Impact Analysis Statement

Summary Impact Analysis Statement

Details

Lead department	Queensland Health
Name of the proposal	Pharmacy Business Ownership Regulation 2025
Submission type	Summary Impact Analysis Statement
Title of related legislative or regulatory instrument	*Pharmacy Business Ownership Act 2024*
Date of issue	October 2025

What is the nature, size and scope of the problem? What are the objectives of government action?

Nature, size and scope of the problem

Pharmacy business ownership is regulated in all Australian states and territories. Each jurisdiction has laws that regulate who may own, or have an interest in, a pharmacy business. In general, owners must be pharmacists or pharmacist-controlled corporations. All jurisdictions, other than the Northern Territory and the Australian Capital Territory, impose limitations on the number of pharmacies that a person or entity may own or hold an interest in.

In all jurisdictions, other than Queensland and the Northern Territory, there is a requirement for pharmacy business owners to be licensed, or premises to be registered, or both. In jurisdictions other than Queensland, Northern Territory and the Australian Capital Territory, government regulation of pharmacy ownership is undertaken by a statutory body, rather than by a department.

In Queensland, pharmacy businesses must only be owned by pharmacists; corporations in which the directors and shareholders are either all pharmacists or a combination of pharmacists and their spouses and adult children; certain friendly societies; and the Mater Misericordiae Limited. Business ownership structures range from very simple (e.g. sole trader) to very complex (e.g. multiple corporations and trusts). As at 1 July 2025, there are approximately 1,329 active pharmacies in Queensland.

On 19 March 2024, the Queensland Parliament passed the *Pharmacy Business Ownership Act 2024* (Act). The Act will provide a modern and effective framework for the regulation of pharmacy business ownership in Queensland. When commenced in full, the Act will repeal and replace the *Pharmacy Business Ownership Act 2001* (2001 Act). The 2001 Act is outdated and no longer appropriately regulates pharmacy business ownership in Queensland, especially in relation to monitoring and enforcing compliance with legislative obligations.

The main purposes of the Act are to promote the professional, safe and competent provision of pharmacy services by pharmacy businesses and to maintain public confidence in the pharmacy profession. The Act achieves these purposes by:

- establishing a new licensing framework for pharmacy business ownership;
- establishing the Queensland Pharmacy Business Ownership Council (Council) as a statutory body and transferring responsibility for regulating pharmacy business ownership from Queensland Health to the Council;
- maintaining and clarifying requirements from the 2001 Act regarding who may own or hold an interest in a pharmacy business;

- requiring the Council to maintain a register of information about pharmacy businesses and publish the results of monitoring and enforcement activities; and
- contemporising relevant Act provisions to support the effective monitoring and enforcement of pharmacy business ownership requirements.

Certain provisions of the Act have already been commenced to enable establishment of the Council, appointment of a Chief Executive Officer, and recruitment of Council staff. It is expected that the Act will commence in full (by proclamation) in November 2025, with repeal of the 2001 Act also effective from this date.

The Act provides a head of power for the making of regulations (see section 212) and expressly provides for certain essential elements of the new licensing framework being prescribed in subordinate legislation. These elements include standards that all pharmacy business premises must meet (Premises Standards) (see section 11(1)(b)), and the fees payable under the Act for licence applications and certain other matters (see sections 25, 27, 29, 33, 34, 38, 43, 49, 50, 53, 59 and 74).

Under the 2001 Act, pharmacy business owners are not required to pay fees to support regulatory activity undertaken by Queensland Health. The new regulatory framework established by the Act is intended to be self-funded on a cost-recovery basis. This will be achieved through fee revenue received from pharmacy business owners once the licensing scheme has been fully implemented. Similar regulatory entities in other jurisdictions are funded primarily by licence and registration fees.

In most Australian jurisdictions, pharmacy premises standards form part of the legislative framework for regulating pharmacy ownership. Premises standards are integral to ensuring the professional, safe and competent provision of pharmacy services to the community and the efficient regulation of pharmacy businesses. Although the content of, and approach taken to, the standards vary between jurisdictions, there are common themes such as requirements for security, design and equipment.

Queensland pharmacy premises were previously regulated to some degree under now-repealed legislative instruments such as the *Health (Dispensary) Regulation 1993*, *Health Regulation 1996*, and the *Health (Drugs and Poisons) Regulation 1996*. However, premises standards do not form part of the regulatory framework of the 2001 Act. As such, there are currently no regulatory requirements in Queensland that cover the entirety of a pharmacy premises. Rather, there are limited premises requirements based on the storage and security of medicines, and the provision of specific pharmacy services, with these requirements dispersed across multiple instruments. Also, these requirements place the compliance responsibility on the pharmacist on duty, who may not necessarily be the pharmacy business owner. The absence of comprehensive pharmacy premises standards has led to:

- Queensland Health (the regulator for the 2001 Act) lacking a robust mechanism to enable it to objectively determine whether a pharmacy premises is appropriate for the provision of the pharmacy services being provided, so that risks can be identified and addressed;
- pharmacy business owners having a lack of clarity regarding their obligations relating to the minimum standards their pharmacy premises must meet, and
- Queensland having an inconsistent regulatory approach to most other jurisdictions.

Objectives of government action

The objective of government action for this regulatory proposal is to achieve full implementation of the legislative framework for the pharmacy business ownership licensing scheme, in accordance with the main purposes of the Act, by November 2025.

What options were considered?

The following options were considered:

- **Option 1** – Commence the Act without the Pharmacy Business Ownership Regulation (Regulation) ('base case'/'no action' option).
- **Option 2a** – Make a Regulation under the Act prescribing fees, and Premises Standards applicable to all pharmacy businesses (one-size-fits-all approach).
- **Option 2b** – Make a Regulation under the Act prescribing fees, and Premises Standards with applicability/exemptions based on specified criteria.

Option 1: Commence the Act without a Regulation

The option would involve not making a Regulation prescribing fees and Premises Standards.

This option is not viable as full implementation of the legislative framework for the licensing scheme cannot be achieved by the Act alone.

Fees and Premises Standards must be prescribed in regulation and be in force when the Act commences in full. This is necessary for the legislative framework to be operable, and to enable the Council and pharmacy business owners to discharge their obligations and responsibilities under the Act.

For example, before the Council can grant an application for a pharmacy business licence, the Council must satisfy itself that the proposed pharmacy business premises are 'authorised premises' (see section 28(b)). Section 11 of the Act provides that premises are 'authorised' if they are (a) not located in, or directly accessible from, a supermarket, and (b) meet the standards prescribed by regulation. Further, when applying for a pharmacy business licence, an applicant must pay the relevant application fee prescribed by regulation (see section 25(1)(c)) and may be required by the Council to pay a fee prescribed in regulation for inspecting the proposed pharmacy premises (see section 27(1)(b)).

Further, the Council will not receive any recurrent funding from Government. As noted above, it is intended that the Council will be self-funded, with its operating, regulatory and compliance costs met through revenue from the prescribed fees.

As Option 1 is not feasible, it has not been subject to further analysis under this Summary Impact Analysis Statement (IAS).

Option 2a: Make a Regulation prescribing fees, and Premises Standards applicable to all pharmacy businesses (Recommended Option)

This option involves making a Regulation that prescribes fees payable under the Act, and Premises Standards that outline minimum requirements applicable to all pharmacies irrespective of size of premises, scope of pharmacy services provided, or geographic location.

Fees

In 2020, Queensland Health publicly released a Consultation Regulatory Impact Statement (Consultation RIS) *Proposed Regulatory Fees and Licensing Framework for Pharmacy Ownership in Queensland*. As part of this process, the Consultation RIS considered three broad fee structure options:

- a (one-size-fits-all) flat fee structure;
- a tiered fee structure, based on the complexity of the pharmacy business ownership model (preferred option); and
- a fee structure that included fees per application related to pharmacy businesses plus additional fees based on the number of financial interests in a pharmacy business held by individuals.

In November 2023, the then Queensland Government approved the fees framework for the new licensing scheme to be implemented under the Act. The fee framework adopts a tiered fee structure that reflects the complexity of pharmacy business ownership structures, and the associated level of regulatory effort required by the Council to determine their compliance with the Act.

The tiered fee structure will apply to licence application fees, with pharmacy businesses categorised under three tiers (Tier 1, Tier 2, and Tier 3) as outlined in Table 1 below:

Table 1: Pharmacy Business Ownership Fee Framework – Tiers for Application Fees

Tiers	Definition
Tier 1 (simple) (low regulatory effort)	A Tier 1 application means: (a) an application by one person, if the person's ownership of the pharmacy business to which the application relates – (i) does not involve ownership as trustee of a trust; or (ii) involves ownership as trustee of only one trust; OR (b) an application made jointly by two persons if – (i) not more than one of the persons is a corporation; and (ii) the person's joint ownership of the pharmacy business to which the application relates – (A) does not involve ownership as trustee of a trust; or (B) involves ownership as trustee of only one trust.
Tier 2 (moderately complex) (medium regulatory effort)	A Tier 2 application means: (a) an application by one person, if the person's ownership of the pharmacy business to which the application relates involves ownership as trustee of only two trusts; OR (b) an application made jointly by two persons if – (i) it is not a Tier 1 application; and (ii) the persons' joint ownership of the pharmacy business to which the application relates – (A) does not involve ownership as trustee of a trust; or (B) involves ownership as trustee of only one or two trusts. OR (c) an application made jointly by three, four or five persons, if – (i) not more than two of the persons are corporations; and (ii) the persons' joint ownership of the pharmacy business to which the application relates – (A) does not involve ownership as trustee of a trust; or (B) involves ownership as trustee of only one or two trusts.
Tier 3 (complex) (high regulatory effort)	A Tier 3 application means an application other than a Tier 1 or Tier 2 application.

In Queensland, the creation and setting of regulatory fees and charges, including licensing fees, is governed by various legislation and whole-of-government policies. These include the *Financial Accountability Act 2009, Financial Accountability Regulation 2019, Financial and Performance Management Standard 2019, Queensland Government Full Cost Pricing Policy* (2010) and *Queensland Treasury Principles for Fees and Charges Policy* (2021).

These requirements informed the development of the licensing fee framework and proposed schedule of fees outlined in Attachment 1. The proposed framework will comprise the following fee types:

(a) an application fee for a new pharmacy business licence;
(b) an annual application fee for renewal of a pharmacy business licence;
(c) an application fee for restoration of a pharmacy business licence (after a licence has expired);
(d) an annual licence fee (new and renewal);

(e) a number of fees for licence changes, including a change in business particulars, such as a change of address;

(f) a fee for an inspection (or re-inspection) of pharmacy business premises (if required), for the purpose of assessing an application for a pharmacy business licence; and

(g) a fee for assessing a trust or other commercial arrangement (if required), for the purpose of assessing an application for a pharmacy business licence.

The fees payable at items (a) to (c) are scaled according to Tier type, while the fees payable for items (d) to (f) are fixed irrespective of Tier type. The relevant fees are discussed further below.

In line with Queensland Government policy, the fees are intended to fully recover the costs of operating the licensing scheme, including the operation of the Council, and will be indexed annually. As the fees are subject to indexation, they are prescribed in terms of 'fee units', rather than monetary amounts, in the proposed Regulation. The value of fee units is prescribed in legislation. From 1 July 2025 to 30 June 2026, one fee unit equals $1.096 (see section 2 of *Acts Interpretation (Fee Unit) Regulation 2022*). Unless otherwise specified, all fee costs stated in this IAS reflect dollar amounts calculated using this fee unit value.

Licence application and licence issue fees

The licensing framework requires a person or entity to apply for a licence for each Queensland pharmacy business that is owned, or proposed to be owned, by the person or entity. The relevant tiered application fee (for either a new application, annual renewal or restoration application) will be payable on application. Table 2 below outlines the relevant application fees payable from 1 July 2025 to 30 June 2026, by tier.

Table 2: Pharmacy Business Ownership Fee Framework – Application Fees by Tier

Application Fees	**Tier 1**	**Tier 2**	**Tier 3**
New licence	$2,274.69	$2,584.92	$3,308.66
Annual renewal	$1,757.71	$1,964.53	$2,584.92
Restoration of licence (after expiry)	$1,861.12	$2,067.93	$2,688.32

Fees will also be payable if an inspection of the premises, and/or a review of a written contract, agreement or arrangement relating to a pharmacy business, is required to decide an application. The Council may appoint an appropriately qualified person to review the document to determine if it contains a provision that is void because it purports to authorise or permit a prohibited form of external control under section 22(1) of the Act. On approval of the licence, a single licence fee ($413.58) will be payable.

The variability in application fee costs across application types and tiers reflects the relative regulatory effort required to assess and decide the application. Each licence application will be comprehensively assessed by the Council against the criteria for eligibility to own a pharmacy business. These criteria include:

- whether the applicant(s) are eligible to own a pharmacy business in Queensland; and
  - whether they are 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* (Cth); and
  - if the person is a qualified pharmacist, information about their professional registration and any conditions placed on their registration;
- whether the person has previously held a pharmacy business licence in Queensland, had any conditions placed on their licence, or had a licence cancelled or suspended;
- whether the premises for the pharmacy business meets the requirements for an 'authorised premises';
- whether there is sufficient evidence to demonstrate compliance with legislated pharmacy ownership requirements, such as not having an interest in more than the permitted number of pharmacies, and not being in a commercial arrangement that allows an external party to exercise inappropriate control over the pharmacy business; and

- any other matter the Council considers relevant to determining whether the person is a fit and proper person to carry on a pharmacy business.

The licensing framework also provides for the Council to charge a fee when a material change is required to a licence, including adding a new person to a licence ($930.56), removing a person from a licence ($516.98), removing a material interest holder or director from a licence ($516.98); change of licenced premises ($672.07), and changing of other stated detail on the licence ($413.58).

Fee for inspection of premises

The licensing framework provides for the Council to charge a fee for conducting an inspection of a pharmacy business premises. This fee ($930.56) will apply only to inspections undertaken for the purpose of enabling the Council to decide an application for a pharmacy business licence or an application for a change of premises. It will not apply to other inspection activity that may be undertaken by Council inspectors to monitor and enforce compliance with the Act.

Premises inspections may be attended by two Council inspectors, based on assessment of risk. This is consistent with Department of Health policy regarding the attendance at business premises of persons authorised under the *Public Health Act 2005* to monitor and enforce compliance under that Act. The inspection fee reflects this increased labour and associated costs.

Fee for external assessment of a contract, agreement or arrangement

In response to feedback from pharmacy business owners and the Pharmacy Guild of Australia (Queensland) during the development of the Act, the Council will take a proactive approach to considering whether commercial agreements of pharmacy business owners allow for external control. The licensing framework provides for the Council to charge a fee to facilitate an appropriately qualified person (e.g. a lawyer) to independently review a document evidencing a contract, agreement or arrangement relating to a licensed pharmacy business. This review forms part of the Council's determination about whether a person is a fit and proper person to hold a pharmacy business licence by assisting the Council to determine whether the document contains a provision to which section 22(3) of the Act applies. The fee ($2,584.92) reflects the cost of the Council engaging the services of an appropriately qualified person to undertake the review and write the report.

Premises Standards

Premises standards do not form part of the regulatory framework of the 2001 Act. As such, there are currently no regulatory requirements within the pharmacy business ownership framework in Queensland that cover the entirety of a pharmacy premises. Rather, there are limited premises requirements and/or premises-related obligations dispersed across multiple regulatory or non-regulatory instruments including, for example:

- the *Medicines and Poisons Act 2019* (MP Act), which contains the risk management system for regulated substances, including scheduled medicines, and regulates matters such as dispensing, storing, labelling and securing medicines;
- the *Extended Practice Authority 'Pharmacists'*, issued under the MP Act, which states the scope of regulated activities (e.g. immunisations, prescribing hormonal contraceptives) that a pharmacist is authorised to carry out with specified regulated substances;
- *Work Health and Safety Act 2011* (Qld) (WHS Act), which has the primary duty of care obligation to provide a safe work environment, and a further duty of persons conducting a business to ensure, so far as is reasonably practicable, that the means of entering and exiting the workplace and anything arising from the workplace are without risks to the health and safety of any person;
- the Pharmacy Board of Australia Codes, Guidelines and Policies, which provide guidance to the pharmacy profession a range of matters, including professional behaviour and the prescribing and dispensing of medicines;
- the Pharmaceutical Society of Australia (PSA) *Professional Practice Standards*, which outline the minimum performance expectations of pharmacists in Australia, and *Australian Pharmaceutical Formulary*, a mandated essential reference that pharmacists must be able to access when reviewing, dispensing, providing advice and during clinical assessments; and

- the *Quality Care Pharmacy Program*, a voluntary quality assurance scheme which accredits pharmacies against the Australian Standard *AS 85000:2017 Quality Care Pharmacy Standard*.

The proposed Premises Standards will operate as a consolidated framework that accommodates existing requirements and addresses any regulatory gaps.

Under the Act, a pharmacy business premises will not be able to be licenced unless it is an 'authorised premises' as defined by section 11(1) of the Act. Under this option, the proposed Premises Standards prescribe minimum standards that a pharmacy business premises must meet in order to be deemed an 'authorised premises'.

The Premises Standards aim to ensure that that the following are not compromised:

- the standard of pharmacy services provided at the premises;
- the safety and comfort of persons at the premises (including staff and customers);
- the integrity and security of medicines kept at the premises;
- hygiene and infection control;
- the comfort, privacy and confidentiality of customers receiving consultations; and
- the physical security of the premises, especially the dispensary.

To achieve these aims, the Premises Standards prescribe requirements relating to the following general matters:

- prohibited premises types (caravans and vehicles);
- design and fit-out of the pharmacy, dispensary and consultation area;
- lighting, ventilation and temperature control;
- cleanliness, organisation and physical security of the premises, and
- licence information that must be on display to customers.

The proposed Premises Standards are outlined in Attachment 2. In summary, pharmacy business premises must:

- be, or be part of, a building or other structure and must not, for example, be a caravan or vehicle;
- be appropriately lit, temperature controlled and ventilated;
- be appropriately organised and uncluttered;
- be clean and hygienic, and have appropriate measures in place to minimise the risk of contamination and infection;
- have a sink;
- have a dispensary that is of appropriate size and design and is constructed to minimise the risk of unauthorised entry to the dispensary, and that has the equipment necessary for dispensing, including a refrigerator dedicated to storing medicines;
- have an area for conducting private consultations that is separate from the dispensary, is of appropriate size and design to ensure privacy and not compromise the standard of the consultation, and has the equipment necessary for the consultation;
- be constructed in a way that minimises the risk of unauthorised entry to the premises;
- have each means of access secured to minimise risk of unauthorised access and have equipment that detects unauthorised access to the premises; and
- display the name of the licence holders and, if the authorised pharmacist is not a licence holder, display the name of the authorised pharmacist.

The provision of pharmacy services is a dynamic and rapidly evolving environment with a range of practice settings and a continually evolving scope of practice, such as immunisations and prescribing authorisation for certain acute conditions. What is required from pharmacy premises will evolve as the scope of practice evolves. The regulatory framework therefore needs to be sufficiently flexible in response. In this context, the Premises Standards in the proposed Regulation are designed to:

- establish a baseline of minimum essential standards required to ensure:
  - pharmacy premises in Queensland are appropriately structured, maintained and equipped to support the professional, safe and competent provision of pharmacy services to the community; and
  - pharmacy business can be appropriately and efficiently regulated by the Council;
- provide a targeted, proportionate and flexible regulatory response to risk, consistent with regulatory best practice;
- minimise regulatory complexity for pharmacy business owners and the Council, particularly given that it is a new regulatory environment;
- be readily applied in all pharmacy settings irrespective of size of premises, scope of pharmacy services provided, or geographic location;
- be responsive to continually evolving pharmacy scope of practice requirements; and
- be outcomes focused, rather than prescriptive, thereby providing pharmacy business owners with the flexibility to consider how best to meet the standards given the scope of services they provide.

Option 2b: Make a Regulation under the Act prescribing fees, and Premises Standards with applicability/exemptions based on specific criteria.

Under this option, the proposed fee structure and general matters covered by the proposed Premises Standards, would be the same as for Option 2a. However, this option would involve, where feasible, applying specific requirements to certain categories of premises, or conversely, exempting certain categories of premises from specific requirements. Premises could potentially be categorised by size, scope of services provided, or geographical location. Hypothetical examples illustrating how this option might operate in practical terms are outlined below:

- requiring pharmacies that provide high/higher risk services to have an external risk assessment report;
- requiring pharmacies that provide certain services to have a fully-enclosed room for private consultations; or
- exempting smaller premises with space constraints from certain requirements.

This option is not recommended as this regulatory approach would have potentially more adverse impacts arising from the Premises Standards than Option 2a. This issue is discussed in greater detail below.

What are the impacts?

This section considers the impacts of Option 2a and Option 2b.

Option 2a: Make a Regulation prescribing fees, and Premises Standards applicable to all pharmacy businesses

Benefits

Regulation of pharmacy business ownership is critical to the delivery of professional, safe and competent pharmacy services by pharmacy businesses and maintaining community confidence in the pharmacy profession. By enabling full implementation of the new regulatory framework provided by the Act, the Premises Standards and fees prescribed in the proposed Regulation will ensure that the purposes of the Act can be achieved.

The Premises Standards in the proposed Regulation are consistent with jurisdictional best practice and will form a key part of the Council's risk-based compliance and enforcement framework. The Premises Standards will benefit pharmacy owners, pharmacy employees and the community by ensuring:

- pharmacies are appropriately structured, maintained and equipped to support the delivery of safe and professional pharmacy services;
- pharmacy business owners have clarity and visibility regarding their obligations under the Act with respect to the minimum standards that must be met by their pharmacy premises;
- the Council is regulating the pharmacy industry in Queensland in a consistent, transparent and equitable manner, according to specified requirements; and

- Queensland's regulatory approach achieves greater consistency with most other Australian jurisdictions.

Without the Premises Standards, some Queensland pharmacy premises may not meet minimum standards and operate sub-optimally. This would create safety risks to pharmacy employees and customers, and potentially jeopardise community confidence in the pharmacy industry. Further, without the Premises Standards, the Council will not have a robust tool within its compliance and enforcement framework for objectively determining whether pharmacy premises meet the appropriate standards for the delivery of their pharmacy services. Without such a tool, compliance monitoring and enforcement is likely to be more complex, resource intensive and inefficient.

As previously discussed, it is intended that the Council will be self-funded, with the Council's operating, regulatory and compliance costs funded through revenue from the prescribed fees. This will benefit pharmacy owners, pharmacy employees and the community by enabling the Council to:

- deliver robust and transparent regulation of pharmacy business ownership in Queensland, including strengthened compliance reporting, monitoring and enforcement activities; and
- support pharmacy business owners to achieve, and maintain, compliance with the Act, through education and awareness activities.

The benefits of a tiered fee model are that it provides a system that:

- supports the level of regulatory attention and oversight required for the different levels of ownership complexity across the sector; and
- ensures a more equitable distribution of the compliance burden, as pharmacy owners will incur fee costs relative the level of oversight required to regulate them.

Compliance costs

Community

There are no direct costs to the community. However, there may be some indirect impacts. As with other business costs, such as leasing and electricity, pharmacy business owners may elect to pass on the costs of compliance to their customers. Since any such decision would be at the discretion of the individual owner(s) of a pharmacy business, the potential indirect community impacts cannot be readily quantified. Nevertheless, it is anticipated that the compliance costs to industry will not result in significant or disproportionate indirect impacts for the community, such as a reduction or withdrawal of services in rural or remote communities, as:

- the tiered licensing fees framework means that owners with less complex structures, such as sole traders, will pay less than more complex ownership structures;
- compliance costs associated with the Premises Standards are not anticipated to be significant; and
- no existing services will be impacted by caravans and vehicles being prohibited as pharmacy premises.

Government

There will be initial costs to Government. The Government has allocated $9.841 million over four years to 2026-27 to establish the Council and implement the licensing framework. Initially, costs associated with regulating the Premises Standards and administering the fee framework will be subsidised from within these existing resources. From 2027-28 onward, it is intended that there will be no cost to Government as the Council will be self-funded with revenue from the prescribed fees.

Industry

There will be costs to the pharmacy industry. With respect to licence fees, until the licensing scheme is implemented, Queensland Health will not have valid data on the percentage of pharmacies that will be captured under each Tier. Using data collected under the 2001 Act and applied to the proposed fee structure, it is estimated that 49 per cent may be categorised as Tier 1 (and hence pay the lowest application fees), 34 per cent as Tier 2 and 17 per cent as Tier 3. However, compared to the 2001 Act, the Act makes a greater distinction between 'owning' a pharmacy business and holding a lesser 'material interest' in a pharmacy business. This difference may affect the accuracy of these estimates.

Table 3 below illustrates the minimum and maximum total fee costs that would be incurred by a Tier 1 applicant under two licensing scenarios:

- an initial application for a new pharmacy business ownership licence (scenario 1), made between 1 November 2025 and 30 June 2026; and
- an annual licence renewal (scenario 2), made between 1 July 2026 and 30 June 2027.

The minimum total assumes no premises inspection or legal review of a written contract, agreement or arrangement is required. The maximum total assumes both are required. Annual renewal costs reflect the prescribed fee unit value of $1.133 in force from 1 July 2026 to 30 June 2027.

Table 3: Pharmacy Business Ownership Fee Framework – Licence Fee Scenarios

Fee	**Scenario 1** (new application)	**Scenario 2** (annual renewal)
Application fee	$2,274.69	$1,817.05
Licence fee	$413.58	$427.54
TOTAL (minimum)	**$2,688.27**	**$2,244.59**
Inspection fee (if required)	$930.56	$961.97
Legal review of written contract, agreement or arrangement (if required)	$2,584.92	$2,672.18
TOTAL (maximum)	**$6,203.75**	**$5,878.74**

Aside from prescribed fees, pharmacy business owners will incur costs associated with cooperating with Council premises inspections and undertaking any required follow-up actions post-inspection. Some pharmacy owners may also, if required, incur costs associated with adapting physical premises and/or equipment to comply with the proposed Premises Standards. However, while the Premises Standards represent a new regulatory standard for pharmacy business owners, the cost of compliance is not expected to be onerous or impose a significant burden. This is because most premises are likely to already be operating in compliance with these minimum requirements, given existing regulatory and non-regulatory obligations.

Further, in February 2025, stakeholders, including pharmacy business owners, were invited to provide feedback on the practicality of the Premises Standards across all practice settings (e.g. metropolitan/regional/rural), any anticipated barriers or unintended consequences, any additional premises requirements that should be included, and the types of guidance/supporting materials or resources that would assist them with meeting the requirements. No respondents raised concerns in their submission that the Premises Standards requirements would have a significant impact on their business.

A partial estimate of the regulatory compliance burden for the pharmacy industry has been calculated using the Queensland Treasury simplified direct costs calculator tool. This calculation reflects estimated costs associated with premises inspections only, as the variation in, and scope of, products and/or services that some pharmacies may be required to purchase for premises upgrades prevents accurate estimation of an average cost per pharmacy for this activity.

The assumptions in the calculation were informed by consultation and research and/or knowledge of the pharmacy industry. An indicative labour cost assumption of $50 per person per hour has been used. This labour cost reflects the weighted average of hourly rates for different pharmacy business staff (e.g. pharmacist, senior pharmacy assistant) performing the same activity. It is important to note that there is large variation in the size, location and pharmacy services of pharmacy businesses. This makes it very difficult to accurately quantify the compliance impacts and direct costs using a labour price assumption, which may impact the accuracy and validity of the compliance burden estimates. Additionally, the detail of the premises inspection program will be a decision for the Council once the licensing scheme becomes

operational from November 2025. However, it is anticipated that premises will be subject to a risk-based schedule of periodic Council inspection.

For the purpose of this IAS, the compliance burden has been costed using the assumption that a pharmacy premises will be inspected on average once every three years, as is the case in Victoria, with two pharmacy staff each spending three hours undertaking pre-inspection preparation (e.g. self-audits), assisting the Council inspectors and undertaking any required follow-up action. The estimated compliance burden associated with premises inspections is anticipated to be $265,800 in the first year and $1,131,674 over the first ten years.

The language of the Regulation

As discussed previously, the Premises Standards have been drafted in an outcomes-focused and less prescriptive manner to ensure that they can be met in a variety of practice settings and retain sufficient flexibility to be responsive to ongoing changes in scope of practice. As such, the language of the proposed Regulation is open-ended and/or not distinctly defined. For example, use of terms and concepts such as 'appropriate measures', 'appropriate size and design', 'an area for conducting private consultations that is separate from the dispensary', 'appropriately organised and uncluttered" and 'all other necessary equipment'.

However, with this less-prescriptive approach comes a greater risk of adverse impacts for pharmacy business owners arising from uncertainty regarding their obligations, and the potential for conflicting interpretations of the requirements between owners and the Council. For example, the requirement for 'an area for conducting private consultations that is separate from the dispensary', could be narrowly interpreted as requiring all pharmacies to have a separate fully enclosed private and confidential consultation room, when this is not the policy intent. There is a risk that this could result in some business owners undertaking unnecessary and potentially costly renovations of their premises. Alternately, a pharmacy business owner will be significantly adversely impacted if uncertainty regarding their obligations results in them being denied a licence due to non-compliance with the Premises Standards.

To mitigate these risks, the Council will issue supplementary guidance material, that provides further detailed advice regarding the Premises Standards requirements, to ensure clarity regarding their rationale and intent, and how they may be met in practice. In addition, the Council will provide compliance support tools such as audit checklists to enable business owners to self-assess their compliance readiness and identify any required actions; and will undertake significant communication and engagement with business owners regarding the Premises Standards requirements. Further, the Act provides for affected persons to seek a review of an original decision made by the Council. This will provide an additional safeguard for pharmacy business owners in the unlikely event that a conflicting interpretation of specific premises requirements between the owner and the Council results in a decision not to grant them a licence.

Competition impacts and consistency with other policies and legislation

Competition Principles Agreement

Clause 5(1) of the Competition Principles Agreement (CPA), requires that legislation should not restrict competition unless it can be demonstrated that:

(a) the benefits of the restriction to the community as a whole outweigh the costs; and

(b) the objective of the legislation can only be achieved by restricting competition.

The prescribed fees and Premises Standards requirements contained in the proposed Regulation have been assessed for potential competition impacts, against the Organisation for Economic Co-operation and Development competition checklist set out in the Better Regulation Policy. Based on this assessment, it has been determined that the proposed Regulation will not:

- restrict or reduce the number or range of pharmacy businesses in Queensland;
- restrict or reduce the ability of pharmacy businesses to compete in the market, or their incentive to do so; or
- limit the choice or information available to consumers.

As such, the proposed Regulation has no competition impacts and is consistent with clause 5(1) of the CPA.

Consistency with other policies and legislation

No inconsistencies between the proposed Regulation with other policies and legislation relevant to pharmacy premises have been identified.

Jurisdictional comparison

Pharmacy business ownership is regulated in all Australian jurisdictions. However, in relation to compliance and enforcement models, licensing/registration requirements and fee structures, this regulation may differ greatly across jurisdictions. As such, it is not possible to produce a meaningful like-for-like jurisdictional comparison of fees.

Attachment 3 shows baseline fees applicable for new pharmacy business licences and annual renewals for all Australian jurisdictions, other than the Northern Territory which does not charge fees. The attachment shows that Queensland's licence application fees are higher than other jurisdictions, while its annual licence fee is comparable to, and in some cases less than, other jurisdictions. Queensland's fee structure reflects the costs of delivering a contemporary regulatory framework, underpinned by a rigorous and proactive compliance and enforcement model, by an independent statutory body, in a large and decentralised state.

Queensland has a widely dispersed population. This includes rural and remote communities, many of which have a pharmacy business. The time and cost involved in travelling to these businesses is far higher than for other jurisdictions. For example, Victoria is geographically smaller and has a population that is much more geographically contained and urban.

The requirement, based on risk assessment, for potentially two inspectors to inspect premises will add to the cost of compliance. Also, the Council's regulation of pharmacy business ownership is intended to be proactive, which will add to the regulatory costs. For example, it will include compliance checks on renewal applications and educational activities.

Premises standards form part of the legislative framework for regulating pharmacy business ownership in most Australian jurisdictions. The Premises Standards in the proposed Regulation are consistent with best practice and the requirements in other Australian jurisdictions, however, Queensland's proposed approach is less prescriptive than some. For example:

- with respect to security, the Victorian standard requires a premises to be fitted with a functional 24-hour monitored intrusion detector alarm which is monitored by an appropriately graded monitoring centre or an on-site security service approved by the regulator in special circumstances; whereas Queensland's proposed Premises Standards simply requires that the premises must have equipment that detects unauthorised access; and
- with respect to the size of the dispensing area, the New South Wales standard requires that it must be of at least $8m^2$, or such lesser area as the regulator may approve in a particular case, and have a bench that is at least 40cm wide and of sufficient length to provide not less than $1m^2$ of free working space; whereas Queensland's proposed Premises Standards simply requires that the dispensary be of appropriate size and design to ensure the standard of dispensing medicines, and tasks associated with the dispensing of medicines, are not compromised.

Option 2b: Make a Regulation under the Act prescribing fees, and Premises Standards with applicability/exemptions based on specific criteria.

As the fees element of Option 2b is identical to Option 2a, the fee-related impacts (both benefits and costs) identified above for Option 2a will also be applicable to Option 2b.

With respect to the Premises Standards, the approach taken in Option 2b would likely result in significantly more adverse impacts than Option 2a. Rather than applying a uniform set of minimum requirements to all pharmacy premises (the one-size-fits all approach) as for Option 2a, Option 2b would, where feasible, apply specific requirements to certain categories of premises, or conversely, exempt certain categories of premises from specific requirements.

Implementation of Option 2b would involve a more complex regulatory approach, requiring:

- multiple individual standards to address distinct operational risks and/or specialised needs (e.g. immunisation services, complex compounding, smaller premises in rural and remote locations), and
- robust categorisation of pharmacy premises having regard to a complex matrix of characteristics and variables (size of premises, scope of service, and geographical location).

As such, if implemented Option 2b would be likely to result in the following significant adverse impacts:

- increased confusion and uncertainty for pharmacy business owners, due to a lack of uniform expectations and compliance requirements;
- increased costs of regulation, which would ultimately be borne by industry, as a regulatory framework comprising multiple standards and exemption options would be:
  - more difficult and costly for the Council to monitor and enforce than a one-size-fits-all framework, and
  - more administratively burdensome and costly for pharmacy business owners with multiple premises captured under different premises categories, who may need to navigate multiple compliance requirements;
- the complex regulatory framework lacking sufficient flexibility to respond as the scope of pharmacy practice evolves; and
- increased risks of duplication and/or inconsistency with other legislation and policies relevant to pharmacy premises, including regulatory approaches in other jurisdictions.

Who was consulted?

The new regulatory framework for pharmacy business ownership has been informed by comprehensive consultation with key stakeholders. These include pharmacy business owners and interest holders, and industry representative bodies such as the Pharmacy Guild of Australia (Queensland) and the Pharmaceutical Society of Australia.

In July 2020, Queensland Health released a Consultation RIS. This was to assess the impacts of options arising from the Queensland Government response to the then Health, Communities, Disability Services and Domestic and Family Violence Committee *Report No. 12 – Inquiry into the establishment of a pharmacy council and transfer of pharmacy ownership in Queensland*. The Consultation RIS considered options relating to the monitoring and enforcement of pharmacy ownership, establishment of a council and fee structures.

In October 2022, a consultation paper, an initial consultation draft of the Pharmacy Business Ownership Bill (Bill), and an indicative fee list were sent to stakeholders. These included industry representative bodies and pharmacy business owners and interest holders. Over 450 responses were received. In February 2023, a further consultation draft of the Bill and associated consultation paper were sent to stakeholders, with over 350 responses received.

Most pharmacy owners who provided feedback on the draft Bills, and the Pharmacy Guild of Australia (Queensland) as the representative body for pharmacy business owners, strongly advocated for the establishment of an independent regulatory council to regulate community pharmacy ownership in Queensland. Many indicated a willingness to pay reasonable licensing fees to support this increased enforcement and noted that fees needed to be calculated relative to the powers and capabilities of the Council to enforce compliance with the legislation.

In February 2025, a consultation package comprising a consultation paper and consultation draft of the proposed Regulation were publicly released for consultation via the Queensland Health website. The consultation package was also provided directly to over 1,300 stakeholders with a direct interest in the Regulation and/or who provided input into the development of the Act, including:

- pharmacy business owners;

- pharmacy management groups and franchisors;
- industry stakeholders (e.g. accounts and lawyers representing pharmacy business owners)
- Pharmacy Guild of Australia (Queensland);
- Pharmaceutical Society of Australia;
- Australian Health Practitioner Regulation Authority;
- medical and nursing peak bodies (Australian Medical Association (Queensland), Royal Australian College of General Practitioners (Queensland), and Queensland Nurses and Midwives' Union);
- allied health peak bodies; and
- Health Consumers Queensland.

With respect to the Premises Standards, stakeholders were invited to provide feedback on the practicality of the standards across all practice settings (e.g. metropolitan/regional/rural), any anticipated barriers or unintended consequences, any additional premises requirements that should be included, and the types of guidance/supporting materials or resources that would assist them with meeting the requirements. With respect to fees, stakeholders were provided with high-level background information regarding previous consultation undertaken on fee structure (2020 Consultation RIS), the fee model (cost-recovery), fee structure (tiered fees) and the proposed fees expressed in both fee units and dollar amounts calculated using the relevant fee unit value in force at the time. Stakeholders were also advised that the fees would be subject to annual indexation.

In response, 16 in-scope submissions were received, with most of the feedback relating to the Premises Standards. Many respondents supported the intent of the requirements and broadly found the requirements practicable and reasonable to meet. Some raised concerns regarding the practicality of certain requirements such as: compliance with AS 2201 for electronic security and alarm systems, lighting and temperature control, and privacy requirements for consultation areas, in some settings. In this context, many respondents raised the importance of having access to additional guidance from the Council to support pharmacy business owners to meet their compliance obligations. No respondents raised concerns that the Premises Standards would have a significant impact on their business.

Three submissions included comment on the proposed fees. One respondent supported the proposed tiered approach and the differentiation between levels of ownership complexity. One respondent had concerns that the proposed fees in Queensland are higher than other jurisdictions. One respondent submitted that the proposed fees should be the absolute minimum required to fund the administration of the licensing scheme as the application and licensing fees are new and additional costs of doing business.

Feedback provided in the submissions was carefully considered and, where appropriate, has been reflected in changes to the proposed Premises Standards. For example, the requirements relating to premises security no longer prescribe compliance with AS 2201. Rather, they are now outcomes focused to enable pharmacy owners to implement a compliant solution having regard to their operational model, premises type, and the products and services available in their location. The feedback will also inform the development of guidance material to provide further detail on particular requirements.

The Council has been actively engaged in the development of the proposed Premises Standards. On 11 June 2025, the Council considered the final version of the proposed Premises Standards and advised the Minister for Health and Ambulance Services of its support for them to be prescribed.

What is the recommended option and why?

Option 2a is the recommended option as it generates the greatest net benefit, having regard to the overall anticipated costs and benefits to the community, government and industry, and the objectives of Government action with respect to this regulatory proposal.

The Regulation is necessary to meet the ensure successful implementation of the Act. The fees paid by pharmacy owners to hold a pharmacy business licence will provide funding for the Council's regulatory functions and ensure that the regulatory cost burden is not borne by the community. The requirement for pharmacy business premises to meet prescribed Premises Standards will help to ensure the provision of

professional, safe and competent provision of pharmacy services, and efficient regulation of pharmacy businesses. Together, these requirements will contribute to greater community confidence in pharmacy businesses.

When compared to Option 2b, Option 2a will deliver a streamlined, agile and cost-efficient framework for regulating pharmacy business ownership in Queensland and ensure that regulation and enforcement of pharmacy business ownership can be undertaken by the Council in a simple, consistent, efficient and transparent manner in accordance with best practice. This is particularly important given that the regulatory environment involves both a new regulatory framework and a new regulator.

Implementation, evaluation and compliance support

In 2024, a temporary project team was established in Queensland Health to commence implementing the Act, including facilitating the establishment of the Council, coordinating the transfer of functions and resources to the Council, facilitating an ICT solution for the licensing function, developing required subordinate legislation, and undertaking ongoing communications and engagement with pharmacy business owners and other key stakeholders.

On commencement of the Act in full in November 2025, implementation responsibility will transfer from Queensland Health to the Council.

The Council will monitor and evaluate the scheme on an ongoing basis to support continuous improvement and the delivery of regulatory best practice. The Council will develop and publish a risk-based regulatory approach to compliance and auditing, with annual review.

Transitional provisions in the Act provide existing pharmacy business owners between one to two years in which to apply for a licence once the Act commences in full. Application and compliance support for pharmacy business owners will be provided through communication and engagement activities (e.g. webinars, newsletters, email communications), and the development of formal guidance material containing detailed advice on key compliance requirements (e.g. Premises Standards) and other compliance tools such as self-audit checklists.

Impact assessment

	First full year	First 10 years
Direct costs – *Compliance costs** **(pharmacy businesses)**	**$265,800***	**$1,131,674***
Direct costs – *Government costs*	**Managed within existing resources.**	**Managed within existing resources to 2026-27.**

*This figure reflects the estimated compliance costs for industry relating to the conduct of premises inspections only, as other potential compliance costs to industry associated with implementation of the Premises Standards, such as upgrades to premises and equipment, cannot be readily estimated.

Dr David Rosengren
Director-General
Queensland Health

Date: 5/09/2025

Timothy Nicholls MP
Minister for Health and Ambulance Services

Date: 13 Sept 2025