

Year 2 Evaluation Report

Pharmacy Ownership Audit Program

Victorian Pharmacy Authority

30 June 2021

Victorian Pharmacy Authority
PHARMACY OWNERSHIP AUDIT PROGRAM
YEAR 2 EVALUATION REPORT

INTRODUCTION

The Victorian Pharmacy Authority is committed to ensuring that all pharmacies in Victoria are owned, operated and controlled only by registered pharmacists in accordance with the *Pharmacy Regulation Act 2010* (the Act).

To support this goal, the Authority conducts an annual risk-based pharmacy ownership 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.

The Authority selected 101 pharmacies to undergo an ownership audit and 11 for a financial audit in the 2019 calendar year and of these thirty-five ownership audits and two financial audits were completed. The Year 1 Evaluation Report of the program was published in 2020 and is available on the Authority’s website (www.pharmacy.vic.gov.au).

In the 2020 calendar year, forty-five ownership audits and 1 financial audit were completed from the audits selected in the previous year. [A further 6 financial audits were completed in the first quarter of 2021]. These audits have not identified any cases of silent or undeclared ownership. The remaining audits are planned for completion by 30 June 2021.

A major barrier to progress in 2020 has been delays caused by the coronavirus pandemic. Licensees were given ample time to respond to audits with due consideration for the challenges presented by sustained lockdowns. Delays also occurred as Authority staff adjusted to a different working environment during the pandemic.

The outcomes of the audits completed are summarised in the next section.

FINDINGS

The following tables provide a summary of audits undertaken in 2019 and 2020, including outcomes. The remaining audits are planned for completion by 30 June 2021.

Ownership Audits				
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#	7	7
1Q 2020	-	1	15	11
2Q 2020	-	1	13	9
3Q 2020	-	-	15	15
4Q 2020	-	-	10	10
Total	101	100	97	80

#An ownership audit did not proceed in one case since the pharmacy changed ownership around the time of the audit request.

Outcome of Ownership Audits Completed in 2019-2020	
Compliant	25
Compliant (noting review of established commercial agreement pending)	37
Compliant (noting potential non-compliance with s11)	14
Compliant (noting potential non-compliant clauses in the trust deed)	1
Compliant (noting review of established commercial agreement pending and potential non-complaint clauses in the trust deed)	3
Non-compliant	0
Total	80

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]

Compliant (noting potential non-compliant clauses in the trust deed)

Ownership arrangements consistent with stated arrangements. No evidence of non-compliance but noting potential non-compliant clauses in the trust deed.

Non-compliant

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

Financial Audits				
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
1Q 2020	-	-	6	-
2Q 2020	-	-	-	-
3Q 2020	-	-	-	1
4Q 2020	-	-	-	-
Total	11	11	11	3

Outcome of Financial Audits Completed in 2019-2020		
Compliant	Non-compliant – payment to non-eligible beneficiary	Total
2	1	3

EVALUATION

Forty-five of the (101) ownership audits selected in 2019 were completed in 2020.

In total, eighty of the (101) ownership audits were completed between 2019 to 2020. These audits have not detected any unlawful ownership.

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.

In cases where the pharmacy was operating under a commercial arrangement for which the Authority had not yet completed a formal legal assessment, licensees will be advised that a condition will be imposed on the licence. This “commercial arrangement” condition details the action the Authority may take if, after further investigation, the commercial arrangements are found to contravene the Act.

The “commercial arrangement” condition is a standard licence condition which has been imposed since 2017 on new licences when an applicant wishes to operate a pharmacy business under arrangements which have not yet undergone a detailed assessment for compliance with the Act. It is removed from a licence when the Authority is satisfied that the pharmacy business commercial arrangements comply with the Act.

One financial audit was completed in 2020 and was found to be compliant. [The Authority received the final reports on a further 6 financial audits in the first quarter of 2021. These have been assessed as compliant]. Financial audits often require at least 6 months to a year to complete owing to the volume and complexity of information undergoing assessment and depending on the cooperation of licensees to provide further information and clarification in a timely manner.

Since the beginning of the pandemic, the Authority has provided licensees ample time to respond to requests for further information, often granting time extensions. However, in one case following multiple unsuccessful correspondence and a lengthy engagement, the Authority warned a licensee of its intention to commence proceedings in the Magistrates Court if there was continued failure to produce documents as part of the ownership audit.

The Authority continues to set clear expectations in its correspondence to licensees regarding the turnaround time to respond to an audit request for further information.

COMMUNICATION

In Circular No.24 (published 29 March 2021), the Authority highlighted the requirements of pharmacy ownership according to the Act including penalties associated with breaches as well as outlining the Authority’s approach to franchise agreements and other complex commercial arrangements. Any new commercial arrangements must be assessed as compliant with the Act before the Authority will issue a licence to a person to carry on a pharmacy business pursuant to the arrangements. Established commercial arrangements continue to be reviewed for compliance with the Act on a risk basis as noted in the Year 1 Evaluation Report.

The Circular also served as a reminder that the Act provides for a person to notify the Authority about any matter relating to a licensee if the person has information indicating that the:

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

The Authority will investigate a matter based on such a notification and where the notification relates to the ownership, the Authority may consider initiating an ownership and financial audit of the pharmacy.

PHARMACY OWNERSHIP AUDIT PROGRAM 2021

The Authority has adopted the recommendation outlined in the Year 1 Evaluation Report in 2020 and has revised the annual target to 40 ownership audits for 2021, including at least 10 financial audits.

Regular meetings with the accountants conducting financial audits continued since 2020 to discuss learnings from the audits undertaken and the focus of future audits.

The Authority is currently consulting with stakeholders to identify further improvements to the pharmacy ownership audit program. This will help inform the next round of audits due for commencement in 2021.