

**THE LEGISLATIVE ASSEMBLY FOR
THE AUSTRALIAN CAPITAL TERRITORY**

**MEDICINES, POISONS AND THERAPEUTIC GOODS AMENDMENT
REGULATION 2010 (NO 3)**

SL2010-16

EXPLANATORY STATEMENT

**Circulated by the authority of
Katy Gallagher MLA
Minister for Health**

Medicines, Poisons and Therapeutic Goods Amendment Regulation 2010 (No 3)

Overview

The *Medicines, Poisons and Therapeutic Goods Act 2008* (the Act) consolidated four Acts and their regulations regarding ACT law on medicines, poisons and prohibited substances; by repealing and replacing the *Poisons and Drugs Act 1978*, the *Poisons Act 1933*, the *Public Health (Prohibited Drugs) Act 1957*, and significantly amending the *Drugs of Dependence Act 1989*.

The Act gave effect to reforms required by the National Competition Policy Review of Drugs, Poisons and Controlled Substances Legislation (Galbally Review), and served to provide a more unified and workable scheme. In doing so, the Act adopts the Standard for the Uniform Scheduling of Drugs and Poisons (the SUSDP), developed by the National Drugs and Poisons Schedule Committee established under the *Therapeutic Goods Act 1989* (Cwlth).

The objective of the Act, as recommended by the Galbally Review, is to promote and protect public health and safety by minimising medicinal misadventure with and diversion of regulated substances, accidental or deliberate poisonings and the manufacture of regulated substances that are subject to abuse. The Act also has the purpose of ensuring that consumers of prescription and non-prescription medicines have adequate information to allow them to use medicines safely and effectively.

The Act establishes an authorisation and licensing framework for medicines and poisons, as well as grounds and powers for disciplinary action to be taken against authorised and licensed persons. The Act also controls the way in which medicines and poisons are dealt with through a range of offences, imposing a range of potential penalties, including the imposition of terms of imprisonment where appropriate. Enforcement of the offences is achieved through a comprehensive range of inspection and seizure powers, including the capacity to take and analyse samples.

The Medicines, Poisons and Therapeutic Goods Regulation

The Medicines, Poisons and Therapeutic Goods Regulation (the MPTG Regulation) provides the detail for the regulatory framework established by the Act. The MPTG Regulation contains the more substantive detail, specific requirements, or conditions for a range of activities and obligations contained within the Act. Some provisions of the MPTG Regulation prescribe additional information required for licences or authorisations, whereas other provisions impose statutory licence conditions. There are also provisions of the MPTG Regulation specifying requirements for activities such as labelling or packaging.

This Regulation

The Act and the MPTG Regulation were developed to maintain, as much as possible, the status quo for health professionals in the ACT in the performance of their duties. On that basis, what a health professional, including nurse practitioners, could and could not do prior to the commencement of the Act was intended to be the same following the commencement of the Act.

Nurse practitioners in the ACT are prohibited from prescribing Schedule 8 medicines, generally referred to as Controlled Medicines. Nurse practitioners across the border in New South Wales, however, are able to prescribe Schedule 8 medicines. So too are nurse practitioners in Victoria, Tasmania and Queensland.

The inability of ACT nurse practitioners to prescribe controlled medicines is a significant restriction, and one which is particularly disadvantageous to nurse practitioners providing end-of-life care and treatment for acute pain management. Establishing the role of nurse practitioners is part of the ACT Government commitment to building a strong, sustainable nursing workforce in the Territory. Aligning the powers and functions of nurse practitioners in the Territory will enhance the use of these health professionals in the ACT. Accordingly, this Regulation amends the MPTG Regulation

Clauses

Clause 1 – Name of regulation

This section sets out the name of the Regulation as the *Medicines, Poisons and Therapeutic Goods Amendment Regulation 2010 (No 3)*.

Clause 2 – Commencement

Pursuant to this provision, all of the Regulation, with the exception of Schedule 1, is to commence on the day after notification.

The commencement of Schedule 1 is linked to that of section 3 in the *Health Practitioner Regulation National Law (ACT) Act 2010*.

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 establishes a national scheme of registration and accreditation for health professions in Australia (the National Scheme) by 1 July 2010. The *Health Practitioner Regulation National Law (ACT) Act 2010* represents the ACT's involvement in the third and final stage of the implementation process of the National Scheme.

The National Scheme's proposed implementation date is 1 July 2010. Until that time, current State and Territory based regulation will continue to apply to registered health practitioners.

Clause 3 - Legislation amended

This section expressly states that the legislation amended is the *Medicines, Poisons and Therapeutic Goods Regulation 2008*.

Clause 4 – Section 510 (a), except note

Doctors, dentists, optometrists, podiatrists and veterinary surgeons are *prescribed persons* for Chapter 11 of the MPTG Regulation by virtue of section 510(a). This amendment adds nurse practitioners to section 510(a), and in doing adds nurse practitioners to the list of *prescribed persons* for Chapter 11.

Clause 5 – Section 510 (a), new note 2

This provision inserts a new note, note 2, which will follow section 510(a).

The note explains that a nurse practitioner does not include a person who is conditionally registered as a nurse practitioner. The reader is also directed to the dictionary. Clause 13 of this Regulation amends the dictionary to insert a definition of nurse practitioner that will apply for chapters 11 and 12 only.

Clause 6 – Section 532 (1), definition of *designated person*, paragraph (a)

Section 532 of the MPTG Regulation imposes obligations on *designated persons* in regard to the storage of controlled medicines.

A *designated person* includes, in section 532(1)(a), a dentist, doctor, or veterinary surgeon, other than such a health professional at an institution. Again, a reference to a dentist, doctor or veterinary surgeon does not include trainees or interns.

This provision adds nurse practitioners to section 532(1)(a) to the health professionals already included in that paragraph.

Dentists, doctors, nurse practitioners and veterinary surgeons at an institution are not a *designated person* because in those circumstances the person in charge of the ward at the institution is responsible for recording and storage of controlled medicines.

Clause 7 – Section 532 (1), definition of *designated person*, note 2

This provision inserts a new note 2 after section 532(1). The existing note 2 becomes note 3, by virtue of this provision.

The note explains that a nurse practitioner does not include a person who is conditionally registered as a nurse practitioner. The reader is also directed to the dictionary. Clause 13 of this Regulation amends the dictionary to insert a definition of nurse practitioner that will apply for chapters 11 and 12 only.

Clause 8 - Section 533 (1), definition of *excluded person*, paragraph (a)

Persons to which section 533 of the MPTG Regulation applies must ensure that controlled medicines are stored in a storage receptacle, which includes medicine cabinets, safes, strong rooms and vaults.

Unless excluded, section 533 of the MPTG Regulation applies to persons listed in section 510 as *prescribed persons*. If they work at an institution, section 533(1) excludes a dentist, doctor, veterinary surgeon and, by virtue of this amendment, a nurse practitioner.

Dentists, doctors, nurse practitioners and veterinary surgeons at an institution are excluded because in those circumstances the person in charge of the ward at the institution is responsible for recording and storage of controlled medicines.

Clause 9 – Table 540, new item 14

Within section 540 of the MPTG Regulation is Table 540. Table 540 lists 13 items, each of which is a profession or category of person deemed to be *prescribed persons* who must keep a controlled medicines register for all controlled medicines in their possession. Column 3 of the same table specifies where the register is to be kept.

A fourteenth item is added to Table 540 by this provision. Column 2 of the new item serves to make nurse practitioners a *prescribed person* for the purposes of section 540 of the MPTG Regulation. This means that any nurse practitioner in possession of a controlled medicine will need to keep a controlled medicines register. Column 3 of the new item instructs that the controlled medicine is to be kept at the nurse practitioner's place of practice.

Clause 10 - Section 541 (1), definition of *designated person*, paragraph (a)

The MPTG Regulation establishes a bag or container of medicines and other medical supplies kept by a person for the purposes of health care or emergency treatment is a first-aid kit.

Under section 541 of the MPTG Regulation, if a first-aid kit includes a controlled medicine the *designated person* who possesses that first-aid kit must also keep a controlled medicines register with the first-aid kit. A *designated person* for the purposes of section 541 includes a first-aid kit licence-holder, and ambulance officers employed by the Commonwealth, or by a State or Territory. Section 541(1)(a) also includes dentists, doctors and veterinary surgeons as *prescribed persons*, although interns and trainees are excluded.

This provision adds nurse practitioners to section 541(1)(a) to the health professionals already included in that paragraph.

Clause 11 - Section 541 (1), definition of *designated person*, note 2

This provision inserts a new note 2 after section 541(1). The existing note 2 becomes, by virtue of this provision note 3.

The note explains that a nurse practitioner does not include a person who is conditionally registered as a nurse practitioner. The reader is also directed to the dictionary. Clause 13 of this Regulation amends the dictionary to insert a definition of nurse practitioner that will apply for chapters 11 and 12 only.

Clause 12 - Schedule 1, part 1.6, item 5, column 3, paragraph (d)

Schedule 1 of the MPTG Regulation sets out the authorisations for medicines held by each type of health-related occupation. This includes nurses, who are listed in Part 1.6 of the Schedule. Part 1.6 consists of a table with three columns; item, person authorised, and authorisation. There are a total of five items.

Prior to this amendment item 5 of Part 1.6 authorised a nurse practitioner to prescribe medicines, other than controlled medicines. The authorisation was, and will continue to be, subject to two key restrictions. The first is that the authorisation is to the extent necessary to practise nursing and within the scope of employment. The other is that the authorised prescription is in accordance with their approved scope of practice as set out in section 11 of the Health Regulation 2004.

The effect of this amendment is simply to remove the words “(other than controlled medicines)” thereby now enabling nurse practitioners to prescribe controlled medicines in the same way, and subject to the same rules and restrictions, as other prescribers (such as doctors).

Clause 13 – Dictionary, new definition of *nurse practitioner*

The dictionary in ACT *Legislation Act 2001* explains that a nurse practitioner is a person registered as a nurse in the specialist area of nurse practitioner, and refers the reader to the Health Professionals legislation.

This provision inserts into the dictionary of the MPTG Regulation a definition of nurse practitioner that will apply for chapters 11 and 12. The definition to be inserted states that a nurse practitioner does not include a person who is conditionally registered as a nurse practitioner.

The effect of the definition is to narrow that in the ACT *Legislation Act 2001*, as it would otherwise apply to Chapters 11 and 12 of the MPTG Regulation, so that the provisions in those chapters only apply to unconditionally registered nurse practitioners.

Schedule 1 – Amendments consequential on Health Practitioner Regulation National Law (ACT) Act 2010

This Regulation has amended or inserted a number of notes in the MPTG Regulation, as well as inserted a definition of nurse practitioner into the dictionary of the MPTG Regulation. Once the *Health Practitioner Regulation National Law (ACT) Act 2010* commences, however, some definitions will become obsolete.

This Schedule has been included in this Regulation because it is recognised that changes to the MPTG Regulation are imminent due to the expected commencement in 2010 of the *Health Practitioner Regulation National Law (ACT) Act 2010*. Schedule 1 of this Regulation contains amendments that are consequential on the *Health Practitioner Regulation National Law (ACT) Act 2010*.

Provision 1.1 of this Schedule makes further amendments to the MPTG Regulation on commencement of the *Health Practitioner Regulation National Law (ACT) Act 2010*. Those amendments are to places in the MPTG Regulation that make mention of conditionally registered nurse practitioners, terminology that will be abandoned once the *Health Practitioner Regulation National Law (ACT) Act 2010* is in operation.

Accordingly, provision 1.1 of this Schedule will replace references to “a person who is conditionally registered as a nurse practitioner” with “a person holding limited or provisional registration to practise as a nurse practitioner”. Despite the change in terminology, the effect is the same; only nurse practitioners with full registration will be covered by Chapters 11 and 12 of the MPTG Regulation.

The changes made by provision 1.1 of this Schedule will apply to note 2 in sections 510(a), 532(1) and 541(1), as well as to the definition of *nurse practitioner* in the dictionary.