Australian Capital Territory

Medicines, Poisons and Therapeutic Goods Amendment Regulation 2021 (No 2)

Subordinate Law SL2021-28

The Australian Capital Territory Executive makes the following regulation under the *Medicines, Poisons and Therapeutic Goods Act 2008*.

Dated 27 October 2021.

ANDREW BARR
Chief Minister

RACHEL STEPHEN-SMITH
Minister

J2021-1058

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Medicines, Poisons and Therapeutic Goods Act 2008

Contents

1 Name of regulation

This regulation is the *Medicines, Poisons and Therapeutic Goods Amendment Regulation 2021 (No 2).*

2 Commencement

This regulation commences on the day after its notification day.

Note The naming and commencement provisions automatically commence on the notification day (see Legislation Act, s 75 (1)).

3 Legislation amended

This regulation amends the *Medicines, Poisons and Therapeutic Goods Regulation 2008*.

4 Section 31 (2) and note

substitute

(2) In this section:

national residential medication chart means a medication chart within the meaning of the *National Health (Pharmaceutical Benefits) Regulations 2017* (Cwlth), section 41 (4), as in force from time to time.

Note The *National Health (Pharmaceutical Benefits) Regulations 2017* (Cwlth) does not need to be notified under the Legislation Act because s 47 (6) does not apply (see s 863).

5 Section 41 (4), definition of *relevant approval particulars*

omit

6 Section 121 (3), definition of *authorised prescriber* and examples

substitute

authorised prescriber means—

(a) for a prescription prescribing buprenorphine or methadone for treatment of opioid dependency—a prescriber approved under division 13.1.3 to prescribe the medicine for the treatment of opioid dependency; or

(b) for any other prescription—a prescriber.

Example—paragraph (a)

A doctor employed by an alcohol and drug service prescribing buprenorphine or methadone to treat the opioid dependency for a patient.

Example—paragraph (b)

A doctor practising as a general practitioner prescribing buprenorphine or methadone to treat chronic pain for a patient.

7 Section 124 (1)

substitute

(1) This section does not apply to—

(a) a prescription written in the medical records of an in-patient at a hospital; or

(b) an electronic prescription, within the meaning of the *National Health (Pharmaceutical Benefits) Regulations 2017* (Cwlth), section 5.

8 Section 124 (3)

after

dispensed electronic prescription

insert

(other than an electronic prescription mentioned in subsection (1) (b))

9 Section 124 (4), new definition of *national residential medication chart*

insert

national residential medication chart—see section 31 (2).

10 Section 430 (4), definition of *authorised activity*, new paragraph (d)

insert

(d) if the relevant medicine is integral to genuine medical or scientific research at the institution—reasonable use of the medicine to carry out the research.

11 Sections 555 and 556

substitute

555 Standing approval to prescribe controlled medicines for hospital in-patient or patient discharge

A designated prescriber is approved to prescribe a controlled medicine for a patient of the prescriber if—

(a) the patient is an in-patient at a hospital; or

(b) the prescription is issued—

(i) as part of the patient's discharge from a hospital; and

(ii) for the patient's use of the controlled medicine for a period of not more than 7 days.

Note A hospice is a hospital (see *Macquarie Dictionary*, 8th ed, def ***hospice***).

556 Standing approval to prescribe controlled medicines for short-term treatment

(1) A designated prescriber is approved to prescribe a controlled medicine for a patient of the prescriber during a short-term treatment period if—

(a) the prescriber believes on reasonable grounds that the patient—

(i) is not a drug-dependant person in relation to a controlled medicine or prohibited substance; and

(ii) has not been prescribed the same controlled medicine by another prescriber in the 2-month period immediately before the day the prescriber prescribes the controlled medicine; and

(b) the prescriber has not prescribed the same controlled medicine to the patient in the 2-month period immediately before the short-term treatment period; and

(c) the prescriber prescribes the controlled medicine for the patient's use during the short-term treatment period only.

Note For prescribing controlled medicines for more than a short-term treatment period, see division 13.1.3.

(2) In this section:

short-term treatment period, for a patient to be prescribed a controlled medicine, means a consecutive 2-month period beginning on the day the prescriber first prescribes the controlled medicine for the period.

12 Section 561 (1) (c) (i), except note

substitute

(i) the form, strength and the daily dose for a specified period of time; or

13 Section 635 (1)

omit

Minister

substitute

director-general

14 Section 635 (1), note 2

omit

15 Sections 637 and 644

omit

Minister

substitute

director-general

16 Section 695 (3), definition of *authorised activity*, new paragraph (d)

insert

(d) if the poison is integral to genuine medical or scientific research at the institution—reasonable use of the poison to carry out the research.

17 Section 863 (d)

substitute

(d) the *National Health (Pharmaceutical Benefits) Regulations 2017* (Cwlth);

18 New section 863 (g) to (k)

insert

(g) Australian Immunisation Handbook;

(h) Australian Technical Advisory Group on Immunisation (ATAGI) Clinical guidance on use of COVID-19 vaccine in Australia;

(i) National guidelines for medication-assisted treatment of opioid dependence;

(j) National Immunisation Education Framework for Health Professionals;

(k) National Vaccine Storage Guidelines: Strive for 5.

19 Section 863, new note

insert

Note 2A The following are accessible at www.health.gov.au:

- The Australian Immunisation Handbook
- The clinical guidance on use of COVID-19 vaccine
- The National guidelines for medication-assisted treatment of opioid dependence
- The National Immunisation Education Framework for Health Professionals
- The National Vaccine Storage Guidelines: Strive for 5.

20 Schedule 1, part 1.11, item 1, column 3, paragraph (a) (ii)

substitute

(ii) not more than 30 ampoules, each of 1mL or less, of morphine sulphate, at a concentration of 30mg or less of morphine sulphate per mL;

(iii) not more than 5 ampoules, each of 1mL or less, of hydromorphone, at a concentration of 2mg or less of hydromorphone per mL;

21 Schedule 3, section 3.1, new definition of *approved indication*

insert

approved indication means an indication that is accepted by the Secretary of the Australian Government Department of Health in relation to the medicine in the Australian Register of Therapeutic Goods.

Note Approved indications are shown in the public summary of the Australian Register of Therapeutic Goods on the Therapeutic Goods Administration website at www.tga.gov.au.

22 Schedule 3, part 3.2, item 5, column 2

after

specialist area of

insert

dentistry,

23 Schedule 3, part 3.2, item 6, column 2

omit

designated

24 Schedule 3, part 3.2, new items 7 to 9

insert

7	specialist practising in specialist area of dermatology, gastroenterology and hepatology, infectious diseases, paediatric gastroenterology and hepatology, paediatric infectious diseases	ivermectin	for initial treatment for an indication that is not an approved indication
8	prescriber	ivermectin	(a) for initial and continued treatment for an indication that is an approved indication; or (b) for continuation of treatment initiated by a specialist under item 7
9	prescriber	nicotine for human use	

25 Schedule 3, part 3.2, new note

insert

Note 2 The *Poisons Standard Amendment (Hydroxychloroquine and Salbutamol) Instrument 2020* (Cwlth) (F2020L00291) commenced on 24 March 2020.

26 Dictionary, definition of *national residential medication chart prescription*

substitute

national residential medication chart prescription means a medication chart prescription within the meaning of the *National Health (Pharmaceutical Benefits) Regulations 2017* (Cwlth), section 41 (4), as in force from time to time.

Note The *National Health (Pharmaceutical Benefits) Regulations 2017* (Cwlth) does not need to be notified under the Legislation Act because s 47 (6) does not apply (see s 863).

Endnotes

1 Notification

Notified under the Legislation Act on 4 November 2021.

2 Republications of amended laws

For the latest republication of amended laws, see www.legislation.act.gov.au.