THE LEGISLATIVE ASSEMBLY FOR

THE AUSTRALIAN CAPITAL TERRITORY

MEDICINES, POISONS AND THERAPEUTIC GOODS (PRESCRIBING AUTHORISATION – OPTOMETRISTS) AMENDMENT REGULATION 2012 (No 1)

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EXPLANATORY STATEMENT

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Medicines, Poisons and Therapeutic Goods (Prescribing Authorisation – Optometrists) Amendment Regulation 2012 (No 1)

Overview

The National Registration and Accreditation Scheme (NRAS) to centralise registration and regulation of ten major health professions – including optometry – commenced in July 2010. Since then, all States and Territories except the ACT have amended their regulatory frameworks to allow endorsed optometrists to prescribe, or supply for topical use, the Schedule 4 poisons listed in the Optometry Board of Australia (OBA) *Endorsement for scheduled medicines registration standard* (the national list).

At present, the ACT Medicines, Poisons and Therapeutic Goods Regulation 2008 (the MPTG Regulation) lists the medicines that endorsed optometrists may prescribe in the ACT. The list of medicines in the MPTG Regulation is not consistent with the national list, which has resulted in a lack of consistency in optometry practice between the ACT and other States and Territories, most notably between the ACT and NSW.

This Regulation seeks to achieve consistency in this area by amending the Medicines, Poisons and Therapeutic Goods Regulation (the MPTG Regulation) to apply the national list.

Background information

The *Medicines, Poisons and Therapeutic Goods Act 2008* (the MPTG Act) adopted the Standard for the Uniform Scheduling of Drugs and Poisons developed by the National Drugs and Poisons Schedule Committee established under the *Therapeutic Goods Act 1989* (Cwlth). The Standard for the Uniform Scheduling of Drugs and Poisons was later renamed the Standard for the Uniform Scheduling of Medicines and Poisons (the SUSMP).

The objective of the MPTG Act 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 MPTG 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 MPTG 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 licences persons. The MPTG 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 MPTG Regulation provides the detail for the regulatory framework established by the MPTG Act. The MPTG Regulation contains the more substantive detail, specific requirements and 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.

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 NRAS) in Australia by 1 July 2010. In the ACT the NRAS 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 1993* and Health Professionals Regulation 2004. Prior to the NRAS local boards for a range of health professionals, including optometrists, were established through Schedules in the Health Professionals Regulation 2004. To give effect to the NRAS, and thereby the shift to National boards, relevant Schedules in the Health Professionals Regulation 2004 were removed by the *Health Practitioner Regulation National Law (ACT) Act 2010.*

Clause 1 Name of regulation

The first clause of the Regulation declares that the name of the Regulation to be the Medicines, Poisons and Therapeutic Goods (Prescribing Authorisation – Optometrists) Amendment Regulation 2012 (No 1).

Clause 2 Commencement

Pursuant to this provision, the Regulation is to commence on the day after 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 Medicines, Poisons and Therapeutic Goods Regulation 2008.

Upon commencement this Regulation will alter the Medicines, Poisons and Therapeutic Goods Regulation 2008 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 Medicines, Poisons and Therapeutic Goods Regulation 2008 will be available. That new republication will feature the alterations made by this Regulation.

Clause 4 Section 12 (2), example

Section 12 of the MPTG Regulation essentially reiterates that section 44 of the MPTG Act requires a person authorised to deal with a medicine to comply with conditions to which the authorisation is subject.

The section also draws the reader's attention to the fact that conditions on authorisations are additional to other restrictions that may be placed upon a person's authorisation under the MPTG legislation. To aid understanding of the provision an example is included in the section.

The example previously provided in section 12 related to optometrists, but is no longer accurate or relevant due to the amendments made by this Regulation. Accordingly, a new example is to be inserted into section 12.

The new example relates to limitations imposed on prescribing rights of eligible midwives. Part 1.5 of Schedule 1 of the MPTG Regulation sets out the authorisations applying to midwives, and item 2 of the part specifically pertains to 'eligible midwives'. Specifically, prescribing of items on the Pharmaceutical Benefits Scheme is authorised by an 'eligible midwife' if they are also an 'authorised midwife' for the purposes of the *National Health Act 1953* (Cwlth).

Clause 5 Section 863 (2)

Section 47 of the Legislation Act notes that in some circumstances it is simpler to adopt someone else's law or instrument rather than remake it. One reason to adopt a law or instrument is to achieve a uniform national approach to dealing with a common problem. The *Health Practitioner Regulation National Law (ACT) Act 2010* is such an example. For technical areas it is also often easier to adopt a law or instrument prepared outside of the ACT than it would be to reproduce the detail of the requirements directly in a law or instrument. This is especially so if the technical documentation, instrument or law is particularly voluminous, or if national consistency is particularly critical. The adoption of the SUSMP by the MPTG Act is an example of a technical and voluminous document for which consistent adoption Australia wide was highly important.

Although there may be good practical reasons to adopt a law or instrument, there are also a number of policy issues relevant to the adoption of laws and instruments from another source. If the law or instrument is adopted on the basis that future changes will automatically apply, this means that the entity who makes the changes becomes a 'lawmaker' not only where the law or instrument originally applied but also where it has been adopted. To this extent the Legislative Assembly is by-passed.

As such, section 47 (3) of the Legislation Act provides establishes that the normal rule is that a law or instrument prepared outside of the ACT is applied as in force at a particular time. Subsection (4) however, provides that this normal rule can be displaced. In this Regulation that has been done through the definition of *Optometry Endorsement Scheduled Medicines Registration Standard* to be inserted by clause 9.

When a law or instrument is applied as in force from time to time, section 47 (6) sets a number of requirements designed to ensure that the requirements for accessibility are satisfied. These include that the adopted law or instrument is taken to be a notifiable instrument. Furthermore, if the law or instrument applies as in force from time to time, each amendment of the law or instrument is also to be a notifiable instrument.

Through this provision, the normal operation of section 47(6) of the Legislation Act is displaced in regard to the *Optometry Endorsement Scheduled Medicines Registration Standard*. Accordingly, the *Optometry Endorsement Scheduled Medicines Registration Standard* does not need to be placed on the ACT Legislation Register as a notifiable instrument. Links to the *Optometry Endorsement Scheduled Medicines Registration Standard* on the website of the Optometry Board of Australia are included to ensure accessibility.

Clause 6 Section 863, new note 3

The effect of the previous clause is to displace the operation of section 47(6) of the Legislation Act in regard to the *Optometry Endorsement Scheduled Medicines Registration Standard*.

This provision inserts a new note into section 863. The new note, note 3, alerts the reader to the web address at which the *Optometry Endorsement Scheduled Medicines Registration Standard* can be accessed. That address is http://www.optometryboard.gov.au, which is the website for the Optometry Board of Australia.

Clause 7 Schedule 1, part 1.8, table

The table currently in Part 1.8 of Schedule 1 of the MPTG Regulation is replaced by virtue of this clause.

It is through Schedule 1 of the MPTG Regulation that the various health related occupations are assigned authorisation to deal with medicines. There are 13 Parts to Schedule 1, each containing a table dealing with a different health related occupation. Part 1.8 pertains to optometrists. The person authorised in the table is listed in column 2, and what that person is authorised to do is specified in column 3. Currently in Part 1.8 the person authorised is an optometrist.

The replacement table inserted by this provision will contain two items as it will now set out authorisations for optometrists generally, as well as authorisations for an optometrist whose registration has been endorsed by the Optometry Board of Australia.

The new table alters the authorisations applying to optometrists generally. To the extent necessary to practice optometry, and confined to the scope of their employment, all optometrists will now be able to obtain, possess and administer medicines set out in Schedules 2, 3 and 4 of the SUSMP. They will also be able to issue purchase orders or requisitions for these medicines.

The *Guidelines for use of scheduled medicines* as approved by the Optometry Board of Australia, which is available at http://www.optometryboard.gov.au**,** may be used to determine the Schedule 2, 3 and 4 medicines that would be considered necessary to practice optometry, or within the scope of an optometrist's employment.

Medicines in Schedule 2 of the SUSMP are pharmacy only medicines. Medicines in Schedule 3 of the SUSMP are pharmacist only medicines, and prescription only medicines are set out in Schedule 4 of the SUSMP. The terms *requisition* and *purchase order* are defined in the Dictionary of the MPTG Act.

The *Optometry Endorsement Scheduled Medicines Registration Standard* contains a list of scheduled medicines endorsed by the Optometry Board of Australia for optometry use. This list is referred to as the national list. Clause 9 of this Regulation inserts into the dictionary of the MPTG Regulation definitions for 'Optometry Endorsement Scheduled Medicines Standard' and 'national list'.

Medicines that are included on the national list can be prescribed by an optometrist whose registration has been endorsed by the Optometry Board of Australia. Endorsed optometrists will also be able to supply medicines that are included on the list during consultations, provided that the medicines are labelled as required by section 161 of the MPTG Regulation. Section 161 details the information that must be included on a label for medicines supplied during a consultation. Standard information that is to appear includes the name of the person that supplied the medicines, the date of supply, the form, strength and quantity of the medicine, and directions about the use of the medicine. Optometrists will also need to satisfy paragraph (k) of the section by including the words "for optometry use only" on the label.

Like optometrists generally, endorsed optometrists will also be able to obtain, possess and administer medicines set out in Schedules 2, 3 and 4 of the SUSMP. This authorisation is again limited to the extent necessary to practice optometry, and confined to the scope of their employment.

A note is also included below the table to be inserted, which refers the reader to the Dictionary of the MPTG Regulation for the meaning of *national list*. Clause 9 of this Regulation will insert into the dictionary that definition.

Clause 8 Schedule 2

Clause 8 removes from the MPTG Regulation Schedule 2.

Schedule 2 currently contains two tables; Table 2.1 and Table 2.2. Table 2.1 identifies general optometry medicines and the prescribed purposes for which those medicines could be used. Table 2.2 sets out restricted optometry medicines and the conditions to which the medicines can be used. At present, dealing with a restricted optometry medicines in Table 2.2 is restricted to optometrists that hold a restricted medicines authority. When the MPTG Regulation was first created the restricted medicines authority was issued by the ACT Optometrists Board. When the *Health Practitioner Regulation National Law (ACT) Act 2010* commenced the reference to the ACT Optometrists Board in the MPTG Regulation was simply replaced with a reference to the Optometrist Board of Australia.

As this Regulation is adopting and applying the national list of medicines endorsed by the Optometry Board of Australia, Schedule 2 of the MPTG Regulation is no longer required and is to be deleted.

Clause 9 Dictionary, new definitions

Clause 9 inserts two new definitions into the Dictionary in the MPTG Regulation.

The first new definition to be added to the Dictionary of the MPTG Regulation is ***Optometry Endorsement Scheduled Medicines Standard***. Pursuant to this definition, the term '*Optometry Endorsement Scheduled Medicines Registration Standard*' means the Optometry Endorsement Scheduled Medicines Registration Standard that was approved by the Ministerial Council under section 12 of the *Health Practitioner Regulation National Law (ACT) Act 2010,* as in force from time to time.

The inclusion of the words 'from time to time' expressly displaces the operation of section 47(3) of the Legislation Act. Accordingly, any new versions of the *Optometry Endorsement Scheduled Medicines Registration Standard*' will automatically have application to the MPTG Regulation.

The second new definition to be added is ***national list***. Applying this definition, a reference in the MPTG Regulation to national list is to be read as the *Optometry Endorsement Scheduled Medicines Registration Standard, table 1*. Essentially, this is a list of medicines endorsed by the Optometry Board of Australia that have been endorsed for optometry usage.

A note to the definition alerts the reader to the web address at which the *Optometry Endorsement Scheduled Medicines Registration Standard* can be accessed. That address is http://www.optometryboard.gov.au, which is the website for the Optometry Board of Australia.