Public Health (Community Pharmacy) Code of Practice 2012 (No 1)

Disallowable instrument DI2012-211

made under the

Public Health Act 1997, s 133 (Codes of practice)

EXPLANATORY STATEMENT

Part 3 of the *Public Act 1997* (the PHA) establishes the regulatory framework for public health risk activities and procedures. The Minister is given the power to declare an activity that may result in the transmission of disease, or risk to public health, to be a public health risk activity.

The operation of a community pharmacy has been declared a licensable public health risk activity pursuant to section 18 of the PHA.

Under section 133 of the PHA the Minister also has the power to declare a code of practice that sets out minimum standard or guidelines relating to a public health matter or public health risk activity.

As a code of practice pertaining to community pharmacies has been established by this instrument, persons carrying on the licensable public health risk activity of operating a community pharmacy are required by section 20 of the PHA to comply with the code of practice. Failure to do so is an offence, and will carry a maximum penalty of 50 penalty units, 6 months imprisonment, or both.

This Community Pharmacy Code of Practice 2012 has been developed in order to provide a framework and a set of minimum standards for community pharmacy in the ACT in which community pharmacy licensees are required to meet as part of their licence obligations.

The technical requirements of the code of practice are consistent with guidance provided by the Pharmacy Board of Australia for pharmacy owners and with the current Health (Community Pharmacy Premises) Approved Standard 2010 (No 1); NI2010-349.

The Health (Community Pharmacy Premises) Approved Standard 2010 (No 1) is a notifiable instrument, approved by the Minister in accordance with section 128B of the *Health Act 1993* (the Health Act). Compliance with an approved standard was intended to be mandatory, as is evident from subsection 4 which states that 'a pharmacist must comply with any standard approved under this section'. The problem, however, is that the Health Directorate as the Regulator has no ability to determine, or enforce, compliance with the approved standard. There is no offence within the Health Act for failing to comply with an approved standard. Furthermore, the Health Act does not establish a licensing system for community pharmacies, which means that administrative sanctions such as the suspension or cancellation of a licence are not available to enforce compliance with the approved standard.

Even if Part 9 of the Health Act did contain an offence, the absence of inspection powers under the Health Act would prevent the Health Directorate from being able to identify or investigate contraventions.

Unlike the Health (Community Pharmacy Premises) Approved Standard 2010 (No 1), failure to comply with a code of practice declared under the PHA is an offence, and is supported by a suite of enforcement powers available to the Health Directorate. As such, many of the requirements that were in the Health (Community Pharmacy Premises) Approved Standard 2010 No 1) have been replicated in the code of practice, albeit with necessary modifications to ensure currency and validity.

Retaining the Health (Community Pharmacy Premises) Approved Standard 2010 No 1) together with this code of practice is not necessary, and may risk confusion or even inconsistency. For this reason the Health (Community Pharmacy Premises) Approved Standard 2010 No 1), NI2010-349, will be revoked by a notifiable instrument under the *Health Act 1993* to take effect on the commencement of the code of practice.

The first section of the code of practice addresses terminology used in the code of practice. In many instances references are made to specific items of ACT legislation where the term used has been defined. For example, this section refers the reader to the *Health Act 1993* for the meaning of *supermarket*. Another example is the term *public trustee*, which is defined in the dictionary of the *Public Trustee Act 1985*.

An important term defined in the section is that of a *pharmacist in charge*. The code of practice, and the definition of a pharmacist in charge provided, reinforce that the person that owns and controls a pharmacy business is separate and distinct from the pharmacist in charge at a community pharmacy on any given day.

The pharmacist in charge at a community pharmacy is responsible for the delivery of the actual pharmacy service; being the supply, compounding, or dispensing of a medicine, and the provision of advice and counselling on the effective use of a medicine. As such they have professional obligations and a range of duties under other legislation such as the Medicines, Poisons and Therapeutic Goods legislation. Nevertheless, they are not responsible for the ordinary business operations of the community pharmacy, such as matters involving employment and payment of staff, payment of rent, rates or services, or the design and fit out of the community pharmacy.

In effect, this declaration recognises that whilst the role and functions of a pharmacist in charge at a community pharmacy are well defined, there are aspects of a pharmacy business that are beyond the control of the pharmacist in charge, but which can still have a very significant impact on the provision of pharmacy services and, by extension, the wider health of the community. As such, pharmacists that may be from time to time a pharmacist in charge at a community pharmacy do not need to hold a licence under this declaration. Rather, it is the person or persons that own the pharmacy that will be required to hold a licence.

The next section of the code of practice determines reference works that must be kept at, and maintained, at a community pharmacy. The reference materials required to be kept by a community pharmacy are those listed in the *Guidelines on Practice-Specific Issues – Guideline 1 (List of References)*, as in force from time to time, produced by the Pharmacy Board of Australia. Applying the list of references prepared by the Pharmacy Board of Australia increases the prospects of consistency with other Australian jurisdictions. The *Guidelines on Practice-Specific Issues – Guideline 1 (List of*

References) are available without cost from the website of the Pharmacy Board of Australia; http://www.pharmacyboard.gov.au/Codes-Guidelines.aspx.

Minimum standards or guidelines for pharmacy premises are set out in the third section. The code of practice establishes that premises at which a pharmacy business that is a community pharmacy must meet a range of criteria, such as having direct access to a public place, and contain facilities for the secure and appropriate storage of medicines. The premises must also have a dedicated fax facility for the receipt of urgent communication, such as product recalls from the Therapeutic Goods Association or alerts from the Health Directorate.

Section 4 of the code of practice is the area in which the concept of a *pharmacist in charge* is introduced. The section imposes requirements related to the conduct of the business, specifically about the identification in a displayed notice of the names of all pharmacists that work at the pharmacy, and the name of which pharmacist is currently the *pharmacist in charge*.

As stated previously, the pharmacist in charge is responsible for the delivery of the actual pharmacy service; being the supply, compounding, or dispensing of a medicine, and the provision of advice and counselling on the effective use of a medicine. The pharmacist in charge is not responsible for the ordinary business operations of the community pharmacy, such as matters involving employment and payment of staff, payment of rent, rates or services, or the design and fit out of the community pharmacy, which are the responsibility of the licensed owner.

A key requirement of section 4 of the code of practice is the requirement that a community pharmacy must always be under the control of a pharmacist in charge during the times that the pharmacy is open for business.

The final section of the code of practice deals with the operation of a community pharmacy that was owned by pharmacist that has died. Following the death of a pharmacist that owns a community pharmacy, the executor of the deceased pharmacist may be called upon to deal with the assets of the deceased pharmacist's estate. If no executor has been appointed, or the pharmacist dies intestate, the public trustee may be called upon to deal with the assets of the deceased pharmacist's estate.

As the pharmacy business would be such an asset, this provision of the code of practice enables the executor or the public trustee to be able to operate the pharmacy business for up to 12 months to allow for the sale or disposal of the community pharmacy.

To do so, an application must be made in writing to the Chief Health Officer within 10 working days of the death of the pharmacist that owned the community pharmacy.

This enables the executor or the public trustee, who would otherwise not be able to legally own or operate a community pharmacy, to keep the business operating until such time as the business can be sold. By enabling the pharmacy business to continue operating past 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 or the public trustee 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.

To ensure professional standards and requirements are still observed, any approval under this provision will subject to conditions. The first is that the pharmacy must remain under the direct, personal control of a pharmacist at all times. This person would be the *pharmacist in charge* as per section 4 of the code of practice. Compliance with the code of practice remains mandatory, as does

compliance with any conditions that may have been imposed on the licence held by the deceased

pharmacist.