Pharmacy Business Ownership Regulation 2025

Explanatory notes for SL 2025 No. 131
made under the

Pharmacy Business Ownership Act 2024

General Outline

Short title

Pharmacy Business Ownership Regulation 2025

Authorising law

Sections 11 and 212 of the *Pharmacy Business Ownership Act 2024*

Policy objectives and the reasons for them

On 28 March 2024, the *Pharmacy Business Ownership Act 2024* (Act) received Royal Assent. The Act establishes a new licensing scheme for Queensland pharmacy businesses. Its purpose is 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, among other things:

- establishes the Queensland Pharmacy Business Ownership Council (Council) as a statutory body responsible for regulating pharmacy business ownership in Queensland;
- establishes a licensing scheme for the ownership of, and interests in, pharmacy businesses;
- clarifies who may own or hold an interest in a pharmacy business; and
- limits the number of pharmacy businesses that a person may own or hold an interest in.

When the licensing scheme commences, responsibility for regulating pharmacy business ownership will transition from Queensland Health to the Council. Section 2 of the Act provides that the Act commences on a day to be fixed by Proclamation. To support the operational implementation of the Act, the commencement of provisions of the Act have been staggered.

On 1 September 2024, the first Proclamation commenced the provisions of the Act that were necessary for the Council to start performing its non-licensing functions (SL No. 193 of 2024).

On 16 June 2025, the second Proclamation commenced the provisions of the Act relating to the Council's chief executive officer and Council staff (SL No. 29 of 2025).

On 1 November 2025, a third and final Proclamation will commence the remaining provisions of the Act. This includes the provisions in relation to ownership and material interests, licensing, investigation and enforcement, review of decisions, and transitional and miscellaneous provisions. The *Pharmacy Business Ownership Regulation 2025* (Regulation) will commence on the same day.

Section 28(b) of the Act provides that a pharmacy business licence may only be granted if the premises for the pharmacy business are authorised premises. Section 11(1)(b) of the Act provides that pharmacy business premises are only 'authorised premises' if they meet the standards prescribed by regulation (Premises Standards). Under section 11(2) of the Act, the Minister may recommend the making of a regulation prescribing the Premises Standards only after receiving advice from the Council.

Section 212 of the Act provides general regulation-making powers. This includes a specific power to make a regulation prescribing the fees payable under the Act.

The objective of the Regulation is to prescribe the Premises Standards and the fees payable under the Act. This will ensure that when the new licensing scheme commences, the regulatory requirements needed to support the scheme are in place.

Achievement of policy objectives

Schedule 1 of the Regulation prescribes the Premises Standards. The Premises Standards set the minimum standards that all pharmacy business premises must meet, including general requirements, security, pharmacy design, equipment for pharmacy services and the information required to be displayed.

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 Premises Standards in the 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 businesses 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.

Schedule 2 of the Regulation prescribes the fees payable under the new licensing scheme. These include application and licence fees, fees for inspection of premises and fees for a reviewer to review a document and prepare a report for the Council.

Consistency with policy objectives of authorising law

The Regulation is consistent with the policy objectives of the Act.

Inconsistency with policy objectives of other legislation

No inconsistencies with the policy objectives of other legislation have been identified.

Alternative ways of achieving policy objectives

No alternative ways of achieving the policy objectives have been identified. The Regulation is the only effective means of achieving the policy objectives. Certain elements of the new licensing scheme must be prescribed in regulation and be in force when the Act commences in full. This is necessary to enable the Council and pharmacy business owners to discharge their obligations 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’. Section 11 of the Act provides that premises are ‘authorised’ if they (a) are not located in, or directly accessible from, a supermarket, and (b) meet the standards prescribed by regulation. Under section 25(1)(c) of the Act, when applying for a pharmacy business licence, an applicant must pay the relevant application fee prescribed by regulation.

Accordingly, full implementation of the regulatory framework cannot be achieved by the Act alone. The Premises Standards and fees payable for relevant matters under the licensing scheme must be prescribed by regulation.

Benefits and costs of implementation

The Premises Standards and licensing fees are integral to ensuring the professional, safe and competent provision of pharmacy services to the community and the efficient regulation of pharmacy business ownership.

The Premises Standards will form a key part of the Council's risk-based compliance and enforcement framework. This 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.

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. The proposed licence application fees are structured as 'tiered fees', where higher fees apply to pharmacies with more complex ownership structures. This recognises the higher cost of evaluating more complex structures against the requirements of the Act. Schedule 2 of the Regulation sets out a three-tier structure, with Tier 1 relating to the least complex ownership structures, up to Tier 3 relating to the most complex ownership structures.

A tiered fee model supports the level of regulatory attention and oversight required for the different levels of ownership complexity across the sector. It 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.

There are no direct costs to the community associated with the proposed Regulation. However, implementation costs are anticipated for Government and pharmacy businesses.

To establish the Council and implement the licensing scheme, the Government has allocated $9.841 million over four years to 2026-27. Initially, the 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.

Some pharmacy owners may incur costs to comply with the Premises Standards. These costs may include upgrading security arrangements, ensuring equipment is fit for purpose, participating in monitoring and enforcement audits undertaken by the Council, and adapting physical premises and/or equipment, as required.

However, the Premises Standards only set the minimum baseline requirements. Pharmacy businesses are already subject to a range of regulatory and non-regulatory premises requirements, including requirements under the *Medicines and Poisons Act 2019* and the Quality Care Pharmacy Program. The requirements in the Premises Standards consolidate and complement these existing requirements. As such, it is expected that most pharmacy premises

will already meet the requirements in the Premises Standards. This means that the Premises Standards are not anticipated to have a significant impact on pharmacy businesses.

Pharmacy business owners will also incur the costs of new licensing fees. In line with Queensland Government policy, the fees are calculated on a cost-recovery basis and are subject to annual indexation.

It is estimated that approximately half of pharmacy businesses may be categorised as Tier 1. For an initial application for a new Tier 1 pharmacy business ownership licence made between 1 November 2025 and 30 June 2026, the minimum cost will be $2,688.27. This reflects the combined costs of the licence application fee and the licence fee itself. If a premises inspection and a legal review of a written contract, agreement or arrangement are also required, the total combined cost would be $6,203.75.

For a Tier 1 pharmacy business licence that is renewed between 1 July 2026 and 30 June 2027, the minimum cost will be $2,244.59. This reflects the combined costs of the licence renewal application fee and the licence fee itself. It also accounts for indexation from 1 July 2026 to 30 June 2027. If a premises inspection and a legal review of a written contract, agreement or arrangement are also required, the total combined cost, including indexation, would be $5,878.74.

Consistency with fundamental legislative principles

The Regulation is generally consistent with the fundamental legislative principles in section 4 of the *Legislative Standards Act 1992*. However, as outlined below, the Premises Standards and licensing fees may infringe upon the fundamental legislative principle that legislation should have sufficient regard to the rights and liberties of individuals (section 4(2)(a) of the Legislative Standards Act). Queensland Health considers that the Regulation is otherwise consistent with fundamental legislative principles.

For legislation to have sufficient regard to the rights and liberties of individuals, a person's right to liberty and freedom of movement and association should be protected as far as practicable. The list of examples in section 4(3) of the Legislative Standards Act is not exhaustive of the issues relevant to deciding whether legislation has sufficient regard to the rights and liberties of individuals. Additional considerations include whether the legislation infringes on individuals' rights to own property, including the right to not be arbitrarily deprived of the person's property.

Whether the legislation has sufficient regard to the rights and liberties of individuals (Legislative Standards Act 1992, s 4(2)(a))

Premises standards

Pharmacy owners may incur costs to comply with the Premises Standards, including costs to upgrade security arrangements, ensure equipment is fit for purpose and participate in monitoring and enforcement audits undertaken by the Council. Incurring these costs may deprive a pharmacy business owner of their property.

The Premises Standards will form a key part of the Council's risk-based compliance and enforcement framework. The Premises Standards are minimum baseline requirements. As

such, while the Premises Standards impose a new regulatory standard on pharmacy business owners, they are not expected to be onerous or impose a significant burden. This is because most premises are already likely to be operating in compliance with these minimum requirements, given other existing regulatory and non-regulatory obligations.

As the Premises Standards are critical to ensuring that the purposes of the Act are achieved, any deprivation of a person's property arising from the Premises Standards is not arbitrary. For this reason, any infringement on the fundamental legislative principle regarding individual rights and liberties is justified.

Licence fees

The licensing scheme requires a person or entity to pay certain fees to carry on a pharmacy business. This includes application and licence fees, fees for inspection of premises and fees for a reviewer to review a document and prepare a report for the Council. Schedule 2 of the Regulation sets out the licensing fee structure and prescribes the fees payable. Paying these fees may deprive a pharmacy business owner of their property.

The purpose of fees is to fund the costs of the new licensing scheme and the operations of the Council. Accordingly, the fees have been calculated on a cost-recovery basis.

As the fee amounts are not intended to operate as penalties or as barriers to entry to the industry and are a reasonable means to improve the regulation of pharmacy services in Queensland, any deprivation of a person's property arising from the licence fees is not arbitrary. For this reason, any infringement on the fundamental legislative principle regarding individual rights and liberties is justified.

Consultation

The new licensing scheme for pharmacy business ownership has been informed by comprehensive consultation with key stakeholders over several years.

In February 2025, a consultation draft of the Regulation was published on the Queensland Health website. It was also provided directly to over 1,300 stakeholders, including:

- pharmacy business owners;
- pharmacy management groups and franchisors;
- industry stakeholders (for example, accountants 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.

In response to the consultation draft of the Regulation, 16 in-scope submissions were received. Most of the feedback related 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. 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, given the application and licensing fees are new and additional costs of doing business.

Stakeholder feedback was carefully considered and, where appropriate, has been reflected in changes to the proposed Premises Standards. The feedback will also inform the development of guidance material to provide further detail on particular requirements.

The Council was consulted and supports the Premises Standards. Pursuant to section 11(2) of the Act, this advice was provided to the Minister for Health and Ambulance Services.

Queensland Health assessed the Regulation in accordance with the *Queensland Government Better Regulation Policy* and a Summary Impact Analysis Statement has been prepared. The Minister for Health and Ambulance Services and the Director-General of Queensland Health are satisfied that the regulatory review requirements have been met and have approved the Summary Impact Analysis Statement for publication.