

THE LEGISLATIVE ASSEMBLY FOR  
THE AUSTRALIAN CAPITAL TERRITORY

PUBLIC HEALTH (COMMUNITY PHARMACY OWNERSHIP)  
AMENDMENT REGULATION 2012 (No 1)

SL2012-30

EXPLANATORY STATEMENT

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# Public Health (Community Pharmacy Ownership) Amendment Regulation 2012 (No 1)

## Overview

When the *Health Practitioner Regulation National Law (ACT) 2010* was enacted by the Legislative Assembly it did not contain a provision that would ensure that pharmacies can only be owned by registered pharmacists or a complying pharmacy corporation. This was an important and unintended oversight.

To correct this problematic oversight, section 13 of the *Health Practitioner Regulation National Law (ACT) 2010* was used to make a Regulation that modified the *Health Practitioner Regulation National Law (ACT) 2010*, and consequentially the *Health Act 1993* (the Health Act). The modification made was the insertion into the Health Act of section 129A, which limits pharmacy ownership to pharmacists or a complying pharmacy corporation by way of an offence.

Modification of the *Health Practitioner Regulation National Law (ACT) 2010* is authorised by section 13 of the *Health Practitioner Regulation National Law (ACT) 2010*. Section 13 provides that a regulation may prescribe transitional matters necessary or convenient to be prescribed because of the enactment of the *Health Practitioner Regulation National Law (ACT) 2010*. Transitional powers are inserted into legislation where there is some complexity arising from a reforming Bill. A clause of this nature ensures that any matters that may have been inadvertently omitted or inadequately dealt with when developing a Bill can be addressed.

The Health Practitioner Regulation National Law (ACT) (Transitional Provisions) Regulation 2010 (No 2) was made pursuant to section 13 of the *Health Practitioner Regulation National Law (ACT) 2010* to modify the Act, and consequentially amend the Health Act. However, the Health Practitioner Regulation National Law (ACT) (Transitional Provisions) Regulation 2010 (No 2) is a transitional provision that has a limited life, and as such will expire on 1 July 2012.

Subsequently, section 129A as inserted into the Health Act also expires on 1 July 2012 at midnight. The purpose of this Regulation is essentially to permanently preserve the restriction on pharmacy ownership beyond 1 July 2012. This is being achieved by reproducing in the Public Health Regulation 2000, as much as possible, the offence currently in section 129A of the Health Act.

Several factors influenced the decision to place the permanent restriction on pharmacy ownership in the Public Health Regulation 2000. The first factor is the objectives of the *Public Health Act 1997* (the PHA), which include protection of the public from public health risks, including those associated with facilities, products and activities not adequately controlled by another Territory or Commonwealth law. To this end regulations may be made under the PHA, including in relation to matters pertaining to drug preparation and supply. As pharmacies are integral to the preparation and supply of drugs and medicines to the community, the Public Health legislation is an appropriate place to house provisions restricting pharmacy ownership. This is reflected by the fact that the Public Health Regulation 2000 already contains a Division applying to Pharmacies; Division 5.6. Accordingly, it is appropriate for additional provisions pertaining to pharmacies to be located within that Division of the Public Health Regulation 2000.

Another influencing factor is that it is intended to declare the operation of a community pharmacy to be a licensable public health risk activity pursuant to section 18 of the PHA. This will enable greater regulatory oversight and scrutiny of community pharmacies. Furthermore, it will enhance the ability of the regulator to identify and assess the suitability of all persons that own and are operating community pharmacies. In the absence of a licensing regime, it is considered that the ability of the Health Directorate as the regulator to identify all persons with ownership or control of a pharmacy business is limited. Furthermore, the powers available to the regulator where contraventions of the requirements for pharmacies have been identified would be very limited.

It is also expected that the declaration of community pharmacies as a licensable public health risk activity would be supported by a code of practice under the PHA to which licensed operators of community pharmacies would need to comply.

The preparation and supply of drugs and medicines has the ability to have a significant impact on the health of individuals in the context of the wider health of the community. It is critically important to the wider health of the community that the supply of medicines from community pharmacies be supported by advice and guidance from suitably qualified and registered persons (pharmacists), who are bound by ethical responsibilities, and unencumbered by competing and inappropriate considerations and influences. Put simply, the community expects that pharmacists at community pharmacies are independent, and not beholden to competing business interests or influences which may undermine, detract or counter the provision of a vital health service. On this basis it is regarded that restrictions on pharmacy ownership are directly relevant to the protection of public health because of the central role pharmacies play in the preparation and supply of drugs and medicines in the ACT.

## Background information

On 26 March 2008 the Council of Australian Governments (COAG) signed the 2008 *Intergovernmental Agreement for a National Registration and Accreditation Scheme for Health Professions* (the Agreement). The objective of the agreement was to fully implement a national scheme of registration and accreditation for health professions (the National Scheme) in Australia by 1 July 2010.

In the ACT the final stage was achieved through the *Health Practitioner Regulation National Law (ACT) Act 2010*. The consequential amendment section of the *Health Practitioner Regulation National Law (ACT) Act 2010* contained amendments to other existing ACT legislation affected by the reforms; such as the Health Act and Health Professionals Regulation 2004.

Among the amendments to the Health Act were provisions about pharmacists and pharmacy premises. The explanatory statement for the amendments stated the purpose of the amendments that inserted Part 9 into the Health Act was "to ensure that the status quo regarding pharmacy premises is maintained". The intended position was that in order to protect the wider health of the community that pharmacists have direct, personal control of the operation of community pharmacies.

It was later identified that this position was not given full effect. Consequently, the power in the *Health Practitioner Regulation National Law (ACT) 2010* was used to modify the Health Act to give effect to the intended position.

### **Clause 1 Name of regulation**

The first clause of the Regulation declares that the name of the Regulation is to be the Public Health (Community Pharmacy Ownership) Amendment Regulation 2012 (No 1).

### **Clause 2 Commencement**

Clause 2 provides for the commencement of the Act, which is to occur on 2 July 2012.

The Health Practitioner Regulation National Law (ACT) (Transitional Provisions) Regulation 2010 (No 2) utilised the power in the *Health Practitioner Regulation National Law (ACT) 2010* to make modifications to the Act.

Modification of the *Health Practitioner Regulation National Law (ACT) 2010* is authorised by section 13 of the same Act, which provides that a regulation may prescribe transitional matters necessary or convenient to be prescribed because of the enactment of the Act. Transitional powers are inserted into legislation where there is some complexity arising from a reforming Bill. A clause of this nature ensures that any matters that may have been inadvertently omitted or inadequately dealt with when developing a Bill can be addressed.

When the *Health Practitioner Regulation National Law (ACT) 2010* was enacted by the Legislative Assembly it did not contain a provision that would ensure that pharmacies can only be owned by registered pharmacists or a complying pharmacy corporation. This was an important and unintended oversight. Accordingly, section 13 of the *Health Practitioner Regulation National Law (ACT) 2010* was used to correct this oversight by modifying the Health Act by inserting section 129A (ownership of pharmacy business). Section 129A restored the restriction on pharmacy ownership to pharmacists or a complying pharmacy corporation by way of an offence.

However, the Regulation used to make the modifications is a transitional provision that was to have a limited life, and as such will expire on 1 July 2012. Subsequently, section 129A as inserted into the *Health Act 1993* also expires on 1 July 2012. Pursuant to section 85(3) of the *Legislation Act 2001*, the expiry of the modification occurs at midnight on 1 July 2012.

The purpose of this Regulation is essentially to preserve the restriction on pharmacy ownership beyond 1 July 2012. This is being achieved by reproducing in the Public Health Regulation 2000, as much as possible, the offence currently in section 129A of the Health Act.

Therefore, the amendments in this Regulation will take effect at the beginning of 2 July 2012 in accordance with section 74(1) of the *Legislation Act 2001*. This will ensure that a restriction on pharmacy ownership to pharmacists or a complying pharmacy corporation continues seamlessly beyond 1 July 2012.

### **Clause 3 Legislation amended**

This provision alerts the reader that this Regulation amends the Public Health Regulation 2000.

Upon commencement this Regulation will alter the Public Health Regulation 2000 in accordance with the provisions that this Regulation contains. This Regulation will then be immediately repealed. Consequentially, from the date that this Regulation commences a new republication of the Public Health Regulation 2000 will be available. That new republication will feature the alterations made by this Regulation.

#### Clause 4      New section 62

Clause 4 inserts a new section 62 into Division 5.6 of the Public Health Regulation 2000, relates to pharmacies.

The first subsection of the new section 62 makes it an offence for a person to own a pharmacy unless the person is a pharmacist or a complying pharmacy corporation. The offence carries a maximum penalty of 10 penalty units. Unless the offence applies to a utility, section 138(3) of the PHA determines that 10 penalty units is the highest maximum penalty that can imposed in the Public Health Regulation 2000.

Contained with subsection 62(2) are explanations of terms utilised in the offence in subsection 1. The provision directs the reader to section 128A of the Health Act for the meaning of *complying pharmacy corporation*. Similarly, the reader is directed to the section 11 of the *Medicines, Poisons and Therapeutic Goods Act 2008* for the meaning of *medicine*, and to the dictionary of that Act for the meaning of *community pharmacy*.

For the purposes of the offence, the supply, compounding or dispensing of a medicines is considered to be a pharmacy service, as is the provision of advice and counselling regarding the effective use of a medicine. As a consequence, a business that provides one or more of these pharmacy services will be considered a pharmacy business to which the offence relates.

According to subsection 62(2), owning a pharmacy includes having a legal or beneficial interest in the pharmacy business. This extends the concept of ownership of the pharmacy, and ensures that anyone that may have the ability to influence the operation of the pharmacy business through a legal or beneficial interest is relevant to the application of the provision.

However, the subsection also recognises that following the death of a pharmacist that owns a community pharmacy, the public trustee or a legal representative of the deceased pharmacist may be called upon to deal with the assets of the deceased pharmacist's estate. As the pharmacy business is likely to be one of those assets, the provision makes it clear that the legal representative or the public trustee will not be considered to own the pharmacy business for the purposes of the offence. This prevents the offence from applying merely because a legal representative or the public trustee has taken control of assets from the estate of a deceased pharmacist.

The operation of the offence will however, prevent the legal representative or the public trustee from transferring ownership of the pharmacy to a beneficiary or next of kin of the pharmacist, unless that person also happens to be a pharmacist. In such circumstances the legal representative or public trustee would need to organise for the sale of the pharmacy business, and the proceeds of the sale would be become part of the deceased pharmacist's estate.

It should be noted however, that it may be possible for the executor of a deceased pharmacist's estate to apply to the Chief Health Officer for permission to operate the pharmacy briefly to allow for the sale or disposal of the pharmacy. Section 128B of the Health Act enables the Minister for Health to approve standards about premises for community pharmacies, which the Minister has done through the Health (Community Pharmacy Premises) Approved Standard 2010 (No 1). Part 4 of those declared standards has application in circumstances where a pharmacist operating a community pharmacy dies. The provision in the Standard is reasonable and appropriate to prevent a community pharmacy from needing to immediately cease operating due to the death of the owner pharmacist. This prevents the loss of employment for staff at the pharmacy, and the associated impact on the community. It also ensures that the executor of the

deceased pharmacist's estate has reasonable time to organise for the sale of the pharmacy, without the value of the pharmacy and the good will of the business being lost.

The offence within section 62 does not involve strict or absolute liability. It also does not displace any defences or rights of a defendant, or place any evidentiary burden on the defendant. As such, the offence in section 62 does not engage or limit any rights under the *Human Rights Act 2004*.

#### **Clause 5      Dictionary, note 2**

This clause amends the Dictionary in the Public Health Regulation 2000 by adding the word "pharmacist" to Note 2 of the Dictionary. The purpose of Note 2 is to alert the reader to the fact that the dictionary in the *Legislation Act 2001* defines a range of terms that are used in the Public Health Regulation 2000. These terms include *ACT*, *chief health officer*, *doctor*, and *nurse*. As this regulation will add references to a 'pharmacist', which is also a term defined in the *Legislation Act 2001*, it is appropriate to amend Note 2 accordingly.