

Health Insights

No half doses in pharmacy ownership

A reminder to pharmacy proprietors of their key responsibilities

Meridian Lawyers regularly assists a range of healthcare professionals to understand the legal and professional obligations that attach to their particular profession.

Recently, in NSW, we have assisted a number of proprietor pharmacists who have come under close scrutiny by the Pharmacy Council of NSW following audits of opioid dosing point pharmacies across the State by the Pharmaceutical Regulatory Unit of NSW Health, and in response to complaints made about inappropriate dispensing of medicines more generally.

This serves as a timely reminder to proprietors across Australia of the need to review and ensure adherence to the Pharmacy Board of Australia's Guidelines for Proprietor Pharmacists (**the Proprietor Guidelines**), which provide guidance to pharmacy proprietors/owners of the professional responsibilities not set out in the legislation or a registration standard. The Proprietor Guidelines apply to all registered pharmacists who own or hold a proprietary or pecuniary interest in a pharmacy business.

Pharmacy proprietors need to be aware that non-compliance with the Proprietor Guidelines may be viewed as a breach of their professional obligations and notified to the relevant Board or Council for appropriate action under the Health Practitioner Regulation National Law, as in force in each State and Territory (**the National Law**). The Proprietor Guidelines are approved by the Pharmacy Board of Australia and as such, they may be used in disciplinary proceedings under the National Law as evidence of what constitutes appropriate professional conduct or practise for pharmacists¹.

The Proprietor Guidelines can also be considered in immediate action proceedings under the National Law, if the relevant Board or Council in each State and Territory has cause to consider if it is appropriate to suspend or place conditions on the registration of a pharmacist in order to protect the health and safety of the public, or when it is in the public interest to do so. Recently, we have seen an increase in interim suspension orders made under the National Law, where non-compliance with the Proprietor Guidelines has been of concern.

¹ Section 41 of the National Law

Summary of the Proprietor Guidelines

The Proprietor Guidelines state that a registered pharmacist who is a proprietor of, or who has a pecuniary interest in, a pharmacy business, **must**:

- maintain, and be able to demonstrate an awareness of, the manner in which that pharmacy business is being conducted; and
- where necessary, intervene to ensure that the practise of pharmacy is conducted in accordance with applicable laws, standards and guidelines.

This means that pharmacy proprietors must vigilantly maintain an active interest in how the practise of pharmacy is being conducted at any and all of the pharmacies in which they have an interest. A proprietor/owner or partner-in-ownership of a pharmacy should be aware that they cannot delegate their professional obligations, even if they are not present at or work in the pharmacy on a regular basis.

A proprietor pharmacist must ensure that procedures and policies for all services provided by the pharmacy are documented and available within the pharmacy for all staff to access and follow, and have a system in place for ensuring that those policies and procedures are being followed, reviewed and updated when necessary.

This requires proprietor pharmacists to conduct regular on-site visits, audits, inspections and staff meetings, to ensure that the proprietor is able to fulfil the responsibilities set out in the Proprietor Guidelines. It is also important that proprietors are able to evidence that they have an appropriate level of oversight and are complying with the responsibilities set out in the Proprietor Guidelines. Having a system in place to record when meetings, inspections and audits occur is also paramount.

What if I am unable to physically visit my pharmacy?

Pharmacy proprietors may not always live close to where the pharmacy is located and could even reside in a different State or Territory. The recent COVID-19 pandemic may also mean that proprietors have difficulty traveling to or visiting their pharmacies. Nevertheless, proprietors should ensure that they:

- Communicate regularly with pharmacy staff and with their business partners via telephone or Audio Visual Link technology (**AVL**);
- Have the ability to conduct off-site audits (via remote access to computer systems) so that any deficiencies or issues can be identified;
- Arrange on-site inspections and audits by an independent auditor or a business partner who can visit the premises;
- Take appropriate action when any deficiencies or concerns are identified;
- Have the ability to obtain and review key data on a daily, weekly and monthly basis;
- Conduct staff meetings and partnership meetings via AVL; and
- Have systems in place to record when such meetings, inspections and audits occur.

Useful Tips

Being a pharmacist and running a pharmacy business is not easy. Some of the ways in which proprietors can maintain and demonstrate an awareness of the manner in which their pharmacy business is being conducted include:

- Being familiar with the legislation governing the dispensing of medicines in the relevant State and Territories in which they have ownership or a pecuniary interest in a pharmacy.
- Keeping up to date with legislative changes in pharmacy practises and any guidelines issued that impact upon the practise of pharmacy (and ensuring that any changes are distributed and communicated to pharmacy staff).
- Having input into the policies and procedures in place at each pharmacy they own and regularly reviewing these to ensure they remain current.
- Arranging regular meetings with their managing pharmacists/ pharmacists in charge and documenting when such meetings occur.
- Conducting regular on-site visits, audits and inspections (for example, auditing Drugs of Dependence (DD) registers, inspecting drug safes, performing spot checks of cancelled prescriptions, checking that all expired medicines are stored separately from in-date medicines, etc).
- Document when such visits, audits and inspections occur and act when any inappropriate or inadequate dispensing practises are uncovered.
- Engage in partnership meetings with business partners, to discuss issues arising in the pharmacy and what action needs to be taken.
- Provide adequate training for all pharmacy staff and document when such training has been provided.

The Proprietor Guidelines make it clear that proprietor pharmacists must adhere to their professional and ethical responsibilities and should not sacrifice them out of pecuniary considerations only². Proprietor pharmacists are required to be closely involved in overseeing the overall workings of the pharmacies they own, ensure that their pharmacies are compliant with all legislative obligations relevant to the State or Territory where pharmaceutical services are being provided, and be committed to ensuring that the high standards of the pharmacy profession are maintained.

For further information and assistance, contact AHPRA or your professional indemnity insurer.

Meridian Lawyers assists proprietor pharmacists in understanding their professional obligations to adhere to Proprietor Guidelines and regularly advises on the legal and ethical issues that present themselves in day-to-day operations.

² *Health Care Complaints Commission v Visvis* [2020] NSWCATOD 87

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This article was originally published by Pharmacy Defence Limited (PDL) and was included in the September edition of the *Australian Journal of Pharmacy*. The article was written by Special Counsel Chandrika Darroch. Please contact Chandrika if you have any questions or would like more information.



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