Australian Capital Territory

Medicines, Poisons and Therapeutic Goods Amendment Regulation 2023 (No 1)

Subordinate law SL2023-5

made under the

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

EXPLANATORY STATEMENT

PURPOSE AND OUTLINE

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 outlines the appropriate prescription and supply of medicines and defines the concepts of deal, supply, prescribe and administer in relation to medications.

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 health professionals can deal with a medicine and the conditions for such dealings. Some provisions of the MPTG Regulation also prescribe additional information required for licences or authorisations.

Overview of amendments

In July to August 2022, the ACTHD consulted with key stakeholders on options for amendments to the MPTG Regulation to expand medicine authorisations for allied health practitioners (AHPs), registered nurses (RNs), and registered midwives (RMs) within public institutions. This consultation was undertaken to identify a more efficient process to authorise people working within public institutions to deal with medicines as part of their professional scope of practice and employment. The consultation paper also invited submissions on any other issues related to medicine authorisations identified by the ACT health care community.

In response to the consultation outcomes the Medicines, Poisons and Therapeutic Goods Amendment Regulation 2023 (No 1) (Amendment Regulation) seeks to make two changes to the MPTG Regulation. These changes concern the prescribing of medicines by intern doctors and dealings with regulated substances and regulated goods by public employees. Both these changes seek to create efficiencies in the public health system through enabling

people employed in health professional roles to deal with medicines in accordance with their scope of professional practice and employment. These changes will commence on the day after the amendment regulation is notified on the ACT Legislation Register.

Intern doctors

The amendment regulation seeks to authorise intern doctors to prescribe medicines for people on discharge from the institution. The MPTG Regulation currently limits intern doctors prescribing medicines for administration within the institution. Other Australian states and territories do not place this condition on intern doctor prescribing. All intern doctors must practice within a structured professional relationship with a medical practitioner and health institution irrespective of where a prescribed medicine is supplied or administered. Limiting prescribing practices of intern doctors in the ACT limits them from working to their full scope of professional practice as well as creating inequitable training opportunities and inefficiencies within the ACT health system.

Authorising intern doctors to prescribe medicines for patients on discharge from an institution is not considered to increase risk to patients or the community and was supported by stakeholders during consultation in July - August 2022.

Director-General authorisation for public employees to deal with regulated substances and regulated therapeutic goods

Chapter 24 of the MPTG Regulation already enables the Chief Health Officer to authorise individual ACT Government public employees to deal with regulated substances or regulated therapeutic goods (public employee permits). Public employee permits are used in clinical, research or law enforcement settings to permit public employees to deal with regulated substances or goods as part of their employment e.g. to provide patient care, undertake research, or substance analysis.

The amendment regulation aims to expand on this existing mechanism by enabling the Director-General to authorise a group or class of public employees (however described) to deal with regulated substances or regulated therapeutic goods as part of their employment. The change also expands the scope of this section to include Calvary Public Hospital staff as employed under the *Public Sector Management Act 1994.* These changes have been made to improve flexibility in the safe and quality use of medicines within our public health system. A Director-General authorisation under new section 861A is a notifiable instrument. This ensures that any orders relating to the use of medicines by a class of public employee are transparent and accountable.

This change aims to facilitate a streamlined approach to medicines authorisations across the entire public health system by decreasing administrative burden and maximising efficiencies within the existing public health workforce. This policy approach is comparable to that taken by New South Wales in the Poisons and Therapeutic Goods Regulation 2008 (NSW).

During consultation in 2022, a majority of respondents supported making change to the MPTG Regulation to authorise publicly employed allied health practitioners, nurses and midwives to obtain, possess, supply and administer medicines. Authorising a class or group of public employees to deal with regulated substances meets this policy objective and is consistent with existing practices across the ACT and NSW public health systems.

Regulatory Impact Statement

In accordance with the *Legislation Act 2001,* a regulatory impact statement was not required to be presented with the Amendment Regulation as the amendments do not impose appreciable costs or regulatory burden on the community. These amendments do not operate to the disadvantage of anyone or impose additional liabilities on a person.

Human rights considerations

During the development of the Amendment Regulation, due regard was given to its compatibility with the *Human Rights Act 2004* (HR Act).

The Amendment Regulation engages the following HR Act rights:

- Section 9 – Right to life

Ensuring the effective regulation of medicines and poisons in the ACT and the authorities that deal with them through the Amendment Regulation as described above engages and promotes the right to life under the HR Act. The right to life is concerned with preventing the arbitrary deprivation of life and is relevant to the delivery of medical treatment.

The amendment enables the Director-General to authorise a class of public employees to deal with medicines within the scope of their employment to ensure timely and safe delivery of medicines, indirectly improving patient access to medical treatment. This amendment also enables intern doctors to prescribe medicines for patients on discharge from an institution.

Through enabling greater flexibility in the health workforce and in the safe and quality use of medicines within the public health system, these changes are considered to indirectly engage and promote the right to life.

CLAUSE NOTES

Clause 1 Name of Regulation

This clause declares the name of the Amendment Regulation to be the Medicines, Poisons and Therapeutic Goods Amendment Regulation 2023 (No 1).

Clause 2 Commencement

Under this provision, the Regulation commences the day after notification.

Clause 3 Legislation amended

This clause advises 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. Consequentially, from the date that this Amendment Regulation commences, a republication of the MPTG Regulation will be available. The new republication will feature the amendments made by this Amendment Regulation.

Clause 4 Section 860 heading

This clause updates the heading of section 860 of the MPTG Regulation in-line with current

drafting practices to better describe the purpose and functions of section 860.

Clause 5 Section 861 heading

This clause updates the heading of section 861 of the MPTG Regulation in-line with current drafting practices to better describe the purpose and functions of section 861.

Clause 6 New Section 861A

This clause inserts new section 861A to the MPTG Regulation that enables the Director-General to authorise a public employee or class of public employee (however described) to deal with a regulated substance or regulated therapeutic good. A Director-General authorisation under new section 861A is a notifiable instrument and must include relevant particulars listed under s861A(2).

Public employee is a defined term under the *Legislation Act 2001*. However, for the purposes of new section 861A, a public employee may also include a police officer and any employee of Calvary Health Care ACT limited to whom the *Public Sector Management Act 1994* applies. This expanded definition of public employee was taken to ensure that the Director-General can authorise all relevant people to deal with medicines as part of their employment in the public health system.

Clause 7 Schedule 1, part 1.3, item 2, column 3, new paragraph (da)

This clause updates Schedule 1 of the MPTG Regulation to authorise intern doctors to prescribe medicines for patients on their discharge from an institution.