

Medicines, Poisons and Therapeutic Goods Amendment Regulation 2025 (No 2)

Subordinate Law SL2025-29

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

Dated 28 November 2025.

ANDREW BARR
Chief Minister

RACHEL STEPHEN-SMITH
Minister

J2025-599



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Medicines, Poisons and Therapeutic Goods Act 2008

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1 Name of regulation

This regulation is the *Medicines, Poisons and Therapeutic Goods Amendment Regulation 2025 (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 11

substitute

11 Overview of medicines authorisations etc under this regulation

Medicines authorisations, approvals and endorsements are given under the following provisions of this regulation:

- (a) section 30 (which is about authorisations under schedule 1 to prescribe medicines);
- (b) section 50 (which is about authorisations under schedule 1 to issue requisitions for medicines);
- (c) section 60 (which is about authorisations under schedule 1 to issue purchase orders for medicines);
- (d) section 70 (which is about authorisation of CHO to issue standing orders for supply of medicines in public health emergencies);

- (e) section 71 (which is about authorisation of CHO to issue standing orders for administration of medicines for public health matters);
- (f) section 75 (which is about authorisation of doctors to issue standing orders for administration of medicines at institutions);
- (g) section 77 (which is about authorisation of CHO to issue standing orders for supply and administration of medicines at walk-in centres);
- (h) section 110 (which is about authorisations under schedule 1 to supply medicines);
 - Note Supply includes dispense on prescription (see Act, s 24).
- (i) section 251 (which is about authorisation of pharmacists to supply certain medicines without prescription in emergencies);
- (j) section 255 (which is about authorisation of approved pharmacists to supply certain medicines without prescription);
- (k) section 260 (which is about authorisation to supply medicines to pharmacists for disposal);
- (1) section 261 (which is about authorisation to supply medicines to commercial disposal operators for disposal);
- (m) section 350 (which is about authorisations under schedule 1 for people in health-related occupations to administer medicines);
- (n) section 352 (which is about authorisation of pharmacists and intern pharmacists to administer vaccines without prescription);
- (o) section 353 (which is about authorisation of nurses and midwives to administer vaccines without prescription);
- (p) section 360 (which is about authorisation for self-administration of medicines);

- (q) section 361 (which is about authorisation for the administration of medicines by assistants);
- (r) section 370 (which is about authorisations under schedule 1 to obtain and possess medicines);
- (s) section 371 (which is about authorisation to obtain and possess medicines for certain personal use-related dealings);
- (t) section 380 (which is about authorisations under schedule 1 to manufacture medicines);
- (u) section 390 (3) (which is about authorisation to discard controlled medicines in certain ways);
- (v) section 400 (which is about authorisation to deliver medicines under supply authorities);
- (w) section 401 (which is about authorisation for commercial disposal operators for disposal of medicines);
- (x) section 410 (which is about authorisation to supply and administer adrenaline, naloxone and salbutamol);
- (y) section 420 (which is about authorisations for CYP authorised people);
- (z) section 421 (which is about authorisations for corrections officers);
- (za) section 422 (which is about authorisations for court and police cell custodians);
- (zb) section 430 (which is about authorisations for non-controlled medicines research and education);
- (zc) section 440 (which is about authorisations under controlled medicines research and education program licences);
- (zd) section 450 (which is about authorisations under first-aid kit licences);

- (ze) section 460 (which is about authorisations under medicines wholesalers licences);
- (zf) section 470 (which is about authorisations under opioid dependency treatment licences);
- (zg) section 480 (which is about authorisations under pharmacy medicines rural communities licences);
- (zh) section 490 (which is about authorisations for endorsed health practitioners);
- (zi) section 490A (which is about authorisations for health practitioners for certain dealings approved by CHO);
- (zj) section 554 (which is about standing CHO approvals of classes of designated prescribers to prescribe controlled medicines in certain circumstances);
- (zk) section 555 (which is about standing approval of designated prescribers to prescribe controlled medicines for hospital in-patient or patient discharge);
- (zl) section 556 (which is about standing approval of designated prescribers to prescribe controlled medicines for short-term treatment);
- (zm) section 557 (which is about standing interim approval of designated prescribers to prescribe buprenorphine and methadone for patients of certain institutions);
- (zn) division 13.1.3 (which is about CHO approvals of designated prescribers to prescribe controlled medicines for individuals);
- (zo) division 13.1.4 (which is about endorsement by CHO of designated prescribers to treat drug-dependency);
- (zp) section 591 (which is about standing approvals of certain prescribers under schedule 3 to prescribe ACT listed appendix D medicines);

- (zq) section 593 (which is about CHO approval of prescribers to prescribe appendix D medicines);
- (zr) section 860 (which is about authorisation of public employees exercising functions under the Act for certain dealings);
- (zs) section 861 (which is about authorisation of public employees for certain dealings under CHO permit);
- (zt) section 861A (which is about authorisation of public employees for certain dealings under director-general authorisation).

5 Section 12 (1), example

omit

an authorised person

substitute

a person or endorsed health practitioner who is authorised

6 Section 12 (2) and example and note

substitute

(2) The conditions are additional to other restrictions on a person's or endorsed health practitioner's authority to deal with a medicine.

Note Conditions may also be imposed under other provisions of the Act including, for example, s 89 which sets out conditions on licences.

7 Section 30 (1) (c)

omit

8 Section 30 (2)

substitute

- (2) However, a person is not authorised to self-prescribe a medicine if—
 - (a) the person is a trainee dentist, intern doctor or endorsed health practitioner; or
 - (b) the medicine is a restricted medicine.
- (3) In this section:

prescribe includes self-prescribe.

restricted medicine means—

- (a) an anabolic steroid; or
- (b) an appendix D medicine; or
- (c) a monitored medicine.

9 Section 31 (1)

after

section 30

insert

or section 490

10 Section 32 (d)

substitute

(d) if the approval is for a maximum daily dose of the medicine—the prescription is for not more than the maximum daily dose approved;

11 Section 41 (1) (h) to (j)

omit

12 New section 49

in division 3.2.1, insert

49 Meaning of issuer—pt 3.2

In this part:

issuer means the following:

- (a) a person who is authorised under section 50 to issue a requisition for a medicine;
- (b) an endorsed health practitioner who is authorised under section 490 to issue a requisition for a medicine.

13 Section 51

omit

A person's authorisation under section 50

substitute

An authorisation under section 50 or section 490

14 Section 51 (b) (i)

omit

the person

substitute

the issuer

15 Section 55 (a)

omit

person (the *issuer*) issuing

substitute

issuer of

16 Section 56 (a) and (b)

substitute

- (a) the issuer's name;
- (b) the capacity in which the issuer is issuing the requisition;

17 Section 61

omit

A person's authorisation under section 60

substitute

An authorisation under section 60 or section 490

18 Section 61 (b), except example

substitute

(b) the issuer must, not later than 24 hours after they receive the medicine, send the supplier a document signed by the issuer acknowledging receipt of the medicine.

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19 Section 61 (b), example

omit

buyer

substitute

issuer

20 New section 61 (2)

insert

(2) In this section:

issuer—see section 62 (1) (a).

21 Section 100, note

omit

s 11 (2) (Overview of medicines authorisations under this regulation)

substitute

s 11 (Overview of medicines authorisations etc under this regulation)

22 Section 120 (1)

omit

A person's authorisation under section 110

substitute

An authorisation under section 110 or section 490

23 Section 123 (b) to (d)

omit

omit

A person's authorisation under section 110

substitute

An authorisation under section 110 or section 490

25 Section 134

omit

A person who supplies a medicine to someone else on requisition *substitute*

A person or endorsed health practitioner who supplies a medicine to someone else on requisition (a *supplier*)

26 Section 134 (e), except note

substitute

(e) the supplier's name or initials.

27 Section 140

omit

A person's authorisation under section 110

substitute

An authorisation under section 110 or section 490

omit

A person

substitute

A person or endorsed health practitioner

29 Section 150 (1)

omit

A person's authorisation under section 110

substitute

An authorisation under section 110 or section 490

30 Section 150 (1) (c)

omit

person's

substitute

supplier's

31 Section 150 (3), new definition of *supplier*

insert

supplier—see section 153 (1).

after

section 110

insert

or section 490

33 Section 161 (i) to (k)

omit

34 Section 163 (d)

substitute

(d) if the approval is for a maximum daily dose of the medicine the supply is for not more than the maximum daily dose approved;

35 Section 163, 2nd example

omit

36 **Section 180 (2)**

substitute

- (2) An authorisation under section 110 or section 490 to supply a pharmacist only medicine is subject to the following conditions:
 - (a) the supplier personally hands the medicine to a recipient attending in person;
 - (b) the supplier gives the recipient adequate instructions, either orally or in writing, for the medicine's use at the time of supply.

(3) In this section:

supplier means the following:

- (a) a person who is authorised under section 110 to supply a pharmacist only medicine;
- (b) an endorsed health practitioner who is authorised under section 490 to supply a pharmacist only medicine.

37 Section 351 (1)

after

section 350

insert

or section 490

38 Section 360 (2) (a) (i)

substitute

(i) a trainee dentist, intern doctor or endorsed health practitioner; or

39 Section 360 (3), definition of restricted medicine

omit

section 30

substitute

section 30 (3)

40 Chapter 6 heading, new note

insert

Note

An endorsed health practitioner may be authorised to obtain and possess a medicine in accordance with an endorsement of the health practitioner's registration (see s 490).

41 Section 390 (3)

omit

a person who is authorised

substitute

a person or endorsed health practitioner who is authorised

42 Section 410 (2), definition of authorised adrenaline

substitute

authorised adrenaline means adrenaline in an automatic injector or intranasal delivery device that delivers a predetermined dose of adrenaline.

43 Section 490

substitute

490 Authorisations for endorsed health practitioners—Act, s 20 (1) (d)

- (1) This section applies to a health practitioner whose registration is endorsed under the *Health Practitioner Regulation National Law* (ACT), division 8 (Endorsement of registration) if the endorsement provides for dealing with a medicine (an *endorsed health practitioner*).
- (2) The endorsed health practitioner is authorised to deal with the medicine in accordance with the endorsement.

(3) If there is an inconsistency between the endorsement and this regulation, the endorsement prevails to the extent of the inconsistency.

44 Section 510 (a) and notes

substitute

- (a) a dentist, doctor, endorsed health practitioner, medical radiation practitioner or veterinary practitioner;
 - Note 1 **Dentist** and **doctor** does not include an intern or trainee (see defs of these terms in dict).
 - Note 2 **Medical radiation practitioner** does not include a person holding student, limited or provisional registration to practise in the profession (see dict).

45 Section 532 (1), definition of *designated person*, paragraphs (a) and (b)

substitute

- (a) a dentist, doctor, endorsed health practitioner, medical radiation practitioner or veterinary practitioner (other than 1 of those health practitioners at an institution); or
- (b) an ambulance officer or paramedic employed by the Commonwealth, the Territory or a State; or

46 Section 532 (1), note 2

substitute

Note 2 **Medical radiation practitioner** and **paramedic** does not include a person holding student, limited or provisional registration to practise in the profession (see defs of these terms in dict).

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

substitute

- (a) a dentist, doctor, endorsed health practitioner, medical radiation practitioner or veterinary practitioner at an institution; or
- (aa) the person in charge of an ambulance service (whether or not operated by the Commonwealth, the Territory or a State); or

48 Section 533 (1), new note

insert

Note 5 State includes the Northern Territory (see Legislation Act, dict, pt 1).

49 Table 540, item 14

substitute

14	endorsed health	the endorsed health practitioner's
	practitioner	place of practice

50 Section 541 (1), definition of *designated person*, paragraphs (a) and (b)

substitute

- (a) a dentist, doctor, endorsed health practitioner or veterinary practitioner; or
- (b) an ambulance officer or paramedic employed by the Commonwealth, the Territory or a State; or

51 Section 541 (1), note 2

substitute

Note 2 **Paramedic** does not include a person holding student, limited or provisional registration to practise in the profession (see dict).

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substitute

544 Prescribed witnesses for administration of controlled medicines—Act, s 53 (a) and (b)

- (1) The following people are prescribed as witnesses in relation to the administration of a controlled medicine:
 - (a) if the medicine is administered by an intern doctor—
 - (i) an ambulance officer or paramedic employed by the Commonwealth, the Territory or a State; or
 - (ii) a dentist; or
 - (iii) a doctor; or
 - (iv) a medical radiation practitioner; or
 - (v) a midwife; or
 - (vi) a nurse; or
 - (vii) a pharmacist;
 - Note 1 **Dentist**, **doctor** and **pharmacist** does not include an intern or trainee (see defs of these terms in dict).
 - Note 2 **Medical radiation practitioner** and **paramedic** does not include a person holding student, limited or provisional registration to practise in the profession (see defs of these terms in dict).
 - Note 3 Nurse does not include an enrolled nurse (see Legislation Act, dict, pt 1).
 - Note 4 State includes the Northern Territory (see Legislation Act, dict, pt 1).
 - (b) if the medicine is administered by a person who is not an intern doctor—
 - (i) a person prescribed under paragraph (a); or

- (ii) an intern doctor or enrolled nurse.
- (2) However, a person mentioned in subsection (1) is not prescribed as a witness to the administration of a controlled medicine if the person is—
 - (a) related to, a close friend of or employed by the person administering the medicine; or
 - (b) the supervisor of the person administering the medicine; or
 - (c) supervised by the person administering the medicine.

53 Section 545 (1) (a)

after

officer

insert

or paramedic

54 Section 545 (1), new note

insert

Note 2A Medical radiation practitioner and paramedic does not include a person holding student, limited or provisional registration to practise in the profession (see defs of these terms in dict).

55 **Section 545 (2)**

omit

must not be a prescribed witness

substitute

is not prescribed as a witness

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56 Section 551, definition of designated prescriber

substitute

designated prescriber means the following:

- (a) a prescriber (other than a veterinary practitioner) in relation to whom prescribing a controlled medicine is included in schedule 1, column 3;
- (b) an endorsed health practitioner if prescribing a controlled medicine is—
 - (i) in accordance with the endorsement of their registration; and
 - (ii) if not inconsistent with the endorsement of their registration—allowed under this regulation.

57 New section 554

in division 13.1.2, insert

554 Standing CHO approvals to prescribe controlled medicines in certain circumstances—Act, s 20 (1) (c)

- (1) A designated prescriber is approved to prescribe a controlled medicine for a patient of the prescriber if the prescriber—
 - (a) is a member of a class of designated prescribers approved under this section to prescribe the controlled medicine; and
 - (b) believes on reasonable grounds that the patient is not a drug-dependant person in relation to a controlled medicine or prohibited substance.
- (2) The chief health officer may approve a class of designated prescribers to prescribe a controlled medicine, or category of controlled medicine, if the chief health officer is satisfied that the approval is appropriate in the circumstances.

- (3) The approval must be in writing and include the following information:
 - (a) the class of designated prescribers to whom the approval relates;
 - (b) the controlled medicine, or category of controlled medicine, to which the approval relates;
 - (c) if the approval is for a particular form of the controlled medicine—the form of the medicine;
 - (d) if the approval is for a particular strength of the controlled medicine—the strength of the medicine;
 - (e) if the approval is for a maximum daily dose of the controlled medicine—the maximum daily dose of the medicine;
 - (f) any condition to which the approval is subject;
 - (g) a unique identifying number for the approval;
 - (h) the date the approval starts;
 - (i) if the approval applies for a stated period—the stated period.
- (4) An approval is a notifiable instrument.

58 New section 559

in division 13.1.3, insert

559 Application—div 13.1.3—standing CHO approvals to prescribe controlled medicines in certain circumstances

This division does not apply in relation to a controlled medicines approval by the chief health officer under section 554.

59 Section 561 (1) (c) (i) and note

substitute

(i) the form, strength and maximum daily dose of the medicine; or

Note

Other forms and strengths of the medicine, and a daily dose less than the maximum daily dose, may be prescribed in accordance with s 32.

60 Section 564

omit

(not longer than 3 years)

61 Section 571 (1) (b) (i)

substitute

(i) the form, strength and maximum daily dose of the medicine that may be prescribed under the approval; or

62 Section 575 (1) (b) and examples

substitute

(b) a form, strength and maximum daily dose of a controlled medicine.

Example

approval to prescribe all forms or strengths, up to a maximum daily dose, of certain controlled medicines for people with terminal illness

63 Schedule 1, part 1.1 heading

substitute

Part 1.1 Ambulance services, officers and paramedics

64 Schedule 1, part 1.1, item 1, column 2

after

officer

insert

or paramedic

65 Schedule 1, part 1.1, item 1, new note

insert

Note

Paramedic does not include a person holding student, limited or provisional registration to practise in the profession (see dict).

66 Schedule 1, part 1.1, item 2, column 3, paragraph (d)

after

officers

insert

and paramedics

67 Schedule 1, part 1.4A, item 1, new note

insert

Note

Medical radiation practitioner does not include a person holding student, limited or provisional registration to practise in the profession (see dict).

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68 Schedule 1, part 1.5, item 2

omit

69 Schedule 1, part 1.6, item 2, column 3

omit

nurse, nurse practitioner or midwife

substitute

nurse or midwife

70 Schedule 1, part 1.6, item 4

omit

71 Dictionary, note 3

insert

- authorised, to deal with a regulated substance (see s 20)
- dispense
- pharmacist only medicine (see s 11)
- possess, for a regulated substance (see s 24)
- prescribe
- register, for a regulated substance
- requisition

72 Dictionary, definition of eligible midwife

omit

73 Dictionary, new definitions

insert

endorsed health practitioner—see section 490 (1).

issuer, for part 3.2 (Requisitioning medicines)—see section 49.

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paramedic—

- (a) means a person holding registration to practise in the paramedicine profession under the *Health Practitioner Regulation National Law (ACT)*; but
- (b) does not include a person holding student, limited or provisional registration for the purpose of undertaking a period of supervised practice or course of training, or both, to allow the person to be registered to practise without supervision.

74 Dictionary, definition of *prescriber*

substitute

prescriber, in relation to a medicine, means the following:

- (a) a person in relation to whom prescribing the medicine is included in schedule 1, column 3 in relation to the person;
- (b) an endorsed health practitioner if prescribing the medicine is—
 - (i) in accordance with the endorsement of their registration; and
 - (ii) if not inconsistent with the endorsement of their registration—allowed under this regulation.

Endnotes

1 Notification

Notified under the Legislation Act on 15 December 2025.

2 Republications of amended laws

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

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