



Year 1 Evaluation Report

# Pharmacy Ownership Audit Program

Victorian Pharmacy Authority

17 July 2020

**Victorian Pharmacy Authority**  
PHARMACY OWNERSHIP AUDIT PROGRAM  
YEAR 1 EVALUATION REPORT

**EXECUTIVE SUMMARY**

A program of risk-based audits of pharmacy businesses was a key recommendation of the 2017 *PharmConsult* review.

The audit program was to address a perception among pharmacists that there are breaches of the Act due to silent or undeclared interests in pharmacy businesses. By contrast, undue influence by third party service providers was poorly understood and seemingly, of less importance to pharmacists.

The Authority conducted a pilot audit program in 2017 and commenced the full program in December 2018. This report is an evaluation of the first year of the audit program.

The audit program involves 'ownership audits' and 'financial audits'. Ownership audits are conducted by Authority staff to determine if the ownership and commercial arrangements comply with the Act. Financial audits are conducted by an external accountancy firm to confirm the veracity of the information & documentation submitted by the licensees.

In parallel, the Authority commenced a program to review franchise agreements, associated commercial arrangements and other service agreements and, where necessary, have them amended by engaging with franchisors and service providers to ensure compliance with the Act.

The Authority set an annual target of 100 ownership audits and up to 10 financial audits; these initial targets were then carried over to the Authority's current Statement of Expectations.

During the 2019 calendar year 101 ownership audits and six financial audits were initiated. Of these, thirty-five ownership audits and two financial audits were completed.

A major barrier to progress has been delays caused by licensees failing to provide information in a timely manner. It is clear that a firmer approach is needed.

The thirty-five completed ownership audits have not identified any cases of silent or undeclared ownership. The two completed financial audits have identified one case of distribution of profits via a trust to family members who were not eligible to have a proprietary interest.

Additionally, the parallel franchise agreement review program has found extensive evidence that franchise agreements and other complex commercial arrangements provide for third parties to exert control or undue influence over pharmacy businesses.

It is apparent that financial audits together with the parallel review of franchise and service agreements are the most effective tools to identify non-compliant arrangements.

Considering the high demand on staff resources and lack of evidence of non-compliance to date, maintaining the ownership audit program in its current format does not appear to be warranted.

Recommendations:

1. The ownership audit process be amended to include new areas of scrutiny and investigation;
2. The annual target for ownership audits be reduced;
3. The number of financial audits be maintained or increased; and
4. The rolling program of franchise and service agreement reviews be accelerated.

## INTRODUCTION

### Legislation

#### *Ownership of a pharmacy business*

The Pharmacy Regulation Act 2010 (**the Act**) regulates who may own or have a “proprietary interest” in a pharmacy business. To that end, section 5 of the Act provides that:

- 1) A person must not own or have a proprietary interest in a pharmacy business unless the person is:
  - a) a registered pharmacist;
  - b) a company registered under the Corporations Act—
    - i. whose directors are all registered pharmacists;
    - ii. in which all of the shares and the beneficial and legal interest in those shares are held by registered pharmacists.<sup>1</sup>

“Proprietary interest” is defined under s 3 of the Act as meaning:

“a legal or beneficial interest and includes a proprietary interest as a sole proprietor, as a partner, as a director, or member or shareholder of a company and as the trustee or beneficiary of a trust.”

Section 5(2) of the Act states that a registered pharmacist and a company referred to in subsection (1)(b) must not own or have a proprietary interest in more than 5 separate pharmacy businesses.

#### *Undue Influence/control of a pharmacy business*

The Act also places restrictions on who can control or influence the way in which a pharmacy business is carried on.

In particular, section 11 of the Act relates to undue influence over a pharmacy business. It provides that:

A provision in a bill of sale, mortgage, lease or in any other commercial arrangement in respect of a pharmacy or pharmacy business that gives to any person other than the person licensed under section 38 to carry on the pharmacy business—

- a) the right to control the manner in which the pharmacy business is carried on; or
- b) the right of access to books of accounts or records kept in respect of that business, otherwise than for the purpose of determining whether or not the conditions of the relevant document are being complied with; or
- c) the right to receive any consideration that varies according to the profits or takings in respect of the business—

is void.

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<sup>1</sup> Section 5(1)(c)-(f) sets out various exceptions to s 5(1)(a)-(b) that relate to friendly societies.

## The PharmConsult Review

1. In December 2016, the Authority commissioned *PharmConsult* to conduct an external review of its licence application and renewal processes. The objective of the review was to ensure the processes are adequate to determine compliance with the Act.
2. A copy of the Final Report *Review of the Pharmacy Business Licence Application and Renewal Processes in Victoria* published on 31 August 2017 is available at [www.pharmacy.vic.gov.au](http://www.pharmacy.vic.gov.au) under *Resources*.

## Pharmacy business audit program

3. *PharmConsult's* recommendations included the introduction of a program of risk-based audits of pharmacy businesses. It recommended that the audit program be undertaken for a short term initially (e.g. three years) with a requirement to monitor, evaluate and report outcomes.
4. The audit program was recommended to address the widely held perception among the pharmacists with whom *PharmConsult* met, that there have been, and continue to be breaches of the Act in regard to undeclared interests. It was *PharmConsult's* belief that *“the issue of most concern to the stakeholders consulted, is that of undeclared ownership and a lack of resource application to this perceived risk. By contrast, undue influence was poorly understood and seemingly, of less importance to the pharmacists consulted”*.
5. Following a pilot in 2018, the Authority commenced the audit program in December 2018 with the first audit forms sent out in February 2019.
6. Audit questionnaires were sent to licensees requiring production of documents/information relating to pharmacy ownership and commercial arrangements pursuant to section 8 of the Act.
7. In each case, an **ownership audit** carried out by Authority staff examined the pharmacy ownership and commercial arrangements (following a process developed in consultation with the Authority's lawyers and accountants) to ensure they are consistent with VPA records/stated arrangements, and that they comply with the ownership and undue influence provisions of the Act.
8. If ownership arrangements are assessed as compliant but the pharmacy operates pursuant to commercial arrangements (e.g. a franchise agreement) that have not yet undergone a detailed legal review for compliance with the Act, a condition is imposed providing for the Authority to revoke the licence or impose further conditions if the arrangements are subsequently found to breach the Act:

*‘the Authority may revoke this licence or impose further conditions if, after completing a review of the commercial agreements pursuant to which the pharmacy business is or is proposed to be conducted, it determines that the agreements contravene the ownership or undue influence provisions in Part 2 Division 1 of the Pharmacy Regulation Act 2010.’*

**(Commercial arrangement condition)**

9. Additionally, the financial records of a subset of pharmacies selected for ownership audit were examined by an accounting firm to confirm the stated ownership arrangements and determine if there are undeclared arrangements in place (**financial audit**).
10. If auditing identifies potential non-compliance, the Authority obtains legal advice pending further action. This may include a panel hearing or legal proceedings. The Authority plans to publish information on actions taken following identification of non-compliance in stakeholder communications as applicable.
11. The Authority set an initial 2019 target of 100 ownership audits and up to 10 financial audits. These targets were carried over to the Authority’s Statement of Expectations for 1 July 2019 to 30 June 2021.
12. Current risk-based selection criteria for audit include:
  - Association with franchise/banner group (number selected proportional to footprint in market) – Approximately 80%
  - Association with medical centre/clinic
  - Commercial arrangement or association with a person who has a proprietary interest in five pharmacies
  - Recent graduate pharmacist(s) as licensees
  - Licensees residing interstate
  - Other on order of Authority (may follow receipt of Notification<sup>2</sup> or consideration of licence application)
13. The Authority received a one-off grant of \$130,000 from the Department of Health and Human Services (DHHS Grant) in January 2019 to support implementation of the audit program. The DHHS Grant also provided for additional franchise reviews (see page 8). The DHHS Grant was expended in full by 29 February 2020 and the Authority continues to fund the audit program through licensing fees.

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<sup>2</sup> The Authority reminds stakeholders in its communications that a person may make notifications about a licence if there is an indication that:

- the licensee has contravened the requirements regarding ownership of pharmacies; or
- the licensee is no longer eligible to hold a licence; or
- the licence was or may have been improperly obtained because the Authority was provided with false or misleading information.

[See VPA Communiqué 2, 2019]

## FINDINGS AND DISCUSSION

### Output evaluation

The following tables provide a summary of audits undertaken including outcomes.

<b>Ownership Audits</b>				
Time	Number of Ownership Audit Request Sent	Number of Responses Received	Number of Ownership Audits Commenced	Number of Audits Completed
1Q 2019	26	25	1	-
2Q 2019	25	15	25	10
3Q 2019	-	11	11	18
4Q 2019	50	47 <sup>#</sup>	7	7
<b>Total</b>	<b>101</b>	<b>98</b>	<b>44</b>	<b>35</b>

# One pharmacy changed ownership in Nov 2019 and did not provide a response

<b>Outcome of Ownership Audits Completed</b>	
Compliant	8
Compliant (noting review of established commercial agreement pending)	16
Compliant (noting potential non-compliance with s11)	11
Non-compliant	0
<b>Total</b>	<b>35</b>

#### Key:

##### *Compliant*

Ownership arrangements consistent with stated arrangements and compliant with the Act.

##### *Compliant (noting review of established commercial agreement pending)*

Ownership arrangements consistent with stated arrangements. No evidence of non-compliance but formal legal review of established commercial arrangements for compliance with Act still pending. Commercial arrangement condition imposed or to be imposed.

##### *Compliant (noting potential non-compliance with s11)*

Ownership arrangements consistent with stated arrangements. Pharmacy operated pursuant to commercial arrangements that have been subject to a formal legal review for compliance with the Act and required amendment. Potential non-compliance with control and undue influence provisions identified due to documents not being agreed precedent versions. [Process requiring licensees/franchisors to update pre-existing arrangements ongoing]

##### *Non-compliant*

Ownership arrangements not consistent with stated arrangements (e.g. undeclared interests) or otherwise not compliant with the Act.

<b>Financial Audits</b>				
Time	Number of Financial Audit Requests Sent	Number of Responses Received	Number of Financial Audits Commenced	Number of Audits Completed
1Q 2019	6	6*	1	-
2Q 2019	-	-	4	-
3Q 2019	-	-	-	1
4Q 2019	5	5#	-	1
<b>Total</b>	<b>11</b>	<b>11</b>	<b>5</b>	<b>2</b>

\* Partial information provided for one financial audit which is insufficient to complete review

# Licensees failed to submit financial statements in the initial response in 3 cases

<b>Outcome of Financial Audits Completed</b>		
Compliant	Non-compliant – payment to non-eligible beneficiary	Total
1	1	2

## Process and outcome evaluation

1. Thirty-five of the (101) ownership audits commenced in 2019 were completed.
2. There have been no identified cases of undeclared ownership from ownership audits to date.
3. Ownership audits have identified potential non-compliance with the control and undue influence provisions of the Act. However, these instances involved franchisees operating pharmacies pursuant to franchise agreements/other commercial agreements that required amendment following a formal legal review for compliance with the Act and were already subject to an ongoing process requiring licensees/franchisors to update their agreements to compliant versions.
4. Two of six financial audits were completed. One of these identified the potential distribution of profits via a trust to family members who were not eligible to have a proprietary interest (the audit otherwise confirmed the stated ownership arrangements).
5. Four financial audits are still ongoing. In one case there have been continued delays in obtaining requested financial information.
6. The Authority is reviewing audit selection criteria to ensure that they remain suitable and risk-based. Current selection criteria and commentary are summarized in the following table.

Selection criteria	Comments
Association with franchise/banner group (number selected proportional to footprint in market)	<ul style="list-style-type: none"> <li>• Auditing pharmacies on this basis appears to be of little value in cases where a formal legal review of the franchise or similar agreement and any associated documents has yet not been undertaken.</li> <li>• In cases where a formal legal review of the arrangements has been undertaken and the commercial arrangements have been amended to ensure compliance, auditing pharmacies to ensure they are operating under compliant versions of the arrangements may continue to be of value (although existing processes aim to ensure that necessary amendments to commercial arrangements are rolled out across the franchise/banner group).</li> <li>• This was initially considered appropriate on the basis that such pharmacies are operating pursuant to complex commercial arrangements.</li> </ul>
Association with medical centre/clinic	<ul style="list-style-type: none"> <li>• The Authority investigated two separate pharmacy businesses based on information that (non-pharmacist) doctors had a proprietary interest in the pharmacies.</li> <li>• The AMA has issued revised guidelines on ownership of pharmacy and dispensing by doctors which may mislead doctors into believing that they may own or have a proprietary interest in a pharmacy business. The Authority wrote to the AMA requesting an amendment to the guidelines.</li> <li>• Auditing pharmacies on this basis may continue to identify cases of non-compliance.</li> </ul>

Selection criteria	Comments
Commercial arrangement or association with a person who has a proprietary interest in five pharmacies	<ul style="list-style-type: none"> <li>• The rationale for this selection criterion is that licensees who reach the permitted limit of five pharmacy ownership/proprietary interests may seek to have interests in further pharmacies through silent or complex commercial arrangements.</li> <li>• Experience suggests (anecdotally) that this might also occur where pharmacists have interests in less than five pharmacies.</li> </ul>
Recent graduate pharmacist(s) as licensees	<ul style="list-style-type: none"> <li>• This was seen as a useful inclusion because the Authority has seen cases of recent graduates purchasing pharmacies of significant value and needs to be satisfied that there are no undeclared interests.</li> </ul>
Licensees residing interstate	<ul style="list-style-type: none"> <li>• This is no longer seen as a criterion which should prompt an ownership audit.</li> </ul>
Other on order of Authority	<ul style="list-style-type: none"> <li>• Auditing should continue on Authority order for other reasons. This may follow receipt of information or a complaint about ownership arrangements.</li> </ul>
Licensees who have held a licence for five or more years	<ul style="list-style-type: none"> <li>• This is not a current criterion for selection but may be worthy of consideration because some commercial arrangements associated with these licences may not have been reviewed at the time of application.</li> </ul>

7. It is suggested that further stakeholder consultation be undertaken to help identify possible additional selection criteria.
8. The ownership audit process is lengthy and complex. Progress has been slower than expected due to delayed responses, submission of incomplete information, and in some cases failure to provide information. In two cases, the Authority warned licensees that it would commence proceedings in the Magistrates Court and in one case that it would not renew a licence if there was continued failure to produce documents.
9. The initial annual target of 100 ownership audits is not likely to be achieved with existing resources. If current targets are maintained for ownership audits, the Authority will require additional resources.
10. Weaknesses of the program include:
  - Difficulty extracting information from licensees despite requiring information pursuant to s8 of the Act.
  - Ownership audits considering aspects of control that would be better tackled via formal legal reviews of franchise agreements and other complex commercial arrangements.
  - An association with a franchise/banner group, the basis for ownership audit in the majority of cases, no longer appears to be a suitable criterion for audits probing for undeclared interests. Further, auditing pharmacies operating pursuant to commercial arrangements that have not yet been subject to a formal legal review appears to be of limited value.
11. The Authority needs to employ a stronger mechanism to facilitate the production of information and documents. This could include resorting earlier to issuing formal

warnings that legal proceedings will be commenced in cases where information is not provided or incomplete.

12. Financial audits progressed slowly initially as the external auditors refine the process. Regular meetings with the accountants conducting financial audits will occur to discuss learnings from audits undertaken and the focus of future audits.
13. Even though a limited number of financial audits have been completed, early indications are that financial auditing is more likely to yield information indicative of non-compliance compared to ownership audits.
14. Some recent findings:
  - i. Two pharmacies subject to recent financial audit made nil profit & were incurring significant franchise fees.
  - ii. Financial audit of one pharmacy identified the distribution of the profit of a partner to trust beneficiaries not eligible to have a proprietary interest.
  - iii. A number of pharmacies have changed hands during the course of an audit.
15. The Authority believes the value of the audit program would be enhanced by:
  - i. Applying additional resources and tools to ownership audits – this could include requiring licensees to provide information and/or inspections to examine documents such as electronic funds transfer (EFT) records, Medicare claim statements, invoices for goods received.
  - ii. Significantly reducing the number of ownership audits to be undertaken annually.
  - iii. Maintaining and potentially increasing the number of financial audits undertaken on a case by case basis.

## **OTHER INITIATIVES**

The Authority believes that resources would be better applied to the assessment of franchise agreements and other complex commercial arrangements as detailed legal reviews of these arrangements to date has invariably identified significant non-compliance with the control and undue influence provisions of the Act. In addition, the increased scrutiny of complex commercial arrangements through improved application assessment processes appears to be a better application of resources than a resource-intensive ownership audit program that has not identified cases of undeclared interests in pharmacy businesses.

### **Review of franchise agreements**

The Authority is concerned at the degree to which franchise agreements incorporate provisions that may give franchisors the right to control pharmacy businesses.

- Franchise agreements by their nature tend to offend the undue influence provisions, and in some cases the ownership provisions, of the Act.
- The Authority continues to review existing franchise agreements and other complex commercial arrangements for compliance with the Act progressively on a risk basis. This involves obtaining a formal legal opinion on the agreements, writing to the licensee highlighting the problematic clauses and inviting them, the franchisor and respective legal representatives to a meeting to discuss the areas of non-compliance.
- Such reviews invariably identify a multitude of clauses that appear to be in breach of either section 5 (ownership provisions) and/or section 11 (undue influence/control provisions) of the Act.
- If the Authority considers that the commercial arrangements pursuant to which the pharmacy business is conducted contravene the ownership and undue influence provisions in Part 2 Division 1 of the Act, the Authority may consider whether to:
  - revoke the licence; or
  - impose further conditions on the licence, including that the pharmacy business is not carried on under or pursuant to the Franchise Agreement.
- Prior to making a final determination, the Authority considers any proposed amendments or submissions from the Licensee in respect of the problematic clauses identified.
- Engaging conditional licensees and franchisors in this process has to date been successful in effecting necessary changes, with the plan being for amended compliant agreement(s) to be rolled out across pharmacies in the respective groups.
- The Authority requires submission of any agreed compliant commercial arrangements in the form of marked-up precedent documents for the purpose of future applications. All such applications and arrangements continue to be subject to a high level of scrutiny on a case by case basis.
- The Authority plans to increase the rate of franchise reviews due to the extensive non-compliance and existing backlog.

- Current considerations (in relation to a franchise group) prompting formal review of franchise agreements include:
  - Footprint in market
  - Time in market
  - Significant expansion
  - Receipt of notifications

### **Improved licence application processes**

- The new licence application processes are working well to ensure that (proposed) ownership arrangements comply with the Act. Scrutiny of complex commercial arrangements has identified numerous cases of potential non-compliance. Some recent examples include:
  - Licence application (purchase of existing pharmacy) denied August 2019 as trust arrangements did not comply with the Act.
  - Licence application (new pharmacy) denied August 2019 as aspects of the proposed commercial arrangements offended the Act and the Authority could not be satisfied that a third party did not have a proprietary interest (amended application subsequently submitted, applicant advised still non-compliant, application withdrawn prior to consideration at next VPA meeting).
  - Licence application deferred as contract of sale indicated that a transfer of ownership may have already occurred - investigation of current ownership arrangements ongoing.
  - Two notifications alleging undisclosed/unlawful ownership arrangements received, audit/investigation of current ownership arrangements commenced.
- Some applications have not progressed or been withdrawn following requests for further information to support the applicants' ability to self-fund purchases.
- The Authority made changes to its staffing profile in order to administer the new processes while continuing to maintain service standards.
- The Authority recently hosted a stakeholder forum aimed at identifying improvements to licence application processes. Stakeholders generally agreed that the service standard provided by the Authority is acceptable and appreciate that the Authority's staff is available to take calls and assist with applications. Stakeholders also appreciated having a platform like the forum to provide feedback and would welcome similar forums and forums on other topics in the future.

## RECOMMENDATIONS<sup>3</sup>

1. Review selection criteria for audit to ensure that audits are undertaken on an appropriate risk basis.
  - a. Remove *Association with franchise/banner group* and *Licensees residing interstate* as selection criteria.
  - b. Consult with stakeholders to help identify possible additional criteria for audit.
2. Apply additional resources and tools to (a reduced number of) ownership audits – this may include carrying out premises inspections in parallel with ownership audits to examine documents such as electronic funds transfer (EFT) records, Medicare claim statements, invoices for goods received.
3. Reduce the base number of ownership audits to be undertaken annually.
4. Maintain and consider increasing the number of financial audits subject to consideration of further audits findings.
5. Accelerate the formal legal review of franchise agreements and other complex commercial arrangements to ensure compliance with the Act.
6. In cases where information is not provided or is incomplete without reasonable excuse, advise licensees that continued failure to provide information may lead to prosecution.

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<sup>3</sup> Adopted by Victorian Pharmacy Authority 10 March 2020