

Australian Capital Territory

Medicines, Poisons and Therapeutic Goods Amendment Regulation 2020 (No 2)

Subordinate law SL2020–21

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 2) (amendment regulation) amends the MPTG Regulation to provide clarity on record keeping requirements concerning faxed or electronically submitted supply authorities (prescriptions) during a 'Commonwealth special arrangement' as notified under Section 100 of the *National Health Act 1953 (Cwth)*. This amendment regulation seeks to recognise the record keeping obligations of a faxed prescription as detailed by a Commonwealth special arrangement, as in force from time to time. The incorporation of a Commonwealth special arrangement has the effect of varying existing record keeping requirements for pharmacists and prescribers regarding the keeping of an original prescription following its transmission to a pharmacy.

All special arrangements published under section 100 of the *National Health Act 1953 (Cwth)* are freely available from the Federal Register of Legislation at www.legislation.gov.au. Section 863(e) of the MPTG Regulation already identifies the *National Health Act 1953 (Cwth)* as not requiring publication in accordance with section 47(6) of the *Legislation Act 2001*.

This amendment regulation seeks to enable local health professionals to access pharmaceutical benefits in accordance with any special determinations made by the Australian Government. One such example is the *National Health (COVID-19 Supply of Pharmaceutical Benefits) Amendment (Expansion of Telehealth and Telephone Attendances) Special*

Arrangement 2020 (Cwth), which concerns the supply of pharmaceutical benefits arising from a telehealth or phone attendance service.

Record keeping obligations placed on prescribers and pharmacists are subject to the uniform Pharmaceutical Benefits Scheme (PBS) as administered by the Australian Government. As any regulatory burden imposed by this amendment regulation is consequential to the Territory giving effect to the national PBS, section 36(g) of the *Legislation Act 2001* notes that the preparation of a regulatory impact statement to support these amendments is unnecessary.

The changes proposed by this amendment regulation are not considered to engage the *Human Rights Act 2004* as they only seek to adopt or incorporate aspects of the *National Health Act 1953 (Cwth)* to enable access to pharmaceutical benefits under the PBS.

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 2).

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 31 (1) (b) (iv)

This clause amends section 31(1)(b)(iv) to provide a greater time period in which prescribers must submit an original prescription to the pharmacy following its transmission by fax. This period is increased from 24 hours to seven days to better meet the needs of prescribers and pharmacists.

Clause 5 New section 31A

This clause inserts new section 31A to the Regulation to allow a prescriber to retain a prescription in accordance with a special arrangement instrument published under the *National Health Act 1953 (Cwth)* for the purposes of claiming a PBS subsidy for the prescription.

This clause provides for alternative record keeping requirements to those required by the MPTG Regulation, in favour of those described by a special arrangement. It is noted that this variation is associated with an offence under section 44 of the MPTG Act concerning the handling of regulated substances as prescribed by regulation and has potential to cause confusion among health professionals regarding the record keeping obligations and associated liability for faxed prescriptions. It is considered that the benefits of the variation for prescribers

and pharmacists outweigh the minor risks and that these can be suitably managed with information and support from the ACT Health Directorate.

Clause 6 Section 120 (1) (g)

This clause updates section 120 (1)(g) of the MPTG Regulation to increase the time allowed for a pharmacist to receive a prescription from 7 days to 14 days following dispensing a regulated substance at the oral direction of a prescriber or based on a faxed prescription. This increased time period is made to align with other provisions as amended by this amendment regulation.

Clause 7 New section 120A

This clause inserts new section 120A to provide that a pharmacist is not required to advise the Chief Health Officer of an instance where a prescription was not provided following dispensing of a substance based on a faxed prescription, if the prescription must be retained by the prescriber in accordance with a Commonwealth special arrangement.