Medicines, Poisons and Therapeutic Goods Amendment Regulation 2020 (No 5)

Subordinate law SL2020-39

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 MPTG Act also provides for adoption of the Commonwealth Poisons Standard, which is used to categorise medicines and poisons for regulatory purposes as adopted by each State and Territory.

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

This Medicines, Poisons and Therapeutic Goods Amendment Regulation 2020 (No 5) (amendment regulation) amends the MPTG Regulation to authorise medical radiation practitioners to deal with scheduled medicines as part of their employment and within their professional scope of practice. A medical radiation practitioner is a person registered to practice as a medical radiation practitioner with the Medical Radiation Practice Board, which is a recognised National Board under the *Health Practitioner Regulation National Law (ACT)* (the National Law). The Australian Health Practitioner Regulation Agency (AHPRA) is the Australian Government agency which supports National Boards' registration of health professionals in accordance with the National Law and the National Registration and Accreditation Scheme.

This amendment regulation also incorporates the *Professional Capabilities for Medical Radiation Practitioners* (Professional Capabilities) [also referred to as the *Professional Capabilities for Medical Radiation Practice*], which is a document developed by the Medical Radiation Practice Board of Australia and approved by the Ministerial Council under the under the *Health Practitioner Regulation National Law (ACT)*. The incorporation of the Professional Capabilities informs the professional scope of practice of medical radiation practitioners in their professional scope and their authorisation to deal with scheduled medicines under the MPTG Regulation. The Professional Capabilities are available at no cost from the Medical Radiation

Practice Board and AHPRA websites <u>www.medicalradiationpracticeboard.gov.au/</u> and <u>www.ahpra.gov.au/</u>.

Other health professionals that have registration with a National Board are already authorised under the MPTG Regulation to deal with scheduled medicines within their employment and scope of practice e.g. pharmacists, doctors and nurses. This amendment regulation is considered consistent with existing regulatory controls applied to registered health professionals that may deal with scheduled medicines as determined by a National Board.

In accordance with the *Legislation Act 2001*, a regulatory impact statement was not required to be presented with this amendment regulation as the proposed subordinate law is not likely to impose appreciable costs on the community, or a part of the community. This regulation is not considered to limit civil protections afforded by the *Human Rights Act 2004*.

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 2020 (No 5).

Clause 2 Commencement

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

Clause 3 Legislation amended

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

Upon commencement this amendment regulation will alter the MPTG Regulation in accordance with the provisions that this amendment regulation contains. This amendment regulation will then be immediately repealed. Consequently, from the date that this amendment regulation commences, a new republication of the MPTG Regulation will be available. That new republication will feature the alterations made by this amendment regulation.

Clause 4 Section 510 (a), except notes

This clause updates section 510(a) of the MPTG Regulation to insert 'medical radiation practitioner' as a prescribed person with responsibility for the storage of medicines.

Clause 5 Section 532 (1), definition of designated person, paragraph (a)

This clause updates section 532(1) of the MPTG Regulation to insert 'medical radiation practitioner' as a designated person with responsibility for the storage of controlled medicines. Section 532 of the MPTG Regulation is associated with an offence provision under section 61 of the MPTG Act, which provides an offence for a designated person if they fail to store a declared substance as prescribed by regulation.

Clause 6 Section 533 (1), definition of excluded person, paragraph (a)

This clause updates section 533(1) of the MPTG Regulation to insert 'medical radiation practitioner' to the list of excluded professions that can be appointed as a designated person for the storage of controlled medicines. This is a consequential amendment to update the MPTG Regulation as a result of changes made by this amendment regulation.

Clause 7 Table 540, new item 15

This clause updates the table appearing under section 540 of the MPTG Regulation to provide that medical radiation practitioners must keep and store a controlled medicines register at their place of professional practice if they possess a controlled medicine.

Clause 8 Section 544 (a)

This clause updates section 544 (a) of the MPTG Regulation to provide that a medical radiation practitioner may act as a prescribed witness for the administration of a controlled medicine.

Clause 9 New section 545 (a) (da)

This clause updates section 545 of the MPTG Regulation to provide that a medical radiation practitioner may act as a prescribed witness for the discarding of a controlled medicine.

Clause 10 New section 863 (f)

This clause updates section 863 of the MPTG Regulation to disapply section 47(6) of the *Legislation Act 2001* as it applies to the MPTG Regulation's adoption of the Medical Radiation Practitioner (MRP) registration standard. This updated section allows the MPTG Regulation to adopt the MRP Registration Standard by reference from time to time without formal publication requirements of the *Legislation Act 2001*.

Clause 11 Section 863, new note

This clause inserts a new note below section 863 of the MPTG Regulation identify where the adopted MRP Registration standard may be publicly accessed.

Clause 12 Schedule 1, new part 1.4A

This clause inserts new Part 1.4 into Scheduled 1 of the MPTG Regulation to identify a medical radiation practitioner as an authorised person to deal with scheduled medicines in accordance with the MRP Registration Standard and their scope of employment. New Part 1.4A as inserted by this amendment regulation would authorise medical radiation practitioners to issue purchase orders and requisitions for medicines, obtain, possess and administer medicines.

Clause 13 Dictionary, new definitions

This clause inserts a new dictionary definition for medical radiation practitioner and further explanatory notes regarding the MPTG Regulation's incorporation of MRP Registration Standard. A medical radiation practitioner is defined as a person holding registration to practise in the medical radiation practice profession under the *Health Practitioner Regulation National Law (ACT)* but does not include students or persons with provisional registration for purposes of supervised practice or course of training.