Establishing a Queensland Pharmacy Council funded by Industry.

Stakeholder	Costs	Potential Benefits
Business / Industry	<ul style="list-style-type: none"> • Prescribed fee to administer the Council 	<ul style="list-style-type: none"> • Integrated / coordinated approach to health policy having representatives from pharmacy sector and consumers (other expert representatives include legal / business experts, financial management experts) • Increased transparency as annual reports will be publicly available
State Government	<ul style="list-style-type: none"> • Nil identified 	<ul style="list-style-type: none"> • Integrated / coordinated approach to health policy having representatives from pharmacy sector and consumers (other expert representatives include medical professionals, legal / business experts, financial management experts) • Increased transparency as annual reports will be publicly available • Increased effectiveness as a regulatory body through leveraging broad expertise of Council members to continuously improve Queensland Health's regulatory activities.
Community	<ul style="list-style-type: none"> • Potential for any associated fees and / or increased compliance costs to be passed on by industry to health consumers via higher costs of medicines 	<ul style="list-style-type: none"> • Increase confidence in governments ability to regulate pharmacy ownership • Increased transparency as annual reports will be publicly available

Queensland Health currently has other Ministerial advisory bodies, the Radiation Advisory Council (RAC)¹³ established in 1999 and the Sexual Health Ministerial Advisory Committee established in 2017.

¹³ <https://www.health.qld.gov.au/system-governance/health-system/managing/statutory-agencies/foundations#ministerial>

Refer text box 3.2 for RAC example and box 3.3 for Sexual Health Ministerial Advisory Committee example.

Box 3.2 – Radiation Advisory Council (RAC) Example

The RAC consists of at least eight, but no more than 15 members appointed by the Minister comprising:

- the Chief Health Officer, Queensland Health;
- at least six, but no more than 13 persons (the appointed members) with experience or knowledge relating to radiation practices, transportation of radioactive material and ways of preventing or minimising health risks or harm to the environment; and
- at least one community representative (who is also designated as an appointed member).

The RAC is established under the Radiation Safety Act 1999. The main objective of this Act is to protect person and the environment from the harmful effects of particular sources of ionising radiation and harmful non-ionising radiation. This is achieved mainly by establishing a licensing framework for relevant persons to carry out a radiation practice to which a licence relates. The Radiation Safety Act 1999 also requires the chief executive of Queensland Health to keep a register about licensees, accredited persons, qualified persons, inspector, State radiation analysts and prescribed licensees whose licences have been suspended or cancelled. The information contained within the register is prescribed by regulation and the chief executive must keep the register open for inspection, free of charge, by members of the public during office hours on business days. Members of the public are allowed to take extracts, also free of charge, from the register. Key achievements for 2019 included:

- Endorsed criteria for the assessment of persons requesting authorisation for specific diagnostic or therapeutic procedures under Schedule 6 of the Radiation Safety Regulation 2010
- Endorsed information for consumers on light - based cosmetic services that is easy to navigate, easy to understand, accessible via mobile devices and answers common questions or concerns, to empower consumers to make better decisions, for progression to departmental approval of publication
- Reviewed a report on the Investigation into limiting Dual Energy X-ray Absorptiometry (DEXA) Devices reports in Queensland, endorsing the approach proposed by Queensland Health to require service providers to keep a record of certain information, including obtained consent, treatment frequency and dosage
- Provided advice on proposals to remove red tape by amending the radiation safety legislation to remove the requirement for licensing wherever possible. This will commence with:
 - removing the requirement for a licence for the transport of radioactive substances, provided certain prerequisites have been met
 - removing the requirement for a licence for dentists using intraoral dental diagnostic X-ray apparatus for intra-oral dental radiography
- Endorsed Queensland Health's response to the external audit of the Queensland Radioactive Waste Store, conducted by ARPANSA in 2017 and recommended external

The RAC operates in a similar way to the proposed pharmacy Council. Its functions are to examine and make recommendations to the Deputy Premier, about the operation and application of the *Radiation Safety Act 1999* and other issues relating to radiation safety standards.

Box 3.3 – Sexual Health Ministerial Advisory Committee Example

The Sexual Health Ministerial Advisory Committee was established in 2017 to provide advice to the Deputy Premier, Minister for Health and Minister for Ambulance Services on sexual and reproductive health-related matters aligned to the Queensland Sexual Health Strategy 2016–2021 and its associated action plans.

The committee also:

- provides advice on priorities and future challenges on sexual and reproductive health-related matters, including investment priorities under the Strategy and research activities;
- provides opportunities for clinicians, service providers and advocates to communicate and share in information of strategic;
- importance to the delivery of effective sexual and reproductive health services in Queensland;
- provides input into state-wide, evidence-based sexual and reproductive health, sexually transmissible infections and blood-borne-virus policies and other clinical guidelines where appropriate; and
- reports on progress towards actions in the Strategy and associated action plans.

A key achievement for 2019 was the ‘Facilitating Primary Care in the Prevention, Treatment and Management of Blood-Borne Viruses and Sexually Transmissible Infections’ Forum (Forum). The Forum was hosted by the Sexual Health Ministerial Advisory Committee (the Committee) in Brisbane on 9 October 2019. The focus of the Forum on primary care was determined in alignment with the Queensland Sexual Health Strategy 2016–2021 and in response to rising notification rates of some blood-borne viruses (BBVs) and sexually transmissible infections (STIs). The Forum was opened by the Honourable Steven Miles MP, Deputy Premier, Minister for Health and Minister for Ambulance Services, and was facilitated by Emeritus Professor Cindy Shannon, Chair of the Committee. Approximately 130 representatives involved in delivering or supporting delivery of sexual health services and primary care across Queensland attended the Forum. This included general practitioners, sexual health physicians, infectious disease and public health physicians, along with representatives from Primary Health Networks (PHNs), Hospital and Health Services, Aboriginal Medical Services, non-government organisations (NGOs), Health Consumers Queensland, pathology providers, and medical professional peak bodies.

The Committee was formed without a specific legislative basis as a non-remunerated limited-term advisory body to help guide the implementation of the Queensland Sexual Health Strategy 2016–2021 and provide expert sexual and reproductive health advice to the Deputy Premier, Minister for Health and Minister for Ambulance Services. The eleven expert government and non-government members were ministerially-appointed to create a representative advisory body that reflects the broad nature of the Strategy. The current term is set to expire next year, and Queensland Health is currently reviewing these arrangements through re-establishment/continuation. They are also investigating possible remuneration

This option will establish the Council underpinned by a legislative framework, with the core functions of the Council being to provide advice to the Deputy Premier and Chief Executive. These functions are not to be interpreted as enabling the Council to act as a regulatory body or review applications for a licence received by Queensland Health from a person or entity. The Deputy Premier or chief executive will determine if a matter relating to the transfer of pharmacy ownership is referred to the Council for advice. Under this option, the Council will be subject to the directions of the Deputy Premier in performing its functions under any amended legislation. The Council will be required to comply with a lawful direction provided by the Deputy Premier and any Ministerial direction must be recorded in a Council Annual Report.

The QPC Report found one of the possible benefits of having a pharmacy council with an advisory function may be its ability to provide specialist advice efficiently and effectively¹⁴. In other jurisdictions, the composition of their pharmacy councils is dominated by members of the profession. A membership weighted in favour of the profession creates a perception that the group may not be objective in the policy advice they provide on business ownership. Pharmacists do not usually have the skills required to determine whether a business ownership structure is compliant with the Act. For this reason, it is proposed that members will include experts across a range of fields as earlier mentioned.

Discussions with stakeholders revealed there were instances where changes to health regulation could result in better patient outcomes and/or lower health expenditure. The Pharmacy Guild indicated that a council would help drive these beneficial changes.

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.

Option 3 – Establish a voluntary Pharmacy Round Table

This option is to establish a voluntary Pharmacy Round Table. A proposed Pharmacy Round Table (PRT) will provide advice on the recommendations from the Committee, including the proposed amendments to the legislative framework and the establishment of the proposed licencing framework. The PRT may have up to eight members with expertise in law, business management, community pharmacy, hospital pharmacy as well as consumer representatives. It may be established for a nominated term to advise Queensland Health in its implementation of the Government response to the recommendation of the Committee. The PRT would be informally established to support Queensland Health in implementing the Committee's recommendation to amend the PBO Act, however the PRT cannot be remunerated, and be time limited.

Assessment of Option 3

Members of Government bodies that are advisory in nature are, as a general rule, not remunerated and therefore the appointment of such members is not considered to be

¹⁴ The QPC Report also highlighted that potentially bureaucratic complexities may impede efficient advice to government regarding improving the quality and timeliness of policy advice, which the report states, may be more effective to address at the cause rather than establishing a function for a regulatory pharmacy council to address.

significant. The general policy is that the responsible Minister may approve non-remunerated appointments.

Typically, Round Tables are time limited which would only provide Queensland Health with an interim advisory group to support the early stages of implementing the Committee's recommendations. This option would not provide for ongoing advice to support the compliance monitoring stages and 'business as usual'. Further, this option has undergone previous consultation through Committee processes and was discounted as a long-term solution. Under this option it may be difficult to retain high quality membership given the lack of remuneration weighted against the level of commitment and expertise required. This option will not meet the policy objectives of government and therefore is not considered to be a viable option. There are no costs or benefits for establishing a PRT as an ongoing concern as it cannot be maintained into the future. For this reason, it was not investigated further.

Option 4 – Establish a Pharmacy Council as a Regulatory Authority

Prior to July 2010, the ownership provisions were administered by the Pharmacists Board of Queensland under the Pharmacists Registration Act 2001. Following the establishment of the National Registration and Accreditation Scheme in July 2010, the Pharmacists Board of Queensland was abolished and its regulatory functions for pharmacy business ownership were transferred to Queensland Health.

The administration of pharmacy ownership and premises varies across jurisdictions. Most have established independent pharmacy authorities to replace the abolished State/Territory pharmacy/Pharmacists Boards post 2010. Queensland and the Northern Territory do not have independent pharmacy administration authorities, and pharmacy premises are currently registered/licensed in all jurisdictions except Queensland and the Northern Territory. This option proposes to establish a Pharmacy Council as an independent regulatory authority.

Assessment of Option 4

While a pharmacy council funded through industry fees may appear 'cost neutral' to the government¹⁵, 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). Moreover, depending on membership composition, there could be potential conflicts of interest, where pharmacy council members are also pharmacy owners and are tasked with enforcing pharmacy ownership regulation.

Additionally, the Committee found there is no public interest case for establishing a separate statutory authority, such as a Council, in Queensland with the regulatory functions of ensuring compliance with the pharmacy ownership restrictions and pharmacy premises regulation. Further, the summary findings of the QPC Report found that there would be a net cost from forming a pharmacy council in Queensland ranging from \$7.7 million to \$11.1 million over a 10-year period. The QPC Report stated these figures were conservative. Additionally, the QPC Report stated that any of the possible impacts it has identified from forming a pharmacy council are unlikely to produce a material benefit. Rather it adds to the general cost of regulation. However, of greater concern is that an industry-dominated institution, such as a

¹⁵ https://qpc.blob.core.windows.net/wordpress/2018/08/Pharmacy_CBA_final_report.pdf

Council with regulatory function, may dampen innovation and competition in the industry at a cost to Queensland consumers. The QPC Report found that the Queensland community will be unambiguously worse off with the transfer of the function from Queensland Health. For this reason, this option is not considered feasible and is not investigated any further.

4. Preferred Policy Approach

The preferred policy approach to achieve government objectives is to combine Part A – Option 3 and Part B – Option 2. This proposed policy approach will ensure:

- a licensing scheme be introduced that will require each owner of a pharmacy business to obtain a licence for each pharmacy premises that is owned, or proposed to be owned;
- a Council to be established which is funded solely by industry in accordance with the recommendations made by the Committee; and
- a register of pharmacies / licence holders be developed and published.

This option will be underpinned through a modernised regulatory update to current pharmacy ownership legislation to increase transparency of compliance. Appendix 2 provides a summary of changes proposed to the existing regulation of ownership of pharmacy business.

If adopted, the preferred approach will require the introduction of fees and charges for the administration of the licensing scheme and the operation of the Council. To ensure any model implemented is consistent with Queensland Treasury Principles for Fees and Charges, it must be fully cost recovered through industry participation. This will mean that in licensing pharmacy businesses to operate in Queensland, the pharmacy licence holders will be required to fund the cost of establishing and administering the new licensing framework and the costs of the Council. The combined options will efficiently recover governments costs of administration and provide for increased transparency and reporting of compliance outcomes.

Queensland Health has identified three different licensing fee frameworks for consultation. These are to:

- a) Establish of a one size fits all fee structure (flat fee scheme);
- b) Establish of a tiered fee scheme based on complexity of business structure; and
- c) Establish of a fee framework that includes fees per application related to pharmacy businesses as well as additional fees based on the number of financial interests' individuals hold in a pharmacy business.

Each fee framework proposed is summarised below. All the proposed licensing schemes contain common non-recurrent fees that relate to changes in ownership or business particulars.

A Notice of Change of Ownership Particulars / Licence Variation – is a fee payable where the removal of a financial interest, change in business details is required when a financial interest is removed from the pharmacy business. Additionally, it will apply when details of the

business change (which includes address or trade name but not as a result of a change in material commercial arrangement (like a franchise agreement).

All fee frameworks contain a fee for special circumstances. A special circumstance is a notifiable change where the interest (or control) in the pharmacy business has changed due to exceptional circumstances not generally covered under a change of ownership or material commercial arrangement.

For example, Notice of Change of Ownership Particulars / Licence Variation – special circumstances are fees required should the following events arise:

- Pharmacist whose registration is suspended or cancelled (s139C);
- Person who stops being pharmacist's spouse (s139D);
- An Executor, administrator or trustee of pharmacist's estate is appointed (s139E);
- A Friendly Society demutualises (s139F); and
- A trustee, liquidator, receiver or administrator is appointed (s139G).

The fee covers the immediate costs of processing the notice and licence variation, and also covers the expected on-going costs associated with monitoring the adherence to conditions placed upon the licence as a result of the special circumstances.

Additionally, all fee frameworks require a new licence where a direct financial interest is introduced into the ownership structure of the pharmacy business. This is a result in the change of ownership and consequently a new licence will be required and applies to all fee options proposed.

Together the preferred approach is recommended as, of all options investigated, it best addresses the identified problems with the current framework and achieves the objectives of government action. All other options proposed either do not meet or only partially address the policy objectives and are not considered to be preferred policy options.

Proposed Fee Frameworks

a) Establishing a one size fits all fee framework (flat fee structure)

This proposed fee framework has been developed based on the average pharmacy in Queensland and costs associated with the licence framework have been applied through standardised cost of activities. Table 12 below shows recurrent and non-recurrent fees associated with the licensing and notification process.

Table 12. Option 3, A: Proposed Fees – Flat fee structure

Recurrent fees	
<i>License type</i>	<i>Proposed Fee</i>
Application for a License (3-year licence)	\$2130.00
Renewal of a License (3-year licence)	\$1270.00
Annual Compliance Declaration (annually)	\$105.00
Pharmacy Council Fee (annually)	\$265.00
Non-recurrent fees (only applicable in certain circumstances)	
Notice of Change of Ownership Particulars / Licence Variation – removal of a financial interest, change in business details	\$135.00
Notice of Change of Ownership Particulars / Licence Variation – change in material commercial arrangements (not resulting in a change of ownership)	\$455.00
Notice of Change of Ownership Particulars / Licence Variation – special circumstances	\$250.00

These fees were determined based on an average pharmacy business in Queensland, which includes an ownership structure with two corporations (one of which is a Trustee of a discretionary trust) in an informal partnership. The structure includes 2 pharmacists (relevant persons), of which each is the sole director and shareholder of the respective corporations.

Incorporating the assessment and processing of supporting documentation common to the ‘average’ pharmacy business includes (but not limited to): franchise agreements, service and supply arrangements, leases, and licences. An ‘average’ pharmacy business will usually provide at least three pieces of supporting documentation, as part of the licence application and renewal.

It is not proposed to set any fees and charges above levels to recover efficient costs (e.g. setting fees at the ratio of cost to output). The same principle was applied when estimating the administration costs for the annual Council fee. Further, it is proposed that indexation of the fees will occur in line with the current government indexation policy, which provides for the annual indexation of fees and charges by applying the Government-endorsed indexation factor. A flat fee structure however does not take into account the smaller pharmacy businesses, such as sole trader pharmacies, or likewise, the large multiple structured entities, as the fees proposed have been based on an average pharmacy business structure (refer example above).

Case study example: Sole pharmacist fee

A pharmacist owns a pharmacy business as either a sole trader, or as the sole director and shareholder of a company. The pharmacist or company may hold the interest in the business as trustee for a discretionary trust. The fee for a new application would be \$2130.00.

Note: Fees are applicable at time of application, though a licence is valid for three-years. Assuming no licence variations occur over the three-year period, an annualised cost is approximately \$710.00.

Case study example: Multiple owners / business structures fee

Three pharmacists own a pharmacy business in their capacities of directors and shareholders of their own distinct companies, the fee for a new application would be \$2130.00.

Note: Fees are applicable at time of application, though a licence is valid for three-years. Assuming no licence variations occur over the three-year period, an annualised cost is approximately \$710.00

b) Establishing a tiered fee model based on complexity of business structure

Implementing a tiered fee framework will impose fees within certain rules or parameters. The tier framework aligns with enhancing the transparency and predictability of processes and evidence requirements associated with notification and licensing approvals. The benefits of this option are that it provides a system that supports the level of regulatory attention and oversight required for the different complexities across the pharmacy business sector. Direct costs are recovered through the processes determined by the level of regulatory oversight required within each tier type (see Table 13 below). This allows for cost-effective prioritisation of resources required to manage the notification system while ensuring added benefits of license tracking to level of scrutiny required to ensure compliance. Table 13 below shows recurrent and non-recurrent fees associated with the licensing under a tiered framework. Note: variations in ownership structures may result in moving between tiers. Where a tier adjustment increases, a licence holder will be required to pay the pro-rata three-year difference in fees. However, should a change in ownership structure result in a decrease in tier type, rebates are not proposed where a licence holder moves from a higher tier to a lower tier type.

Table 13. Option 3, B: Proposed Fees – Tier Model

Recurrent 3-year Licence Fees		
*Tier type	Ownership Structure	Fee
Tier 1	Maximum Financial Interests: 1 natural person, 1 company The ownership structure may only include one discretionary trust.	\$1290.00 for licence applications and \$730.00 for a licence renewal
Tier 2	Maximum Financial Interests: 3 natural persons, 2 companies The ownership structure may only include two discretionary trusts	\$1935.00 for licence applications and \$1225.00 for a licence renewal
Tier 3	Any business structure outside of tiers 1-2	\$4225.00 for licence applications and \$2250.00 for a licence renewal
Recurrent Annual Fees		
<i>Annual Compliance Declaration (annually)</i>		\$105.00
<i>Pharmacy Council Fee (annually)</i>		\$265.00
Non-recurrent fees (only applicable in certain circumstances)		
Notice of Change of Ownership Particulars / Licence Variation – removal of a financial interest, change in business details		\$135.00
Notice of Change of Ownership Particulars / Licence Variation – change in material commercial arrangements (not resulting in a change of ownership)		\$455.00
Notice of Change of Ownership Particulars / Licence Variation – special circumstances		\$250.00

***Tier type is determined on satisfying the ‘Ownership Structure’ criterion.**

The administrative fee is calculated according to the nature, size and/or capacity of the activity undertaken, and resources required for government administration for those licenses within each tier type. This option will also incur additional current and recurrent fees as well as variation fees should an amendment to licence be required (refer to Appendix 1).

Case study example: Sole pharmacist fee

A pharmacist owns a pharmacy business as either a sole trader, or as the sole director and shareholder of a company. The pharmacist or company may hold the interest in the business as trustee for a discretionary trust. This type of ownership structure is within Tier 1; therefore, the new application fee is \$1290.00.

Note: Fees are applicable at time of application, though a licence is valid for 3-years. Assuming no licence variations occur over the three-year period, an annualised cost is approximately \$430.00.

Case study example: Multiple owners / business structures fee

Three pharmacists own a pharmacy business in their capacities of directors and shareholders of their own distinct companies. This type of ownership structure is within Tier 3, therefore the new application fee is \$4225.00

Note: Fees are applicable at time of application, though a licence is valid for 3-years. Assuming no licence variations occur over the three-year period, an annualised cost is approximately \$1409.00.

c) Establishing a fee framework that includes fees per application related to pharmacy businesses as well as additional fees based on the number of financial interests' individuals hold in a pharmacy business

The proposed fee framework in this option will require an initial standard application fee as well as additional fees based on the number of persons (including body corporates) (collectively known as financial interests') in the pharmacy business. Applications involving trust structures may incur an additional cost as well as additional fees per agreement as required. Other recurrent fees required include renewal fees, Council annual fees and compliance declaration fees refer Table 14 below. Non-recurrent fees are also listed in Table 15 below.

Table 14. Option 3, C: Licence fee including additional fees per financial interest

Recurrent fees	
License type	Proposed Fees
Application for a License (3-year licence)	\$1499.00
Additional cost per natural person's beneficial interest	\$275.00
Additional cost per corporation's beneficial interest	\$180.00
Additional cost per trust	\$365.00
Renewal of a License (3-year licence)	\$580.00
Additional cost per natural person's beneficial interest	\$275.00
Additional cost per corporation's beneficial interest	\$170.00
Additional cost per trust	\$90.00
Annual Compliance Declaration (annually)	\$105.00
Pharmacy Council Fee (annually)	\$265.00
Non-recurrent fees (only applicable in certain circumstances)	
Notice of Change of Ownership Particulars / Licence Variation – removal of a financial interest, change in business details	\$135.00
Notice of Change of Ownership Particulars / Licence Variation – change in material commercial arrangements (not resulting in a change of ownership)	\$455.00
Notice of Change of Ownership Particulars / Licence Variation – special circumstances	\$250.00

The standard application fee has been based on cost recovery for the resources required to do initial checks, reviews and assessments to ensure an application is eligible for the grant of a licence (see Table 15. Option 3, C: Standard application fee breakdown). This includes assumptions regarding time to review supporting documentation common to an 'average' pharmacy business. These documents include (but not limited to) franchise agreements, service arrangements, leases, and licences. It is anticipated that pharmacy businesses will

usually provide at least three pieces of supporting documentation, as part of the licence application and renewal. This option is based on a user-pays model, for example, per business arrangement and per financial interest. This is similar to how the Pharmacy Council of New South Wales implements their fee framework where applications for new pharmacies incur a fee per financial interest and /or applications involving trust structures.

Table 15. Option 3, C: Standard application fee breakdown

Description of activity	Cost
Administrative functions including data entry, payment processing and production of correspondence	\$95.00
Assessment of application including fit and proper person test and production of licence (incl. cost of administrative searches)	\$334.00
Professional services costs (incl. legal review of relevant documents)	\$1070.00
TOTAL	\$1499.00

Case study example: Average ownership model

Two pharmacists own a pharmacy business. Two corporate entities hold beneficial interests. The company holds the interest in the business as trustee for a discretionary trust. The fee framework applicable under this option would consist of:

- Application fee \$1499.00 (initial pharmacist)
- Additional cost per corporation's beneficial interest fee \$360.00 (2 x corporation beneficial interest)
- Additional cost per natural person's beneficial interest (1 x \$275.00)
- Additional cost per trust fee \$365.00

Total fee for application: \$2499.00

Note: Fees are applicable at time of application, though a licence is valid for 3-years. Assuming no licence variations occur over the 3-year period, an annualised cost is approximately \$833.00.

Case study example: Multiple owners / business structures fee

Three pharmacists own a pharmacy business in their capacities of directors and shareholders of their own distinct companies. The fee framework applicable under this option would consist of:

- Application fee \$1499.00 (initial pharmacist)
- Additional cost per natural person's beneficial interest fee of \$550.00 per person (2 x additional pharmacists)
- Additional cost per corporation's beneficial interest fee of \$540.00 per company (3 x additional companies)

Total fee for application: \$2589.00

Note: if a company held an interest as trustee for a trust, then an additional \$365 per trust would be payable

Note: Fees are applicable at time of application, though a licence is valid for three-years. Assuming no licence variations occur over the three-year period, an annualised cost is approximately \$863.00.

Case study example: Multiple owners / business structures fee

Nine pharmacists own a pharmacy business in their capacities of directors and shareholders of their own distinct companies. One of the companies is the corporate trustee of a trust. The fee framework applicable under this option would consist of:

- Application fee \$1499.00 (initial pharmacist);
- Additional cost per natural person's beneficial interest fee of \$2200.00 per person (8 x additional pharmacists);
- Additional cost per corporation's beneficial interest fee of \$1620.00 per additional company (9 x companies); and
- Additional cost per trust of \$365.00

Total fee for application: \$5684.00

Note: fees are applicable at time of application, though a licence is valid for 3-years. Assuming no licence variations occur over the three-year period, an annualised cost is approximately \$1895.00.

Box 4.1. Case study example – Pharmacy Council of New South Wales

Using NSW as an example, administrative requirements to assess financial interest in a pharmacy, require a person who intends to acquire a financial interest in a pharmacy to give at least 14 days written notice to the Council beforehand. The documents which must accompany such notice are set out in legislation and include, but are not limited to:

- details of the nature of the financial interest intended to be acquired,
- details of the basis on which the person is entitled to hold a financial interest,
- any bill of sale in relation to the acquisition,
- any sale agreement for business,
- any partnership agreement for the business,
- any agreement under which any other person has a financial interest in the business,
- any share sale/purchase agreement,
- any transfer of shares form (share register),
- any minutes of meeting of directors approving share sale/allotment,
- any shareholders' agreement,
- any notice of appointment of director,
- any minutes of meeting of directors regarding appointment of new director,
- any lease of the pharmacy business premises,
- any management services agreement,
- any trust deed if a pharmacists' body corporate or service entity is acting as a trustee,
- any agreement between persons having financial interests in the pharmacy business, which regulates their rights e.g. a shareholders' agreement,
- any loan or mortgage document that provides for a right to impose a charge on any assets of the pharmacy business.

In NSW, the National Law requires the Council to keep a Register of Pharmacies. Changes to the Register of Pharmacies occur upon the approval of applications to the Council, satisfactory inspection of premises where required and payment of the relevant fee where applicable. During 2017/18 there were 397 changes to the Register of Pharmacies according to the Pharmacy Council of NSW Annual Report 2017/18 (the Report). The Pharmacy Council of NSW is a statutory body established in July 2010 under the Health Practitioner Regulation National Law (NSW) and manages complaints and where necessary monitors the conduct and performance of practitioners. The Council also approves pharmacy premises in NSW and maintains a Register of Pharmacies and financial interest holders of NSW pharmacies. According to the Report, overall complaints directly managed by the Council were 94.9% more than last year and mostly around medication management issues (p 156, Part 2). Operating expenditure exceeded revenue received for the same period indicating registration and licensing fees are not set at a scale to recover costs (p166, Part 2). This information is presented within this RIS to demonstrate the administration complexities and resources required to meet regulatory requirements for managing pharmacy ownership, generally.

Ownership Compliance Activity – Pharmacy Ownership

For the purpose of this impact analysis it is assumed that, on average the overall compliance under the licensing framework will consist of a desktop analysis of licence compliance via annual Compliance Declarations provided by pharmacy owners on a per annum basis.

The department proposes that a random sample of approximately 10% of Compliance Declarations will be selected each year for a full desktop assessment to ensure compliance with the PBO Act. The annual compliance declaration fee will support this compliance approach.

The issuing of licences includes ensuring that each license application made is validated at that point in time. The administration costs to verify properly made applications for new or renewing licenses has been built into the costs reflected within the licence fee frameworks. The estimated compliance cost is listed in Table 16 below.

Table 16. Ownership Compliance Activity – cost recovery

Description of activity	Cost
Administrative functions including data entry, payment processing, production of correspondence and applicable searches of public registers	\$100.00

5. Jurisdictional Comparison

Pharmacies are regulated businesses in all states and territories of Australia. Jurisdictional legislation mandates the registration of pharmacies and establishes authorities responsible for registering premises; with Queensland (Qld) operating a notification system. Pharmacies can only be registered where they meet criteria laid out in regulation and comply with standards issued by each authority. Each jurisdiction has rules about who may own a pharmacy, which show some consistency across Australia. In general, all owners must be individual pharmacists, pharmacists operating in partnership, companies owned by pharmacists (and / or relatives of a pharmacist), or eligible trusts connected to a pharmacist. In some States and Territories, friendly societies, Aboriginal health services or other exempted groups may also own a pharmacy, under limited circumstances. In the Australian Capital Territory (ACT) and the Northern Territory (NT), there is no limit on the number that can be owned. In Tasmania (Tas) and Western Australia (WA), only four pharmacies can be concurrently owned. In New South Wales (NSW), Qld and Victoria (VIC), a person may own five pharmacies at the same time. In South Australia (SA), this figure is six pharmacies. Refer to Appendix 3 for a summary of regulation around Australia.

Given the current gaps in the PBO Act notification requirements, Queensland Health is not able to establish ownership compliance unless a pharmacy owner agrees to provide all relevant information to assess ownership compliance against the PBO Act. This creates another issue where the Australian Department of Human Services may not approve a pharmacy to dispense medicines in Queensland under the PBS, if they are not compliant with the PBO Act.

Tables 17 and 18 below shows licence comparisons in other states, noting Qld and NT do not have licence / registration fee requirements currently.

Table 17. Jurisdictional comparison – licence / registration

Jurisdiction	Person or entity licensed to own pharmacy	Premises licensed or registered	Entity administering pharmacy ownership (and premises)
New South Wales	✘	✓	Pharmacy Council of NSW
Victoria	✓	✓	Victorian Pharmacy Authority
South Australia	✘	✓	Pharmacy Regulation Authority SA
Western Australia	✘	✓	Pharmacy Registration Board of WA
Tasmania	✘	✓	Tasmanian Pharmacy Authority
Queensland	✘	✘	Queensland Health
Australian Capital Territory	✓	✘	ACT Health
Northern Territory	✘	✘	NT Health

A comparison of information collected during registration / licensing by different Australian pharmacy registering authorities is provided in Table 18 below. This table was taken from the *Review of Community Pharmacy Ownership in Western Australia – Final Report, March 2019*¹⁶ and highlights the complexities associated with assessing ownership applications.

The information / documentation required to assess licence applications in Queensland will depend on which option best achieves the policy objectives and aims to strike a pricing position recognising the cost industry is able to bear on an equitable basis (see Table 20 to demonstrate fee comparisons, nationally).

¹⁶ <https://ww2.health.wa.gov.au/Reports-and-publications/Review-of-Community-Pharmacy-Ownership-in-Western-Australia>

Table 18. Current application requirements for pharmacy registration/notification around Australia

Information required	WA	VIC	NSW	ACT	NT	SA	TAS	QLD
Plans	✓	✓	✓	✓	✓	✓	✓	
Bill of sale	✓							
Lease	✓		✓				✓	
Security interest documents	✓							
Finance/guarantee documentation	✓		✓					
Partnership agreement/company constitution or memorandum of articles/trust deed	✓	✓	✓	✓	✓	✓	✓	✓
ASIC business name registration	✓		✓		✓			
ASIC company extract	✓	✓	✓	✓	✓			✓
ABN registration					✓			
Franchise/banner group agreement	✓	✓	✓				✓	
Service agreement	✓	✓	✓				✓	
Sale agreement	✓							
Evidence to support relationship to beneficiaries declared to be close relatives				✓				✓
Proof of identification		✓		✓				
Person with overall responsibility specified	✓	✓						
Planning permit restriction on what can be sole from the premises	✓	✓						
Services to be provided from the premises		✓						
Persons other than the licensee that will conduct any business or activity in the premises		✓					✓	
List of other pharmacy businesses applicant has a proprietary interest in		✓				✓		✓
Declaration	✓	✓	✓	✓	✓	✓	✓	✓
TOTAL ITEMS	14	12	9	6	6	4	7	5

The primary functions of the separate entities (such as pharmacy councils, authorities and boards) in other jurisdictions is regarding 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 (See Table 19 below). These entities are funded by registration fees. No information is publicly available for the costs of operating the respective functions in the Qld government, ACT government and NT 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: VIC, WA, ACT and NT.

Table 19. Annual ongoing costs and sources of funding of administering entity

Jurisdiction	Entity	Annual ongoing costs and sources of funding
QLD	Department of Health	Funding sourced from the Consolidated Fund
NSW	Pharmacy Council of NSW	\$2.66 million (2016-17) Funding sourced from registration fees and other revenue
VIC	Victorian Pharmacy Authority	\$1.16 million (2016-17) Funding sourced from application, licence and registration fees, fines and penalties and income from investments
TAS	Tasmanian Pharmacy Authority	\$76,079 (2016-17) Funding sourced from initial application fees, renewal fees and other miscellaneous fees
SA	Pharmacy Regulation Authority SA	\$428,162 (2016-17) Funding sourced from the payment of registration fees, required notification of changes to the registers and sundry revenue
WA	Pharmacy Registration Board of WA	\$530,763 (2016-17) Funding sourced from licence fees and application fees
ACT	ACT Health	Funding sourced from the Consolidated Fund
NT	Pharmacy Premises Committee	Funding sourced from the Consolidated Fund

Adapted from Committee Report No. 12, 56th Parliament Health, Communities, Disability Services and Domestic and Family Violence Prevention Committee October 2018.

Table 20. Annual Pharmacy fees around Australia (2019-2020)

	WA	VIC	NSW	ACT	NT	QLD	SA	TAS
New Pharmacy application fee	\$1,000.00	\$715.00 - \$810.00 (registration of pharmacy business) + \$630.00 - \$1365.00 (licence to carry on a pharmacy business)	\$480 + \$550 per financial interest	\$641.00	\$0	\$710 annualised (3 yr. fee \$2130)	\$450	\$502.20 (registration of pharmacy premise) + (\$56.70 - \$1458) (eligibility certificate)
Change of ownership application fee	\$1,000.00	\$630.00 - \$1365.00	\$550 (for each new financial interest)	\$383.00	\$0	\$135.00	\$450	\$56.70 - \$1458
Relocation of existing pharmacy application fee	\$1,000.00	\$715.00 - \$810.00 (registration of pharmacy business) + \$630.00 - \$1365.00 (licence to carry on a pharmacy business)	\$480	\$641.00	\$0	\$455.00	\$450	\$502.20
Alterations to existing pharmacy application fee	\$650.00	\$430.00	\$480	\$0	\$0	\$455.00	\$450	\$0
Renewal fee	\$850.00	\$285.00 (registration) + \$290.00 - \$645.00 (licence)	\$320 \$80 Late Fee if lodged after due date	\$641.00	\$0	\$423.35 annualised (3 yr. fee \$1270)	\$500	\$405.00 (registration) + \$113.40 - \$226.80 (eligibility certificate)
Administration Fee	Change of Pharmacy Name \$50	Trust or commercial arrangement assessment \$1900.00 Site re-inspection \$430	Inspection of Pharmacy \$30	\$0	\$0	\$0	Reprint of Certificate \$50 List of Pharmacy premises/pharmacy service providers (corporate) \$250	Late fees \$24.30 - \$162.00 Exemption Application \$56.70 Inspection \$24.30 Copy of notice or Extract from register \$8.10 per page
Pharmacy Council Fee	\$0	\$0	\$0	\$0	\$0	\$265.00	\$0	\$0

Table 20 highlights the current fees nationally, comparing the proposed fees for Qld. Fees in Qld assumed based on flat fee structure (refer Option 1 and used for baseline purposes only). Appendix 4 provides detailed information on administration and processing fees for VIC, NSW and TAS for information.

6. Summary

In summary, the Committee found and the QAO Report demonstrated that the current regulatory scheme is inadequate, in that, Queensland Health is unable to effectively monitor and enforce compliance with the current version of the PBO Act. This is primarily due to a lack of penalties in the PBO Act itself and a lack of a regulatory authority to allow for the proactive on-going monitoring and enforcement of the PBO Act by Queensland Health.

In response to the recommendations made by the Committee and the QAO Report, Queensland Health is seeking to introduce a licensing scheme. A licensing scheme will allow Queensland Health to obtain information from pharmacy owners on a regular basis that will identify any non-compliance through assessing the relevant material provided as part of the licensing process. It will also assist in providing and maintaining accurate information for a register of pharmacy businesses, to improve transparency of compliance audit results.

Queensland Health proposes the cost of the administration of the new licensing scheme, including the costs of the Council, would be covered by the licensing fees. However, there is a potential 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 (as identified by the Committee Report). The fee models proposed are full cost recovery models with fees similar to, or lower than overall, licensing schemes in other jurisdictions. This will ensure Queensland continues to be competitive for existing pharmacy investment.

A licensing framework is consistent with Queensland Treasury Principles for Fees and Charges as it covers the cost of administering the new licensing scheme and the costs of the Council. It allows for the costs of increased regulation of pharmacy ownership in Queensland which aims to achieve a pricing position that recognises costs on an equitable basis to the pharmacy industry. This option enables Queensland Health to more effectively regulate and enforce pharmacy ownership requirements and improve transparency of compliance outcomes in the pharmacy industry and the wider community.

7. Consultation

This Consultation RIS follows initial consultation between May 2018 and October 2018, as part of the Inquiry. The Committee accepted and published 210 written submissions from community pharmacists and pharmacy assistants, medical and pharmacy peak bodies, pharmacy franchise organisation, patient advocates and members of the public. The Committee also held public hearings in Brisbane, Toowoomba, Cairns and Townsville.

The responses to this Consultation RIS will assist in refining the final regulation and inform government decision making about the licensing framework and transitional arrangements for commencement should the recommended option go ahead.

8. Consistency with other polices and regulation

Consistency with other legislation

No inconsistencies with other legislation have been identified. The *Health Act 1937*¹⁷ and the *Health (Drugs and Poisons) Regulation 1996*¹⁸, to be replaced by the *Medicines and Poisons Act 2019*¹⁹ contain the risk-management system for regulated substances including scheduled medicines. It is not intended to duplicate this system by regulating matters such as dispensing, storing, labelling and securing medicines, in the proposed licensing framework.

Competition principles agreement

The guiding principle of the Competition Principles Agreement, under the National Competition Policy is that legislation should not restrict competition unless it can be demonstrated that the:

- benefits of the restriction to the community as a whole outweigh the costs, or
- objectives of the legislation can only be achieved by restricting competition.

The PBO Act already identifies that there are competition restrictions, such as the number of pharmacies that are owned by a pharmacist, and the amendments will not change this. It is believed that the proposed amendments will not impact competition within the industry, as the proposed amendments will apply equally across all pharmacy businesses within Queensland. As recommended by the Committee, the intent of pharmacy ownership in any updated legislative reform should remain the same as the current legislation. Being to promote the professional, safe and competent provision of pharmacy services; to maintain public confidence in the pharmacy profession. This is achieved by: limiting who may own a pharmacy business; limiting the number of pharmacy businesses that may be owned by a person; and providing for compliance with the PBO Act to be monitored and enforced.

Even though businesses will be subject to new fees, the Queensland Health considers that the proposed fees are not seen as a barrier to business viability and / or industry competition. This is evidenced by the growth across the industry, including in those jurisdictions which have licensing and / or registration fees currently (IBIS 2018). The Pharmacy Board of Australia Annual Report 2017-18 reported an overall 2.5% increase in the number registered pharmacists than previous year (p9). Further, the report also concluded that all jurisdictions saw an increase in registrant numbers in the reporting year, with NSW, Vic and Qld being the principal place of practice for over 75% of all registered pharmacists (p7). Pharmacy ownership rules

¹⁷ <https://www.legislation.qld.gov.au/view/pdf/inforce/current/act-1937-031>

¹⁸ <https://www.legislation.qld.gov.au/view/pdf/2017-10-01/sl-1996-0414>

¹⁹ <https://www.legislation.qld.gov.au/view/pdf/bill.first/bill-2018-004>

¹⁵ <https://www.ibisworld.com.au/industry-trends/market-research-reports/retail-trade/other-store-based-retailing/pharmacies.html>

require pharmacists as owners, this information provides a good indication of the relatively high stability and indeed survival rate of the industry. Further, revenue is forecast to grow by 5.1% over the next five years, reaching \$40.1 billion by 2024 adding an estimated 300 establishments during the same period (IBIS 2018). Also, an ageing population is driving demand for pharmaceutical goods and services. Discount pharmacies and supermarkets who provide cheaper generic medicines can create deflationary pressures due to competition, however the national pharmaceutical industry is expected to continue growing, as a result of evolving consumer preference and changing demographics among others (IBIS 2018). Queensland Health does not foresee any regulatory reform contained within this Consultation RIS to have impacts on discount pharmacies any more than any other franchised or independently owned pharmacies.

By introducing a more contemporary regulatory framework in Queensland, the Department considers the regulatory burden and inefficiencies (as is the current situation) will be reduced, allowing a more equal environment for pharmacy businesses that is nationally consistent.

9. Fundamental Legislative Principles

The fundamental legislative principles under the *Legislative Standards Act 1992*²⁰ were considered during the development of the proposed regulatory framework. The framework may give rise to several fundamental legislative principle issues in relation to whether it has sufficient regard to the rights and liberties of individuals. Whether the proposed framework has sufficient regard depends on whether it is consistent with a number of principles including natural justice, protection against self-incrimination and privacy of information.

The licensing framework may give rise to fundamental legislative principle issues in relation to natural justice about licence decisions. These issues will be mitigated through ensuring the framework contains comprehensive review rights about licence decisions.

The introduction of an annual compliance statement may give rise to an issue as to whether there is appropriate protection against self-incrimination if a person is unable to provide a statement due to non-compliance with the PBO Act. As the framework requires honest and transparent reporting it is considered necessary that a person not be able to rely on protection against self-incrimination.

Queensland Health will obtain personal information about pharmacy business owners, such as criminal history, as part of determining a licence application and whether a person is a fit and proper person to hold a licence. Any potential breach of a person's right to privacy of information will be mitigated by requiring the confidentiality of such information to be maintained.

10. Implementation for Industry

The regulatory framework to support the implementation of the licensing fee framework and the Council is proposed to be introduced in 2020. A transitional process will occur to allow

¹⁶ <https://www.legislation.qld.gov.au/view/pdf/asmade/act-1992-026>

existing arrangements to evolve over time to the new regulatory framework. This is anticipated to take up to 12 months to occur. Licenses will require renewal every three years. This further supports transitioning licence requirements over the first 12 months once the fees are prescribed by regulation. Further consideration will be given to these arrangements after the consultation process has occurred and the appropriate option has been identified.

11. Evaluation and compliance support strategy

The reform package will be reviewed within five years to assess its appropriateness and effectiveness in terms of Queensland Health's ability to improve transparency through public reporting, increases in monitoring and compliance activities as required. The measures that will be used to evaluate improvements and the effectiveness of the framework include:

- Increased efficiency, over time, as introduction of new regulations aims to reduce government administrative burden, which may, for example, be measured by:
 - decrease in staff resources / time dedicated to assessing and issuing licences; and
 - increase in efficiency for staff to locate records and details for licence holders and undertake compliance checks against records.
- Effectiveness of the new licensing framework will be measured by:
 - the percentage of pharmacy owner's compliance with the requirements of the PBO Act;
 - increased efficiency for staff to locate and analyse records when investigating potential instances of non-compliance; and
 - whether the revenue generated by the licensing scheme covers the relevant administration costs.

Additionally, while not a measure for effectiveness, an added benefit over time, will be the ability to observe changing trends in pharmacy business models which may lead to improved policy advice and better future regulation (if / when required).

Glossary

Terms	Meaning
Applicant	Refers to any Natural Person that has a beneficial or proprietary interest in the pharmacy business in any capacity (for example, as a director/s, shareholder/s, trustee/s, unit holder/s, partner/s, spouse/child, sole trader.
Consumers	Refers to the general public who purchase products from community pharmacies.
Financial interest	Refers to a direct or indirect monetary or financial interest in a pharmacy business. It includes, but is not limited to, the interest of a sole trader, a partner in a pharmacy business, a director and/or shareholder in a pharmacists' body corporate, an interest as a trustee or beneficiary in a pharmacy business.
Industry Stakeholders	Refers to community pharmacies and any relevant industry body related to the pharmacy industry.
Natural person	Refers to an applicant or proxy applicant or is the primary or secondary applicant.
Pharmacy	The premises upon which a community pharmacy business is conducted.
Special circumstances	A special circumstance is a notifiable change where the interest (or control) in the pharmacy business has changed due to exceptional circumstances not generally covered under a change of ownership or material commercial arrangement.
Pharmacy Business	Means – A business providing pharmacy services; but Does not include – <ul style="list-style-type: none"> • 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.
Premises	Includes – <ul style="list-style-type: none"> • A building or other structures; and • A part of a building or other structure; and • Land where a building or other structure is situated.
Relevant persons	Means a person who starts to own the business; and a person who ceases to own the business.
PBO Act	Refers to the <i>Pharmacy Business Ownership Act 2001</i> .

Appendices

Appendix 1. Proposed Licensing Fee Models

Option 3, A – Flat fee scheme

Recurrent fees	
<i>License type</i>	<i>Proposed Fee</i>
Application for a License (3-year licence)	\$2130.00
Renewal of a License (3-year licence)	\$1270.00
Annual Compliance Declaration (annually)	\$105.00
Pharmacy Council Fee (annually)	\$265.00
*Non-recurrent fees (only applicable in certain circumstances)	
Notice of Change of Ownership Particulars / Licence Variation – removal of a financial interest, change in business details	\$135.00
Notice of Change of Ownership Particulars / Licence Variation – change in material commercial arrangements per commercial arrangement (not resulting in a change of ownership)	\$455.00
Notice of Change of Ownership Particulars / Licence Variation – **special circumstances	\$250.00

Recurrent and non-recurrent fee framework has been based on full cost-recovery (assessment hours x cost of government administration for an average Queensland business structure across all business types).

***Non-recurrent fees are only applicable where a change of ownership particulars / licence variation is required.**

****A special circumstance is a notifiable change, where the interest (or control) in the pharmacy business has change due to exceptional circumstances not generally covered under a change of ownership or material commercial arrangement.**

Option 3, B – Tiered fee scheme

Recurrent fees			
License type	Proposed Fees		
	Tier 1	Tier 2	Tier 3
Application for a License (3-year licence)	\$1290.00	\$1935.00	\$4225.00
Renewal of a License (3-year licence)	\$730.00	\$1225.00	\$2250.00
Annual Compliance Declaration (annually)	\$105.00	\$105.00	\$105.00
Pharmacy Council Fee (annually)	\$265.00	\$265.00	\$265.00
*Non-recurrent fees (only applicable in certain circumstances)			
Notice of Change of Ownership Particulars / Licence Variation – removal of a financial interest, change in business details	\$135.00		
Notice of Change of Ownership Particulars / Licence Variation – change in material commercial arrangements (not resulting in a change of ownership)	\$455.00		
Notice of Change of Ownership Particulars / Licence Variation – **special circumstances	\$250.00		

Based on full cost-recovery (assessment hours x cost of government administration for each application type related to business complexity rules).

***Non-recurrent fees are only applicable where a change of ownership particulars / licence variation is required.**

****A special circumstance is a notifiable change, where the interest (or control) in the pharmacy business has change due to exceptional circumstances not generally covered under a change of ownership or material commercial arrangement.**

Option 3, C – *Standard Application Fee plus per Financial Interest Fee

Recurrent fees	
<i>License type</i>	<i>Proposed Fees</i>
<i>Application for a License (3-year licence)</i>	\$1499.00
Additional cost per natural person's beneficial interest	\$275.00
Additional cost per corporation's beneficial interest	\$180.00
Additional cost per trust	\$365.00
<i>Renewal of a License (3-year licence)</i>	\$580.00
Additional cost per natural person's beneficial interest	\$275.00
Additional cost per corporation's beneficial interest	\$170.00
Additional cost per trust	\$90.00
<i>Annual Compliance Declaration (annually)</i>	\$105.00
<i>Pharmacy Council Fee (annually)</i>	\$265.00
**Non-recurrent fees (only applicable in certain circumstances)	
Notice of Change of Ownership Particulars / Licence Variation – removal of a financial interest, change in business details	\$135.00
Notice of Change of Ownership Particulars / Licence Variation – change in material commercial arrangements, per commercial arrangement (not resulting in a change of ownership)	\$455.00
Notice of Change of Ownership Particulars / Licence Variation – ***special circumstances	\$250.00

Based on jurisdictional comparison of fees incorporating full cost-recovery (assessment x cost of government administration related to standard application fees plus per financial interest fee requirement)

***Standard application fee cost has been determined on the assumption that three commercial agreements are standard for any pharmacy business.**

****Non-recurrent fees are only applicable where a change of ownership particulars / licence variation is required.**

*****A special circumstance is a notifiable change, where the interest (or control) in the pharmacy business has changed due to exceptional circumstances not generally covered under a change of ownership or material commercial arrangement.**

Appendix 2. Proposed summarised legislative amendments (Part A option 3)

Summary of changes proposed to the existing regulation of ownership of pharmacy business

Existing (Pharmacy Business Ownership Act 2001)	Proposal	Change
Owning a pharmacy		
<p>No licence is required PBO Act imposes ownership requirements including that a person must be a registered pharmacist to own (s.139B) or may not own more than 5 (s.139H)</p>	<p>A licence will be required to own a pharmacy business The existing ownership requirements in s.139B to 139H will remain. An owner will be required to meet a fit and proper test, the criteria for which will include: the person’s character criminal history insolvency history any disqualification from managing corporations imposed under the Corporations Act any condition placed on, or suspension of, a pharmacist’s registration under the Health Practitioner National Law any agreements that provide for external control of the pharmacy business</p>	<p>A licence is introduced An owner must make an application and provide information to support the application</p>

Change of ownership of a pharmacy		
Pharmacy owners must notify the chief executive of a change of ownership– s.141A It is an offence to fail to notify the chief executive	A new licence will be required for a change in ownership It will be an offence not to obtain a licence for the changed ownership	A licence is introduced An owner must make an application and provide information to support the application
Change in ownership particulars		
Pharmacy owners must notify the chief executive of a change in ownership particulars (name of business, location of business, change in director or shareholders, or change in partnership share) – s.141B It is an offence to fail to notify the chief executive	Pharmacy owners must notify the chief executive of a change in ownership particulars It is an offence to fail to notify the chief executive A pharmacy owner is required to provide the chief executive with an annual statement to advise whether there has or has not been a change in ownership particulars It is an offence not to provide the annual statement	A pharmacy owner must provide an annual statement to the chief executive A new offence is introduced
External control		
Certain commercial arrangements about the control of pharmacy business are void to the extent external control is granted to a person other than the owner of the business No offence for breaching this requirement	Certain commercial arrangements about the control of pharmacy business are void to the extent external control is granted to a person other than the owner of the business An offence will be introduced	A new offence is introduced

Fees		
<p>Powers to prescribe a fee under s.141A (change of ownership) and s.141B (change in particulars)</p> <p>No fee has been prescribed</p>	<p>A fee will be imposed for licences and the annual compliance statement</p>	<p>Introduction of fees for:</p> <ul style="list-style-type: none"> • a licence for a new pharmacy • a licence for a change in ownership • notification of change in business particulars • annual compliance statement • Queensland Pharmacy Council
Powers of inspection and investigation		
<p>Power to request documents</p>	<p>Power to compel production of documents to verify ownership and control arrangements</p>	<p>Expanded powers of inspection</p>
Queensland Pharmacy Council		
<p>Does not exist</p>	<p>Establish the Council</p>	<p>New advisory body and associated fee</p>

Appendix 3. Pharmacy regulation around Australia

The following information, taken from the 'Review of Community Pharmacy Ownership in Western Australia – Final Report, March 2019', is a brief summary of applicable legislation that governs the ownership of pharmacies in each State and Territory of Australia. Readers are referred to the individual regulatory authorities and various respective Acts for further details of full restrictions applicable in each jurisdiction.

Queensland

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

Western Australia

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

Australian Capital Territory (ACT)

- Community pharmacies in the ACT need to be licensed by ACT Health under the *Public Health Act 1997*.

A pharmacy business owner must be a pharmacist, a complying pharmacy corporation, or a former corporate pharmacist.

New South Wales (NSW)

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

Northern Territory

- The Pharmacy Premises Committee registers pharmacies according to Schedule 7 of the *Health Practitioners Act 2004*.
- A person must not own or exercise any control over a pharmacy business unless they are: a pharmacist; a partnership, of which all partners are pharmacists; a corporation, of which all shareholders and directors are pharmacists; or an exempted Aboriginal health service or friendly society.

South Australia

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

Tasmania

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

Victoria

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

Appendix 4. Licensing fees in VIC, NSW and TAS

Victoria Pharmacy Regulation Act 2010

Pursuant to section 104 of the Pharmacy Regulation Act 2010, the Victorian Pharmacy Authority has fixed the following fees for a period of 12 months commencing 1 May 2019.

PROVISION	FEE (\$)
Licences	
Annual licence – individual	\$290.00
Annual licence – corporate	\$645.00
Annual licence – hospital	\$375.00
Registration	
Annual registration – pharmacy business	\$285.00
Annual registration – pharmacy department	\$285.00
Annual registration – pharmacy depot	\$75.00
Applications	
Application for registration of pharmacy business	\$430.00
Application for registration of pharmacy department	\$525.00
Application for registration of pharmacy depot	\$75.00
Application for approval of alterations to a registered pharmacy business	\$430.00
Application for licence to carry on a pharmacy business	\$340.00
Application for licence to carry on a pharmacy business – complex	\$720.00
Application for approval to practice in special circumstances section 29(1)(b)	\$145.00
Other fees	
Site re-inspection	\$430.00
Trust or other commercial arrangement assessment	\$1,900.00

The above fees are exempt from GST (Division 81), viewed February 2020.

Pharmacy Council of New South Wales Schedule of Fees and Charges

Application for New Pharmacy - \$550.00 per financial interest	\$480.00*
Professional Services Room Application	\$480.00
Application for Relocation or Expansion/Reduction in size of Pharmacy Premises	\$480.00
Application for Relocation or Expansion/Reduction in size of Professional Services Room	\$480.00
Application for Change of Pharmacy Ownership / Sole Pharmacist	\$550.00
Application for Change of Pharmacy Ownership / Pharmacist Partnership	\$550.00 for each new financial interest
Application for Change of Pharmacy Ownership / Pharmacist's Body Corporate	\$550.00 for each new financial interest*
Application for Acquisition of Financial Interest by acquiring shares in a Pharmacist's Body Corporate and/or Appointment of a New Director	\$550.00 for each new financial interest*
Application for Acquisition of financial interest in a pharmacy business - as a beneficiary of a Trust	\$550.00 for each new financial interest*
Renewal of Pharmacy Premises Registration Late Fee	\$320.00 \$80.00 payable if lodged after the due date
Notice of Completion - Transfer of Ownership or Sale (Settlement) of a Pharmacy Business	No charge
Notice of Change of Pharmacy Name	No charge
Notice of Disposal of Financial Interest in a Pharmacy	No charge
Notice of Closure	No charge
Application for Inspection of the Register of Pharmacies	\$30.00

*Applications involving trust structures may incur an additional cost.

New South Wales Pharmacy Council Schedule of Fees and Charges, viewed February 2020,
<https://www.pharmacycouncil.nsw.gov.au/application-fees-and-charges>

Tasmanian Pharmacy Authority

The following fee structure has been declared under the *Pharmacy Control (Fees) Amendment Regulations 2013*. Fees are expressed in terms of **Fee Units**, which provides for their indexation in line with movements in the Consumer Price Index for Hobart (CPI). The approved Fee Units must be multiplied by the relevant year's Fee Unit Value to determine the fees due. The fee calculations for 2019-2020 are provided below for convenience. Information about the Fees Unit Act 1997 is available at: <http://www.treasury.tas.gov.au>

TYPE OF FEE	S of Act	Fee Units	FEES 2018/19 @\$1.58\$	FEES 2019/20 @\$1.62\$
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Eligibility Certificate - Initial Application

Each individual involving no Trust	61B	35	55.30	56.70
Each individual involving one Trust	61B	275	434.50	445.50
Each individual with more than one Trust	61B	550	869.00	891.00
Each body corporate with no Trust	61B	350	553.00	567.00
Each body corporate with one Trust	61B	620	979.60	1004.40
Each body corporate with more than one Trust	61B	900	1422.00	1458.00

Annual Renewals

Individual eligibility certificate	61E	70	110.60	113.40
Body Corporate eligibility certificate	61E	140	221.20	226.80
Certificate of Premises Registration	71K	250	395.00	405.00

Late Fees

Individual Eligibility Certificate	61E	15	23.70	24.30
Body Corporate Eligibility Certificate	61E	50	79.00	81.00
Premises Registration	71K	100	158.00	162.00

Other Fees

Initial registration of pharmacy business premises	71D	310	489.80	502.20
Application to exempt premises from registration	71J	35	55.30	56.70
Fee for inspection of register	71M	15	23.70	24.30
Fee for a copy or extract from register - per page	71M	5	7.90	8.10
Fee for a copy of notice - per page	71M	5	7.90	8.10
Application for a Pharmacy Depot				TBA

Appendix 5. Proposed draft Terms of Reference, Queensland Pharmacy Council.



Proposed - DRAFT Terms of Reference

Queensland Pharmacy Council

1. PURPOSE

The purpose of the Queensland Pharmacy Council (Council) is to advise the Department of Health in its administration of the amended Pharmacy Business Ownership Act 2001 and the fulfilment of its regulatory responsibilities. In addition, the Council will advise on issues relating to standards for pharmacy premises and inform Queensland Health on improvements for proactive monitoring of pharmacy premises and enforcement activities. Other duties and / or functions of the Council will be at the Deputy Premier, Minister for Health and Minister for Ambulance Services or the nominated delegate's discretion.

2. AUTHORITY AND DECISION MAKING

The Council functions under the authority and delegations of the Deputy Premier, Minister for Health and Minister for Ambulance Services. The Council, as an advisory body, provides the opportunity for a panel of experts, having a voice, assisting to shape health policy and / or discussions about integrated approaches to health care needs. The Council is not a decision-making authority.

The Council will make recommendations to the Deputy Premier, Minister for Health and Minister for Ambulance Services or the nominated delegate on specific matters referred to it. Council recommendations are made by consensus. If a consensus cannot be reached, the Chair reserves the right to have the casting vote to endorse (or not) a proposed recommendation.

3. GUIDING PRINCIPLES

The Council is committed to establishing, maintaining and promoting good governance by adhering to the following governance principles:

- Accountability – being answerable for decisions and having meaningful mechanisms in place to ensure the agency adheres to all applicable standards.
- Transparency / clarity – having clear roles and responsibilities and clear procedures for making decisions and exercising power.
- Integrity – acting impartially, ethically and in the interests of the agency, and not misusing information acquired through a position of trust.
- Stewardship – using every opportunity to enhance the value of the public assets and institutions that have been entrusted to care.
- Efficiency – ensuring the best use of resources to further the aims of the organisation, with a commitment to evidence-based strategies for improvement.
- Leadership – achieving an agency-wide commitment to good governance, partnering with Queensland Health through strategic leadership

4. FUNCTIONS

The primary functions of the Council are to:

- Provide advice to the Department of Health on pharmacy ownership policy and legislation as required;
- Consider system-wide priorities with respect to driving excellence in pharmacy services through:
 - creating a culture of high reliability;
 - facilitating National harmonisation approaches in pharmacy ownership (as appropriate)
 - reducing avoidable patient harm;
 - promoting effective models of collaborative patient care; and
 - improving patient outcomes where possible.
- Drive system level transparency through public annual reporting
- Advise on relevant industry standards and guidelines for pharmacy ownership and operation in Queensland;
- Consider the adoption of recommendations, policies, codes and standards and advise and report to the relevant delegate as the Council considers appropriate; and
- Any other functions as directed by the Deputy Premier, Minister for Health and Minister for Ambulance Services.

5. SUB-COMMITTEES

Sub-committees or other subordinate bodies may be established from time to time to investigate or progress specific issues.

6. REPORTING AND COMMUNICATION

The Council reports through the Deputy Premier, Minister for Health and Minister for Ambulance Services or their delegate. The Council will provide annual reports detailing the Council's performance. The Council will, on completion of each meeting provide public communiques detailing key outcomes of each meeting.

7. MEMBERSHIP AND TERM OF APPOINTMENT

The Council will consist of at least eight, but no more than 12 members appointed by the Deputy Premier, Minister for Health and Minister for Ambulance Services comprising:

Chair:

- Independent chair

Members:

- Legal expert
- Accounting expert
- Business management expert
- Consumer representative
- Representative Pharmacy Guild of Australia
- Representative Pharmaceutical Society of Australia
- Representative community pharmacist
- Representative Pharmacy Board Australia
- Representative from Academia

In attendance (non-voting):

- Representative/s of Queensland Health

Proxies:

A proxy member may be appointed by prior approval of the Chair taking into account the need for continuity. This includes the Chair.

Expert members do not have proxies. Persons officially acting in a member's position and approved proxies are expected to participate in deliberations and contribute to the Committee's recommendations according to the principles outlined in these terms of reference.

Term of Appointment:

The term of office of an appointed member is up to four (4) years. Appointed members may stand for re-appointment.

8. REMUNERATION POLICY

The Council will be remunerated in line with the Queensland Government policy 'Remuneration Procedure for Part-time Chairs and Members of Queensland Government Bodies'. Remuneration for the membership of government bodies may be paid as an annual fee, daily fee or sessional/meeting fee. Deputy chairs are to be paid at the rates prescribed for members.

9. OTHER PARTICIPANTS

The Chair may from time to time invite other individuals or groups to present to, or observe, meetings of the Committee. Where agreed by the Chair, members may invite guests to attend meetings to provide expert advice and support to a specific topic raised. A guest's attendance is limited to the duration of discussion on that specific topic. Observers and guests do not have authority to make determinations in respect of Committee deliberations.

10. BEHAVIOURS

Minimum governance behaviours of the Committee include:

- All members exercise due diligence and act in good faith.
- Members are provided with timely access to information, and information is shared amongst members.
- Appropriate confidentiality is respected.
- Members review papers in advance of meetings and attend meetings.
- Full and active participation in discussions by all members is promoted.
- Constructive questioning and vigorous debate is encouraged with a focus on the idea or issue rather than the person.
- Members deal with each other with courtesy and respect.
- The right issues are considered, decisions documented and follow up conducted.

11. QUORUM

The quorum of a meeting will be at least 50% of members or their proxies present and will be at the Chair's discretion and the ability of those present to address the items requiring discussion.

In the absence of a quorum the meeting may continue at the Chair's discretion with any items requiring decision to be deferred and circulated, following the meeting, to members as an out-of-session item. Proxies are included in the determination of a quorum.

12. OUT-OF-SESSION PAPERS

Items can be managed out-of-session where:

- the item is urgent and must be considered before the next scheduled meeting; or
- in circumstances when face-to-face meetings are not possible, to enable business to be progressed.

13. PERFORMANCE

Performance activities will include:

- Council self-assessment against designated Council responsibilities at the first meeting of the calendar year.
- Council evaluation of administrative process, timeframes and secretariat responsibilities, annually.

Evaluation of adherence to these performance activities and the minimum governance behaviours (section 9) will be conducted, with the support of Audit Risk and Governance Branch, Corporate Services Division, via:

- A Health Check – 3 months from establishment of the Council.
- A periodic Review – annually following the completion of the Health Check.

14. CONFIDENTIALITY

Members of the Council may receive information that is regarded as ‘commercial-in-confidence’, clinically confidential or have privacy implications. Members and proxies acknowledge their responsibility to maintain confidentiality of all information that is not in the public domain.

15. CONFLICTS OF INTEREST

To meet the ethical obligations under the Public Sector Ethics Act 1994, Council members and proxies must declare any conflicts of interest and manage those in consultation with the Chair. This may relate to a position a member holds (for example, chair of an external organisation) or to the content of a specific item for deliberation.

16. SECRETARIAT

Secretariat support will be provided by a Queensland Health officer from the Chief Medical Officer and Healthcare Regulation Branch, Prevention Division. Responsibilities of the Secretariat include:

- Prepares an annual work plan and meeting schedule.
- Records and maintains meeting proceedings (minutes).
- Confirms and reviews membership on an annual basis (inclusive of Chair and Secretariat).
- Develops, maintains and reviews a risk register capturing health system and corporate risks related to key decisions, strategy or other business.
- Documents actions and decisions and reports them to the Council chair.

17. MEETING SCHEDULE

The Council will meet monthly for a period of approx. three (4) hours. Meeting papers will be distributed at least five working days prior to the meeting.

Document History

Date	Nature of Amendment
x Month YYYY	Proposed draft Terms of Reference

Appendix 6. Extract of section 139I of the PBO Act

139I Certain arrangements about control of pharmacy business void

(1) A bill of sale, mortgage, lease, franchise, agency or other service or commercial arrangement for a pharmacy business is void to the extent it—

(a) gives to a person, other than the owner of the business—

(i) the right to control in whole or part the way in which the business is carried on; or

(ii) the right to receive any consideration that varies according to the profits or takings of the business; or

(b) requires goods or services for the business to be obtained from a stated person or body.

(2) However, subsection (1) does not apply to a bill of sale, mortgage or other form of security to the extent it gives rights to an administrator, receiver, or receiver and manager.