

Pharmacy Business Ownership Bill 2023

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Committee Secretary
Economics and Governance Committee
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By email: egc@parliament.qld.gov.au

Dear Sir/Madam

Re: Committee inquiry into the Pharmacy Business Ownership Bill 2023 (Qld)

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I INTRODUCTION

The ownership of pharmacy businesses in Queensland has been regulated under the *Pharmacy Business Ownership Act 2001* (Qld). The current Bill proposes to repeal and replace the 2001 Act with a modern regulatory framework for pharmacy ownership. Any changes to the law as it relates to pharmacy ownership need to be considered in the context of the regulatory environment of the whole pharmacy profession.

The pharmacy profession is regulated via numerous pieces of State legislation, in addition to Commonwealth legislation. A brief summary of pertinent State legislation is provided for the benefit of the committee:

- The *Health Practitioner Regulation National Law Act 2009* (Qld) provides a National Scheme for regulating the registration and accreditation of health professionals including pharmacists. Queensland is the host jurisdiction for the National Law, which is contained in the schedule to that Act. Other jurisdictions—with the exception of Western Australia, which has enacted corresponding legislation—have adopted and applied the National Law as a law of that jurisdiction. A significant principle of the National Law is to protect the public.¹
- The *Medicines and Poisons Act 2019* (Qld) (‘MPA’) provides for the regulation of substances such as medicines and poisons to ensure that any activity performed using a substance occurs in a safe manner.² This includes ensuring that persons who carry out activities have sufficient competency to do so safely.³
- The *Pharmacy Business Ownership Act 2001* (Qld) provides for the regulation of ownership of pharmacy businesses.

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¹ *Health Practitioner Regulation National Law (Queensland)* s 3A(1)(a).

² *Medicines and Poisons Act 2019* (Qld) s 3(a).

³ *Ibid* s 3(c).

This context is important when considering the legislative changes proposed by the Bill.

II ACKNOWLEDGEMENT

The authors have relied on their own knowledge and experience as pharmacist proprietors in making this submission. The authors are also graduates of a law degree. The views expressed in this submission are the personal views of the authors. The authors wish to declare their membership with the Pharmacy Guild of Australia.

III COMMENTS ON THE BILL

A The main purposes of the Bill require clarification.

Clause 3(b) states that the main purpose of the Bill is to maintain confidence in the pharmacy profession. The authors note that this provision has been included in the Bill from the current 2001 Act.⁴ The 2001 ownership Act was drafted at a time prior to the introduction of the National Law and the *Medicines and Poisons Act 2019* (Qld). The authors wish to clarify whether cl 3(b) is appropriate in a law that regulates ownership, given the context of the regulatory framework discussed above. It is argued that confidence in the profession is maintained via protection of the public under the National Law, and the safe use of medicines and poisons under the MPA. Therefore, the purpose of a law which regulates ownership should be focused solely on the factors mentioned in cl 3(a): ‘to promote the safe and competent provision of pharmacy services by pharmacy businesses.’ The word ‘professional’ should also be removed from cl 3(a) as the professional aspect of regulating pharmacy occurs via the National Law.

B The definition of what is a pharmacy business and core pharmacy services

A pharmacy business is defined in cl 8 as a ‘business that provides pharmacy services in Queensland that include core pharmacy services.’ The term *pharmacy services* is not defined in the legislation. However, the explanatory notes for the Bill state that the term has a ‘common understanding’.⁵ The Bill instead provides a narrow definition for the term *core pharmacy services*. The explanatory notes state the reason for this is to distinguish between similar services provided by a pharmacy (which requires a licence under the Bill) and another business (that would not be expected to require a licence).

The authors believe that the definition of *core pharmacy services* is too narrow and does not adequately define what businesses are intended to be regulated under the framework. The definition focuses on the historical aspects of compounding and dispensing of medicines. However, pharmacy businesses have evolved to offer a broader range of services such as advice about medicines. The pace of evolution can be seen within the last decade, where prior to 2014 pharmacists could not administer vaccines. Fast forward to today and pharmacist administration of vaccines is an essential service provided by community pharmacy businesses. The upcoming *North Queensland Community Pharmacy Scope of Practice Pilot* will further change the core services provided by pharmacy businesses as pharmacists begin to prescribe medicines. Therefore, the proposed definition of *core pharmacy services* risks

⁴ *Pharmacy Business Ownership Act 2001* (Qld) s 8(1)(b).

⁵ Explanatory notes, Pharmacy Business Ownership Bill 2023 (Qld) 39.

not being flexible enough to support industry changes in the way a pharmacy business operates into the future. This means that the legislation will quickly become outdated, almost as soon as it receives assent.

Recommendations:

The authors suggest the following options:

- Adopt a broader definition of *core pharmacy services* by deleting the term and instead defining what is meant by the term *pharmacy services*:

pharmacy services means –

health services (including dispensing, supply, prescribing, selling, administering, repackaging, compounding, possessing, disposing of medicines and the provision of clinical service or advice (either at or from a licensed premises or through digital platforms)) provided in the course of practice by a pharmacist or a person who holds themselves out, or is held out by another, as a pharmacist.

- Provide greater flexibility to the definition of *core pharmacy services* by adding a new subclause 8(3)(c).

One method of providing flexibility would be to legislatively permit industry self-regulation. The reason for this approach is that those within the industry are best placed to know what types of businesses are considered a pharmacy business (and therefore require a licence). This will enable flexibility for the future evolution of pharmacy businesses without the legislation becoming outdated.

A new subclause (c) could be inserted into the definition of *core pharmacy services* as follows:

(c) a service that is widely accepted by a significant number of respected practitioners in the field of pharmacy, who are owners of a pharmacy business, as being a service offered by a pharmacy business.

Adopting this approach would allow flexibility for the Pharmacy Council to consult with pharmacy business owners regarding whether future services ought to fall within the regulatory framework.

C ‘Fit and proper person test’

Clause 72 provides for a ‘fit and proper person test’. This test is used by the Council as a criteria for numerous exercises of power, including: cl 28 granting a new licence; cl 35 deciding an application for renewal or restoration of a licence; cl 40 granting a change to a licence to add an additional licence holder; cl 53 adding or removing a material interest holder or director; and cl 66 cancelling a licence. Clause 76 also provides that a person must notify the Council of a change in circumstances relating to whether they are a fit and proper person.

1 The link between ownership and registration

The use of a ‘fit and proper test’ reintroduces a linkage between pharmacy business ownership and pharmacist registration. This linkage—between ownership and registration—was abandoned in 2010 with the introduction of the National Law. A ‘fit and proper person’ requirement already exists under the National Law in relation to a person holding general registration as a pharmacist. This means that a pharmacist intending to become an owner is unfairly subjected—on two occasions—to a character suitability assessment. The first instance occurs when they seek registration in the profession. The second instance occurs when they seek to become an owner of a business within their chosen profession. Therefore, the authors argue that the ‘fit and proper test’ should be removed from the Bill.

The explanatory notes attempt to justify the fit and proper person test. Reference is made to ensuring ‘individuals...have high levels of integrity and professionalism’ and to ‘protect the public’.⁶ As discussed, the functions of regulating professionalism and protecting the public fall within the National Law. Jurisdiction is conferred on the Australian Health Practitioner Regulation Authority (AHPRA) to carry out these functions. Therefore, it is not within the scope of a law regulating pharmacy business ownership to assess whether a prospective owner is a fit and proper professional. This supports the authors’ argument for removal of the fit and proper test.

If, however, it is intended to retain the fit and proper person test, the authors argue that a rebuttable presumption should be introduced. A presumption should be applied in favour of an applicant or licence holder, to deem them a fit and proper person if they hold general registration as a pharmacist.

2 Factors relating to whether a person is fit and proper.

Clause 72(d) provides that consideration may be given to whether a person has contravened a law, irrespective of whether they have been convicted for that contravention. Punishing a person who has not been convicted of an offence is a breach of human rights. The clause also breaches a fundamental legislative principle as it does not have sufficient regard to the rights and liberties of individuals. Furthermore, the provision infringes upon the principle of the presumption of innocence. This is because an administrative power may be exercised to grant, suspend or cancel a licence based on a contravention without conviction. For the reasons outlined above, the authors argue that cl 72(d), and by extension cls 65(1)(c) and 66(1)(a),(c) should be removed.

D Audits

Clause 208 compels a licence holder to give ‘full and free access to all documents and property’ that is relevant to an audit. The authors note that there is no immunity offered to the licence holder against prosecution. This may be a breach of fundamental legislative principles regarding the rights and liberties of individuals. The relevant question for the committee is whether the legislation provides adequate protection against self-incrimination.⁷ The purpose of an audit is to identify non-compliance and to promote transparency with the regulatory framework. This is different from the purpose of investigative and enforcement mechanisms

⁶ Explanatory notes, Pharmacy Business Ownership Bill 2023 (Qld), 17-18.

⁷ *Legislative Standards Act 1992* (Qld) s 4(3)(f).

outlined in Part 8 of the Bill. The explanatory notes state that non-compliance identified during an audit may be addressed via education or enforcement. It is unreasonable to compel a person to give full and free access during an audit and then expose them to punishment. If an audit is intended to educate licence holders, then an immunity should be offered from prosecution against an identified non-compliance. This would provide an opportunity for licence holders to voluntarily comply with the regulatory framework based on the outcome of the audit. The circumstances are different if a subsequent and separate investigation finds non-compliance, as enforcement mechanisms would be appropriate in this instance. The authors argue for an immunity to be introduced into cl 208 of the Bill.

Where an immunity is offered, the fundamental legislative principles require adequate justification.⁸ Such an immunity may be justified as follows: the purpose of an audit is to educate licence holders not prosecute them; there are separate provisions in the Bill relating to investigations and enforcement; licence holders—as practising pharmacists—are subject to professional and ethical standards under the National Law and therefore, would be presumed to voluntarily comply with the framework.

E The power to sub-delegate

The fundamental legislative principles require that the delegation of a power only occur in ‘appropriate cases and to appropriate persons’.⁹ Clause 184(2) permits a council member or the chief executive officer to sub-delegate a function that has been delegated to them by the Council. The administrative powers of the Council include taking serious action such as suspending or cancelling a licence. The authors argue that sub-delegating the power to suspend or cancel a licence to a member of the Council’s staff is a breach of the fundamental legislative principles. Such a severe administrative action should only be exercised by the Council or a Council Member and not sub-delegated any further. The authors recommend inserting a new subclause as follows:

- Clause 184(2A): Despite subsection (2), a function of the Council to suspend or cancel a licence must not be sub-delegated.

F The test of a ‘reasonable suspicion’

Numerous clauses throughout the Bill permit the Council to act on forming a ‘reasonable suspicion’. These include: cl 65(1) to suspend a licence; cl 66(1) to cancel a licence; cl 68(1) to immediately suspend or cancel a licence without a show cause notice; and cl 47 removing a licence holder on the Council’s own initiative. The authors argue that the threshold test of a ‘reasonable suspicion’ is too low and not commensurate with the gravity of the consequences. Suspending or cancelling a licence is a serious administrative action that should only occur if the Council forms a ‘reasonable belief’ that a set of circumstances exist. A ‘reasonable belief’ is a higher threshold that is commensurate with the consequences of acting. Therefore, the authors argue that the threshold test should be changed from a ‘reasonable suspicion’ to a ‘reasonable belief’.

1 Taking immediate action without a show cause notice.

⁸ *Legislative Standards Act 1992* (Qld) s 4(3)(h).

⁹ *Ibid* s 4(3)(c).

The test for taking immediate administrative action in cl 68 comprises two parts. The first limb requires a ground for suspending or cancelling the licence. The second limb requires an ‘immediate risk’ to public health or safety. Both parts are subject to the threshold test of a ‘reasonable suspicion’; as discussed, the authors consider this to be too low of a threshold. The second limb of the cl 68 test, an ‘immediate risk’ is also too low of a threshold. The authors argue that given the consequences of taking immediate administrative action, the test in cl 68(1)(b) should require a ‘serious risk’ or a ‘significant risk’. A higher threshold test is required because taking immediate administrative action without a show cause notice is a breach of natural justice principles. Therefore, cl 68 should be amended.

G Notification about temporary closures

Clause 80 requires a licence holder to notify the Council of a temporary closure exceeding 1 week duration. The authors consider the period of 1 week to be arbitrary and unnecessarily burdensome. Covid has shown us that during a pandemic, a business may need to be closed for deep cleaning; and staff may be unable to attend work due to isolation requirements (this period was 14 days isolation at the start of the pandemic). Consideration should also be given to small pharmacies in rural / remote areas. There may only be a single pharmacist or sole owner-operator who needs to take a period of annual leave, such as 10 days over Christmas and New Year. Even in metropolitan areas, it is not uncommon for businesses, regardless of industry, to close for 10 days during this period. A further consideration is the impact of natural disasters or unforeseen events. A pharmacy may have to temporarily close to allow for repairs so that the business can operate safely. Given these factors, it is questionable whether 1 week is an appropriate period. Therefore, the authors argue that period of time in cl 80 should be amended to 15 business days.

H Material interest in a pharmacy business

The definition of a material interest in cl 13(1)(c) is inconsistent with other jurisdictions as it does not refer to a ‘legal or beneficial’ interest. This means that it may be difficult for the Council to deem an interest as unlawful.

Recommendation:

- Clause **13(1)(c)** should be amended:
 - (c) any other interest, *legal* or *beneficial* in the business, other than an interest of an owner of the business.
 - (2) to remove any doubt, an interest includes, but is not limited to, having a right to receive consideration directly or indirectly that varies according to the profits or takings of the pharmacy business.

The existing clause 13(2) would be renumbered 13(3).

I Matters relating to the Council.

There are some clauses which create issues with the operation of the pharmacy Council. To ensure transparency, the Council must be required to publish a register of licensed pharmacy businesses. The function of the Council should not be diluted by becoming involved in the functions of other Acts. The Council in an industry body to regulate the ownership of pharmacy businesses. The composition of the Council should reflect the fact that the best persons to regulate the industry are pharmacy business owners. The current Bill has the risk

of pharmacy business owners being outnumbered by other experts. Therefore, there must be a majority of pharmacy business owners as members of the council. A limit should also be imposed on the number of terms that a council member may be reappointed.

Recommendations:

- Clause 207 (5) must be amended:
*The council **must** publish the information contained in the register on the council's website.*
- Clause 147 (1)(g) must be amended:
any other function given to the council under this Act.
- Clause 150 (4) must be amended:
the council must consist of –
(a) a majority of persons mentioned in subsections (3)(a)(i) and (3)(a)(ii) with the actual number dependent on the size of the council
- Clause 153 (2) should be amended to include a limit to the number of times a council member can be reappointed:
(2) a council member may be reappointed a maximum of two terms

J Online pharmacy businesses

1 Definition of a supermarket

The definition of a supermarket in cl 11(3) is not broad enough to capture the likely increase in online supermarket businesses in the future. The word 'premises' in the definition ties the concept of a supermarket to a physical 'bricks and mortar' place. Consequently, the definition is not able to adequately capture the growing online marketplace. One of the policy objectives of the Bill is to prohibit a licence being issued to a pharmacy business that is located within a supermarket. To ensure the policy objectives are met, the Bill must have application to pharmacy businesses and supermarkets, whether they are online or physical locations.

Recommendation:

- To adopt the following definition of a supermarket:

supermarket means a premises or online store used primarily for selling a range of food, beverages, groceries and other domestic goods.

2 Circumventing the legislative framework via online pharmacy businesses.

The authors question whether the Bill adequately regulates the digital presence of pharmacy businesses. It is important to note that large national and multinational corporations (such as Woolworths and Amazon) have shown a recent and particular interest in the healthcare sector, including pharmacy. The authors believe that a pharmacy business operating digitally should not be able to circumvent the intent of the legislative framework. If the digital business is owned by the licence holder of the physical business, this would not be considered

an attempt to circumvent the legislation. However, a digital business may be owned or operated by a person in any jurisdiction. A problem therefore arises with the fact that legislation is presumed not to have extraterritorial effect. The authors argue that consideration should be given to the operation of digital pharmacy businesses which may circumvent the intent of the legislation.

Recommendation:

- Consider amending cl 19 pharmacy businesses must be licensed:
 - (1) A person must not carry on a pharmacy business, whether physical or digital, unless the business is a licensed pharmacy business.
 - (2) Despite subsection (1), a digital pharmacy business does not require a licence if:
 - (a) It is operated out of a physical pharmacy business for which the owner holds a pharmacy business licence.

The authors wish to thank the Committee for the opportunity to provide feedback on the Bill.

Yours sincerely,
Andrew Calabro and Daniel Calabro