

NORTHERN TERRITORY OF AUSTRALIA

MEDICINES, POISONS AND THERAPEUTIC GOODS LEGISLATION
AMENDMENT ACT 2022

Act No. 25 of 2022

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NORTHERN TERRITORY OF AUSTRALIA

Act No. 25 of 2022

An Act to amend the *Medicines, Poisons and Therapeutic Goods Act 2012* and the *Medicines, Poisons and Therapeutic Goods Regulations 2014*

[Assented to 9 December 2022]
[Introduced 12 October 2022]

The Legislative Assembly of the Northern Territory enacts as follows:

Part 1 Preliminary matters

1 Short title

This Act may be cited as the *Medicines, Poisons and Therapeutic Goods Legislation Amendment Act 2022*.

2 Commencement

This Act commences on the day after the day on which the Administrator's assent to this Act is declared.

Part 2 Amendment of Medicines, Poisons and Therapeutic Goods Act 2012

3 Act amended

This Part amends the *Medicines, Poisons and Therapeutic Goods Act 2012*.

4 Section 5 amended (Definitions)

- (1) Section 5, definitions ***amphetamine***, ***approved ATSI health practitioner***, ***approved midwife***, ***approved nurse***, ***approved paramedic***, ***COVID-19, COVID-19 vaccine***, ***COVID-19 vaccine administration protocol***, ***excluded person*** and ***Scheduled substance treatment protocol***

omit

- (2) Section 5

insert

approved SSTP, for Chapter 2, Part 2.3, Division 1, Subdivision 3A, see section 70.

pest authorisation, for Chapter 2, Part 2.7, Division 4A, see section 112A.

prescribed health practitioner, for Chapter 2, Part 2.3, Division 1, Subdivision 3A, see section 70.

prescribed healthcare worker, for Chapter 2, Part 2.3, Division 1, Subdivision 3A, see section 70.

Schedule 3 authorisation, see section 123A.

Schedule 4 supplier certificate of registration, see section 122A.

Scheduled substance treatment protocol, see section 70B(1).

SSTP means a Scheduled substance treatment protocol.

- (3) Section 5, definition ***authorised purpose***, paragraph (b)

omit

- (4) Section 5, definition ***authorised purpose***, paragraph (c)

omit

another

insert

a

- (5) Section 5, definition ***certificate of registration***, paragraph (b)
omit
registration.
insert
registration; or
- (6) Section 5, definition ***certificate of registration***, after paragraph (b)
insert
(c) a Schedule 4 supplier certificate of registration.

5 Section 10 amended (Meaning of *unrestricted Schedule 8 substance* and *restricted Schedule 8 substance*)

- Section 10(2)
omit, insert
- (2) A ***restricted Schedule 8 substance*** is a Schedule 8 substance declared under section 246(1)(b) to be a restricted Schedule 8 substance.

6 Section 11 repealed (Meaning of *amphetamine*)

Section 11
repeal

7 Section 21 amended (Meaning of *supply and sell*)

- (1) Section 21(1)(b)
omit
prescription; and
insert
prescription.
- (2) Section 21(1)(c)
omit

8 Section 25 amended (Meaning of *nurse, midwife* and related terms)

Section 25(4) and (7)

omit

9 Section 28 amended (Meaning of *Aboriginal and Torres Strait Islander health practitioner* and *approved ATSI health practitioner*)

(1) Section 28, heading

omit

and *approved ATSI health practitioner*

(2) Section 28(1)

omit

(1)

(3) Section 28(2)

omit

10 Section 28A amended (Meaning of *paramedic* and *approved paramedic*)

(1) Section 28A, heading

omit

and *approved paramedic*

(2) Section 28A(1)

omit

(1)

(3) Section 28A(2)

omit

11 Sections 37 and 38 replaced

Sections 37 and 38

repeal, insert

37 Supply of Schedule 3 substance

- (1) A person commits an offence if:
- (a) the person intentionally supplies a substance to another person; and
 - (b) the substance is a Schedule 3 substance and the person is reckless in relation to that circumstance; and
 - (c) the supply of the substance by the person is not authorised under this Act.

Maximum penalty: 50 penalty units.

- (2) Strict liability applies to subsection (1)(c).

38 Administration of Schedule 3 substance

- (1) A person commits an offence if:
- (a) the person intentionally administers a substance to another person; and
 - (b) the substance is a Schedule 3 substance and the person is reckless in relation to that circumstance; and
 - (c) the administration of the substance by the person is not authorised under this Act.

Maximum penalty: 50 penalty units.

- (2) Strict liability applies to subsection (1)(c).

- (3) It is a defence to a prosecution for an offence against subsection (1) if the defendant believed on reasonable grounds that:

- (a) the person to whom the Schedule 3 substance was administered was in danger of dying or of suffering a serious disability; and

-
- (b) the administration of the Schedule 3 substance to that person was required to prevent the person from dying or suffering a serious disability.

Note for subsection (3)

The defendant has an evidential burden in relation to this defence (see section 43BU of the Criminal Code).

12 Section 48 amended (Supplying and administering for therapeutic use or treating addiction)

- (1) Section 48, heading

omit

for therapeutic use or treating addiction

insert

in prohibited circumstances

- (2) Section 48(2)

omit, insert

- (2) Each of the following is a ***prohibited circumstance*** for the supply or administration of an unrestricted Schedule 8 substance:
- (a) for treating a person's addiction to a substance;
- (b) for another purpose prescribed by regulation.

13 Section 62 repealed (Qualified pharmacist may supply and administer Schedule 4 vaccine)

Section 62

repeal

14 Sections 63 to 65 replaced

Sections 63 to 65

repeal, insert

63 Administering Schedule 4 or 8 substances under administration order – Aboriginal and Torres Strait health practitioners, nurses, midwives and pharmacists

- (1) Subject to subsection (2), if an authorised prescriber has, by administration order, authorised an Aboriginal and Torres Strait Islander

health practitioner, a nurse, a midwife or a pharmacist (the **practitioner**) to administer a Schedule 4 or 8 substance to another person, the practitioner may, in the course of practising in the practitioner's health profession, administer the substance to the person.

Note for subsection (1)

See section 92(1)(a)(i) to (iv) in relation to the persons to whom an authorised prescriber for a Schedule 4 or 8 substance may, by administration order, authorise the administration of the substance to.

- (2) The practitioner must administer the substance in accordance with any instructions given by the authorised prescriber.
- (3) A practitioner who is authorised to administer a Schedule 4 or 8 substance to a person under this section may, in the course of practising in the practitioner's health profession, possess the substance for that purpose.

64 Administering Schedule 4 or 8 substances supplied on supply order – nurses employed at residential facilities

- (1) Subject to subsection (2), a nurse employed at a residential facility may, in the course of practising in the nursing profession, administer a Schedule 4 or 8 substance to a resident at the facility if:
 - (a) the substance was supplied by a pharmacist on a supply order issued by an authorised prescriber; and
 - (b) the prescriber authorised the supply of the substance for the purpose of its administration to the resident.

Notes for subsection (1)

1 Under section 92(1)(b)(ii), an authorised prescriber for a Schedule 4 or 8 substance may, by supply order, authorise the supply of the substance by a pharmacist to a nurse employed at a residential facility for administration to a resident at the facility.

2 Under section 57(1)(c)(ii), a pharmacist may supply a Schedule 4 or 8 substance on a written supply order for the substance to a nurse employed at a residential facility for administration to a resident at the facility.

- (2) The nurse must administer the substance in accordance with any instructions for its administration specified by the authorised prescriber in the supply order.
- (3) A nurse who is authorised to administer a Schedule 4 or 8 substance to a resident at a residential facility under this section may, in the course of practising in the nursing profession, possess the substance for that purpose.

15 Section 67 repealed (Dental therapists, dental hygienists and oral health specialists)

Section 67

repeal

16 Chapter 2, Part 2.3, Division 1, Subdivision 3A inserted

After section 69

insert

Subdivision 3A Administering, supplying and possessing Scheduled substances under SSTP**70 Definitions**

In this Subdivision:

approved SSTP means an SSTP for which an approval under section 254 is in effect.

prescribed health practitioner means a health practitioner of a type prescribed by regulation under section 70A(1).

prescribed healthcare worker means a person who is a member of a class of persons prescribed by regulation under section 70A(2).

70A Prescribed health practitioners and healthcare workers

- (1) The regulations may prescribe a type of health practitioner that may be authorised under this Subdivision to administer or supply a Schedule 4 or 8 substance in accordance with an approved SSTP.
- (2) The regulations may prescribe a class of persons that provide health services, other than a health practitioner, that may be authorised under this Subdivision to administer or supply a Schedule 3, 4 or 8 substance in accordance with an approved SSTP.

Note for section 70A

For the administration or supply of a Schedule 3 substance by a health practitioner, see sections 71 and 72.

70B Form and content of SSTP

- (1) A ***Scheduled substance treatment protocol*** is a document setting out protocols for the administration or supply of:
 - (a) a Schedule 4 or 8 substance by the prescribed health practitioner, or the class of prescribed health practitioners, specified in the document in the circumstances specified in the document; or
 - (b) a Schedule 3, 4 or 8 substance by the prescribed healthcare worker, or the class of prescribed healthcare workers, specified in the document in the circumstances specified in the document.
- (2) An SSTP must specify the following matters:
 - (a) the prescribed health practitioner or prescribed healthcare worker, or the class of prescribed health practitioners or prescribed healthcare workers, in relation to which it applies;
 - (b) if the SSTP applies to a prescribed health practitioner or a class of prescribed health practitioner – the Schedule 4 or 8 substance in relation to which it applies;
 - (c) if the SSTP applies to a prescribed healthcare worker or a class of prescribed healthcare worker – the Schedule 3, 4 or 8 substance in relation to which it applies;
 - (d) the circumstances in which the substance may be administered or supplied to another person in accordance with the SSTP, including with reference to the matters prescribed by regulation;
 - (e) any other matter prescribed by regulation.
- (3) For subsection (2)(a), a class of prescribed health practitioners or class of prescribed healthcare workers may be identified in an SSTP by reference to one or more of the following criteria:
 - (a) a qualification held, or training that has been undertaken, by members of the class;
 - (b) the employment circumstances of members of the class;
 - (c) a place at which members of the class practise their health profession or provide health services;
 - (d) any other criteria prescribed by regulations.

Note for section 70B

An SSTP is required to be approved by the CHO under section 254 before a prescribed health practitioner or prescribed healthcare worker to which the SSTP applies may administer or supply the specified Scheduled substance in accordance with it.

70C Administering, supplying and possessing Schedule 4 or 8 substance under SSTP – prescribed health practitioners

- (1) Subject to subsection (2), a prescribed health practitioner may, in the course of practising in the practitioner's health profession, administer a Schedule 4 or 8 substance to another person if:
 - (a) an approved SSTP for the administration of the substance applies to the practitioner; and
 - (b) the administration of the substance to the other person is in the circumstances specified in the approved SSTP.
- (2) The prescribed health practitioner must administer the substance in accordance with the approved SSTP.
- (3) Subject to subsection (4), a prescribed health practitioner may, in the course of practising in the practitioner's health profession, supply a Schedule 4 or 8 substance to another person if:
 - (a) an approved SSTP for the supply of the substance applies to the practitioner; and
 - (b) the supply of the substance to the other person is in the circumstances specified in the approved SSTP.
- (4) The prescribed health practitioner must supply the substance in accordance with the approved SSTP.
- (5) A prescribed health practitioner who is authorised to administer or supply a Schedule 4 or 8 substance to another person under this section may, in the course of practising in the practitioner's health profession, possess the substance for that purpose.

70D Administering, supplying and possessing Schedule 3, 4 or 8 substance under SSTP – prescribed healthcare workers

- (1) Subject to subsection (2), a prescribed healthcare worker may, in the course of providing health services, administer a Schedule 3, 4 or 8 substance to another person if:
 - (a) an approved SSTP for the administration of the substance applies to the healthcare worker; and
 - (b) the administration of the substance to the other person is in the circumstances specified in the approved SSTP.
- (2) The prescribed healthcare worker must administer the substance in accordance with the approved SSTP.

- (3) Subject to subsection (4), a prescribed healthcare worker may, in the course of providing health services, supply a Schedule 3, 4 or 8 substance to another person if:
 - (a) an approved SSTP for the supply of the substance applies to the healthcare worker; and
 - (b) the supply of the substance to the other person is in the circumstances specified in the approved SSTP.
- (4) The prescribed healthcare worker must supply the substance in accordance with the approved SSTP.
- (5) A prescribed healthcare worker who is authorised to administer or supply a Schedule 4 or 8 substance to another person under this section may, in the course of providing health services, possess the substance for that purpose.

17 Sections 71 and 72 replaced

Sections 71 and 72

repeal, insert

71 Supplying Schedule 3 substances

- (1) Subject to subsection (4), a health practitioner may, in the course of practising in the practitioner's health profession, supply a Schedule 3 substance to another person (the **recipient**).
- (2) A health practitioner who supplies a Schedule 3 substance under subsection (1) must, at the time of the supply, give the recipient adequate instructions (written or oral) for the administration of the substance.
- (3) The health practitioner must give the instructions to the recipient under subsection (2) even if the Schedule 3 substance that is supplied is to be used by a person other than the recipient.
- (4) Subsection (1) does not authorise the sale by retail of a Schedule 3 substance by a health practitioner other than a pharmacist.

72 Administering Schedule 3 substances

A health practitioner may, in the course of practising in the practitioner's health profession, administer a Schedule 3 substance to another person.

18 Section 75 replaced

Section 75

repeal, insert

75 Supplying and administering Schedule 3 substance supplied by health practitioner

- (1) If a health practitioner has supplied a Schedule 3 substance to a person (the **recipient**) for use by a person other than the recipient, the recipient may supply, but not sell, the substance to the person.
- (2) If a health practitioner has supplied a Schedule 3 substance for administration to a person (the **patient**), any person may administer the substance to the patient in accordance with the instructions given by the health practitioner.

Note for subsection (2)

See section 71 in relation to the supply of a Schedule 3 substance by a health practitioner.

19 Section 78 amended (Possessing, supplying and administering Schedule 3, 4 and 8 substances under emergency authorisation)

Section 78

omit

an authorised person

insert

a person who is authorised, or a member of a class of health practitioners that is authorised,

20 Section 84 amended (Unrestricted Schedule 8 substance – therapeutic use or treating addiction)

- (1) Section 84, heading

omit

therapeutic use or treating addiction

insert

prohibited circumstances

(2) Section 84(2)(a)

omit

21 Section 92 amended (Authorised prescriber may authorise administration and supply by order)

(1) Section 92(1)(a)

omit

all words from "verbal order" to "health practitioner"

insert

oral order (an **administration order**), authorise the administration of the substance by an Aboriginal and Torres Strait Islander health practitioner, a nurse, a midwife or a pharmacist

(2) Section 92, note

omit, insert

Note for section 92

An administration order or supply order may be issued electronically in accordance with the Electronic Transactions (Northern Territory) Act 2000.

22 Section 99 amended (Administering Schedule 3, 4 or 8 substance at hospital, residential facility or declared place)

(1) Section 99(2)

omit

professional

insert

practitioner

(2) Section 99(2)(c)

omit, insert

(c) does not administer the substance in accordance with the instructions of the authorised prescriber.

23 Section 100 replaced

Section 100

repeal, insert

100 Administration or supply of Schedule 8 substance to be witnessed

- (1) Subject to subsections (3) and (4), a health practitioner must not administer or supply a Schedule 8 substance to a relevant patient unless a person other than the practitioner or the patient witnesses the administration or supply of the substance.
- (2) Subject to subsections (3) and (4), if a health practitioner administers or supplies a Schedule 8 substance to a relevant patient and the administration or supply of the substance is witnessed by another person, the health practitioner must record the name of at least one person who witnessed the administration or supply of the substance in the record prescribed by regulation (the **prescribed record**).
- (3) Subsections (1) and (2) do not apply to a health practitioner if:
 - (a) the health practitioner is an Aboriginal and Torres Strait Islander health practitioner, a nurse, a midwife or a pharmacist (the **practitioner**); and
 - (b) another person is not reasonably available to witness the practitioner administer or supply the Schedule 8 substance to the relevant patient because of:
 - (i) the remote location of the place where the substance is administered or supplied; or
 - (ii) other special circumstances; and
 - (c) the practitioner records the reason why the administration or supply of the substance was not witnessed in the relevant patient's clinical record.
- (4) Subsection (1) and (2) do not apply to a health practitioner if:
 - (a) the health practitioner is a pharmacist; and
 - (b) the Schedule 8 substance that is administered or supplied to the relevant patient by the pharmacist is a restricted Schedule 8 substance; and
 - (c) the relevant patient is taking part in a pharmacotherapy program conducted at the hospital, residential facility or declared place.

- (5) A health practitioner commits an offence if:
- (a) the health practitioner administers or supplies a Schedule 8 substance to a relevant patient; and
 - (b) the administration or supply of the substance is required to be witnessed under subsection (1); and
 - (c) the administration or supply of the substance is not witnessed by a person other than the health practitioner or the relevant patient.

Maximum penalty: 20 penalty units.

- (6) A health practitioner commits an offence if:
- (a) the health practitioner administers or supplies a Schedule 8 substance to a relevant patient; and
 - (b) the administration or supply of the substance is witnessed by a person other than the health practitioner or the relevant patient; and
 - (c) the health practitioner is required to record the name of at least one of the persons who witnessed the administration or supply of the substance in the prescribed record under subsection (2); and
 - (d) the health practitioner fails to record the name of at least one of the persons who witnessed the administration or supply of the substance in the prescribed record.

Maximum penalty: 20 penalty units.

- (7) An offence against subsection (5) or (6) is an offence of strict liability.

- (8) In this section:

relevant patient means a person who is:

- (a) a patient of a hospital; or
- (b) a resident of a residential facility; or
- (c) receiving medical treatment at a declared place.

24 Chapter 2, Part 2.7, Division 4A inserted

After section 112

insert

Division 4A Advertising use of pesticides**112A Definition**

In this Division:

pest authorisation means:

- (a) a pest management technician licence; or
- (b) a licence granted under Part 5, Division 2 of the *Agricultural and Veterinary Chemicals (Control of Use) Act 2004*; or
- (c) an S7 authorisation issued under the *Agricultural and Veterinary Chemicals (Control of Use) Regulations 2005*.

112B Representation by unauthorised person

- (1) A person commits an offence if the person:
 - (a) represents, by any means, that the person carries out pest control operations involving the use of a pesticide for fee or reward; and
 - (b) is not authorised under a pest authorisation to use the pesticide.

Maximum penalty: 100 penalty units.

- (2) An offence against subsection (1) is an offence of strict liability.

112C Advertisement to include authorisation number

- (1) An advertisement for pest control operations that are offered by a business and involve the use of a pesticide must state:
 - (a) if the owner of the business holds a pest authorisation – the number of that authorisation; or
 - (b) otherwise – the number of the pest authorisation held by at least one person who is employed or contracted by the owner to carry out pest control operations for the business.
- (2) A person commits an offence if:
 - (a) the person:

-
- (i) places or distributes an advertisement for pest control operations that are offered by a business and involve the use of a pesticide; or
 - (ii) authorises another person to place or distribute an advertisement mentioned in subparagraph (i); and
- (b) the advertisement does not state the information required under subsection (1).

Maximum penalty: 100 penalty units.

(3) An offence against subsection (2) is an offence of strict liability.

(4) In this section:

advertisement means every form of advertisement or notice, however displayed, and whether or not displayed to the public.

Examples for definition advertisement

1 A post on a social media platform.

2 A flyer on a noticeboard.

25 Section 117 amended (Types of authorities)

(1) After section 117(b)

insert

(ba) a Schedule 4 supplier certificate of registration;

(2) After section 117(c)

insert

(ca) a Schedule 3 authorisation;

26 Section 120 amended (Suitability of nominated person – certificate of registration)

Section 120(b), after "activities"

insert

or services

27 Section 122A inserted

After section 122

insert

122A Schedule 4 supplier certificate of registration

A **Schedule 4 supplier certificate of registration**, for a place, is an authority that authorises its holder:

- (a) to supply, but not to sell, the Schedule 4 substances stated in the certificate from the place in the course of carrying out the service of distributing the substances to health practitioners or health services; and
- (b) to possess the substances for a purpose mentioned in paragraph (a).

28 Section 123A inserted

After section 123

insert

123A Schedule 3 authorisation

A **Schedule 3 authorisation** is an authority that authorises its holder, and the persons stated in it, to supply, but not to sell, the Schedule 3 substances stated in it.

29 Section 128 amended (Prohibited substance authorisation)

- (1) Section 128(1)

omit

all words from "**authorisation**," to "and other"

insert

authorisation issued to an authorised health practitioner (the **authority holder**) is an authority that authorises the authority holder, and another

- (2) Section 128(3)

omit

authorisation, for etorphine,

insert

authorisation issued to a veterinarian or other person prescribed by regulation

30 Section 129 amended (Research authorisation)

Section 129(a), after "administer"

insert

or supply, but not to sell,

31 Section 130 amended (Medical kit authorisation)

Section 130(1)(a), after "administer"

insert

or supply, but not to sell,

32 Section 131 amended (Making application)

Section 131(c), after "activities"

insert

or services

33 Section 134 amended (Considering and deciding application)

(1) Section 134(2), note

omit

(2)(d)

insert

(2)(c)

(2) Section 134(2), note

omit

140(1)(e),

insert

136A(1)(b), 140(1)(f)

34 Section 135 amended (Certificate of registration)

- (1) Section 135, after "activities"

insert

or services

- (2) Section 135(a)(ii), after "registration"

insert

or Schedule 4 supplier certificate of registration

35 Section 136A inserted

After section 136

insert

136A Schedule 3 authorisation

- (1) The CHO may issue a Schedule 3 authorisation for a Schedule 3 substance only if satisfied that:
- (a) the applicant, and each person to be authorised under the authority to supply the substance, is competent to:
 - (i) safely handle the substance; and
 - (ii) give instructions for the safe use of the substance when supplying it; and
 - (b) the security arrangements for the place where the substances are to be stored by the applicant are adequate to prevent the unlawful use or removal of the substances from the place.
- (2) In considering the matters referred to in subsection (1)(a), the CHO may have regard to:
- (a) the applicant's proposed policies or guidelines for supplying the substance; and
 - (b) whether the applicant, and each person to be authorised under the authority to supply the substance, have any appropriate training, experience or qualifications for supplying the substance.

36 Section 140 replaced

Section 140

repeal, insert

140 Prohibited substance authorisation

- (1) The CHO may issue a prohibited substance authorisation for a prohibited substance only in the circumstances mentioned in subsection (2) or (3).
- (2) The CHO may issue a prohibited substance authorisation for a prohibited substance if satisfied:
 - (a) the applicant is an authorised health practitioner; and
 - (b) a person is suffering an illness for which there is a therapeutic need for treatment with the substance; and
 - (c) the substance is to be:
 - (i) administered to the person by the applicant or another authorised health practitioner to treat the illness; or
 - (ii) self-administered by the person to treat the illness; and
 - (d) the administration of the substance is justified in the circumstances because the person is suffering from symptoms unresponsive to other available treatment; and
 - (e) if the substance is to be self-administered:
 - (i) it is not reasonably practicable in the circumstances for the substance to be administered by an authorised health practitioner; and
 - (ii) the person is competent to properly self-administer the substance; and
 - (f) security arrangements for the place where the substance is to be stored are adequate to prevent the unlawful use or removal of the substance from the place.
- (3) The CHO may issue a prohibited substance authorisation for a prohibited substance if satisfied:
 - (a) the applicant is a veterinarian or other person prescribed by regulation; and
 - (b) the substance is for use to sedate animals or for another use prescribed by regulation; and

- (c) security arrangements for the place where the substance is to be stored are adequate to prevent the unlawful use or removal of the substance from the place.

37 Section 141 amended (Research authorisation)

Section 141(1)

omit

4

insert

3, 4

38 Section 145A inserted

After section 145

insert

145A Conditions – Schedule 3 authorisation

- (1) A Schedule 3 authorisation is subject to the condition that an authorised person who supplies a Schedule 3 substance to another person under the authority must, at the time of the supply, give the person adequate instructions (written or oral) for the use of the substance.
- (2) The regulations may provide for matters relating to the content of the instructions that are required to be given in accordance with the condition imposed by subsection (1).
- (3) In this section:

authorised person means the holder of the Schedule 3 authorisation and any other person stated in the authority.

39 Section 230 amended (Application of Therapeutic Goods Act as law of Territory)

Section 230

omit

Territory.

insert

Territory, and the Therapeutic Goods Act so applies as if it extended to:

- (a) things done or omitted to be done by persons who are not corporations; and
- (b) things done or omitted to be done in the course of trade and commerce within the limits of the Territory.

40 Section 244 amended (CHO may make code of practice)

- (1) Section 244(4)

omit, insert

- (4) If the CHO makes a code of practice under this section, the CHO must publish on the Agency's website the code of practice and notice of its making.

- (2) Section 244(6)

omit

41 Section 245 amended (Exemption from holding Schedule 8 authorisation)

Section 245(4)(b)

omit

Gazette notice.

insert

notice published on the Agency's website.

42 Section 246 amended (Restricted Schedule 4 and 8 substances)

- (1) Section 246(1)

omit

Gazette notice,

insert

notice published on the Agency's website,

- (2) Section 246(1)(b)
omit
(other than an amphetamine)

- (3) Section 246(1)(b), note
omit

43 Sections 247 to 250 repealed

Sections 247 to 250

repeal

44 Section 251 amended (Emergency authorisation for possessing, supplying and administering Schedule 3, 4 and 8 substances)

Section 251(1)

omit, insert

- (1) The CHO may, by notice published on the Agency's website, authorise a person, or a class of health practitioners, to possess, supply or administer stated Schedule 3, 4 or 8 substances in an emergency relating to public health (an **emergency authorisation**).

45 Section 252 amended (Declared places)

Section 252

omit

Gazette notice,

insert

notice published on the Agency's website,

46 Section 253 amended (Approval for pharmacist to supply Schedule 8 substance or restricted Schedule 4 substances on interstate prescription)

Section 253(1)

omit

Gazette notice,

insert

notice published on the Agency's website,

47 Section 254 replaced

Section 254

repeal, insert

254 Approval of SSTP

- (1) The CHO may approve, in writing, an SSTP if the CHO considers:
 - (a) the SSTP contains adequate information to satisfy the requirements specified in section 70B(2); and
 - (b) having regard to the matters to which the SSTP relates, it is appropriate to do so.
- (2) The approval of an SSTP takes effect:
 - (a) on the date it is approved; or
 - (b) if the CHO specifies a later effective date in the approval of the SSTP – the later date.
- (3) The approval of an SSTP remains in effect until the expiry of the period, not exceeding 2 years, specified by the CHO in the approval, unless it is sooner revoked.
- (4) An SSTP approved under subsection (1) and the CHO's written approval of it must be published on the Agency's website as soon as practicable after the SSTP has been approved.
- (5) The CHO may revoke, in writing, the approval of an SSTP.

48 Chapter 7, Part 7.2, Division 1A repealed (Dealings with COVID-19 vaccine)

Chapter 7, Part 7.2, Division 1A

repeal

49 Section 257 amended (Information relating to supply and use of substances)

Section 257(1)

omit

Gazette notice,

insert

notice published on the Agency's website,

50 Section 266 amended (Duration of appointment)

Section 266

omit

2

insert

3

51 Section 268 amended (Chairperson and deputy chairperson)

Section 268(1)(a)

omit

appointed member

insert

member

52 Section 269 amended (When member ceases to hold office)

Section 269(2)

omit

a member

insert

an appointed member

53 Chapter 9, Part 9.5 inserted

After section 298

insert

Part 9.5 Transitional matters for Medicines, Poisons and Therapeutic Goods Legislation Amendment Act 2022**299 Definitions**

In this Part:

amending Act means the *Medicines, Poisons and Therapeutic Goods Legislation Amendment Act 2022*.

commencement means the commencement of section 3 of the amending Act.

COVID-19 vaccine means a Scheduled substance for vaccination against the Coronavirus disease named "COVID-19" by the World Health Organization.

former CVAP means a COVID-19 vaccine administration protocol that was approved under section 254B(1), as in force immediately before the commencement.

former SSTP means a Scheduled substance treatment protocol that was approved under section 254(1), as in force immediately before the commencement.

300 Scheduled substance treatment protocols approved before commencement

- (1) For sections 301 and 302, a former SSTP continues in force after the commencement until the earlier of the following:
 - (a) the approval of the former SSTP is revoked by the CHO under subsection (2);
 - (b) the day that is 2 years after the commencement.
- (2) The CHO may revoke, in writing, the approval of a former SSTP that continues to remain in force under subsection (1).

301 Transitional authority for health practitioners approved to administer Schedule 4 or 8 substance before commencement

- (1) This section applies to an Aboriginal and Torres Strait Islander health practitioner, a nurse, a midwife or a paramedic who was declared by *Gazette* notice under section 250, as in force immediately before the commencement, to be approved to administer a Schedule 4 or 8 substance stated in the notice in accordance with the former SSTP stated in the notice (an **approved practitioner**).
- (2) Subject to subsection (3), an approved practitioner may, in the course of practising in the approved practitioner's health profession, administer the substance to another person after the commencement if the former SSTP stated in the notice for the approved practitioner continues to remain in force under section 300 at the time of the administration of the substance.
- (3) The approved practitioner must administer the substance in accordance with:
 - (a) the former SSTP; and
 - (b) any conditions or limitations that were specified in the notice for the approved practitioner.
- (4) An approved practitioner who is authorised to administer a Schedule 4 or 8 substance under subsection (2) may, in the course of practising in the approved practitioner's health profession, possess the substance for that purpose after the commencement.

302 Transitional authority for health practitioners approved to supply Schedule 4 or 8 substance before commencement

- (1) This section applies to an Aboriginal and Torres Strait Islander health practitioner, a nurse or a midwife who was declared by *Gazette* notice under section 250, as in force immediately before the commencement, to be approved to supply a Schedule 4 or 8 substance stated in the notice in accordance with the former SSTP stated in the notice (an **approved practitioner**).
- (2) Subject to subsection (3), an approved practitioner may, in the course of practising in the approved practitioner's health profession, supply the substance to another person after the commencement if the former SSTP stated in the notice for the approved practitioner continues to remain in force under section 300 at the time of the supply of the substance.
- (3) The approved practitioner must supply the substance in accordance with:
 - (a) the former SSTP; and

(b) any conditions or limitations that were specified in the notice for the approved practitioner.

(4) An approved practitioner who is authorised to supply a Schedule 4 or 8 substance under subsection (2) may, in the course of practising in the approved practitioner's health profession, possess the substance for that purpose after the commencement.

303 COVID-19 vaccine administration protocols approved before commencement

(1) A former CVAP continues in force after the commencement until the earlier of the following:

(a) the approval of the former CVAP is revoked by the CHO under subsection (2);

(b) the effective period that was specified in the former CVAP expires;

(c) the day that is 2 years after the commencement.

(2) The CHO may revoke, in writing, the approval of a former CVAP that remains in force under subsection (1).

304 Transitional authority for persons authorised to deal with COVID-19 vaccine before commencement

(1) This section applies to a person who was authorised under section 254C(1), as in force immediately before the commencement, to possess, supply or administer a COVID-19 vaccine in accordance with the former CVAP specified in the person's authorisation (an **approved person**).

(2) Subject to subsection (3), an approved person continues to be authorised after the commencement to possess, supply or administer a COVID-19 vaccine in accordance with the former CVAP while it continues to remain in force under section 303.

(3) An approved person who possesses, supplies or administers a COVID-19 vaccine under subsection (2) must comply with the person's authorisation under the former CVAP.

305 Supply of Schedule 3 substances – authorities issued before commencement

A person who is authorised to administer a Schedule 3 substance to another person under a medical kit authorisation or a research authorisation that is in force immediately before the commencement is authorised to supply, but not to sell, the substance under that authority after the commencement.

306 Declared places

A declaration made under section 252 that is in force immediately before the commencement continues in force after the commencement as if it were published on the Agency's website.

307 Offence provisions – before and after commencement

- (1) Sections 37, 38, 100, 112B and 112C, as inserted by the amending Act, apply only in relation to offences committed after the commencement.
- (2) Sections 37, 38 and 100, as in force before the commencement, continue to apply in relation to offences committed before the commencement.
- (3) For this section, if any of the conduct constituting an offence occurred before the commencement, the offence is taken to have been committed before the commencement.

54 Act further amended

The Schedule has effect.

Part 3 Amendment of Medicines, Poisons and Therapeutic Goods Regulations 2014**55 Regulations amended**

This Part amends the *Medicines, Poisons and Therapeutic Goods Regulations 2014*.

56 Regulation 3 amended (Definitions)

Regulation 3

insert

amphetamine, see regulation 3A.

57 Regulation 3A inserted

After regulation 3

insert

3A Meaning of *amphetamine*

- (1) An ***amphetamine*** includes:
 - (a) beta-aminoisopropylbenzene; and

-
- (b) a substance structurally derived from amphetamine or beta-aminoisopropylbenzene by substitution in the side chain or by ring closure (or both).
- (2) Despite subregulation (1), a substance mentioned in subregulation (1)(a) or (b) is not an amphetamine when contained in a Schedule 2, 3 or 4 substance.

58 Part 2, Division 1A inserted

After regulation 17

insert

Division 1A Administering, supplying and possessing Scheduled substances under SSTP**17A Prescribed health practitioners**

For section 70A(1) of the Act, the following types of health practitioner are prescribed:

- (a) Aboriginal and Torres Strait Islander health practitioner;
- (b) dental hygienist;
- (c) dental therapist;
- (d) midwife;
- (e) nurse;
- (f) oral health therapist;
- (g) paramedic;
- (h) pharmacist.

17B Prescribed healthcare workers

- (1) For section 70A(2) of the Act, an orthoptist is a prescribed class of person.
- (2) In this regulation:

orthoptist means a person whose name is recorded in the register of orthoptists kept by the Australian Orthoptists Registration Body Pty Ltd ACN 095 117 678.

17C Content of SSTP

- (1) For section 70B(2)(d) of the Act, the following matters are prescribed:
- (a) the indications for use of the Scheduled substance by a person;
 - (b) any contraindications against use of the Scheduled substance by a person;
 - (c) a description of any persons to whom the Scheduled substance must not be administered or supplied.
- (2) For section 70B(2)(e) of the Act, an SSTP must specify the following matters:
- (a) the form, strength, dose, route and frequency of administration of the Scheduled substance;
 - (b) any monitoring requirements after administration of the Scheduled substance to a person;
 - (c) any procedures or requirements in relation to documenting the administration or supply of the Scheduled substance to a person.

59 Regulation 18 amended (Record of supply or administration of Schedule 8 substance)

Regulation 18

omit

100(1A)(b)

insert

100(2)

60 Regulation 23 amended (Storage of Schedule 3 substance by authority holder)

Regulation 23(1), after "of a"

insert

Schedule 3 authorisation,

61 Regulation 42 amended (Contents of authority)

(1) Regulation 42(d)

omit

(2) Regulation 42(i)

omit

person.

insert

person;

(3) After regulation 42(i)

insert

(j) for a pest management technician licence – the holder's date of birth.

**62 Part 4, Division 1, Subdivision 6 heading amended
(Manufacturer/wholesaler register)**

Part 4, Division 1, Subdivision 6, heading

omit

Manufacturer/wholesaler

insert

Manufacturer/wholesaler/Schedule 4 supplier

63 Regulation 61 replaced

Regulation 61

repeal, insert

61 Period of retention of registers

- (1) A Scheduled substance register, other than a register in relation to Schedule 7 substances, must be kept for at least 2 years after the day on which the last entry is made in the register.
- (2) A register in relation to Schedule 7 substances must be kept for at least 7 years after the day on which the last entry is made in the register.

64 Regulations 87A and 88 repealed

Regulations 87A and 88

repeal

65 Regulation 90 replaced

Regulation 90

repeal, insert

90 Appointed Committee members

For section 265 of the Act, the following are the qualification requirements for appointed members of the Committee:

- (a) 2 members must be doctors with expertise in pain management or rehabilitation;
- (b) 2 members must be doctors with experience in general practice;
- (c) one member must be a doctor who is employed in the Agency and working in the community drugs program managed by the Agency;
- (d) one member must be a person who is employed in the Agency and working in the community drugs program managed by the Agency but who is not a doctor;
- (e) one member must be a pharmacist with experience in the community pharmacy practice area;
- (f) one member must be a pharmacist with experience in the hospital or clinical pharmacy practice area;
- (g) any other appointed member must be:
 - (i) a health practitioner; or
 - (ii) a veterinarian; or
 - (iii) a lawyer; or
 - (iv) a person who is employed in the Agency and working in the community drugs program managed by the Agency but who is not a doctor.

66 Schedule 1 amended

Schedule 1

omit

sections 97(2) and (3), 107(1) and 176(1) and (2) 1

insert

sections 97(2) and (3) and 107(1)	1
sections 112B(1) and 112C(2)	3
section 176(1) and (2)	1

67 Schedule 2 amended

(1) Schedule 2, after item 1(b)

insert

(ba) Schedule 4 supplier certificate of registration of 50 plus 100 for each year the certificate will be in force

(2) Schedule 2, after item 1(c)

insert

(ca) Schedule 3 authorisation of 50 for each year the authorisation will be in force

(3) Schedule 2, after item 2(b)

insert

(ba) Schedule 4 supplier certificate of registration of 100 for each year the certificate will be in force after renewal

Part 4 Repeal of Act

68 Repeal of Act

This Act is repealed on the day after it commences.

Schedule Medicines, Poisons and Therapeutic Goods Act 2012 further amended

section 54

Provision	Amendment	
	<i>omit</i>	<i>insert</i>
section 61, heading	verbal	oral
section 61(1)(a)	verbally	orally
Chapter 2, Part 2.3, Division 1, Subdivision 3, heading	and health-related occupations	
