Medicines, Poisons and Therapeutic Goods Amendment Regulation 2017 (No 1)

Subordinate law SL2017-27

made under the

Medicines, Poisons and Therapeutic Goods Act 2008, Section 184 (Regulation-making power)

EXPLANATORY STATEMENT

The objective of the *Medicines, Poisons and Therapeutic Goods Act 2008* (MPTG Act) is to promote and protect public health and safety by minimising medicinal misadventure with, and diversion of, regulated substances, and the manufacture of regulated substances that are subject to abuse.

The Medicines, Poisons and Therapeutic Goods Regulation 2008 (MPTG Regulation) provides the detail for the regulatory framework established by the MPTG Act. The MPTG Regulation sets out which health professionals are able to prescribe, administer and dispense a medicine, and conditions relating to such dealings. Some provisions of the MPTG Regulation also prescribe additional information required for licences or authorisations.

Section 560 of the MPTG Regulation establishes that any designated prescriber may apply to the Chief Health Officer (CHO) for approval to prescribe a controlled medicine. However, in the context of seeking approval to prescribe a controlled medicine to treat drug-dependency the applicant must first hold an endorsement under section 582 of the MPTG Regulation.

This Regulation makes minor technical changes to the MPTG Regulation to enable a designated prescriber to become authorised to prescribe controlled medicines (methadone and buprenorphine) to treat drug-dependency. This authorisation is subject to approval and endorsement by the CHO. For example, a nurse practitioner will, within their scope of practice, be able to prescribe controlled medicines to treat drug-dependency subject to approval to prescribe a controlled medicine and endorsement to treat drug-dependency by the CHO.

This change aims to better align the ACT with other jurisdictions and improve timely access to alcohol and other drug services for people with substance misuse disorders.

Details

A detailed explanation of each clause of the Regulation follows.

Clauses

Clause 1 Name of regulation

The first clause of the Regulation declares the name of the Regulation to be the *Medicines, Poisons and Therapeutic Goods Amendment Regulation 2017 (No 1).*

Clause 2 Commencement

Pursuant to this provision, the Regulation is to commence on the day after its notification day.

Clause 3 Legislation amended

This provision alerts the reader that this Regulation amends the MPTG Regulation.

Upon commencement this Regulation will alter the MPTG Regulation 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 MPTG Regulation will be available. That new republication will feature the alterations made by this Regulation.

Clause 4 Section 557 (1)

Schedule 1, part 1.3 item 2 (d) of the MPTG Regulation allows for an intern doctor to prescribe medicines (including controlled medicines) in restricted circumstances.

This provision amends section 557 (1) to provide that an intern doctor can only prescribe controlled medicines (methadone and buprenorphine) to treat drug-dependency when acting under the direct supervision of a doctor.

Clause 5 Section 557 (2) and (3)

Clause 7 Section 563 (b) (i)

Clause 9 Section 563 (b) (iii) to (v)

Clause 12 Section 581

Clause 14 Section 581 (2)

Clause 16 Section 582

Clause 17 Section 582 (5)

Clause 18 Section 583 (a)

Clause 19 Section 584

These provisions amend relevant sections of the MPTG Regulation to replace select references to a 'doctor' with references to a 'designated prescriber'. This is a necessary alteration to enable broadening, beyond just doctors, of the range of health practitioners authorised to prescribe controlled medicines to treat drug-dependency. Under this change health professionals with the requisite authorisations (as set out in Schedule 1 of the MPTG Regulation) will, after obtaining approval and endorsement by the CHO, be able to prescribe controlled medicines to treat drug-dependency.

This change aims to better align the ACT with other jurisdictions and improve the access needs of people with substance misuse disorders.

Clause 6 New Section 563 (1) Clause 15 New Section 581 (4)

These provisions insert a subsection into the above named sections of the MPTG Regulation which establish that the meaning of a 'designated prescriber' in these sections does not capture an intern doctor.

Clause 8 Section 563 (b) (ii), new note

This provision inserts a note into section 563 (b) (ii) relating to a 'doctor' as it is the only place in this section where the term is mentioned.

Clause 10 Section 563 (b) (v), note

Clause 13 Section 581 (1), note

These provisions omit a note currently within sections 563 and 581 of the MPTG Regulation. The retention of the notes is made unnecessary by other amendments made by this Regulation.

Clause 11 Section 580, note

This provision substitutes the first mention of 'doctor' in the note with 'designated prescriber'. As with other similar substitutions made by this Regulation this change is necessary so that designated prescribers, subject to approval to prescribe a controlled medicine and endorsement to treat drug-dependency by the CHO, be able to prescribe controlled medicines to treat drug-dependency.