THE LEGISLATIVE ASSEMBLY FOR THE AUSTRALIAN CAPITAL TERRITORY

PUBLIC HEALTH (COMMUNITY PHARMACY OWNERSHIP) AMENDMENT REGULATION 2013 (No 1)

SL2013-4

EXPLANATORY STATEMENT

Circulated by the authority of Katy Gallagher MLA Minister for Health

Public Health (Community Pharmacy Ownership) Amendment Regulation 2013 (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 limited by way of an offence pharmacy ownership to pharmacists or a complying pharmacy corporations.

Modification of the *Health Practitioner Regulation National Law (ACT) 2010* was authorised by section 13 of the *Health Practitioner Regulation National Law (ACT) 2010*. Section 13 provided 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 had a limited life, and as such expired on 1 July 2012. Subsequently, section 129A as inserted into the Health Act also expired on 1 July 2012.

The Public Health (Community Pharmacy Ownership) Amendment Regulation 2012 (No 1) was made under section 138 of the *Public Health Act 1997* to permanently preserve the restriction on pharmacy ownership beyond 1 July 2012. To the extent possible, section 62 of the Public Health Regulation 2000 reproduced the offence that was outlined in the section 129A of the Health Act.

In addition, the *Public Health (Community Pharmacy) Risk Activity Declaration 2012 (No 1)* was made under section 18 of the *Public Health Act 1997* declaring the operation of community pharmacy as a licensable public health risk activity from 1 March 2013. The combined effect of the offence in section 62 of the Public Health Regulation 2000 and the declaration of the operation of community pharmacy as a licensable public health Regulation 2010 and the declaration of the 1 March 2013 all owners of community pharmacies in the ACT will require a licence to operate.

This Regulation has been prepared in recognition of the fact that a small number of pharmacy corporations that legitimately and legally owned a community pharmacy prior to 1 July 2010 do not fully comply with the current provisions under section 128A of the Health Act.

In some cases this is because it was possible in the ACT prior to 1 July 2010 for corporation to be registered as a corporate pharmacist. By extension it was also possible for a corporate pharmacist to be a shareholder of another corporate pharmacist. It was no longer possible for a

corporation to be registered as a pharmacist after 1 July 2010 when the Pharmacy Board of Australia took over the registration of pharmacists. Consequently, a pharmacy corporation that has a former pharmacist corporation as a shareholder does not comply with the provisions now placed in section 128A of the Health Act.

The amendments made by this Regulation seek to allow pharmacy corporations that owned a community pharmacy and through it operated a pharmacy business prior to 1 July 2010 to be able to continue to do so, subject to conditions.

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.

DETAILS

A detailed explanation of each clause of the Regulation follows.

Clauses

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 2013 (No 1).

Clause 2 Commencement

Clause 2 provides for the commencement of the Act, which will commence on the day after its notification.

Due to the operation of section 75(1) of the *Legislation Act 2001* (the Legislation Act) the naming and commencement provisions of this Regulation, clauses 1 and 2, commence automatically on the day the Regulation is notified. A note to that effect is included in the provision.

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 (1) (c)

In 2012 the Public Health Regulation 2000 was amended by SL2012-30; the Public Health (Community Pharmacy Ownership) Amendment Regulation 2021 (No 1). SL2012-30 inserted into the Public Health Regulation 2000 a new section 62, which makes it an offence for a person to own a pharmacy unless the person is a pharmacist or a complying pharmacy corporation.

Clause 4 of this Regulation amends section 62(1) by adding a paragraph (c). The effect of the new paragraph is to permit *former corporate pharmacists* to own a community pharmacy, in addition to pharmacists and complying pharmacy corporations. The meaning of the term *'former corporate pharmacist* is the subject of the next clause to this Regulation.

This provision will not alter the manner in which the offence within section 62 operates. It is neither a strict liability offence or an absolute liability offence, and does not displace any defences or rights of a defendant, or place any evidentiary burden on the defendant. As such, no rights under the *Human Rights Act 2004* are engaged or limited by the amendment to this offence provision.

Clause 5 Section 62 (2), new definition of *former corporate pharmacist*

Contained with section 62(2) of the Public Health Regulation 2000 are explanations of terms utilised in the offence in the preceding subsection. The provision already defines what amounts to a *pharmacy business* and *pharmacy services*, as well as directing the reader to section 128A of the Health Act for the meaning of *complying pharmacy corporation* and to the *Medicines*, *Poisons and Therapeutic Goods Act 2008* for the meaning of *medicine* and *community pharmacy*. The fifth clause of this Regulation inserts into section 62(2) a definition of a *former corporate pharmacist*.

On 1 July 2010 Australia moved to a system of national registration for a range of health professionals, including pharmacists. Prior to that date however, pharmacists in the ACT were registered under the ACT *Health Professionals Act 2004* by the then ACT Pharmacy Board, which also permitted companies to be registered as a *corporate pharmacist*.

The Health Professionals legislation contained criteria that a corporation was to meet in order to be registered as a corporate pharmacist, but these criteria had not been strictly or robustly interpreted or applied. As a result, there are several community pharmacies in the ACT owned by corporations, or trusts administered by corporations as trustee, that would not meet the criteria to be able to obtain a licence under the Public Health legislation to operate a pharmacy business from 1 March 2013 onward.

It would be possible for such corporations to make the necessary changes to meet the new criteria so as to obtain a licence, but doing so has the potential to have significant taxation consequences for the shareholders involved. It is accepted that the incurring of significant taxation liabilities in order to comply with a recently introduced regulatory arrangement would be an unreasonable cost burden on affected companies and shareholders. It would also be undesirable for such a corporation, which previously was legally able to own a community pharmacy, to now be in breach of section 62 of the Public Health Regulation despite no real change in command and control or ownership.

To resolve this potential problem former corporate pharmacists that meet certain criteria will, by virtue of changes made by this Regulation, be permitted under section 62(1) of the Public Health Regulation to own a community pharmacy.

For a company to be considered a *former corporate pharmacist* several essential criteria must be met, starting with the requirement that the company actually owned a pharmacy business on 30 June 2010, and has continuously owned and operated the pharmacy business since that date.

The other requirements to be considered a *former corporate pharmacist* are that since 30 June 2010 the company must have only appointed pharmacists as directors of the corporation, and must not have allowed persons to become new shareholders of the company unless those persons are a company pharmacist, or a close relative of a company pharmacist, and that such persons hold the beneficial ownership of those shares. Pharmacists that have been appointed as directors of the corporation are considered company pharmacists, as are any pharmacists employed in the corporation.

In the event that the corporation practices pharmacy as a trustee under a trust deed, any new beneficiaries added to the trust deed since 30 June 2010 must only be a company pharmacist, or a close relative of a company pharmacist. For the purposes of this section, a company pharmacist includes a pharmacist appointed as a director of the company, or a pharmacist employed by the company.

A definition of *close relative* is contained in the section. The meaning assigned to the term reflects modern drafting approaches, and is consistent with that used in other ACT legislation, including the *Working with Vulnerable People (Background Checking) Act 2011.* The definition recognises the nature of modern families and relationships. The meaning of a close relative has been broadened so as to included step-relationships, such as stepmothers, stepsons and stepsisters. Also expressly included are half brothers and half sisters, as well as in-laws, such as a father-in-law, or even uncles and aunts-in-law.

It has long been the intention that pharmacy businesses are essentially only owned by pharmacists. Recognising commercial reality, in 2001 the ACT made legislative amendments that enabled pharmacy businesses to be owned by corporations, provided the company was essentially owned through its shareholdings by pharmacists or their close relatives, and that it was governed, through its directors, by pharmacists.

The framing of this provision recognises that although this intention has been long standing, its interpretation and enforcement over the years has been inconsistently applied. As such, this provision has been constructed so as to allow for some tolerance for companies that owned a pharmacy business prior to 1 July 2010, which is the date that national registration of pharmacists commenced, and have thereafter continuously owned and operated that pharmacy business.

Accordingly, to be regarded as a former corporate pharmacist since 30 June 2010 the company must only have appointed pharmacists as directors. What this means is that in the event that the company had a director prior to 30 June 2010 who is not a pharmacist, that will be acceptable. In contrast however, if any director appointed on or after 30 June 2010 is not a pharmacist, the company will not meet the definition of a former corporate pharmacist, and will need to make all necessary changes to meet the definition of a complying pharmacy corporation in section 128A of the Health Act before the company will be issue a licence.

Similarly, for a company to be considered a former corporate pharmacist it must not have allowed from 30 June 2010 persons to become new shareholders of the company unless those persons are a company pharmacist, or a close relative of a company pharmacist, and that such persons hold the beneficial ownership of those shares.

As such, any company that owned a pharmacy business prior to 30 June 2010 which had shareholders that are not pharmacists or close relatives of a pharmacist will be accepted. However, if the company has obtained new shareholders since 30 June 2010 the company will not meet the definition of a former corporate pharmacist if those new shareholders are not a pharmacist appointed as a director of the company, or a pharmacist employed by the company.

It should be noted that the restriction applies only to new shareholders. As such, there is no impediment to any person that was a shareholder prior to 30 June 2010, even if they are not a pharmacist or close relative of a pharmacist, from acquiring more shares in the company after 30 June 2010.

Where a corporation practices pharmacy as a trustee, it is the trust deed that dictates the functions and directions of the trust. Again, this Regulation has allowed a measure of tolerance for trusts and company trustees established prior to 30 June 2010, and to persons that are not a pharmacist, or related to a pharmacist, being a beneficiary to such a trust. However, should a person that is not a pharmacist, or related to a pharmacist, be added to a trust deed as a new beneficiary, that the entire trust deed and the trustee corporation will not be regarded as a *former corporate pharmacist*, and all necessary changes will need to be made in order to meet the definition of a complying pharmacy corporation in section 128A of the Health Act.