



Managing transfers in pharmacy ownership

Report 4: 2018–19



Your ref:
Our ref:

28 September 2018

The Honourable C Pitt MP
Speaker of the Legislative Assembly
Parliament House
BRISBANE QLD 4000

Dear Speaker

Report to parliament

This report is prepared under Part 3 Division 3 of the *Auditor-General Act 2009*, and is titled Managing transfers of pharmacy ownership (Report 4: 2018-19).

In accordance with s.67 of the Act, would you please arrange for the report to be tabled in the Legislative Assembly.

Yours sincerely

A handwritten signature in blue ink, appearing to read "Brendan Worrall".

Brendan Worrall
Auditor-General

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Audit objective and scope

On 3 May 2018, the Legislative Assembly of Queensland referred an inquiry to the Health, Communities, Disability Services and Domestic and Family Violence Prevention Committee (the committee). The terms of reference were:

That the Health, Communities, Disability Services and Domestic and Family Violence Prevention Committee inquire into and report to the Legislative Assembly, by 30 September 2018, on:

- the establishment of a pharmacy council, and
- all transfers of pharmacy ownership in Queensland over the past two years to ensure compliance with existing legislation.

The chair of the committee wrote to the Auditor-General on 14 May 2018 to request an audit of how the Department of Health assessed transfers of pharmacy ownership from 1 January 2016.

The Auditor-General agreed to conduct a reasonable assurance audit as per the Australian Auditing and Assurance Standards.

The objective of the audit was to assess whether the Department of Health (the department) ensured the transfers complied with the requirements of the *Pharmacy Business Ownership Act 2001* (the Act). Refer to Appendix D for an extract of the Act.

We assessed:

- the effectiveness of the current systems and processes in regulating pharmacy business ownership in Queensland
- compliance with the Act for a sample of transfers of pharmacy ownership.

Scope exclusions

We have not, as part of this audit:

- commented on the merits of the Act
- tested compliance for changes in business particulars (section 141B of the Act)
- assessed whether non-compliance with the Act can lead to adverse health outcomes
- provided advice on appropriate entity structures to comply with the Act
- tested compliance with any other legislation regulating the pharmacy industry.

Our scope was limited to how effectively the Act is being administered in regulating pharmacy ownership.

Entities subject to this audit

The Department of Health.



Audit approach

We conducted the audit between May and August 2018. We:

- assessed the department's processes and procedures for transfer of pharmacy ownerships
- interviewed Department of Health staff
- consulted with relevant stakeholders
- analysed data and documentation over the period 1 January 2016 to 31 July 2018 to provide reasonable assurance that transfers of pharmacy ownership complied with the Act
- gathered evidence to support the audit conclusion.

Reference to comments

In accordance with section 64 of the *Auditor-General Act 2009*, we provided a copy of this report to the Department of Health and the Health, Communities, Disability Services and Domestic and Family Violence Prevention Committee. In reaching our conclusions, we have considered their views and represented them to the extent we deemed relevant and warranted. Any formal responses from the entities are at Appendix B.

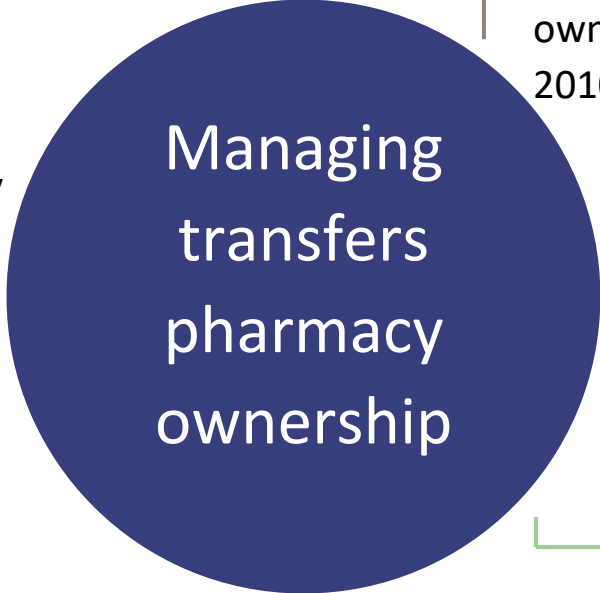


Key facts

The ownership of pharmacy businesses in Queensland is regulated under the *Pharmacy Business Ownership Act 2001* (the Act).

The Department of Health has administered the regulatory function for pharmacy business ownership since July 2010.

316 pharmacies* changed ownership between 1 January 2016 and 31 July 2018.



As at 31 December 2017, community pharmacies provide services to over 4.9 million people in Queensland.

Queensland pharmacies dispensed over 39.3 million medicine items under the Pharmaceutical Benefits Scheme** in the 2017–18 financial year.

* The department received 816 change of pharmacy ownership notification forms relating to 316 pharmacies between 1 January 2016 and 31 July 2018.

** The Pharmaceutical Benefits Scheme allows patients to obtain medicines at a government-subsidised price.



Introduction

In Queensland, only a pharmacist or an entity owned by a pharmacist can own a pharmacy business. This aligns with the requirements of other Australian jurisdictions.

The government regulates this by limiting:

- ownership of pharmacies to pharmacists or a combination of pharmacists and their relatives only
- the number of pharmacies each pharmacist or entity can own
- the control of pharmacies to pharmacists only.

The *Pharmacy Business Ownership Act 2001* (the Act) refers to ownership by a corporation (section 139B). We acknowledge other legal entities such as family trusts may also own a pharmacy. For this reason, we use the term ‘entity’ in this report.

The intent of the Act is to promote the professional, safe and competent provision of pharmacy services, and to maintain public confidence in the pharmacy profession. The legislation in other jurisdictions such as New South Wales, Western Australia and Victoria is similar to that of Queensland. In all four states, the intent is to limit ownership of pharmacies to pharmacists and to limit the number of pharmacies each pharmacist can own.

In addition, in Queensland, New South Wales and Victoria, the legislation ensures only pharmacists can have control over pharmacies. For example, before approving a licence for a new or changed pharmacy to operate, the Victoria Pharmacy Authority assesses the commercial arrangements in place to determine if there is undue influence on a pharmacy owner. (Undue influence is when someone requires the owner to act in a certain way, for example, by having a clause that dictates where the owner gets their pharmacy goods from.)

Queensland does not issue licences or approvals for registration of pharmacies. However, the Australian Department of Human Services will only approve a pharmacy to dispense medicines in Queensland under the Pharmaceutical Benefits Scheme when the Department of Health confirms with them that the requirements of the Act have been fulfilled.

Queensland’s Pharmacy Business Ownership Act 2001

The Department of Health (the department) is responsible for administering the Act.

The department has a process for assessing notifications of changes in pharmacy ownership against the requirements of the Act. It requires the pharmacy owner to complete a transfer of ownership form (a notification) and provide a small number of documents to support it. The department then assesses whether the notification complies with the requirements of the Act.



Objects (purposes) of Act

The purposes of the Act are to:

- promote the professional, safe and competent provision of pharmacy services
- maintain public confidence in the pharmacy profession.

This is to be achieved mainly by:

- limiting who may own a pharmacy business
- limiting the number of pharmacy businesses that may be owned by a person
- providing for compliance with the Act to be monitored and enforced.

139A—definitions

Under the Act, ‘owning’ a pharmacy business includes having a proprietary interest (full or part ownership entitling the owner to a share of the profits). It does not include having an interest in a pharmacy business because of ‘... a bill of sale, mortgage, or other form of security, for the pharmacy business’.

The term ‘relative’ refers to the spouse of the pharmacist or a child of the pharmacist who is at least 18 years of age.

Administration of the Act

Figure A shows the key events relating to administration of pharmacy ownership regulation in Queensland from 2010 to 2018.

Figure A
Key events relating to regulation of pharmacy ownership

Month and year	Event
Prior to 2010	The Pharmacist Board of Queensland administered the <i>Pharmacy Business Ownership Act 2001</i> (the Act).
July 2010	The department assumed the regulatory functions for pharmacy ownership.
2012	<p>The department’s Medicines Regulations and Quality team (the team) took on the responsibility of administering the Act. Four officers administer the notification function.</p> <p>The team’s main function is to administer the <i>Health (Drugs and Poisons) Regulation Act 1996</i>, which prescribes controls over the manufacturing, distribution, sale, handling, storage, packaging, labelling, dispensing, prescribing, supply and use of scheduled medicines and poisons.</p> <p>To accommodate the additional responsibility of regulating pharmacy ownership, the team modified the department’s Monitoring of Drugs of Dependence System (MODDS) database and added an ownership table to capture information relating to transfers of ownership.</p>



Month and year	Event
September 2016	<p>The department introduced a checklist to manage the notification process. It is an internal control document that records a notification and verifies the team has completed the required checks to determine compliance with the Act.</p> <p>It also serves as a form of quality control, as a second person (the verifying officer) is required to sign off once a review of the file has been completed.</p>
May 2018	<p>The department developed a document called <i>Pharmacy Ownership Business Rules</i>. This is an internal document that provides information about the notification process. It covers the requirements of the notification form, compliance checkpoints and reporting requirements.</p>

Source: Queensland Audit Office

Pharmacy regulatory environment

In addition to the *Pharmacy Business Ownership Act 2001* there are other acts and regulatory bodies which regulate the pharmacy industry. For example:

- The Australian Government regulates the location of pharmacies which have been approved to dispense subsidised medicines under the Pharmaceutical Benefits Scheme (PBS).
- The Pharmacy Board of Australia is the national body responsible for the regulation of pharmacists under the umbrella of the Australian Health Practitioners Agency. The Pharmacy Board of Australia registers pharmacists; develops standards, codes and guidelines for the pharmacy profession; handles notifications and disciplinary hearings; and approves accreditation standards and accredited courses of study.
- The *Health (Drugs and Poisons) Regulation 1996* prescribes the handling of medications in Queensland throughout their lifecycle. The regulation also controls the manufacturing of medicines, the advertising and labelling of substances and devices that are used or connected with a therapeutic purpose and the dispensing of medicines and poisons at a pharmacy.
- The Therapeutic Goods Administration regulates national scheduling of medicines, the manufacture of medicines (with some exceptions) and aspects of wholesale practice. Use of prescribed medicines is also influenced by the *National Health Act 1953* and the national health system because the price of many medicines is subsidised under the Pharmaceutical Benefits Scheme.

Compliance with, or the impact of, these other regulatory bodies and pieces of legislation was not within the scope of this audit.



Summary of findings

The Department of Health (the department) has not taken all reasonable steps to ensure the objects (purposes) of the *Pharmacy Business Ownership Act 2001* (the Act) are being met. Gaps in the department's processes and systems have resulted in it not having sufficient appropriate information about pharmacy ownership transfers. This means we have been unable to completely assess its compliance with the Act in administering the transfers over the last two years.

Designing and implementing

Although the department has been responsible for administering the Act since 2010, it has not fully documented the process it undertakes to assess pharmacy ownership notifications.

It introduced a control checklist in 2016 to strengthen the review and approval of notifications. This was in response to an internal improvement review of its business processes. However, we found that this checklist does not address all aspects of the legislation. We also found that the checklist had not been used in some of the files we examined.

Officers at the department are not required to keep evidence of the checks they complete. For example, they do not keep screen shots of the pharmacist's valid registration as recorded on the Australian Health Practitioners Regulation Agency (AHPRA) website or the list of shareholdings in entities that are linked to the pharmacy.

The department does not request enough documentation from pharmacy owners to assess compliance with the 'right to control' elements of the Act. For example, the department does not routinely request the following types of documents as evidence:

- lease documents
- partnership agreement
- any agreement for the provision of management services to the pharmacy business
- guarantee documentation
- franchise agreement.

These types of documents may be needed to assess ownership and control, but the department has only requested them when they have received a complaint about changes in pharmacy ownership.

The department searches its Monitoring of Drugs of Dependence System (MODDS) database (containing pharmacy ownership details) to assist in determining whether a person owns more pharmacies than the Act allows (five). It does not, however, show how many pharmacies an entity (rather than an individual) has.



The database is not fit-for-purpose, as it does not allow officers to enter all the details required for ensuring the notifications comply with the Act. It also requires the officer to enter a pharmacist registration number for non-pharmacists for cases when a relative of a pharmacist is part of a corporation that owns a pharmacy. As a workaround, officers enter dummy registration numbers. This leads to invalid data in the database. Even though the invalid data has no impact on the actual pharmacy ownership transfers, it further demonstrates the database is not fit-for-purpose.

Assessing the notifications

Between 1 January 2016 and 31 July 2018, the department received 816 notification forms about changes in pharmacy ownership. (One pharmacy transfer can have multiple notification forms.) Of the 816 notification forms:

- 299 involved selling or buying as a pharmacist
- 517 involved selling or buying as an entity.

In undertaking our assessment, we considered whether a pharmacy belongs to a franchise group, because the department would need to conduct additional checks for these pharmacies to determine if they comply with the Act. We identified the pharmacies by considering well-known pharmacy franchise group names, because the department does not require the pharmacy owner to provide this information for the notification process. We found 464 notification forms had a pharmacy name that contained the name of a franchise group. Of those:

- 92 notification forms were from individual owners
- 372 notification forms were from entities.

Figure B shows our findings in terms of how well the department is assuring that changes in pharmacy ownership meet legislative requirements. It also shows the sections of the Act we used in testing this.

Figure B
Results of our compliance testing

Section of the <i>Pharmacy Business Ownership Act 2001</i>	Number of notification forms we tested	Findings
139B Restriction on who may own a pharmacy business	333*	<p>We did not find any instances of non-compliance in our sample of pharmacies in the non-franchise group. All pharmacy owners were registered pharmacists.</p> <p>However, s.139A of the Act defines 'own' to include proprietary interest (full or part interest that entitles the owner to a share in the profits). We were unable to determine whether franchise groups had a proprietary interest in those pharmacies because there were insufficient documents in the department's files.</p>

Section of the <i>Pharmacy Business Ownership Act 2001</i>	Number of notification forms we tested	Findings
<p>139H Restriction on number of pharmacy businesses in which a person may have beneficial interest (that is, they benefit from the pharmacy's profitability)</p>	<p>816 (for 316 changes in pharmacy ownership)</p>	<p>We did not find any individual pharmacists listed in the department's Monitoring of Drugs of Dependence System (MODDS) database owning more than five pharmacies in Queensland. But we identified the potential for non-compliance with the ownership rules, specifically, the potential for some pharmacists to have undeclared beneficial interests in more than five pharmacies.</p> <p>The department has not thoroughly tested whether pharmacists have ownership interests in more pharmacies than the Act allows through corporate structures. According to s.139H(2), a pharmacy owner may have a beneficial interest in a pharmacy if they are a director of or shareholder in a corporation that owns a pharmacy.</p> <p>The department does not record sufficient information in its database about entities or individuals such as Australian Company Numbers (ACN) and Australian Business Numbers (ABN) and individuals' dates of birth. This limits the department's ability to detect if pharmacists have ownership interests through corporations.</p>
<p>139I Certain arrangements about control of pharmacy business void (circumstances under which commercial arrangements are not legally binding)</p>	<p>374**</p>	<p>We found 70 instances where a pharmacy file either:</p> <ul style="list-style-type: none"> • did not contain the required corporate documents (Australian Securities & Investment Commission extract, certification of corporation, the corporate's constitution), or • the documents were not certified, or • some documents were missing, and some were not certified. <p>We were unable to determine whether the franchise pharmacy transfers complied with section 139I because there were insufficient documents (such as franchise agreements) in the department's pharmacy file to confirm whether controls by a non-pharmacist exist in the franchise business.</p>

Notes:

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

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

Source: Queensland Audit Office



Monitoring compliance

The department is taking a reactive approach to administering Part 3 of the Act (which addresses monitoring and enforcement), by responding to complaints when and if they are made. This means there is a risk that pharmacies can continue to operate even if they are in breach of the Act. Examples include cases where, after a pharmacy owner notifies the department of an ownership transfer, the business structure or operating practices are changed to a model that does not comply with the legislation.

Officers we interviewed at the department did not feel they were required or had the legislative authority to monitor and enforce compliance. However, the Act provides a clear statement that its intent is to be achieved by ‘... providing for compliance with this Act to be monitored and enforced’. The Act also provides for the chief executive to appoint an inspector(s) who ‘... has the function for conducting investigations and inspections to enforce compliance with this Act’. The department has never appointed any inspectors.

Appendix F provides details of other jurisdictions’ compliance frameworks.



Audit conclusions

The Department of Health (the department) has not designed processes and controls to ensure transfers in pharmacy ownership comply with all the requirements of the Act. It has some controls in place to address the requirements regarding limiting ownership to pharmacists and limiting pharmacy numbers, but it does not always apply them consistently or thoroughly.

The department does not obtain enough information to conduct the tests thoroughly on more complex ownership arrangements such as franchisees. These accounted for approximately sixty per cent of the transfer notifications in the last two years. It also does not request enough personal information from pharmacy owners (such as dates of birth) so it can check if they have any undeclared ownership interests through corporate structures.

In addition, it does not routinely request enough information to conduct tests of compliance with section 139I, which refers to control of a pharmacy business. This means there is a risk that pharmacies may be operating with elements of their commercial arrangements being void (not legally binding) under the Act.

The department has taken appropriate actions by requesting additional information to address concerns about ownership of pharmacies when they receive complaints. However, this reactive approach means it is not effectively identifying potential non-compliance.

It does not monitor if pharmacies make any changes to their structure or commercial arrangements after notifying the department of ownership changes. It can mitigate this risk by actively monitoring or annually reviewing pharmacy ownerships.

The department has not been effectively administering the Act, as it has not adapted its processes to the more complex business structures and commercial arrangements pharmacy businesses now use. Its processes do not adequately address the objects (purposes) of the Act, which are to promote and maintain public confidence in the pharmacy profession by limiting pharmacy ownership and monitoring and enforcing compliance with the Act.

Assurance opinion

Because there was insufficient documentation to completely test compliance with the Act, we have been unable to form an opinion on areas such as:

- the number of pharmacies a person has a beneficial interest in or a corporation owns
- franchise groups having proprietary interests in pharmacies
- commercial arrangements allowing non-pharmacists to control a pharmacy.

Refer to the independent assurance practitioner report at Appendix A for more details.



Recommendations

Department of Health

We recommend that the Department of Health (the department):

1. clarifies its role and obligations in the administration of the *Pharmacy Business Ownership Act 2001* (the Act) and the skills and resources it needs to fulfil its functions effectively
2. re-designs its internal controls so it can effectively administer the Act

This should include:

- revising the *Pharmacy Ownership Business Rules* document and the notification checklist to include all relevant information relating to the notification process
- determining whether decision support tools such as the Monitoring of Drugs of Dependence System (MODDS) database can be modified to better support its notification process or if new tools are required
- defining checks to detect whether pharmacists have undeclared ownership interests in a pharmacy through a corporation.

3. better defines the type of documents pharmacy owners need to provide to support the notification process

This should include:

- requiring owners to provide documents that allow the department to thoroughly test all ownership requirements of the Act, including circumstances under which ownership of pharmacies can be made not legally binding due to control issues (139I)
- requesting all relevant documentation at the time of the notification submission, including information to validate an individual's identity such as date of birth
- keeping sufficient records to enable process validation.

4. implements a process to monitor pharmacies' ongoing compliance with the Act

This should include establishing a monitoring and compliance program to review pharmacy ownership at regular intervals, for example, conducting random inspections of pharmacies at the department's discretion.

5. develops and implements a risk-based strategy for testing that existing commercial arrangements comply with sections 139B, 139H and 139I of the Act.

Note: These recommendations assume the Health, Communities, Disability Services and Domestic and Family Violence Prevention Committee's inquiry does not result in any changes to the legislation or governance arrangements. If changes are made, the accountable parties will need to revisit these recommendations.



The Health, Communities, Disability Services and Domestic and Family Violence Prevention Committee

We recommend that the Health, Communities, Disability Services and Domestic and Family Violence Prevention Committee (the committee):

6. recommends to the Minister for Health to seek amendments to the Act to enable the department to more effectively manage the pharmacy ownership notification process.

This should include defining the legal implication if a commercial arrangement does not meet section 139I of the Act (Certain arrangements about control of pharmacy business void).



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