New South Wales

Medicines, Poisons and Therapeutic Goods Regulation 2026

under the

Medicines, Poisons and Therapeutic Goods Act 2022

Her Excellency the Governor, with the advice of the Executive Council, has made the following regulation under the *Medicines, Poisons and Therapeutic Goods Act 2022*.

RYAN PARK, MP
Minister for Health

Explanatory note

The object of this regulation is to make provision for various matters under the *Medicines, Poisons and Therapeutic Goods Act 2022* (***the Act***), including the following—

(a) licences for wholesale supply and for obtaining wholesale supply of certain scheduled substances and other therapeutic goods,

(b) non-wholesale supply of certain scheduled substances and other therapeutic goods by pharmacists and other persons in certain circumstances,

(c) prescriptions, including the form and content of prescriptions and the verification of prescriptions,

(d) the administration and use of scheduled substances and therapeutic goods,

(e) approvals for supply, prescription and administration of certain therapeutic goods,

(f) Opioid Treatment Program registrations,

(g) the regulation of scheduled substances used for cosmetic purposes,

(h) records of supply and administration of scheduled substances, including drug registers for Schedule 8 substances,

(i) requirements for the storage, preparation, handling, labelling and destruction of scheduled substances,

(j) requirements for the storage, prescription, disposal and delivery of voluntary assisted dying substances, as well as the records required to be kept in relation to voluntary assisted dying substances,

(k) applications and fees for authorisations under the Act,

(l) exemptions of persons by the Health Secretary from a provision of this regulation,

(m) the modification of the Commonwealth therapeutic goods laws relating to advertising,

(n) savings, transitional and other miscellaneous matters.

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under the

Medicines, Poisons and Therapeutic Goods Act 2022

Part 1 Preliminary

1 Name of regulation

This regulation is the *Medicines, Poisons and Therapeutic Goods Regulation 2026*.

2 Commencement

This regulation commences on 5 November 2026.

3 Interpretation

(1) The dictionary in Schedule 4 defines words used in this regulation.

Note— The Act and the *Interpretation Act 1987* contain definitions and other provisions that affect the interpretation and application of this regulation.

(2) On the making of this regulation, no therapeutic goods were prescribed.

4 Schedule 7 substances

For the Act, sections 16 and 26, a Schedule 7 substance specified in the Commonwealth Poisons Standard, Appendix J is a prescribed Schedule 7 substance.

5 Authorised practitioners

(1) For the Act, Schedule 3, definition of ***authorised practitioner***, paragraph (a)(v), the following classes are prescribed—

(a) midwife practitioners,

(b) nurses, midwives, podiatrists and optometrists with an endorsement, to the extent the endorsement qualifies the nurse, midwife, podiatrist or optometrist to carry out the relevant activity.

Note— An endorsement may qualify a health practitioner to administer, obtain, possess, prescribe, sell, supply or use a scheduled substance.

(2) Despite subsection (1), nurses, midwives, podiatrists and optometrists with an endorsement are not prescribed as authorised practitioners for the Act, section 24, definition of ***authorised person***, paragraphs (a)(ii) and (c)(ii).

6 Public health entities

(1) For the Act, Schedule 3, definition of ***public health entity***, paragraph (c), the following statutory health corporations are prescribed—

(a) the Justice Health and Forensic Mental Health Network,

(b) The Sydney Children's Hospitals Network (Randwick and Westmead), incorporating the Royal Alexandra Hospital for Children.

(2) For the Act, Schedule 3, definition of ***public health entity***, paragraph (f), a hospital that is a recognised establishment of an affiliated health organisation under the *Health Services Act 1997* is prescribed.

7 Schedule 4D substances

(1) For the Act, Schedule 3, definition of ***Schedule 4D substance***, the substances specified in Column 1 of the table to this section are prescribed as Schedule 4D substances.

(2) For the *Drug Misuse and Trafficking Act 1985*, section 18C(3), definition of ***prescribed quantity***, the quantity specified in Column 2 for a substance specified in Column 1 is the prescribed quantity for the substance.

(3) The quantity specified in Column 2 is the nominal amount of the substance, not including any other substance with which the substance is prepared or mixed.

(4) Subsection (3) applies for the *Drug Misuse and Trafficking Act 1985*, section 18C only and does not otherwise affect the operation of that Act, section 4.

Column 1	Column 2
Substance	**Prescribed quantity for DMT Act**
Amobarbital that is a Schedule 4 substance	50g
Anabolic steroidal agent and androgenic steroidal agent, except as otherwise referred to in this table	5g
Androisoxazole	5g
AOD-9604 (CAS No. 221231-10-3)	0.1g
Barbiturates that are Schedule 4 substances, except as otherwise referred to in this table	50g
Benzodiazepine derivatives that are Schedule 4 substances, except as otherwise referred to in this table	0.5g
Benzphetamine	5g
Bolandiol	5g
Bolasterone	5g
Boldenone (dehydrotestosterone)	2.5g
Bolmantalate	5g
Bromazepam	5g
Calusterone	30g
Cathine	5g
Chlorandrostenolone	5g
Chlordiazepoxide	5g
Chloroxydienone	5g
CJC-1295 (CAS No. 863288-34-0)	0.5g
Clobazam	2.5g
Clonazepam	0.5g
Clorazepate	3g

Column 1	Column 2
Substance	**Prescribed quantity for DMT Act**
Clostebol (4-chlorotestosterone)	2g
Darbepoetin	0.015g
Dehydrochloromethyltestosterone	5g
Dextropropoxyphene that is a Schedule 4 substance	15g
Diazepam	2.5g
Diethylpropion	5g
Dihydrolone	5g
Dimethandrostanolone	5g
Dimethazine	5g
Doxapram	2g
Drostanolone	2g
Enobosarm	0.3g
Ephedrine	5g
Epoetins	0.01g or 1,000,000 International Units
Erythropoietins, except as otherwise referred to in this table	1,000,000 International Units
Ethchlorvynol	50g
Ethinamate	50g
Ethyldienolone	5g
Ethylestrenol	1g
Fencamfamin	1g
Fenproporex	1g
Fibroblast Growth Factors	0.1g
Fluoxymesterone	2g
Flurazepam	10g
Follistatin	0.1g
Formebolone	1g
Furazabol	0.5g
Glutethimide	50g
Growth Hormone Releasing Hormones (GHRHs), including those that are separately a Schedule 4 substance	0.5g
Growth Hormone Releasing Peptides (GHRPs), including those that are separately a Schedule 4 substance	0.5g
Growth Hormone Releasing Peptide-6 (GHRP-6)	0.5g

Column 1	Column 2
Substance	**Prescribed quantity for DMT Act**
Growth Hormone Secretagogues (GHSs), including those that are separately a Schedule 4 substance	0.5g
Hexarelin	0.5g
Hydroxystenozol	5g
Ibutamoren	0.5g
Insulin-like growth factors	0.005g
Ipamorelin	0.5g
Lorazepam	1g
Mazindol	0.5g
Medazepam	2.5g
Mefenorex	5g
Meprobamate	100g
Mesabolone	5g
Mestanolone (androstalone)	5g
Mesterolone	10g
Metandienone	1g
Methandriol	20g
Methenolone	2g
Methylandrostanolone	5g
Methylclostebol	5g
Methylphenobarbital	50g
Methyltestosterone	20g
Methyltrienolone	5g
Methyprylone	40g
Mibolerone	0.01g
Midazolam	0.5g
Nalbuphine	0.5g
Nandrolone	1g
Nitrazepam	1g
Norandrostenolone	1g
Norbolethone	5g
Norethandrolone	4g
Normethandrone	0.5g
Oxabolone	0.5g
Oxandrolone	1g
Oxazepam	10g

Column 1	Column 2
Substance	**Prescribed quantity for DMT Act**
Oxymesterone	4g
Oxymetholone	40g
Paraldehyde	250mL
Pentobarbital that is a Schedule 4 substance	50g
Perampanel	0.8g
Phenobarbital	50g
Phentermine	10g
Pipradrol	1g
Pralmorelin (Growth Hormone Releasing Peptide-2, GHRP-2)	0.5g
Prasterone (dehydroepiandrosterone, dehydroisoandrosterone (DHEA))	1g
Prazepam	2.5g
Pregabalin	30g
Propylhexedrine	5g
Pseudoephedrine that is a Schedule 4 substance	20g
Pyrovalerone	1g
Quetiapine	40g
Quinbolone	3g
Selective androgen receptor modulators (SARM), including those that are separately a Schedule 4 substance	0.3g
Silandrone	5g
Somatropin (human growth hormone)	0.25g
Stanolone	10g
Stanozolol	2g
Stenabolic (SR9009) and other synthetic REV-ERB agonists	2g
Stenbolone	5g
TB-500	0.3g
Temazepam	5g
Testolactone	100g
Testosterone that is a Schedule 4 substance	20g
Thiomesterone (tiomesterone)	5g
Thymosin Beta 4 (thymosin β4)	0.3g
Tianeptine	3.75g
Tramadol	30g

Column 1	Column 2
Substance	**Prescribed quantity for DMT Act**
Trenbolone (trienbolone, trienolone) that is a Schedule 4 substance	5g
Trestolone	5g
Triazolam	0.05g
Vadadustat	0.081g
Zolazepam	2.5g
Zolpidem	1g
Zopiclone	0.75g

8 Veterinary practitioners and etorphine—the Act, s 6

For this regulation, etorphine is taken to be a Schedule 8 substance, and not a Schedule 9 substance, when obtained or supplied by a veterinary practitioner in accordance with an authority for etorphine granted by the Health Secretary under section 25 or 43.

9 References to publications in force from time to time

In this regulation, a reference to a standard, rule, code or other publication is taken to be a reference to the standard, rule, code or publication as in force from time to time, unless otherwise indicated.

Part 2 Wholesale supply—the Act, ss 10 and 12 and Part 2.2

Division 1 Wholesale supply by pharmacists

10 Wholesale supply by pharmacy businesses

(1) For the Act, section 14(a), wholesale supply of a Schedule 2, 3, 4 or 8 substance by a pharmacy business (the ***supplying pharmacy business***) to another pharmacy business (the ***receiving pharmacy business***) is authorised if the supply occurs because the receiving pharmacy business becomes the owner of the supplying pharmacy business and takes control of the substance.

(2) For the Act, section 14(a), wholesale supply of a Schedule 2, 3, 4 or 8 substance by the following persons to a pharmacist in a pharmacy is authorised if the supply is in connection with the bankruptcy, liquidation or external administration of a pharmacy business—

(a) another pharmacist in a pharmacy,

(b) another approved person.

(3) For the Act, section 14(a), wholesale supply of a Schedule 2, 3 or 4 substance, other than a Schedule 4D substance, by a pharmacy business to another pharmacy business is authorised if—

(a) both pharmacy businesses are entirely owned or controlled by the same individual, or

(b) the substance will expire within 6 months and the pharmacy business supplying the substance is not reasonably likely to supply or administer the substance to a person before the substance expires.

(4) A pharmacy business who supplies or receives a substance under this section must record the following—

(a) the date on which the substance was supplied,

(b) the name, strength and quantity of the substance supplied,

(c) the batch number and expiry date of the substance supplied,

(d) the name of the pharmacy business that supplied the substance,

(e) the name of the pharmacy business that received the substance.

Maximum penalty—Tier 5 penalty.

(5) In this section—

pharmacy business has the same meaning as in the *Health Practitioner Regulation National Law (NSW)*, Schedule 5F.

11 Wholesale supply between pharmacists

(1) For the Act, section 14(a), wholesale supply of a Schedule 2, 3, 4 or 8 substance by a pharmacist in a pharmacy, public health entity or private health facility (the ***supplying pharmacist***) to another pharmacist in a pharmacy, public health entity or private health facility (the ***receiving pharmacist***) is authorised if—

(a) the supplying pharmacist receives a written request from the receiving pharmacist in the following circumstances—

(i) the receiving pharmacist is making the request for the purposes of the treatment of a single patient at a public health entity or private health facility or a single customer at a pharmacy,

(ii) the supplying pharmacist, as far as reasonably practicable, supplies the receiving pharmacist with only the minimum amount of the substance necessary for the treatment of the patient or customer, or

(b) the supplying pharmacist is returning an equivalent amount of the substance to the receiving pharmacist, who had previously supplied the same substance in accordance with paragraph (a)(ii).

(2) The supplying pharmacist must not wholesale supply a Schedule 2, 3, 4 or 8 substance under subsection (1) if the written request referred to in subsection (1)(a) is not signed by the receiving pharmacist.

Maximum penalty—Tier 5 penalty.

(3) The supplying pharmacist and receiving pharmacist must keep a record of a scheduled substance wholesale supplied under this section.

Maximum penalty—Tier 5 penalty.

12 Wholesale supply by pharmacists for urgent use in residential care facilities

(1) For the Act, section 14(a), wholesale supply of a Schedule 2, 3, 4 or 8 substance by a pharmacist in a pharmacy to the authorised person for a residential care facility is authorised if the supply is for urgent use at the residential care facility.

(2) The pharmacist must not wholesale supply a Schedule 2, 3, 4 or 8 substance under subsection (1) unless—

(a) the supply is in accordance with a written order signed by the authorised person, and

(b) the substance is in the manufacturer's original pack, and

(c) the supply has been approved by—

(i) the residential care facility's medicines governance committee, however described, or

(ii) the Health Secretary.

Maximum penalty—Tier 5 penalty.

(3) A pharmacist who supplies a substance under this section must keep a record of the following—

(a) the date on which the substance was supplied,

(b) the name, strength and quantity of the substance supplied,

(c) the batch number and expiry date of the substance supplied,

(d) the name of the pharmacist who supplied the substance,

(e) the name of the authorised person.

Maximum penalty—Tier 5 penalty.

13 Wholesale supply by pharmacists for urgent use by authorised practitioners

(1) For the Act, section 14(a), wholesale supply of a Schedule 4 or 8 substance by a pharmacist in a pharmacy to an authorised practitioner for urgent use is authorised if the supply is in accordance with a written request signed by the authorised practitioner and—

(a) the substance is—

(i) in the form of a registered good, or

(ii) a good approved for supply under the Commonwealth Therapeutic Goods Act, section 19A, or

(b) if the wholesale supply is to a veterinary practitioner—

(i) the substance is in the form of a veterinary chemical product, registered under the Commonwealth Agvet Codes, or

(ii) the pharmacist holds a permit under the *Agricultural and Veterinary Chemicals Code Act 1994* of the Commonwealth, Schedule, Part 7 in relation to the substance.

(2) A pharmacist who supplies a substance under this section must keep a record of the following—

(a) the date on which the substance was supplied,

(b) the name, strength and quantity of the substance supplied,

(c) the batch number and expiry date of the substance supplied,

(d) the name of the pharmacist who supplied the substance,

(e) the name of the authorised practitioner.

Maximum penalty—Tier 5 penalty.

(3) In this section—

registered good has the same meaning as in the Commonwealth Therapeutic Goods Act.

14 Wholesale supply by pharmacists for urgent use by registered health practitioners

(1) For the Act, section 14(a), wholesale supply of an approved Schedule 2, 3, 4 or 8 substance by a pharmacist in a pharmacy to a registered health practitioner of an approved class is authorised if the supply is for urgent use.

(2) A pharmacist who supplies a scheduled substance under this section must keep a record of the following—

(a) the date on which the substance was supplied,

(b) the name, strength and quantity of the substance supplied,

(c) the batch number and expiry date of the substance supplied,

(d) the name of the pharmacist who supplied the substance,

(e) the name of the registered health practitioner.

Maximum penalty—Tier 5 penalty.

15 Wholesale supply by pharmacists to first aiders

For the Act, section 14(a), wholesale supply of a scheduled substance specified in Column 1 of the table to this section by a pharmacist in a pharmacy to a person specified opposite in Column 2 is authorised.

Column 1	Column 2
Scheduled substance	**Person**
Adrenaline, glucagon, glyceryl trinitrate, naloxone, salbutamol or terbutaline	First aider with a current statement of attainment, issued by a registered training organisation, demonstrating competency in the use and administration, including access and preparation, of the substance for first aid
Adrenaline	Person with a current certificate, issued by an approved person, in the use and administration of adrenaline in first aid

Column 1	Column 2
Scheduled substance	**Person**
Naloxone	Person with a current certificate, issued by an approved person, in the use and administration of naloxone in first aid
Salbutamol	Person with a current certificate, issued by an approved person, in the use and administration of salbutamol in emergency asthma management
Terbutaline	Person with a current certificate, issued by an approved person, in the use and administration of terbutaline in emergency asthma management

16 Wholesale supply by pharmacists to masters of vessels

(1) For the Act, section 14(a), wholesale supply of a Schedule 2, 3, 4 or 8 substance by a pharmacist in a pharmacy to the master of a vessel, other than a racing yacht, is authorised if the substance is—

(a) required to be carried on the vessel under—

(i) for a domestic commercial vessel—the *National Standard for Commercial Vessels*, Part C published by the Australian Maritime Safety Authority, or

(ii) for a foreign vessel or regulated Australian vessel—the *Marine Order 11 (Living and working conditions on vessels) 2024* made under the *Navigation Act 2012* of the Commonwealth, or an order that replaces that order, and

(b) supplied in the quantity required to be carried on the vessel by the standard or order referred to in paragraph (a) as the case requires.

(2) For the Act, section 14(a), wholesale supply of a Schedule 2, 3, 4 or 8 substance by a pharmacist to the master of a racing yacht is authorised if the substance is—

(a) required to be carried on the racing yacht under—

(i) the *Special Regulations*, Part 1 published by Australian Sailing Limited, or

(ii) an order of the Health Secretary, and

(b) supplied in the quantity required to be carried on the racing yacht under the following as the case requires—

(i) the regulations,

(ii) the order referred to in paragraph (a)(ii).

(3) An order of the Health Secretary under subsection (2)(a)(ii) prevails to the extent of an inconsistency with the regulations referred to in subsection (2)(a)(i).

(4) A pharmacist must not wholesale supply a substance under subsection (1) unless the pharmacist has a copy of—

(a) an order for the substance signed by the master of the vessel, confirming the substance must be carried on the vessel by the standard or order referred to in subsection (1)(a)(i) or (ii), and

(b) a certificate issued by the vessel's agent in New South Wales confirming the signature on the order is the signature of the master of the vessel.

Maximum penalty—Tier 5 penalty.

(5) A pharmacist must not wholesale supply a substance under subsection (2) unless the pharmacist has a copy of—

(a) proof the racing yacht is entered in a race, and

(b) an order for the substance signed by the master of the racing yacht, confirming the substance must be carried on the racing yacht by the regulations or the order referred to in subsection (2)(a)(i) or (ii), and

(c) a certificate issued by the secretary of the club at which the racing yacht is registered for the race confirming the signature on the order is the signature of the master of the racing yacht.

Maximum penalty—Tier 5 penalty.

(6) A pharmacist must keep a copy of the documents referred to in subsection (4) or (5).

Maximum penalty— Tier 5 penalty.

(7) In this section—

domestic commercial vessel means a commercial vessel within the meaning of the *Marine Safety Act 1998*.

foreign vessel has the same meaning as in the *Navigation Act 2012* of the Commonwealth.

racing yacht means a vessel that is—

(a) owned or crewed by a member of Australian Sailing Limited, and

(b) entered in a race conducted in accordance with the rules of Australian Sailing Limited.

regulated Australian vessel has the same meaning as in the *Navigation Act 2012* of the Commonwealth.

vessel means the following—

(a) a domestic commercial vessel,

(b) a foreign vessel,

(c) a regulated Australian vessel.

Division 2 Other wholesale supply

17 Wholesale supply by National Medical Stockpile

For the Act, section 14(a), wholesale supply of a Schedule 2, 3, 4 or 8 substance by the operator of the National Medical Stockpile is authorised.

18 Unauthorised wholesale supply of samples

A person must not wholesale supply—

(a) a Schedule 4D, 7 or 8 substance as a sample, or

(b) a Schedule 2 or 3 substance or another Schedule 4 substance as a sample to a health practitioner or veterinary practitioner other than in accordance with a written order signed by the health practitioner or veterinary practitioner.

Maximum penalty—Tier 5 penalty.

19 Wholesale supply between veterinary hospital superintendents

(1) For the Act, section 14(a), wholesale supply of a Schedule 2, 3, 4 or 8 substance by a superintendent (the ***supplying superintendent***) to another superintendent (the ***receiving superintendent***) is authorised if—

(a) the supplying superintendent receives a written request from the receiving superintendent in the following circumstances—

(i) the receiving superintendent is making the request for the purposes of the treatment of a single animal at a veterinary hospital,

(ii) the supplying superintendent, as far as reasonably practicable, supplies the receiving superintendent with only the minimum amount of the substance necessary for the treatment of the animal, or

(b) the supplying superintendent is returning an equivalent amount of the substance to the receiving superintendent, who had previously supplied the same substance in accordance with paragraph (a)(ii).

(2) The supplying superintendent must not wholesale supply a Schedule 2, 3, 4 or 8 substance under subsection (1) if the written request referred to in subsection (1)(a) is not signed by the receiving superintendent.

Maximum penalty—Tier 5 penalty.

(3) The supplying superintendent and receiving superintendent must keep a record of a scheduled substance wholesale supplied under this section.

Maximum penalty—Tier 5 penalty.

(4) In this section—

superintendent means superintendent managing a veterinary hospital under the *Veterinary Practice Act 2003*, section 67(a).

Part 3 Obtaining wholesale supply—the Act, ss 10 and 12 and Part 2.3

Division 1 Obtaining wholesale supply generally

20 Obtaining wholesale supply

(1) For the Act, section 21(1)(g), the following health practitioners are prescribed—

(a) a health practitioner for adrenaline for treatment of anaphylaxis,

(b) a midwife practitioner for a Schedule 2, 3, 4 or 8 substance,

(c) a dental therapist or oral health therapist for the following—

(i) a Schedule 2, 3 or 4 substance that is a synthetic local anaesthetic,

(ii) tetracycline and triamcinolone for use in preparation for the treatment of dental pulp,

(d) a dental hygienist for a Schedule 2, 3 or 4 substance that is a synthetic local anaesthetic,

(e) a podiatrist for a Schedule 2 or 3 substance or a Schedule 4 substance that is a synthetic local anaesthetic,

(f) an optometrist for a Schedule 2, 3 or 4 substance for use in ophthalmic preparations for diagnostic purposes.

(2) For the Act, section 22(g), the following entities are prescribed—

(a) the Justice Health and Forensic Mental Health Network,

(b) The Sydney Children's Hospitals Network (Randwick and Westmead), incorporating the Royal Alexandra Hospital for Children.

21 Obtaining wholesale supply by various persons and bodies

For the Act, Part 2.3, obtaining wholesale supply of a scheduled substance specified in Column 1 of the table to this section by a person specified opposite in Column 2 is authorised if the person—

(a) obtains the substance for the purpose specified in Column 3, if any, and

(b) the person complies with conditions imposed on the person, or the class of persons, by the Health Secretary.

Column 1	Column 2	Column 3
Scheduled substance	**Person**	**Purpose**
Schedule 2, 3 or 4 substance	Commissioner of Police	Emergency medical treatment of divers employed or engaged by the NSW Police Force
Schedule 2 or 3 substance, methoxyflurane, nitrous oxide	Member of Mines Rescue Brigade or mines rescue company under the *Coal Industry Act 2001*	First aid
Schedule 2, 3, 4 or 8 substance	Superintendent managing a veterinary hospital under the *Veterinary Practice Act 2003*, section 67(a)	The treatment of animals
Schedule 2, 3, 4 or 8 substance	Operator of National Medical Stockpile	—

Column 1	Column 2	Column 3
Scheduled substance	**Person**	**Purpose**
Schedule 2 or 7J substance	Holder of a retail licence for the Schedule 2 or 7J substance	Retail supply
Adrenaline, glucagon, glyceryl trinitrate, methoxyflurane, naloxone, nitrous oxide, salbutamol, terbutaline	Principal of a government or non-government school under the *Education Act 1990*	First aid
Prohibited scheduled substance, prohibited drug or prohibited plant	Holder of a DMT authority for the prohibited scheduled substance, prohibited drug or prohibited plant	A relevant purpose
Pentobarbital	A local council An animal welfare organisation	Destruction of an animal
Prohibited scheduled substance, prohibited drug or prohibited plant	NSW Health Pathology	A relevant purpose
Methoxyflurane and nitrous oxide	Surf Life Saving NSW	First aid

22 Obtaining wholesale supply by first aiders

For the Act, Part 2.3, obtaining wholesale supply of a scheduled substance specified in the table to this section by a person specified opposite is authorised if the person is authorised to administer the scheduled substance under section 66.

Scheduled substance	Person
Adrenaline, glucagon, glyceryl trinitrate, naloxone, salbutamol, methoxyflurane, nitrous oxide or terbutaline	First aider with a current statement of attainment, issued by a registered training organisation, demonstrating competency in the use and administration, including access and preparation, of the substance for first aid
Adrenaline	Person with a current certificate, issued by an approved person, in the use and administration of adrenaline in first aid
Naloxone	Person with a current certificate, issued by an approved person, in the use and administration of naloxone in first aid
Salbutamol	Person with a current certificate, issued by an approved person, in the use and administration of salbutamol in emergency asthma management
Terbutaline	Person with a current certificate, issued by an approved person, in the use and administration of terbutaline in emergency asthma management

Division 2 Obtaining wholesale supply by research institutions, universities and laboratories

23 Prescribed research institutes

For the Act, section 57(2)(a)(vi), a member of the Association of Australian Medical Research Institutes is prescribed for Schedule 4D, 8 and 9 substances.

Note— The research institutions are authorised to obtain prohibited scheduled substances and prohibited drugs without an obtain licence in certain circumstances. See section 24.

24 Obtaining wholesale supply by research institutions, universities and laboratories

(1) This section applies to the following—

(a) a Schedule 2, 3, 4 or 7J"a" substance, other than a Schedule 4D substance,

(b) a prohibited scheduled substance or prohibited drug, if the substance or drug is an in-vitro diagnostic and analytical preparation containing less than 0.001% of the substance or drug.

(2) For the Act, Part 2.3, obtaining wholesale supply of a substance or drug to which this section applies by the following is authorised, but only if wholesale supply is for a relevant purpose—

(a) a person in charge of a laboratory of a university,

(b) a person in charge of a laboratory or department at a research institution that is a member of the Association of Australian Medical Research Institutes,

(c) a person in charge of a laboratory or department of NSW Health Pathology,

(d) a person in charge of an analytical laboratory accredited by the National Association of Testing Authorities,

(e) a person acting under the direction of a person specified in paragraph (a)–(d).

Division 3 Other

25 Health Secretary may authorise obtaining wholesale supply—the Act, s 10(2)

(1) The Health Secretary may grant an authority that authorises obtaining wholesale supply of a scheduled substance.

(2) An authority may be granted on application or the Health Secretary's own initiative.

(3) An authority may be granted to a particular person or class of persons.

(4) An authority is granted to a class of persons by written notice published on the Ministry of Health's website.

(5) The Health Secretary may, by written notice, require a person applying for an authority to give information that the Health Secretary considers necessary to determine the application.

(6) Without limitation, the Health Secretary may refuse to grant an authority to a person if, in the Health Secretary's opinion, the person is not a fit and proper person to hold the authority.

(7) An authority may be granted subject to conditions.

(8) An authority is not transferable.

(9) The Health Secretary may revoke an authority granted to a class of persons by revoking the authority for—

(a) all the persons of the class, or

(b) specified persons of the class.

(10) An authority remains in force until the authority—

(a) expires, or

(b) is sooner surrendered by the holder or revoked by the Health Secretary.

Part 4 Non-wholesale supply—the Act, ss 10 and 12 and Part 2.4

Division 1 Non-wholesale supply generally

26 Non-wholesale supply under direction

(1) For the Act, section 28(1), supply of a Schedule 2, 3, 4 or 8 substance is authorised if the person supplying is acting under the direction of one of the following—

(a) a medical practitioner acting in the course of practice,

(b) a nurse practitioner acting in the course of practice,

(c) a registered nurse with an endorsement that qualifies the registered nurse to supply the scheduled substance, acting in the course of practice,

(d) a midwife practitioner acting in the course of practice,

(e) a midwife with an endorsement that qualifies the midwife to supply the scheduled substance, acting in the course of practice,

(f) a veterinary practitioner acting in the course of practice,

(g) a dentist acting in the course of practice.

(2) If the supply under subsection (1) is to a patient at a public health entity, private health facility, residential care facility, correctional centre or OTP clinic the direction must be—

(a) written, or

(b) given in an approved way.

(3) Despite subsection (2), the direction may, in an emergency or other urgent circumstances, be given orally in person or by telephone (an ***emergency oral direction***).

(4) As soon as practicable and no later than 24 hours after giving an emergency oral direction, the person must confirm the direction by—

(a) making an entry in the patient's medical record, or

(b) sending an email or facsimile to the person who supplied the substance.

Maximum penalty—Tier 5 penalty.

27 Non-wholesale supply of Schedule 7 substances

(1) For the Act, section 28(1), supply of a Schedule 7 substance, other than a Schedule 7J substance, is authorised if the supply is for non-domestic use.

(2) A person must not supply a Schedule 7 substance as a sample by retail.

Maximum penalty—Tier 5 penalty.

28 Non-wholesale supply of Schedule 7 and Schedule 7J substances

For the Act, section 28(1), supply of a Schedule 7 substance, including a Schedule 7J substance, is authorised if the supply is to a person who is authorised to possess or use the substance under the *Stock Medicines Act 1989*.

29 Non-wholesale supply to NSW Health Pathology or another laboratory

For the Act, section 28(1), supply of a prohibited scheduled substance, prohibited drug or prohibited plant by a person employed or engaged by a public health entity or private health facility is authorised if the supply is—

(a) to NSW Health Pathology or an analytical laboratory accredited by the National Association of Testing Authorities, and

(b) for a relevant purpose.

30 Non-wholesale supply by Ambulance Service of NSW

For the Act, section 28(1), supply of a Schedule 2, 3, 4 or 8 substance by a staff member of the Ambulance Service of NSW is authorised if the supply complies with the approved ambulance protocol.

31 Non-wholesale supply by midwife practitioners

For the Act, section 29(f), a midwife practitioner is prescribed.

32 Limits on non-wholesale supply by dentists

(1) A dentist must not supply a Schedule 8 substance unless the substance is listed in the Dental Schedule of Pharmaceutical Benefits.

Maximum penalty—Tier 5 penalty.

(2) Subsection (1) does not apply to supply by a dentist to a patient of a public health entity or private health facility.

(3) A dentist must not supply a scheduled substance to a patient for a period that, together with all other periods for which a scheduled substance has been supplied by the dentist, would result in one or more scheduled substances being supplied for continuous therapeutic use by the patient for more than one month.

Maximum penalty—Tier 5 penalty.

Division 2 Non-wholesale supply by pharmacists

33 Non-wholesale supply by pharmacists without prescription

(1) For the Act, section 28(1), supply of a Schedule 4 substance, other than a Schedule 4D substance, by a pharmacist in a pharmacy to a person without a prescription is authorised if the pharmacist is satisfied that—

(a) the person is undergoing treatment essential to the person's wellbeing, and

(b) the person has previously been prescribed the substance for the person's treatment, and

(c) the person is in immediate need of the substance for continuation of the treatment, and

(d) it is not reasonably practicable for the person to obtain a prescription for the substance from an authorised practitioner, and

(e) the person has not been supplied the substance under this section within the last 30 days.

(2) The supply must be—

(a) no more than the amount required for 7 days treatment, or

(b) for the supply of an aerosol, anovulant tablet, cream, liquid or ointment—in the smallest standard pack in which the substance is generally available.

Maximum penalty—Tier 5 penalty.

34 Non-wholesale supply by pharmacists in emergencies and urgent circumstances

(1) For the Act, section 28(1), supply of a Schedule 4 or 8 substance by a pharmacist in a pharmacy to a person without a prescription is authorised if—

(a) the supply is in accordance with a direction given by an authorised practitioner in an emergency or other urgent circumstances, and

(b) the direction is given—

(i) by email or facsimile, or

(ii) orally in person or by telephone, or

(iii) in another approved way.

(2) An authorised practitioner who gives a direction must—

(a) as soon as reasonably practicable, complete a prescription that specifies that the prescription has been issued in confirmation of a direction given under this section, and

(b) as soon as practicable and no later than 24 hours after giving the direction—give the prescription to the pharmacist.

Maximum penalty—Tier 5 penalty.

(3) If the pharmacist does not receive the prescription within 14 days after supplying the substance, the pharmacist must notify the Health Secretary.

Maximum penalty—Tier 5 penalty.

35 Non-wholesale supply by pharmacists approved under Commonwealth National Health Act 1953 without prescription

(1) For the Act, section 28(1), supply of a scheduled substance to which the Commonwealth determination applies by an approved pharmacist to a person without a prescription is authorised if the pharmacist is satisfied the person is in immediate need of the substance for continuation of the person's treatment.

(2) The supply must be in accordance with—

(a) the conditions specified in the Commonwealth determination, and

(b) the *Guidelines for the continued dispensing of eligible prescribed medicines by pharmacists* published by the Pharmaceutical Society of Australia.

Maximum penalty—Tier 5 penalty.

(3) In this section—

approved pharmacist has the same meaning as in the *National Health Act 1953* of the Commonwealth.

Commonwealth determination means the *National Health (Continued Dispensing) Determination 2022* of the Commonwealth or a determination that replaces that determination.

36 Non-wholesale supply by pharmacists to registered nurses, midwives and paramedics for administration in pharmacies

For the Act, section 28(1), supply of a Schedule 2, 3 or 4 substance by a pharmacist to a registered nurse, midwife or paramedic is authorised if the registered nurse, midwife or paramedic has an authority to administer the substance in a pharmacy granted by the Health Secretary under section 74.

37 Non-wholesale supply by pharmacists of Schedule 3 substances

For the Act, section 28(1), supply of a Schedule 3 substance by a pharmacist to a person is authorised if the pharmacist gives adequate verbal or written instructions for the use of the substance at the time of the supply.

Division 3 Licences for non-wholesale supply by retail sale—the Act, s 10(3)

38 Non-wholesale supply of Schedule 2 and 7J substances by retail sale

For the Act, section 28(1), supply of a Schedule 2 or 7J substance by a person by retail sale is authorised if the retail sale is authorised under a retail licence granted to the person.

39 Retail licences for Schedule 2 and 7J substances

(1) The Health Secretary may, on application, grant a licence that authorises a person to supply a Schedule 2 or 7J substance by retail sale (a ***retail licence***).

(2) An application for a retail licence must be—

(a) in the approved form, and

(b) accompanied by the application fee specified in Schedule 1.

(3) The Health Secretary may, by written notice, require an applicant to give additional information to the Health Secretary that the Health Secretary considers necessary to determine the application.

(4) Without limitation, the Health Secretary may refuse to grant a retail licence to a person if, in the Health Secretary's opinion, the person is not a fit and proper person to hold the licence.

(5) A retail licence may be granted subject to conditions.

(6) A retail licence is not transferable.

(7) A retail licence remains in force until the licence—

(a) expires, or

(b) is sooner surrendered by the holder or revoked by the Health Secretary.

(8) The holder of a retail licence must not contravene a condition of the retail licence.

Maximum penalty—Tier 5 penalty.

(9) The holder of a retail licence must, on or before 31 March in each year following the year in which the licence was granted, pay to the Health Secretary the annual fee specified in Schedule 1.

(10) The Health Secretary may accept payment of an annual fee up to 3 months after the date required under subsection (9), if an additional late fee of 50% of the annual fee is paid at the same time as the annual fee.

(11) The fees for the following are specified in Schedule 1—

(a) an amendment of an application for a retail licence,

(b) a variation of a retail licence.

40 Restriction on retail licences for Schedule 2 substances

(1) The Health Secretary must not grant or renew a retail licence for a Schedule 2 substance unless the Health Secretary is satisfied that the premises to which the proposed retail licence relates are at least 20km from the nearest pharmacy, measured along the shortest practicable route.

(2) The reference to 20km in subsection (1) must be read as a reference to 6.5km for the renewal of a retail licence that was—

(a) in force under the *Poisons and Therapeutic Goods Regulation 2008*, Part 8, Division 1 immediately before the commencement of this section, and

(b) originally granted before 7 April 1989.

Division 4 Other

41 Restriction on non-wholesale supply of paraquat

A person must not supply a Schedule 7 substance that is a liquid preparation containing paraquat unless the preparation—

(a) is coloured blue or green, and

(b) contains sufficient stenching agent to produce an offensive smell.

Maximum penalty—Tier 5 penalty.

42 Restriction on non-wholesale supply of certain Schedule 4 and 8 substances

(1) An authorised practitioner, other than a veterinary practitioner, must not supply the following—

(a) a nominated Schedule 4 substance,

(b) a Schedule 8 substance to a person with a substance dependence on a prohibited scheduled substance or prohibited drug,

(c) dexamfetamine, lisdexamfetamine or methylphenidate,

(d) N,α-dimethyl-3,4-(methylenedioxy)phenylethylamine (MDMA) or psilocybine,

(e) morphine, oxycodone, fentanyl or hydromorphone in an amount that exceeds the morphine equivalent maximum dose,

(f) a substance (a ***relevant substance***) that is alprazolam, flunitrazepam, methadone or a Schedule 8 substance in an injectable or intranasal preparation, if the administration is for a period that, together with all other periods for which a relevant substance has been administered by the person or has, to the person's knowledge, been administered by another person, would result in one or more relevant substances being administered for continuous therapeutic use by the patient for more than 3 months.

Maximum penalty—Tier 5 penalty.

Note— A health practitioner may be subject to other restrictions on the non-wholesale supply of scheduled substances under the Health Practitioner Regulation National Law in relation to appropriate professional conduct and practice.

(2) A veterinary practitioner must not supply the following—

(a) dexamfetamine or lisdexamfetamine,

(b) N,α-dimethyl-3,4-(methylenedioxy)phenylethylamine (MDMA) or psilocybine.

Maximum penalty—Tier 5 penalty.

(3) Subsection (1) does not apply to a person who supplies the substance in accordance with—

(a) an approval or approval exemption, or

(b) an OTP registration.

(4) Subsection (1)(b) does not apply to a dentist.

43 Health Secretary may authorise non-wholesale supply—the Act, s 10(2)

(1) The Health Secretary may grant an authority that authorises the supply of a scheduled substance.

(2) An authority may be granted on application or the Health Secretary's own initiative.

(3) An authority may be granted to—

(a) a particular person, or

(b) a class of persons by written notice published on the Ministry of Health's website.

(4) The Health Secretary may, by written notice, require a person applying for an authority to give information to the Health Secretary that the Health Secretary considers necessary to determine the application.

(5) Without limitation, the Health Secretary may refuse to grant an authority to a person if, in the Health Secretary's opinion, the person is not a fit and proper person to hold the authority.

(6) An authority may be granted subject to conditions.

(7) An authority is not transferable.

(8) The Health Secretary may revoke an authority granted to a class of persons by revoking the authority for—

(a) all the persons of the class, or

(b) specified persons of the class.

(9) An authority remains in force until the authority—

(a) expires, or

(b) is sooner surrendered by the holder or revoked by the Health Secretary.

Part 5 Prescriptions—the Act, ss 10 and 12 and Part 2.5

Division 1 General

44 Midwife practitioners may issue prescriptions

For the Act, section 37(2)(f), a midwife practitioner is prescribed.

45 Restriction on issue of prescriptions for certain Schedule 4 and 8 substances

(1) An authorised practitioner, other than a veterinary practitioner, must not issue a prescription for the following—

(a) a nominated Schedule 4 substance,

(b) a Schedule 8 substance if the person to whom the prescription is issued has a substance dependence on a prohibited scheduled substance or prohibited drug,

(c) dexamfetamine, lisdexamfetamine or methylphenidate,

(d) N,α-dimethyl-3,4-(methylenedioxy)phenylethylamine (MDMA) or psilocybine,

(e) morphine, oxycodone, fentanyl or hydromorphone if the prescription is for an amount that exceeds the morphine equivalent maximum dose,

(f) a substance (a ***relevant substance***) that is alprazolam, flunitrazepam, methadone or a Schedule 8 substance in an injectable or intranasal preparation, if the administration is for a period that, together with all other periods for which a relevant substance has been administered by the person or has, to the person's knowledge, been administered by another person, would result in one or more relevant substances being administered for continuous therapeutic use by the patient for more than 3 months.

Maximum penalty—Tier 5 penalty.

Note— A health practitioner may be subject to other restrictions on the issue of prescriptions for scheduled substances under the Health Practitioner Regulation National Law in relation to appropriate professional conduct and practice.

(2) A veterinary practitioner must not issue a prescription for the following—

(a) dexamfetamine, lisdexamfetamine or methylphenidate,

(b) N,α-dimethyl-3,4-(methylenedioxy)phenylethylamine (MDMA) or psilocybine.

Maximum penalty—Tier 5 penalty.

(3) Subsection (1) does not apply to a person who prescribes the substance in accordance with—

(a) an approval or approval exemption, or

(b) an OTP registration.

(4) Subsection (1)(b) does not apply to a dentist.

46 Issue of prescriptions by dentists

(1) A dentist must not issue a prescription for a Schedule 8 substance unless the substance is listed in the Dental Schedule of Pharmaceutical Benefits.

Maximum penalty—Tier 5 penalty.

(2) Subsection (1) does not apply to a prescription issued by a dentist to a patient in a public health entity or private health facility.

(3) A dentist must not issue a prescription authorising the supply of a scheduled substance if the prescription authorises supply for a period that, together with another

period for which a scheduled substance has been prescribed by the dentist, would result in one or more scheduled substances being supplied for continuous therapeutic use by the patient for more than one month.

Maximum penalty—Tier 5 penalty.

Division 2 General requirements for prescriptions

47 Types of prescriptions

An authorised practitioner must issue a prescription for a Schedule 4 or 8 substance in one of the following types—

(a) a paper prescription that is not electronically generated,

(b) a paper prescription that is electronically generated and has a handwritten signature,

(c) a conformant electronic prescription,

(d) an approved prescription.

Maximum penalty—Tier 5 penalty.

48 Schedule 4 and 8 substances must be supplied on proper prescription

(1) A pharmacist must not supply a Schedule 4 or 8 substance on prescription unless the prescription complies with the requirements of this part.

Maximum penalty—Tier 5 penalty.

(2) It is not an offence under subsection (1) to supply a Schedule 4 or 8 substance on prescription if the prescription does not specify—

(a) the number of times that an amount of the substance may be supplied, or

(b) for a Schedule 4D substance that is an anabolic-androgenic steroidal substance or a Schedule 8 substance—the intervals at which an amount of the substance may be supplied, or

(c) the following information—

(i) the patient's date of birth, but only if—

(A) the pharmacist confirms the date with the prescriber and records the information, or

(B) the pharmacist has confirmed the date with the patient or the agent or carer of the patient,

(ii) the directions for use of the substance, but only if the pharmacist confirms the directions with the prescriber and records the information.

(3) Subsection (2)(a) and (b) do not apply if it appears to the pharmacist that the substance has previously been supplied on the prescription, regardless of how many times the prescription purports to authorise the supply of the substance.

49 Expiry of prescriptions

(1) A pharmacist must not supply a Schedule 4 substance on prescription if the prescription was issued more than 12 months before the date on which the supply is requested.

Maximum penalty—Tier 5 penalty.

(2) A pharmacist must not supply a Schedule 8 substance on prescription if the prescription was issued more than 6 months before the date on which the supply is requested.

Maximum penalty—Tier 5 penalty.

Division 3 Form and content of prescriptions

50 Information requirements for prescriptions

(1) A prescription for a Schedule 4 or 8 substance must specify the following—

(a) the date on which the prescription is issued,

(b) the patient's name, date of birth and street address,

(c) the name of the substance,

(d) the strength and dosage form of the substance,

(e) adequate directions for the administration of the substance, including, if not readily apparent, the route for administration,

(f) the quantity of the substance to be supplied,

(g) the number of times an amount of the substance may be supplied on the prescription, if applicable,

(h) the name and designation of the person who issued the prescription, and

(i) the name, street address and telephone number of—

(i) if the prescription is issued at a public health entity or private health facility—the public health entity or private health facility, or

(ii) otherwise—the person's principal place of practice.

(2) A prescription for a Schedule 4D substance that is an anabolic-androgenic steroidal substance or a Schedule 8 substance must also specify the intervals at which an amount of the substance may be supplied on the prescription.

(3) The quantity in subsection (1)(f) must be expressed in words and numbers if the substance is a Schedule 8 substance.

(4) Subsection (3) does not apply to a conformant electronic prescription.

51 Requirements for paper prescriptions

(1) This section sets out additional requirements for a paper prescription for a Schedule 4 or 8 substance that is not electronically generated.

(2) The information required to be specified in the prescription under section 50 must be—

(a) legibly handwritten by the person issuing the prescription, or

(b) specified in the prescription in another approved way.

(3) The prescription must be signed by hand by the person issuing the prescription.

(4) If the prescription authorises the supply of a Schedule 8 substance, the prescription must not authorise the supply of another scheduled substance.

(5) A pharmacist must not dispense a paper prescription that is emailed or faxed to the pharmacist unless the pharmacist also receives the original script.

52 Requirements for printed electronic prescriptions

(1) This section sets out additional requirements for a paper prescription for a Schedule 4 or 8 substance that is electronically generated and has a handwritten signature.

(2) The prescription must specify a unique reference number for—

(a) each prescription, or

(b) each substance.

(3) The information required under section 50(1)(c), (d) and (f) must be legibly handwritten on the prescription for a Schedule 8 substance, other than for a prescription for buprenorphine or methadone issued as part of the Opioid Treatment Program.

(4) The prescription must be signed by hand by the person issuing the prescription.

(5) If the prescription authorises the supply of a Schedule 8 substance, the prescription must not authorise the supply of another scheduled substance.

(6) A pharmacist must not dispense the prescription that is emailed or faxed to the pharmacist unless the pharmacist also receives the original script.

53 Requirements for conformant electronic prescriptions

(1) This section sets out additional requirements for a conformant electronic prescription for a Schedule 4 or 8 substance.

(2) The prescription must specify the following—

(a) the conformance ID of the electronic prescribing system used to issue the prescription,

(b) a digitally encrypted signature of the person.

Division 4 Additional requirements for prescriptions

54 Prescriptions for azithromycin for treatment of chlamydia

(1) This section applies to a prescription for azithromycin issued to the partner of a patient for the treatment of chlamydia.

(2) Despite another provision of this part, the prescription is not required to specify the partner's date of birth or street address and may instead specify the partner's email address or telephone number.

55 Prescriptions issued by veterinary practitioners

(1) For a prescription issued by a veterinary practitioner, a reference in this part to a patient's name and street address is a reference to the species of animal and—

(a) the owner's name and street address, or

(b) if there is no owner—the animal's unique identifier.

(2) For a prescription issued by a veterinary practitioner, the patient's date of birth is not required.

Division 5 Records and verification of prescriptions

56 Pharmacists must verify prescriptions for Schedule 8 substances

(1) A pharmacist must not supply more than 2 days supply of a Schedule 8 substance on prescription unless the pharmacist has verified that the prescription has been issued by the person purported to have issued the prescription.

Maximum penalty—Tier 5 penalty.

(2) Despite subsection (1), a pharmacist does not have to verify the prescription if the pharmacist—

(a) is familiar with the handwriting of the person who issued the prescription, or

(b) knows the person for whom the substance is prescribed.

57 Pharmacists must keep copies of certain prescriptions

(1) A pharmacist who supplies a Schedule 4D substance that is an anabolic-androgenic steroidal substance or a Schedule 8 substance on prescription must keep a copy of the prescription, whether or not the prescription authorises more than one supply of the substance.

Maximum penalty—Tier 5 penalty.

(2) The pharmacist must keep the copy of the prescription separately from prescriptions for other substances.

Maximum penalty—Tier 5 penalty.

(3) Subsection (2) does not apply to a conformant electronic prescription.

58 Information about supply required to be recorded on prescriptions

(1) A pharmacist who supplies a Schedule 2, 3, 4 or 8 substance on prescription must, each time the substance is supplied, record the following information on the prescription—

(a) the date the substance is supplied,

(b) the address of the place at which the substance is supplied,

(c) the reference number for the prescription.

Maximum penalty—Tier 5 penalty.

(2) After supplying a Schedule 4D or 8 substance on prescription, the pharmacist must record the word "CANCELLED" on the prescription if—

(a) the number of times an amount of the substance may be supplied is not clearly specified, or

(b) the prescription has reached the last occasion on which an amount of the substance may be supplied according to the number of times specified on the prescription, or

(c) for a Schedule 4D substance that is an anabolic-androgenic steroidal substance or a Schedule 8 substance—the intervals at which an amount of the substance may be supplied are not specified on the prescription.

Maximum penalty—Tier 5 penalty.

(3) Subsection (2) does not apply to a conformant electronic prescription.

59 Records of prescriptions

(1) An authorised practitioner who issues a prescription for a Schedule 2, 3, 4 or 8 substance must make a record of the following information—

(a) the name of the substance,

(b) the strength and dosage form of the substance, if not readily apparent,

(c) the date on which the prescription for the substance was issued,

(d) for a prescription for an individual—the individual's name, street address and date of birth,

(e) for a prescription for an animal—the species and the owner's name and street address,

(f) the number of times an amount of the substance may be supplied on the prescription, if applicable,

(g) for a Schedule 4D substance that is an anabolic-androgenic steroidal substance or a Schedule 8 substance—the intervals at which an amount of the substance may be supplied on the prescription,

(h) the directions for use, as shown on the prescription,

(i) for a prescription for azithromycin for the treatment of chlamydia in a patient's partner—the partner's name and the partner's email address or telephone number.

Maximum penalty—Tier 5 penalty.

(2) The authorised practitioner must keep the record at—

(a) for a prescription issued at a public health entity or private health facility—the public health entity or private health facility, or

(b) otherwise—the authorised practitioner's practice.

Maximum penalty—Tier 5 penalty.

Part 6 Administration of scheduled substances—the Act, s 150

60 Unauthorised administration of scheduled substances

A person must not administer a Schedule 2, 3, 4 or 8 substance to another person unless the administration is authorised under this part.

Maximum penalty—Tier 5 penalty.

61 Administration by registered health practitioners

The following persons are authorised to administer a Schedule 2 or 3 substance to a person—

(a) a registered health practitioner acting in the course of practice,

(b) a person acting under the direction of a registered health practitioner acting in the course of practice.

62 Administration by health practitioners

(1) The following persons are authorised to administer a Schedule 4 or 8 substance to a person—

(a) an authorised practitioner, other than a veterinary practitioner, acting in the course of practice,

(b) a pharmacist administering the substance that has been supplied to the person on prescription,

(c) an optometrist, podiatrist, dental hygienist, dental therapist or oral health therapist acting in the course of practice, if the person is authorised to obtain supply of the substance under the Act,

(d) a person acting under the direction of one of the following—

(i) a medical practitioner acting in the course of practice,

(ii) a nurse practitioner acting in the course of practice,

(iii) a registered nurse with an endorsement that qualifies the registered nurse to administer the schedule substance, acting in the course of practice,

(iv) a midwife practitioner acting in the course of practice,

(v) a midwife with an endorsement that qualifies the midwife to administer the scheduled substance, acting in the course of practice,

(vi) a dentist acting in the course of practice,

(vii) a podiatrist with an endorsement acting in the course of practice,

(viii) for a Schedule 4 substance only—an optometrist with an endorsement acting in the course of practice,

(e) a health practitioner of an approved class, or a person acting under the direction of the health practitioner.

(2) Subsection (1)(d) does not include a member of staff of a public health entity, private health facility, residential care facility, managed correctional centre or OTP clinic.

Note— See sections 63 and 64 for administration of Schedule 4 and 8 substances by a member of staff of a public health entity, private health facility, residential care facility, managed correctional centre or OTP clinic.

63 Administration at public health entities, private health facilities and other places

(1) A member of staff of a public health entity, private health facility, residential care facility, managed correctional centre or OTP clinic acting under the direction of one of the following is authorised to administer a Schedule 4 or 8 substance to a person—

(a) a medical practitioner acting in the course of practice,

(b) a nurse practitioner acting in the course of practice,

(c) a registered nurse with an endorsement that qualifies the registered nurse to administer the scheduled substance, acting in the course of practice,

(d) a midwife practitioner acting in the course of practice,

(e) a midwife, with an endorsement that qualifies the midwife to administer the scheduled substance, acting in the course of practice,

(f) a dentist acting in the course of practice,

(g) a podiatrist with an endorsement acting in the course of practice,

(h) for a Schedule 4 substance only—an optometrist with an endorsement acting in the course of practice,

(i) a health practitioner of an approved class.

(2) The direction must be given—

(a) in writing, or

(b) in an approved way.

Maximum penalty—Tier 5 penalty.

(3) Despite subsection (2), the direction may, in an emergency or other urgent circumstances, be given orally in person or by telephone (an ***emergency oral direction***).

(4) As soon as practicable, and no later than 24 hours, after giving an emergency oral direction, the person must confirm the direction by—

(a) making an entry in the patient's medical record, or

(b) sending an email or facsimile to the person who administered the substance.

Maximum penalty—Tier 5 penalty.

(5) This section does not apply to the administration of a Schedule 4 or 8 substance to a person if the substance has been lawfully supplied to the person by a pharmacist on prescription.

64 Administration of Schedule 8 substances at OTP clinics

A member of staff of an OTP clinic is authorised to administer a Schedule 8 substance to a patient at the OTP clinic if the member of staff is acting in accordance with a written direction lawfully given in relation to the patient by—

(a) a medical practitioner or nurse practitioner in accordance with the practitioner's OTP registration, or

(b) a medical practitioner or nurse practitioner in circumstances in which an OTP registration is not required under section 82.

65 Administration by students

(1) A student is authorised to administer a Schedule 2, 3, 4 or 8 substance to a person if the student, during their studies, is acting under the direction of a registered health practitioner authorised to administer the substance.

(2) In this section—

student has the same meaning as in the Health Practitioner Regulation National Law, section 5.

66 Administration for the purpose of first aid

(1) A first aider or other person giving first aid to a person is authorised to administer a Schedule 2 or 3 substance to the person.

(2) A first aider giving first aid to a person is authorised to administer a Schedule 4 substance to the person.

(3) A first aider is authorised under subsection (2) only if the first aider holds a current statement of attainment, issued by a registered training organisation, demonstrating competency in the use and administration, including access and preparation, of the substance for first aid.

67 Administration by carers

(1) A carer of a person is authorised to administer a Schedule 2 or 3 substance to the person.

(2) A carer of a person is authorised to administer a Schedule 4 or 8 substance to the person if the substance has been lawfully supplied to the person.

68 Administration by Ambulance Service of NSW staff

A member of staff of, or a volunteer engaged by, the Ambulance Service of NSW is authorised to administer a Schedule 2, 3, 4 or 8 substance to a person in accordance with the approved paramedic protocol.

69 Administration by other paramedics

A paramedic is authorised to administer a Schedule 2, 3, 4 or 8 substance to a person if the paramedic is a member of staff of a business, other than the Ambulance Service of NSW, that provides paramedical services or ambulance transport services in New South Wales or another state or territory.

70 Administration of vaccines by registered health practitioner

(1) A registered health practitioner is authorised to administer a vaccine to a person without a prescription if the practitioner—

(a) has an authority to administer the vaccine granted by the Health Secretary under section 74, and

(b) administers the vaccine in compliance with the approved standards.

(2) The practitioner must record the following details—

(a) the name, street address, date of birth and other contact details of the person to whom the vaccine was administered,

(b) the brand, batch number and expiry date of the vaccine,

(c) the part of the body to which the vaccine was administered,

(d) the date on which the vaccine was administered,

(e) the address of the place at which the vaccine was administered,

(f) a reference number for the administration,

(g) the practitioner's name and contact details.

Maximum penalty—Tier 5 penalty.

(3) If the practitioner's authority requires the practitioner to complete a training course for this section, the practitioner must record evidence of completion of the course.

Maximum penalty—Tier 5 penalty.

71 Administration by NSW Police Force dive medical technicians

A dive medical technician that is a member of staff of the NSW Police Force is authorised to administer a Schedule 2, 3 or 4 substance to a diver for the purposes of emergency medical treatment if the dive medical technician is under the supervision of a medical practitioner qualified in underwater medicine.

72 Administration of Schedule 8 substances by dentists

(1) A dentist is authorised to administer a Schedule 8 substance only if the substance is listed in the Dental Schedule of Pharmaceutical Benefits.

(2) This section does not apply to the administration by a dentist to a patient in a public health entity or private health facility.

73 Restriction on administration of certain Schedule 4 and 8 substances

(1) An authorised practitioner, other than a veterinary practitioner, must not administer the following to a person—

(a) a nominated Schedule 4 substance,

(b) a Schedule 8 substance if the person has a substance dependence on a prohibited scheduled substance or prohibited drug,

(c) dexamfetamine, lisdexamfetamine or methylphenidate,

(d) N,α-dimethyl-3,4-(methylenedioxy)phenylethylamine (MDMA) or psilocybine,

(e) morphine, oxycodone, fentanyl or hydromorphone in an amount that exceeds the morphine equivalent maximum dose,

(f) a substance (a ***relevant substance***) that is alprazolam, flunitrazepam, methadone or a Schedule 8 substance in an injectable or intranasal preparation, if the administration is for a period that, together with all other periods for which a relevant substance has been administered by the person or has, to the person's knowledge, been administered by another person, would result in one or more relevant substances being administered for continuous therapeutic use by the patient for more than 3 months.

Maximum penalty—Tier 5 penalty.

Note— A health practitioner may be subject to other restrictions on the administration of scheduled substances under the Health Practitioner Regulation National Law in relation to appropriate professional conduct and practice.

(2) A veterinary practitioner must not administer the following—

(a) dexamfetamine or lisdexamfetamine,

(b) N,α-dimethyl-3,4-(methylenedioxy)phenylethylamine (MDMA) or psilocybine.

Maximum penalty—Tier 5 penalty.

(3) Subsection (1)(b) does not apply to a dentist.

(4) Subsection (1) does not apply to a person who administers the substance in accordance with an approval, approval exemption or OTP registration.

74 Health Secretary may authorise administration—the Act, s 10(2)

(1) The Health Secretary may grant an authority that authorises the administration of a Schedule 2, 3, 4 or 8 substance.

(2) An authority may be granted on application or the Health Secretary's own initiative.

(3) An authority may be granted to a particular person or a class of persons.

(4) An authority is granted to a class of persons by written notice published on the Ministry of Health's website.

(5) The Health Secretary may, by written notice, require a person applying for an authority to give information to the Health Secretary that the Health Secretary considers necessary to determine the application.

(6) Without limitation, the Health Secretary may refuse to grant an authority to a person if, in the Health Secretary's opinion, the person is not a fit and proper person to hold the authority.

(7) An authority may be granted subject to conditions.

(8) An authority is not transferable.

(9) The Health Secretary may revoke an authority granted to a class of persons by revoking the authority for—

(a) all the persons of the class, or

(b) specified persons of the class.

(10) An authority remains in force until the authority—

(a) expires, or

(b) is sooner surrendered by the holder or revoked by the Health Secretary.

Part 7 Approvals for supply, administration and prescription of certain Schedule 4 and 8 substances—the Act, Part 3.3

75 Schedule 4 and 8 substances that require approvals—the Act, s 67(1)

The Act, Part 3.3 applies to the following scheduled substances—

(a) nominated Schedule 4 substances,

(b) Schedule 8 substances.

76 Approvals required for activities involving nominated Schedule 4 substances—the Act, s 69(1)

An authorised practitioner must not supply, administer or issue a prescription for a nominated Schedule 4 substance without an approval.

77 Approvals for nominated Schedule 4 substances not required in certain circumstances—the Act, s 69(1)

(1) This section sets out the circumstances in which an authorised practitioner does not require an approval under section 76 to supply, administer or issue a prescription for a nominated Schedule 4 substance.

Note— The Act, section 69(2) and (3) set out other circumstances in which an approval is not required.

(2) An authorised practitioner does not require an approval for a nominated Schedule 4 substance for the treatment of a patient of—

(a) a public health entity or private health facility, or

(b) a correctional centre for the purposes of continuing the treatment the patient was receiving immediately before the patient became an inmate.

(3) An authorised practitioner (the ***replacement practitioner***) does not require an approval for a nominated Schedule 4 substance if—

(a) the replacement practitioner carries out the activity on behalf of another authorised practitioner who holds an approval for the activity and is temporarily unavailable (the ***original practitioner***), and

(b) the activity is required for the continued treatment of a patient of the original practitioner, and

(c) the replacement practitioner—

(i) practises at the same practice or premises as the original practitioner, or

(ii) is nominated by the original practitioner to carry out the activity.

(4) A veterinary practitioner does not require an approval for a nominated Schedule 4 substance.

(5) A medical practitioner with a specialist registration specified in Column 1 of the table to this subsection does not require an approval for a nominated Schedule 4 substance specified opposite in Column 2.

Column 1	Column 2
Specialist registration	**Nominated Schedule 4 substance**
Dermatology	Acitretin
	Alefacept
	Bexarotene
	Etretinate
	Isotretinoin for oral use
	Thalidomide
Obstetrics and gynaecology	Clomifene
	Corifollitropin alfa
	Cyclofenil
	Dinoprost
	Dinoprostone
	Follitropin alfa
	Follitropin beta
	Follitropin delta
	Luteinising hormone
	Urofollitropin
Physician	Acitretin
	Ambrisentan
	Bexarotene
	Bosentan
	Clomifene
	Cyclofenil
	Enzalutamide
	Etretinate
	Follitropin beta
	Isotretinoin for oral use
	Lenalidomide
	Luteinising hormone
	Macitentan
	Pomalidomide
	Riociguat
	Sitaxentan
	Teriparatide
	Thalidomide
	Tretinoin for oral use

78 Approvals required for activities involving Schedule 8 substances—the Act, s 69(1)

(1) A medical practitioner or authorised nurse must not supply, administer or issue a prescription for a Schedule 8 substance without an approval in the following circumstances—

(a) the patient has a substance dependence on a prohibited scheduled substance or prohibited drug,

(b) the Schedule 8 substance is—

(i) dexamfetamine, lisdexamfetamine or methylphenidate, or

(ii) for medical practitioners only—N,α-dimethyl-3,4-(methylenedioxy)phenylethylamine (MDMA) or psilocybine,

(c) the Schedule 8 substance is morphine, oxycodone, fentanyl or hydromorphone and the amount is more than the morphine equivalent maximum dose,

(d) the substance (the ***relevant substance***) is alprazolam, flunitrazepam, methadone or a Schedule 8 substance in an injectable or intranasal preparation, and the supply, administration or issue of the prescription would result in supply for a period in which, together with all other periods for which any relevant substance has been prescribed by the practitioner or has, to the practitioner's knowledge, been prescribed by another person, one or more relevant substances are supplied for continuous therapeutic use by the patient for more than 3 months.

(2) In this section—

authorised nurse means—

(a) a nurse practitioner, or

(b) a registered nurse with an endorsement.

79 Approvals for Schedule 8 substances not required in certain circumstances—the Act, s 69(1)

(1) This section sets out the circumstances in which a medical practitioner or authorised nurse does not require an approval under section 78(1) to supply, administer or issue a prescription for a Schedule 8 substance.

Note— The Act, section 69(2) and (3) set out other circumstances in which an approval is not required.

(2) A medical practitioner or authorised nurse does not require an approval if the activity is carried out for one of the following purposes—

(a) the palliative treatment of a patient,

(b) the treatment of a patient admitted to, or receiving emergency treatment at, a public health entity or private health facility,

Note— A hospital in the home patient is admitted to a public health entity or private health facility.

(c) the treatment of an inmate in a correctional centre for the purposes of continuing the treatment the person was receiving immediately before the person became an inmate.

(3) A medical practitioner or authorised nurse (the ***replacement practitioner***) does not require an approval if—

(a) the replacement practitioner carries out the activity on behalf of another medical practitioner or authorised nurse who holds an approval for the activity and is temporarily unavailable (the ***original practitioner***), and

(b) the activity is required for the continued treatment of a patient of the original practitioner, and

(c) the replacement practitioner—

(i) practises at the same practice or premises as the original practitioner, or

(ii) is nominated by the original practitioner to carry out the activity.

(4) A medical practitioner does not require an approval if the medical practitioner has a specialist registration—

(a) in palliative medicine, or

(b) in paediatrics and child health, with a field of speciality practice in paediatric palliative medicine or paediatric medical oncology, or

(c) in obstetrics and gynaecology, with a field of speciality practice in gynaecological oncology, or

(d) in radiation oncology, or

(e) as a physician, with a field of speciality practice in medical oncology.

(5) Subsections (2)–(4) do not apply to—

(a) N,α-dimethyl-3,4-(methylenedioxy)phenylethylamine (MDMA), or

(b) psilocybine.

(6) A medical practitioner or authorised nurse does not require an approval for the activity specified in section 78(1)(a), (c) or (d) if the activity—

(a) is for the purposes of urgent pain relief for a patient, and

(b) does not involve treatment for more than 3 consecutive days for the same matter.

(7) A medical practitioner does not require an approval for the activity specified in section 78(1)(b)(i) or (d) in relation to dexamfetamine, lisdexamfetamine or methylphenidate if the medical practitioner has a specialist registration—

(a) in psychiatry, or

(b) in paediatrics and child health, or

(c) as a physician, with a field of speciality practice in neurology, or

(d) as a physician, with a field of speciality practice in respiratory and sleep medicine.

(8) In this section—

authorised nurse means—

(a) a nurse practitioner, or

(b) a registered nurse with an endorsement.

palliative treatment means the palliative treatment of a patient who has—

(a) an incurable, progressive, far-advanced disease or medical condition, and

(b) a prognosis of a limited life expectancy, with death expected within the next 2 years, because of the disease or medical condition.

Part 8 Opioid Treatment Program—the Act, Part 3.4

80 Substances under Opioid Treatment Program

For the Act, sections 74(1) and (4) and 75(1) and (3), buprenorphine and methadone are prescribed Schedule 8 substances when supplied, prescribed or administered under the Opioid Treatment Program.

81 Compliance standards for Opioid Treatment Program

(1) For the Act, section 74(4)(a), a person who supplies, administers or issues a prescription for buprenorphine or methadone under an OTP registration must carry out the activity in compliance with the OTP standards.

Maximum penalty—Tier 5 penalty.

(2) For the Act, section 74(4)(b), a pharmacist who dispenses buprenorphine or methadone at a pharmacy under an OTP registration must carry out the activity in compliance with the OTP standards.

Maximum penalty—Tier 5 penalty.

(3) For the Act, section 74(4)(c), a provider under the Opioid Treatment Program who is the holder of an obtain licence must ensure the OTP clinic is operated in compliance with the OTP standards.

Maximum penalty—Tier 5 penalty.

(4) For the Act, section 74(4)(d), a public health entity operating a public OTP clinic must ensure the OTP clinic is operated in compliance with the OTP standards.

Maximum penalty—Tier 5 penalty.

(5) For the Act, section 74(4)(d), a person carrying out an activity for which an OTP registration is not required under section 82 is prescribed and must carry out the activity in compliance with the provisions of the OTP standards specified in the OTP standards as applying to the person.

Maximum penalty—Tier 5 penalty.

(6) In this section—

OTP standards means the standards for compliance issued by the Health Secretary for the Act, section 74(4).

82 Circumstances in which OTP registration is not required

For the Act, section 74(3)(f), an OTP registration is not required for the activities specified in the Act, section 74(1) in the following circumstances—

(a) the treatment of a patient admitted to, or receiving emergency treatment at, a public health entity or private health facility,

(b) the treatment of a patient by a medical practitioner or nurse practitioner (the ***replacement practitioner***) on behalf of a medical practitioner or nurse practitioner who has an OTP registration and is temporarily unavailable (the ***original practitioner***) if—

(i) the treatment is required for the continued treatment of a patient of the original practitioner, and

(ii) the replacement practitioner—

(A) practises at the same practice or premises as the original practitioner, or

(B) is nominated by the original practitioner to carry out the activity,

(c) the treatment of an inmate in a correctional centre, or within 28 days after the inmate's release, on behalf of a medical practitioner or nurse practitioner who has an OTP registration (the ***first practitioner***) for the purposes of continuing the treatment the patient was receiving from the first practitioner.

Note— The Act, section 75(2) provides that an OTP registration is not required for a person acting under the direction of a medical practitioner or nurse practitioner who has an OTP registration.

83 Authorised activities under OTP registrations—the Act, s 74(3)(b)

(1) A medical practitioner or nurse practitioner is authorised to supply, administer or issue a prescription to a patient under an OTP registration if—

(a) the patient is not an existing patient of another registered health practitioner for the purposes of an opioid treatment program, and

(b) the practitioner has notified the Health Secretary in the approved form of the following details—

(i) the patient's details,

(ii) the substance to be supplied, administered or prescribed to the patient under the prescription, and

(c) the daily dose of the substance to be supplied, administered or prescribed to the patient is not more than—

(i) the standard treatment, or

(ii) the amount approved by the Health Secretary.

(2) In this section—

standard treatment means supplying, administering or prescribing a daily dose that is—

(a) not more than 200mg of methadone, or

(b) not more than 32mg of buprenorphine.

84 Refusal to grant OTP registration—the Act, s 74(3)(a)

The Health Secretary may, by written notice, refuse to grant an OTP registration to a medical practitioner, nurse practitioner or pharmacy if the Health Secretary considers that granting the registration would—

(a) place a patient, or class of patients, at risk of harm, or

(b) not be in the public interest.

85 Suspension, variation and revocation of OTP registrations—the Act, s 74(3)(c)

The Health Secretary may, by written notice given to the holder of an OTP registration, suspend, vary or revoke the OTP registration for reasons the Health Secretary considers appropriate.

Part 9 Cosmetic use substances—the Act, s 54

86 Definitions

In this part—

cosmetic use substance means the following Schedule 4 substances—

(a) botulinum toxins,

(b) calcium hydroxylapatite,

(c) collagen,

(d) deoxycholic acid,

(e) hyaluronic acid and its polymers,

(f) polyacrylamide,

(g) polycaprolactone,

(h) polylactic acid.

responsible provider, in relation to a cosmetic use substance, means a person carrying on a business of administering the substance, for fee or reward and whether or not for profit, but does not include an individual employed or otherwise engaged by the person carrying on the business.

87 Application of part

(1) This part does not apply to the administration of a cosmetic use substance to a patient by—

(a) an authorised practitioner administering the cosmetic use substance in the lawful practice of the practitioner's profession, or

(b) for a patient in a hospital—a person employed at the hospital who is administering the cosmetic use substance on the direction of an authorised practitioner, other than a veterinary practitioner.

(2) For subsection (1)(a), an authorised practitioner does not include a registered nurse with an endorsement.

(3) This part does not apply to the administration of a cosmetic use substance to an animal by—

(a) a veterinary practitioner in the lawful practice of the practitioner's profession, or

(b) another person on the direction of a veterinary practitioner.

88 Administration of cosmetic use substances

(1) A person must not administer a cosmetic use substance to a patient unless the person is a nurse who is—

(a) acting in accordance with a direction of a medical practitioner or nurse practitioner, or

(b) administering the substance to the patient and the substance has been lawfully supplied to the patient in accordance with a prescription issued to the patient.

(2) A medical practitioner or nurse practitioner must not give a direction unless the medical practitioner or nurse practitioner is satisfied the cosmetic use substance is—

(a) included on the Australian Register of Therapeutic Goods, or

(b) approved for supply under the Commonwealth Therapeutic Goods Act, section 19 or 19A, or

(c) supplied by a manufacturer that has a manufacturing licence under the Commonwealth Therapeutic Goods Act.

(3) A nurse administering a cosmetic use substance under the direction of a medical practitioner or nurse practitioner must—

(a) be satisfied there is appropriate equipment available for use in a patient medical emergency, and

(b) be satisfied the substance is—

(i) included on the Australian Register of Therapeutic Goods, or

(ii) approved for supply under the Commonwealth Therapeutic Goods Act, section 19 or 19A, or

(iii) supplied by a manufacturer that has a manufacturing licence under the Commonwealth Therapeutic Goods Act, and

(c) make a written record of the following information for each administration—

(i) the nurse's name,

(ii) the date on which the substance was administered,

(iii) the batch number of the substance,

(iv) the information specified in section 90(1)(a)–(e) and (i), and

(d) give a copy of the written record to—

(i) the relevant medical practitioner or nurse practitioner, and

(ii) the responsible provider.

89 Administration by nurses under direction of medical practitioners and nurse practitioners

(1) A medical practitioner or nurse practitioner giving a direction for section 88(1)(a) must—

(a) have personally reviewed the patient in person or by audiovisual link, and

(b) give the direction in writing, and

(c) sign the direction.

(2) The direction may be given orally in person if the medical practitioner or nurse practitioner is physically present when the substance is administered by the nurse to whom the direction is given.

(3) If the direction is given orally in person, the medical practitioner or nurse practitioner must—

(a) record the direction in the patient's medical record, and

(b) sign the record.

(4) A written direction has effect for the period specified in the direction, being not more than 6 months from the date on which the practitioner giving the direction reviewed the patient under subsection (1)(a).

(5) An oral direction has effect for the particular administration of the substance to which the direction applies.

90 Content of directions

(1) A written direction given under section 89(1) must include the following information—

(a) the patient's name,

(b) the patient's street address,

(c) the name and telephone number of the medical practitioner or nurse practitioner giving the direction,

(d) the street address of the principal place of practice of the medical practitioner or nurse practitioner giving the direction,

(e) the street address of the premises at which the substance will be administered,

(f) the responsible provider's name,

(g) the date on which the medical practitioner or nurse practitioner personally reviewed the patient under section 89(1)(a),

(h) the period for which the direction has effect,

(i) the number of times, and the intervals at which, the substance may be administered,

(j) for each administration of the substance—

(i) the name and form of the substance, and

(ii) the part of the patient's face or body to which the substance will be administered, and

(iii) the route of administration, if not readily apparent, and

(iv) the quantity of the substance to be administered.

(2) An oral direction given under section 89(2) must include the information specified in subsection (1)(a) and (j).

91 Records of directions

(1) A medical practitioner or nurse practitioner who gives a written direction under section 89(1) must—

(a) keep a copy of the direction, and

(b) give a copy of the direction to the responsible provider.

(2) A medical practitioner or nurse practitioner who gives an oral direction under section 89(2) must—

(a) make and keep a record of the direction, which must include the street address of the patient, and

(b) give a copy of the record to the responsible provider.

92 Storage

(1) The person who occupies or has control of premises at which a cosmetic use substance is stored or administered must ensure the substance is stored—

(a) in a room or enclosure to which the public does not have access, and

(b) apart from food intended for consumption by humans or animals, and

(c) in a way that, if the substance's container breaks or leaks, the substance cannot mix with or contaminate food intended for consumption by humans or animals, and

(d) in accordance with the conditions for storage specified on the label of the substance.

(2) A medical practitioner or nurse practitioner who obtains a cosmetic use substance for administration must ensure the substance is stored—

(a) in a room or enclosure to which the public does not have access, and

(b) apart from food intended for consumption by humans or animals, and

(c) in a way that, if the substance's container breaks or leaks, the substance cannot mix with or contaminate food intended for consumption by humans or animals, and

(d) in accordance with the conditions for storage specified on the label of the substance.

93 Duties of responsible providers and staff

(1) A responsible provider, and each medical practitioner or nurse practitioner employed by the provider, must ensure the following—

(a) the administration of a cosmetic use substance in the course of the provider's business is carried out in accordance with this part,

(b) there are appropriate risk management policies and procedures in place to protect the health and safety of patients,

(c) there is appropriate equipment available for use in a patient medical emergency,

(d) each nurse administering a cosmetic use substance is adequately trained for a patient medical emergency.

(2) A responsible provider must keep a copy of—

(a) each direction given by a medical practitioner or nurse practitioner for the administration of a cosmetic use substance by a nurse under this part, and

(b) each record made by a nurse under section 88(3)(c).

94 Category 1 and category 2 requirements

(1) The following provisions are category 1 requirements—

(a) section 88(1), (2) and (3)(a) and (b),

(b) section 89(1)(a),

(c) section 93(1).

(2) The following provisions are category 2 requirements—

(a) section 88(3)(c) and (d),

(b) section 89(1)(b) and (c),

(c) section 90,

(d) section 91,

(e) section 92,

(f) section 93(2).

Note— The Act, section 54(3) provides that a person who contravenes a category 1 or category 2 requirement is guilty of an offence. The maximum penalty for a category 1 requirement is 1,000 penalty units for a corporation and 200 penalty units or imprisonment for 6 months, or both, for an individual. The maximum penalty for a category 2 requirement is 250 penalty units for a corporation and 50 penalty units for an individual.

Part 10 Nitrous oxide—the Act, ss 55 and 150

Division 1 Application

95 Definitions

In this part—

container, in relation to nitrous oxide, includes a bulb.

dealer—

(a) means a person who supplies nitrous oxide as a manufacturer, an importer or exporter or a wholesale or retail dealer, and

(b) includes an authorised practitioner and a pharmacist, in the practitioner's or pharmacist's capacity as a supplier of nitrous oxide.

purchaser means the person to whom nitrous oxide is supplied.

96 Application of part

(1) This part applies to nitrous oxide that is a Schedule 6 substance.

(2) This part does not apply to nitrous oxide that is—

(a) used for therapeutic use, or

(b) kept in a container designed to be mounted and used in a motor vehicle, or

(c) supplied by a full member of the Australia New Zealand Industrial Gas Association for an industrial use.

Division 2 Storage and supply generally

97 Storage of nitrous oxide

(1) A dealer who has possession of nitrous oxide must keep the nitrous oxide in a way that ensures the nitrous oxide, including its container or packaging, is not visible to a member of the public, including a member of the public who is on the premises where the nitrous oxide is kept.

Maximum penalty—Tier 5 penalty.

(2) A dealer does not commit an offence under this section if the nitrous oxide, or its container or packaging, is visible while the dealer is—

(a) supplying the nitrous oxide to a purchaser, or

(b) showing the nitrous oxide to a member of the public at the member of the public's request.

98 Supply of nitrous oxide to minors prohibited

(1) A dealer must not supply nitrous oxide to a minor.

Maximum penalty—Tier 5 penalty.

(2) It is a defence to a prosecution for an offence under this section if the court is satisfied that—

(a) the purchaser was at least 15 years of age at the time of the supply, and

(b) at or before the time of the supply, the defendant was given documentary evidence that might reasonably be accepted as—

(i) applying to the purchaser, and

(ii) proving the purchaser was at least 18 years of age.

(3) In this section—

documentary evidence includes an evidence of age document within the meaning of the *Liquor Act 2007*.

99 Maximum quantity of nitrous oxide to be supplied

(1) A dealer must not supply nitrous oxide to another person in a container that contains more than 10g of nitrous oxide.

Maximum penalty—Tier 5 penalty.

(2) A dealer must not supply another person with more than 250g of nitrous oxide per day.

Maximum penalty—Tier 5 penalty.

100 Nitrous oxide must not be supplied at certain times or delivered same day

(1) A dealer who supplies nitrous oxide must ensure the purchaser, or the purchaser's agent, does not receive the nitrous oxide—

(a) before 5am or after 10pm on a day, or

(b) on the same day the purchaser requests the nitrous oxide.

Maximum penalty—Tier 5 penalty.

(2) Subsection (1)(b) does not apply to a supply that occurs in person between the dealer and the purchaser at the dealer's premises.

Division 3 Food and drink and wholesale storage and supply

101 Application of division

The provisions of this division prevail over the other provisions of this part to the extent of an inconsistency.

102 Definitions

In this division—

food and drink related supply means supply to—

(a) a person carrying on a food business, or

(b) the holder of a liquor licence.

food business means a food business within the meaning of the *Food Act 2003* if one or both of the following apply—

(a) written notice in relation to the food business has been given to the appropriate enforcement agency under the *Food Act 2003*, section 100,

(b) the food business is subject to a licence for a food safety scheme required under regulations made under the *Food Act 2003*.

liquor licence means a licence within the meaning of the *Liquor Act 2007*.

103 Food and drink related supplies and wholesale supplies

(1) A dealer may do the following when supplying nitrous oxide if the supply is a food and drink related supply—

(a) supply more than 250g of nitrous oxide to the purchaser in one day,

(b) enable the purchaser, or the purchaser's agent, to receive the nitrous oxide at any time of the day,

(c) enable the purchaser, or the purchaser's agent, to receive the nitrous oxide on the same day the purchaser requests the nitrous oxide,

(d) give nitrous oxide to a minor during the supply if the minor is an employee of—

(i) the person carrying on the food business, or

(ii) the holder of the liquor licence.

(2) A dealer may do the following when supplying nitrous oxide if the supply is a wholesale supply—

(a) supply more than 250g of nitrous oxide to the purchaser in 1 day,

(b) enable the purchaser, or the purchaser's agent, to receive the nitrous oxide at any time of the day,

(c) enable the purchaser, or the purchaser's agent, to receive the nitrous oxide on the same day the purchaser requests the nitrous oxide,

(d) give nitrous oxide to a minor during the supply if the minor is an employee of the purchaser.

104 Records must be kept by dealer

A dealer must keep a record of supply of nitrous oxide if one or more of the following apply—

(a) the dealer supplies more than 250g of nitrous oxide to the purchaser in 1 day,

(b) the dealer enables the purchaser, or the purchaser's agent, to receive the nitrous oxide before 5am or after 10pm on a day,

(c) for a supply that does not occur in person between the dealer and the purchaser at the dealer's premises—the dealer enables the purchaser, or the purchaser's agent, to receive the nitrous oxide on the same day the purchaser requests the nitrous oxide,

(d) the dealer gives nitrous oxide to a minor during the supply in accordance with section 103(1)(d) or (2)(d).

Maximum penalty—Tier 5 penalty.

105 Content of records

A record kept in accordance with this division must include the following—

(a) the amount of nitrous oxide supplied,

(b) the date the purchase of the nitrous oxide occurred,

(c) the following information about the purchaser—

(i) name,

(ii) street address,

(iii) phone number,

(iv) if the purchaser has an ABN—the ABN,

(v) if the purchaser is a corporation—the name and phone number of the individual acting on behalf of the corporation to arrange the supply,

(vi) if the purchaser is a person carrying on a food business subject to a licence for a food safety scheme required under regulations made under the *Food Act 2003*—the number of the licence,

(vii) if the purchaser holds a liquor licence—the number of the licence,

(d) the name of the dealer,

(e) the address where the nitrous oxide was kept by the dealer before being supplied to the purchaser.

Maximum penalty—Tier 5 penalty.

Part 11 Drug registers for Schedule 8 substances—the Act, ss 55 and 150

106 Definitions

In this part—

relevant place has the same meaning as in section 107.

responsible person has the same meaning as in section 108.

107 Application of part to storage of Schedule 8 substances at certain places

This part applies to the storage of Schedule 8 substances at the following places (a ***relevant place***)—

(a) a hospital ward in a public health entity or private health facility,

(b) a public hospital pharmacy,

(c) a dispensary in a private health facility,

(d) a residential care facility,

(e) a managed correctional centre,

(f) a clinic or other area in a correctional centre controlled by the Justice Health and Forensic Mental Health Network,

(g) an OTP clinic,

(h) a pharmacy,

(i) a veterinary hospital,

(j) another place at which a person is in possession of a Schedule 8 substance for the purposes of manufacture, supply, administration, research or testing.

108 Persons responsible for drug registers

(1) The ***responsible person*** for a relevant place is as follows—

(a) for a hospital ward in a public health entity or private health facility—the director of nursing or, for a public health entity, a person appointed by the chief executive of the public health entity,

(b) for a public hospital pharmacy—the director of pharmacy,

(c) for a dispensary in a private health facility—the licensee of the private health facility or a person appointed by the licensee,

(d) for a residential care facility—the authorised person for the residential care facility,

(e) for a managed correctional centre—the person appointed for the managed correctional centre under subsection (4),

(f) for a clinic or other area in a correctional centre controlled by the Justice Health and Forensic Mental Health Network—the director of nursing,

(g) for a public OTP clinic—the medical practitioner, nurse practitioner, registered nurse, midwife or pharmacist in charge of the public OTP clinic,

(h) for a private OTP clinic—the holder of the obtain licence for the private OTP clinic,

(i) for a pharmacy—the holder of a financial interest, within the meaning of the *Health Practitioner Regulation National Law (NSW)*, Schedule 5F, in the pharmacy,

(j) for a veterinary hospital—the holder of the veterinary hospital licence under the *Veterinary Practice Act 2003*,

(k) for another place referred to in section 107(j)—

(i) the holder of a wholesaler licence, or

(ii) the holder of a DMT authority, or

(iii) the holder of an authority granted by the Health Secretary under section 25, 43 or 74, or

(iv) the holder of an obtain licence, or

(v) if subparagraphs (i)–(iv) do not apply—an authorised practitioner employed or engaged at the place, or

(vi) if the Schedule 8 substance is on premises managed by NSW Health Pathology—the chief executive of NSW Health Pathology, or

(vii) if the Schedule 8 substance is on premises managed by the Ambulance Service of NSW—the chief executive of the Ambulance Service of NSW.

(2) If a public health entity or private health facility does not have a director of nursing, the chief executive, however described, of the public health entity or private health facility must appoint the director of pharmacy or the medical superintendent to have the responsibilities of the responsible person under this part.

(3) If a public hospital does not have a director of pharmacy, the chief executive, however described, of the hospital must appoint the director of nursing or the medical superintendent to have the responsibilities of the responsible person under this part.

(4) The management company for a managed correctional centre must, by written instrument, appoint a pharmacist employed or engaged by the management company as the responsible person for the managed correctional centre.

(5) If there is no pharmacist employed or engaged by the management company for the managed correctional centre, the person appointed may be—

(a) an authorised practitioner, other than a dentist or veterinary practitioner, or

(b) the registered nurse in charge of the medical treatment of inmates at the managed correctional centre.

109 Drug registers for Schedule 8 substances

(1) A responsible person for a relevant place at which a Schedule 8 substance is kept must ensure a drug register is kept in accordance with this part.

Maximum penalty—Tier 5 penalty.

(2) A drug register must specify the particulars required to be entered and be kept—

(a) in the form of a book that—

(i) contains consecutively numbered pages, and

(ii) is bound so the pages cannot be removed or replaced without a trace, or

(b) electronically in a form that complies with the approved standards.

(3) If a drug register is kept in the form of a book, as referred to in subsection (2)(a), a separate page must be used for—

(a) each Schedule 8 substance, and

(b) each brand, strength and dosage form of the Schedule 8 substance.

(4) Despite subsection (3), a separate page is not required for records of the destruction of each Schedule 8 substance.

(5) Despite this section, the responsible person for premises managed by NSW Health Pathology or the Ambulance Service of NSW at which a Schedule 8 substance is kept must ensure a drug register is kept in the approved form.

Maximum penalty—Tier 5 penalty.

110 Entries in drug registers for Schedule 8 substances

(1) For a Schedule 8 substance, a person must enter the following information in the drug register—

(a) if the person manufactures a Schedule 8 substance at a relevant place specified in Column 1—the information specified opposite in Column 2 on the day of manufacture,

(b) if the person receives a Schedule 8 substance at a relevant place specified in Column 1—the information specified opposite in Column 3 on the day of receipt,

(c) if the person supplies a Schedule 8 substance at a relevant place specified in Column 1—the information specified opposite in Column 4 on the day of supply,

(d) if the person administers or uses a Schedule 8 substance, including if all or part of the Schedule 8 substance is lost, at a relevant place specified in Column 1—the information specified opposite in Column 5 on the day of administration, use or loss.

Examples of lost part of substance— a part of the substance that remains in a syringe after the substance is administered or a part of the substance that is spilled

Maximum penalty—Tier 5 penalty.

Column 1	Column 2	Column 3	Column 4	Column 5
Relevant place	**Manufacture**	**Receipt**	**Supply**	**Administration/ use/loss**
Hospital ward in public health entity or private health facility	—	Quantity received Name of supplier Reference number of supply Quantity remaining Name and signature of person receiving Name and signature of witness Date	Quantity supplied Name of patient Street address of recipient Name of authorised practitioner who directed the supply Quantity remaining Name and signature of person supplying Name and signature of witness Date	Quantity administered Name of patient Name of authorised practitioner who directed the administration Quantity remaining Name and signature of person administering Name and signature of witness Date For loss, quantity of loss, including discarded amount, and reason for loss

Column 1	Column 2	Column 3	Column 4	Column 5
Relevant place	**Manufacture**	**Receipt**	**Supply**	**Administration/ use/loss**
Public hospital pharmacy	Quantity manufactured Quantity remaining Reference number Name and signature of person manufacturing Date of manufacture	Quantity received Name of supplier Reference number of supply Quantity remaining Name and signature of person receiving Date	Quantity supplied Name of recipient Street address of recipient Reference number of prescription or requisition Name of person who issued prescription or requisition Quantity remaining Name and signature of person supplying Date	For loss, quantity of loss, including the discarded amount, and reason for loss Date
Dispensary in private health facility	Quantity manufactured Quantity remaining Reference number Name and signature of person manufacturing Date of manufacture	Quantity received Name of supplier Reference number of supply Quantity remaining Name and signature of person receiving Date	Quantity supplied Name of recipient Street address of recipient Reference number of prescription or requisition Name of person who issued prescription or requisition Quantity remaining Name and signature of person supplying Date	For loss, quantity of loss, including the discarded amount, and reason for loss Date

Column 1	Column 2	Column 3	Column 4	Column 5
Relevant place	**Manufacture**	**Receipt**	**Supply**	**Administration/ use/loss**
Residential care facility	—	Quantity received Name of supplier Reference number of supply Quantity remaining Name and signature of person receiving Name and signature of witness Date	Quantity supplied Name of recipient Street address of recipient Name of authorised practitioner who directed the supply Quantity remaining Name and signature of person supplying Name and signature of witness Date	Quantity administered Name of recipient Name of authorised practitioner who directed the administration Quantity remaining Name and signature of person administering Name and signature of witness Date For loss, quantity of loss, including discarded amount, and reason for loss
Managed correctional centre	—	Quantity received Name of supplier Reference number of supply Quantity remaining Name and signature of person receiving Name and signature of witness Date	Quantity supplied Name of recipient Street address of recipient Name of authorised practitioner who directed the supply Quantity remaining Name and signature of person supplying Name and signature of witness Date	Quantity administered Name of recipient Name of authorised practitioner who directed the administration Quantity remaining Name and signature of person administering Name and signature of witness Date For loss, quantity of loss, including discarded amount, and reason for loss

Column 1	Column 2	Column 3	Column 4	Column 5
Relevant place	**Manufacture**	**Receipt**	**Supply**	**Administration/ use/loss**
Clinic or other area in a correctional centre controlled by the Justice Health and Forensic Mental Health Network	Quantity manufactured Quantity remaining Reference number Name and signature of person manufacturing Date of manufacture	Quantity received Name of supplier Reference number of supply Quantity remaining Name and signature of person receiving Name and signature of witness Date	Quantity supplied Name of recipient Street address of recipient Name of authorised practitioner who directed the supply Quantity remaining Name and signature of person supplying Name and signature of witness Date	Quantity administered Name of recipient Name of authorised practitioner who directed the administration Quantity remaining Name and signature of person administering Name and signature of witness Date For loss, quantity of loss, including discarded amount, and reason for loss
Public or private OTP clinic	—	Quantity received Name of supplier Reference number of supply Quantity remaining Name and signature of person receiving Name and signature of witness Date	Quantity supplied Name of recipient Street address of recipient Name of authorised practitioner who issued the prescription or directed the supply Quantity remaining Name and signature of person supplying Name and signature of witness Date	Quantity administered Name of recipient Name of authorised practitioner who directed the administration Name and signature of person administering Name and signature of witness Date For loss, quantity of loss, including discarded amount, and reason for loss

Column 1	Column 2	Column 3	Column 4	Column 5
Relevant place	**Manufacture**	**Receipt**	**Supply**	**Administration/ use/loss**
Pharmacy	Quantity manufactured Quantity remaining Reference number Name and signature of person manufacturing Date of manufacture	Quantity received Name of supplier Reference number of supply Quantity remaining Name and signature of person receiving Date	Quantity supplied Name of recipient Street address of recipient Reference number of prescription Name of person who issued prescription Quantity remaining Name and signature of person supplying Date	For loss, quantity of loss, including discarded amount, and reason for loss Date
Veterinary hospital	Quantity manufactured Quantity remaining Reference number Name and signature of person manufacturing Date of manufacture	Quantity received Name of supplier Reference number of supply Quantity remaining Name and signature of person receiving Date	Quantity supplied Species of animal Name or number of animal Name of animal owner, if applicable Street address of animal owner, if applicable Quantity remaining Name and signature of person supplying Date	Quantity administered Species of animal Name or number of animal Name of animal owner, if applicable Street address of animal owner, if applicable Name and signature of person administering Date For loss, quantity of loss, including discarded amount, and reason for loss

Column 1	Column 2	Column 3	Column 4	Column 5
Relevant place	**Manufacture**	**Receipt**	**Supply**	**Administration/ use/loss**
Another place, as specified in section 108(1)(k)	Quantity manufactured Quantity remaining Reference number Name and signature of person manufacturing Date of manufacture	Quantity received Name of supplier Reference number of supply Quantity remaining Name and signature of person receiving Date	Quantity supplied Name of recipient Street address of recipient Reference number Quantity remaining Name and signature of person supplying Date	Quantity administered or used If administered to a person, name of patient If administered to an animal, name or number of animal If used, purpose of use Name and signature of person administering or using Date For loss, quantity of loss, including discarded amount, and reason for loss

(2) The person making the entry in the drug register must sign and date the entry.

Maximum penalty—Tier 5 penalty.

(3) A person making an entry in the drug register at the following locations for the receipt of a Schedule 8 substance must ensure the entry is countersigned by a person who witnessed the receipt—

(a) a hospital ward,

(b) a residential care facility,

(c) a managed correctional centre,

(d) a clinic or other area in a correctional centre controlled by the Justice Health and Forensic Mental Health Network,

(e) a public or private OTP clinic.

Maximum penalty—Tier 5 penalty.

(4) A person making an entry in the drug register at the following locations for the supply or administration of a Schedule 8 substance must ensure the entry is countersigned by a person who supervised or witnessed the supply or administration—

(a) a hospital ward,

(b) a residential care facility,

(c) a managed correctional centre,

(d) a clinic or other area in a correctional centre controlled by the Justice Health and Forensic Mental Health Network,

(e) a public or private OTP clinic.

Maximum penalty—Tier 5 penalty.

(5) The person countersigning under subsection (4) in a correctional centre or OTP clinic must be a nurse, midwife, pharmacist or authorised practitioner, other than a veterinary practitioner, appointed by the correctional centre or OTP clinic.

111 Inventories of Schedule 8 substances

(1) The responsible person for a relevant place must ensure an accurate inventory of all Schedule 8 substances at the relevant place is made in accordance with this section at the approved times or, if there are no approved times—

(a) every 6 months for the following relevant places—

(i) a hospital ward in a public health entity or private health facility,

(ii) a public hospital pharmacy,

(iii) a dispensary in a private health facility,

(iv) a clinic or other area in a correctional centre controlled by the Justice Health and Forensic Mental Health Network,

(v) a public OTP clinic,

(vi) a residential care facility run by a public health entity, or

(b) otherwise—every 3 months.

Maximum penalty—Tier 5 penalty.

(2) The person making the inventory must—

(a) make the inventory as an entry in the drug register, and

(b) include, immediately under the last entry for each substance—

(i) the quantity of the substance actually kept at the relevant place, and

(ii) the date the inventory was made, and

(c) sign the entry in the drug register.

Maximum penalty—Tier 5 penalty.

(3) A person who, for a period of 1 month or more, takes control of a relevant place at which Schedule 8 substances are kept must, immediately on taking control, ensure an inventory is made as an entry in the drug register in accordance with this section.

Maximum penalty—Tier 5 penalty.

112 Loss or destruction of drug registers for Schedule 8 substances

If a drug register for a relevant place is lost or destroyed, the responsible person for the relevant place must immediately—

(a) give written notice to the Health Secretary of—

(i) the loss or destruction of the drug register, and

(ii) the circumstances of the loss or destruction, and

(b) ensure an accurate inventory of all Schedule 8 substances kept at the relevant place is made, and

(c) ensure the details of the Schedule 8 substances kept at the relevant place are entered in a new drug register.

Maximum penalty—Tier 5 penalty.

113 Ambulance Service of NSW drug register

The chief executive of the Ambulance Service of NSW must ensure a drug register is kept for each of the premises and depots of the Ambulance Service of NSW in accordance with the approved ambulance protocol.

Part 12 Records of supply and administration of scheduled substances—the Act, s 55

114 Records of supply by authorised practitioners

An authorised practitioner who supplies a Schedule 4 or 8 substance must record the following information—

(a) the date on which the substance was supplied,

(b) the name, strength and quantity of the substance supplied,

(c) for supply to an individual—the individual's name, street address and date of birth,

(d) for supply to an animal—the species and the owner's name and street address,

(e) for supply of azithromycin for the treatment of chlamydia in a patient's partner—the partner's name and the partner's email address or telephone number.

Maximum penalty—Tier 5 penalty.

115 Records of supply by pharmacists on prescription

A pharmacist in a pharmacy who supplies a scheduled substance on prescription must record the following information—

(a) the date on which the substance was supplied,

(b) the details required to be specified on the prescription under this regulation,

(c) the name of the pharmacist who supplied the substance,

(d) the reference number for the prescription.

Maximum penalty—Tier 5 penalty.

116 Records of supply by pharmacists in emergencies and urgent circumstances

(1) A pharmacist in a pharmacy who supplies a scheduled substance under section 33 or 34 must record the following—

(a) the date on which the substance was supplied,

(b) the name, strength and quantity of the substance supplied,

(c) the name, street address and date of birth of the person to whom the substance was supplied,

(d) the name of the pharmacist who supplied the substance,

(e) the reference number for the supply.

Maximum penalty—Tier 5 penalty.

(2) A pharmacist who supplies a substance under section 33 must also record the following—

(a) the directions given by the pharmacist for the use of the substance,

(b) the name and address of the person who the pharmacist believes most recently issued a prescription for the substance to the person.

Maximum penalty—Tier 5 penalty.

117 Records of supply to NSW Health Pathology etc

A member of staff who supplies a prohibited scheduled substance, prohibited drug or prohibited plant under section 29 must record the following—

(a) the date on which the substance, drug or plant was supplied,

(b) the name, strength and quantity of the substance, drug or plant supplied,

(c) the name and street address of the person to whom the substance, drug or plant was supplied,

(d) the purpose for which the substance, drug or plant was supplied.

Maximum penalty—Tier 5 penalty.

Part 13 Storage of scheduled substances—the Act, ss 55 and 150

Division 1 Storage requirements

118 Storage requirements generally

(1) This section applies to the following persons who supply a scheduled substance (a ***supplier***)—

(a) a manufacturer,

(b) an importer or exporter,

(c) a wholesale or retail supplier,

(d) an authorised practitioner,

(e) a pharmacist.

(2) A supplier in possession of a scheduled substance must store the substance apart from food intended for consumption by humans or animals.

Maximum penalty—Tier 5 penalty.

119 Storage requirements for Schedule 3 and 4 substances

A supplier in possession of a Schedule 3 or 4 substance must store the substance in a room or enclosure to which the public does not have access.

Maximum penalty—Tier 5 penalty.

120 Storage requirements for Schedule 6 substances

(1) A supplier in possession of a Schedule 6 substance must store the substance—

(a) in a way that prevents access by persons who are less than 16 years of age, and

(b) in a location that is at least 1.2m above the floor and at least 1.2m away from a step, stairway, ramp or escalator to which the public has access.

Maximum penalty—Tier 5 penalty.

(2) This section does not apply to the following substances—

(a) a substance for therapeutic use for animals,

(b) a substance in a container fitted with—

(i) a child-resistant closure, within the meaning of the Commonwealth Poisons Standard, or

(ii) an approved closure,

(c) a substance in a pressurised spray dispenser fitted with a cap that can be removed only by using a levering instrument applied through a slot in the cap,

(d) a substance in a container—

(i) with a capacity of at least 5L, or

(ii) that weighs at least 5kg, including the contents of the container,

(e) hair dye in a container with a capacity of no more than 5mL,

(f) cockroach bait in a complex welded plastic structure.

121 Storage requirements for Schedule 7 substances

A supplier in possession of a Schedule 7 substance for retail sale must store the substance in a way that prevents access by a person other than—

(a) the supplier, or

(b) a member of staff of the supplier, or

(c) a person who is legally permitted to purchase the substance and who is under the direct supervision of the supplier or a member of staff of the supplier.

Maximum penalty—Tier 5 penalty.

122 Storage requirements for Schedule 8 substances in pharmacies

(1) This section applies to the storage of a Schedule 8 substance in a pharmacy or a public hospital pharmacy.

(2) The pharmacist in charge of the pharmacy must ensure Schedule 8 substances are stored in the pharmacy in accordance with this section.

Maximum penalty—Tier 5 penalty.

(3) The substance must be stored—

(a) in a dedicated room, receptacle or refrigerator, and

(b) on its own, unless—

(i) it is stored with a Schedule 9 substance, or

(ii) it is stored in a refrigerator that only contains scheduled substances.

(4) The dedicated room, receptacle or refrigerator must be kept securely locked when not in immediate use.

(5) A receptacle or refrigerator must—

(a) be securely attached to a part of the premises, and

(b) not be accessible by members of the public.

(6) Storage must comply with the medicine storage standards, including in relation to the receptacle.

(7) A key or other device that unlocks the dedicated room, receptacle or refrigerator must be—

(a) kept on the person of a pharmacist when a pharmacist is at the pharmacy or removed from the pharmacy when there is no pharmacist at the pharmacy, or

(b) kept in a separately locked receptacle to which only a pharmacist has access.

(8) A code or combination required to unlock the dedicated room, receptacle or refrigerator must not be divulged to a person who is not a pharmacist.

123 Storage requirements for Schedule 4D and 8 substances in hospitals and other places

(1) This section applies to the storage of a Schedule 4D or 8 substance in the following—

(a) a public health entity, other than a public hospital pharmacy,

(b) a private health facility,

(c) an OTP clinic,

(d) a residential care facility,

(e) a managed correctional centre.

(2) The substance must be stored—

(a) in a dedicated room, receptacle or refrigerator, and

(b) for a Schedule 8 substance—on its own, unless—

(i) it is stored with a Schedule 4D or Schedule 9 substance, or another approved substance, or

(ii) it is stored in a refrigerator that only contains scheduled substances.

(3) The dedicated room, receptacle or refrigerator must be kept securely locked when not in immediate use.

(4) A receptacle or refrigerator must—

(a) be securely attached to a part of the premises, and

(b) not be accessible by members of the public.

(5) Storage must comply with the medicine storage standards, including in relation to the receptacle.

(6) A key or other device that unlocks the dedicated room, receptacle or refrigerator must be—

(a) kept on the person of a relevant person when a relevant person is on the premises or removed from the premises when there is no relevant person on the premises, or

(b) kept in a separately locked receptacle to which only a relevant person has access.

(7) A code or combination required to unlock the dedicated room, receptacle or refrigerator must not be divulged to a person who is not a relevant person.

(8) This section does not apply to the storage of a substance—

(a) on an emergency, anaesthetic or operating theatre trolley, or

(b) to which section 122 applies.

(9) This section also applies to another scheduled substance specified by the Health Secretary generally or in a particular case.

(10) In this section—

appointed person, for a managed correctional centre, means—

(a) a pharmacist who is—

(i) employed or engaged by the management company for a managed correctional centre, or

(ii) appointed by written instrument by the management company as the relevant person for this section, or

(b) if there is no pharmacist employed or engaged by the management company for the managed correctional centre—

(i) a registered nurse in charge of the medical treatment of inmates at the managed correctional centre, or

(ii) an authorised practitioner, other than a dentist or veterinary practitioner, who is appointed by written instrument by the management company as the relevant person for this section.

relevant person means the following—

(a) for a public health entity or private health facility—

(i) a nurse or midwife, or

(ii) a person acting under the direction of a medical practitioner who holds a specialist registration in anaesthesia, or

(iii) an authorised practitioner, other than a veterinary practitioner, or

(iv) a pharmacist,

(b) for an OTP clinic—the medical practitioner, nurse practitioner, registered nurse, midwife or pharmacist in charge of the OTP clinic,

(c) for a residential care facility—a nurse,

(d) for a managed correctional centre—

(i) the appointed person for the managed correctional centre, or

(ii) an authorised practitioner, other than a veterinary practitioner.

124 Storage requirements for Schedule 8 substances in other places

(1) A person in possession of a Schedule 8 substance to which section 122 or 123 does not apply must ensure the Schedule 8 substance is stored in accordance with this section.

Maximum penalty—Tier 5 penalty.

(2) The substance must be stored—

(a) in a dedicated room, receptacle or refrigerator, and

(b) on its own, unless—

(i) it is stored with a Schedule 9 substance, or

(ii) it is stored in a refrigerator that only contains scheduled substances.

(3) The dedicated room, receptacle or refrigerator must be kept securely locked when not in immediate use.

(4) A receptacle or refrigerator must—

(a) be securely attached to a part of the premises, and

(b) not be accessible by members of the public.

(5) Storage must comply with the medicine storage standards, including in relation to the receptacle.

(6) An authorised practitioner or a paramedic complies with this section by keeping a substance, kept for emergency use, in a bag that is in a room or vehicle that is kept locked when not occupied by the person.

Note— See section 130 for storage requirements for a member of staff of the Ambulance Service of NSW.

(7) This section does not apply to a Schedule 8 substance—

(a) lawfully supplied to a person from an authorised practitioner or pharmacist, or

(b) in the custody of a member of the NSW Police Force under the *Drug Misuse and Trafficking Act 1985*, Part 3A.

Division 2 Responsibilities for storage

125 Responsibility for storage in public hospitals and private health facilities

(1) The director of pharmacy of a public hospital or private health facility is responsible for the storage of scheduled substances in the hospital or facility, other than substances that have been supplied to a ward.

(2) If a public hospital or private health facility does not have a director of pharmacy, the chief executive, however described, of the hospital or facility must appoint the director of nursing or the medical superintendent of the hospital or facility to have the responsibilities of the director of pharmacy under subsection (1).

(3) The director of pharmacy, the director of nursing or the medical superintendent of the hospital or facility must ensure scheduled substances are stored in the ward in accordance with this part.

Maximum penalty—Tier 5 penalty.

126 Responsibility for storage in OTP clinics

(1) The medical practitioner, nurse practitioner, registered nurse, midwife or pharmacist in charge of an OTP clinic must ensure scheduled substances are stored in the OTP clinic in accordance with this part.

Maximum penalty—Tier 5 penalty.

(2) The holder of the obtain licence for a private OTP clinic must ensure scheduled substances are stored in the OTP clinic in accordance with this part.

Maximum penalty—Tier 5 penalty.

127 Responsibility for storage in residential care facilities

(1) The authorised person for a residential care facility must ensure scheduled substances are stored at the residential care facility in accordance with this part.

Maximum penalty—Tier 5 penalty.

(2) The approved provider for a residential care facility must ensure scheduled substances are stored at the residential care facility in accordance with this part.

Maximum penalty—Tier 5 penalty.

128 Responsibility for storage in managed correctional centres

(1) The relevant person for a managed correctional centre under section 123 must ensure scheduled substances are stored at the managed correctional centre in accordance with this part.

Maximum penalty—Tier 5 penalty.

(2) The management company for a managed correctional centre must ensure scheduled substances are stored at the managed correctional centre in accordance with this part.

Maximum penalty—Tier 5 penalty.

129 Responsibility for storage in schools

(1) This section applies to the storage of adrenaline, glucagon, glyceryl trinitrate, methoxyflurane, naloxone, nitrous oxide, salbutamol or terbutaline at a government or non-government school under the *Education Act 1990*.

(2) The principal of the school must ensure the substance is stored in a room or enclosure to which the students of the school do not have access.

Maximum penalty—Tier 5 penalty.

Division 3 Other

130 Storage requirements for NSW Health Pathology and Ambulance Service of NSW

(1) Despite another provision of this part, a member of staff of NSW Health Pathology must store a prohibited scheduled substance, prohibited drug or prohibited plant in accordance with the approved pathology standards.

Maximum penalty—Tier 5 penalty.

(2) Despite another provision of this part, a member of staff of the Ambulance Service of NSW must store a scheduled substance in accordance with the approved ambulance protocol.

Maximum penalty—Tier 5 penalty.

Part 14 Labelling of scheduled substances—the Act, ss 55 and 150

Division 1 Labelling requirements for suppliers of scheduled substances

131 Application of division

This division applies to the following persons who supply a scheduled substance (a ***supplier***)—

(a) a manufacturer,

(b) an importer or exporter,

(c) a wholesale or retail supplier,

(d) an authorised practitioner,

(e) a pharmacist.

132 Labelling of scheduled substances

(1) A supplier who supplies a scheduled substance must ensure the substance is packaged and labelled in accordance with—

(a) the Commonwealth Poisons Standard, Part 2, Division 2, and

(b) for a substance to which Therapeutic Goods Order No. 95 applies—in accordance with that Order.

Maximum penalty—Tier 5 penalty.

(2) In this section—

Therapeutic Goods Order No. 95 means the *Therapeutic Goods Order No. 95 Child-resistant packaging requirements for medicines 2017*, as in force from time to time under the *Therapeutic Goods Act 1989* of the Commonwealth.

133 Misleading labelling of substances as scheduled substances

A supplier must not supply a substance in a container with a label that states or implies the substance is a particular scheduled substance, unless the substance is that particular scheduled substance.

Maximum penalty—Tier 5 penalty.

134 Additional requirements for authorised practitioners and pharmacists

(1) This section applies to a supplier who is—

(a) an authorised practitioner, or

(b) a pharmacist in a pharmacy.

(2) A supplier who supplies a scheduled substance must ensure the substance is labelled as required by the Commonwealth Poisons Standard.

Maximum penalty—Tier 5 penalty.

(3) The requirement in the Commonwealth Poisons Standard to include the name, address and telephone number of the dispenser on the label is a requirement to include the name and contact details of the pharmacy from which the substance is supplied, if the supplier is a pharmacist in a pharmacy.

(4) Subsection (2) extends to an authorised practitioner who gives a direction under section 26 to a person for the supply of a Schedule 2, 3, 4 or 8 substance by the person.

135 Additional requirements for Schedule 3 substances

(1) A supplier, other than a pharmacist, who supplies a Schedule 3 substance, other than by wholesale supply, must ensure the substance is labelled with the supplier's name and contact details.

Maximum penalty—Tier 5 penalty.

(2) A pharmacist in a pharmacy who supplies a Schedule 3 substance must ensure the substance is supplied in a package that is labelled with the name and contact details of the pharmacy from which the substance is supplied.

Maximum penalty—Tier 5 penalty.

Division 2 Dose administration aids

136 Additional requirements for dose administration aids

(1) A pharmacist who supplies a scheduled substance in a dose administration aid (a ***DAA***) must ensure the DAA is labelled with the following—

(a) the information required by the Commonwealth Poisons Standard, Appendix L,

(b) the date the substance was packed in the DAA, whether by the pharmacist or another person,

(c) if the pharmacist is using a third party to manufacture a DAA on the pharmacist's behalf—a reference number that links the DAA, the manufacturing instructions for the DAA, as given by the pharmacist under section 137(2), and the prescriptions for the substances included in the DAA,

(d) the patient's date of birth.

Maximum penalty—Tier 5 penalty.

(2) A pharmacist must not supply a scheduled substance in a single DAA that contains both—

(a) substances that are to be taken orally, and

(b) substances that are for external use only.

Maximum penalty—Tier 5 penalty.

(3) A record of the information that must be included on a label under this section must be kept by—

(a) the pharmacist who supplies the substance in the DAA, and

(b) the person who packed the substance in the DAA.

Maximum penalty—Tier 5 penalty.

137 Third party DAA manufacturing services

(1) This section applies if a pharmacist engages a licensed third party to manufacture a DAA on the pharmacist's behalf for the pharmacist to supply to a patient.

(2) The pharmacist must ensure the manufacturing instructions given to the licensed third party are in accordance with—

(a) the prescription given to the pharmacist and any directions for supply from the person who issued the prescription, or

(b) if supply is permitted without a prescription under section 33—any directions for supply given by the authorised practitioner.

Maximum penalty—Tier 5 penalty.

(3) The licensed third party must ensure the DAA is manufactured in accordance with the manufacturing instructions given to the licensed third party by the pharmacist.

Maximum penalty—Tier 5 penalty.

(4) In this section—

licensed third party means a third party licensed to manufacture DAAs under the Commonwealth therapeutic goods laws.

Division 3 Other

138 Labelling of unscheduled therapeutic goods

(1) A person providing a health service must ensure an unscheduled therapeutic good supplied to a patient for therapeutic use is labelled in the same way scheduled substances are required to be labelled under the Commonwealth Poisons Standard, Appendix L.

Maximum penalty—Tier 5 penalty.

(2) This section does not apply if—

(a) the good is supplied to the patient, unopened, in the container in which it was received by the person providing the health service, and

(b) the container is labelled in accordance with the requirements of the Commonwealth therapeutic goods laws.

(3) In this section—

unscheduled therapeutic good means a therapeutic good that is not a scheduled substance or a medical device.

139 Requirements for substances supplied by NSW Health Pathology for research purposes

Despite another provision of this part, a member of staff of NSW Health Pathology who supplies a prohibited scheduled substance, prohibited drug or prohibited plant for a relevant purpose must ensure the substance is labelled with—

(a) the name or unique identifier, and quantity, of the prohibited scheduled substance, prohibited drug or prohibited plant supplied, and

(b) the name and contact details of the pathology laboratory at which the member of staff supplied the substance.

Maximum penalty—Tier 5 penalty.

140 Requirement for substances supplied by Ambulance Service of NSW

Despite another provision of this part, a member of staff of the Ambulance Service of NSW who supplies a Schedule 4 or 8 substance, in accordance with the approved ambulance protocol, must ensure the substance is labelled in accordance with the Commonwealth Poisons Standard, Appendix L.

Maximum penalty—Tier 5 penalty.

Part 15 Preparation and handling of scheduled substances—the Act, ss 55 and 150

141 Application of part

This part does not apply to preparation or handling of a substance by NSW Health Pathology.

142 Preparation and handling of exposed substances

(1) This section applies to a person involved in the preparation or handling of an exposed substance.

(2) The person must ensure a room, surface or equipment used in the preparation or handling of an exposed substance is—

(a) kept clean and hygienic, and

(b) maintained in good working order.

Maximum penalty—Tier 5 penalty.

(3) The person must not use an appliance, article or fitting for preparing or handling an exposed substance unless the appliance, article or fitting is—

(a) designed and constructed to be easily cleaned, and

(b) kept clean.

Maximum penalty—Tier 5 penalty.

(4) The person must ensure no exposed substances come into contact with a surface used for preparing or handling an exposed substance unless the surface is—

(a) designed and constructed to be easily cleaned, and

(b) kept clean.

Maximum penalty—Tier 5 penalty.

143 Personal cleanliness and contact with hands

(1) This section applies to a person involved in the preparation or handling of an exposed substance.

(2) The person must use soap or detergent and water or another suitable cleaning process to clean the person's hands before preparing or handling an exposed substance.

Maximum penalty—Tier 5 penalty.

(3) The person must not—

(a) have unnecessary human contact with an exposed substance, or

(b) handle an exposed substance with the person's fingers or hands unless using a suitable clean implement or disposable gloves, or

(c) place an implement or gloves to be used in preparing or handling an exposed substance in the person's pockets.

Maximum penalty—Tier 5 penalty.

(4) As soon as practicable after using disposable gloves to handle an exposed substance, the person must dispose of the gloves.

Maximum penalty—Tier 5 penalty.

144 Animals and vermin

(1) A person must not use premises for preparing, handling or supplying therapeutic goods unless the premises are free from vermin.

Maximum penalty—Tier 5 penalty.

(2) A person who uses premises for preparing, handling or supplying therapeutic goods must not cause or permit an animal to be on the premises, other than for the purposes of medical or scientific research.

Maximum penalty—Tier 5 penalty.

(3) Subsection (2) does not prevent an assistance animal referred to in the *Disability Discrimination Act 1992* of the Commonwealth, section 9 or other pet from being in a part of the premises accessible to the public.

Example— A dog may accompany a person into a pharmacy.

(4) Subsection (2) does not apply to a veterinary practitioner in the course of practice.

145 Responsibilities of health service providers

(1) A person providing a health service must ensure an exposed substance prepared or handled at the person's place of practice is free from—

(a) contamination, and

(b) anything likely to render the substance harmful, and

(c) anything likely to have an adverse effect on the efficacy of the substance.

Maximum penalty—Tier 5 penalty.

(2) A person providing a health service must ensure all persons employed or engaged by the person and involved in the preparation or handling of an exposed substance comply with the requirements of this part.

Maximum penalty—Tier 5 penalty.

Part 16 Destruction of scheduled substances—the Act, s 55

146 Disposal of scheduled substances generally

A person must not dispose of a scheduled substance in a place or in a way that is likely to constitute a risk to the public.

Maximum penalty—Tier 5 penalty.

147 Destruction of Schedule 8 substances

(1) A person in possession of a Schedule 8 substance must not wilfully destroy the substance, or allow the substance to be destroyed, other than in accordance with sections 148–154.

Maximum penalty—Tier 5 penalty.

(2) This section does not apply to the destruction of a Schedule 8 substance that is carried out—

(a) by or under the direct personal supervision of—

(i) a police officer, or

(ii) an authorised officer, or

(iii) a person authorised, whether generally or in a particular case, under the Act or by the Health Secretary to destroy the substance, or

Example— A person may be authorised to destroy a Schedule 8 substance under a condition of a licence or another instrument.

(b) by a person to whom the substance has been supplied—

(i) by an authorised practitioner, or

(ii) in accordance with a lawfully issued prescription or direction.

148 Destruction of Schedule 8 substances at pharmacies

(1) This section applies to a pharmacist engaged in the supply of Schedule 8 substances at a pharmacy.

(2) The pharmacist (the ***first pharmacist***) may destroy a Schedule 8 substance at the pharmacy in the presence of one of the following persons (the ***witness***)—

(a) another pharmacist who—

(i) is not employed or engaged at the pharmacy, and

(ii) does not have a financial interest, within the meaning of the *Health Practitioner Regulation National Law (NSW)*, Schedule 5F, in the pharmacy, and

(iii) is not a family member of the first pharmacist, or

(b) a medical practitioner or nurse practitioner who is not a family member of the first pharmacist.

(3) The first pharmacist must ensure the following is recorded in the pharmacist's drug register when a Schedule 8 substance is destroyed—

(a) the date of the destruction,

(b) the name and quantity of the substance destroyed,

(c) the first pharmacist's name, professional registration number and signature,

(d) the witness's name, professional registration number and signature.

149 Destruction of Schedule 8 substances by pharmacists on request of authorised practitioners

(1) This section applies to an authorised practitioner who has Schedule 8 substances stored at the practitioner's place of practice.

(2) If the authorised practitioner notifies a pharmacist that a Schedule 8 substance has become unusable or unwanted, the pharmacist may, in the presence of the authorised practitioner, destroy the substance at—

(a) the pharmacist's pharmacy, or

(b) the authorised practitioner's place of practice.

(3) The pharmacist must not be a family member of the authorised practitioner.

(4) The authorised practitioner must ensure the following is recorded in the authorised practitioner's drug register when a Schedule 8 substance is destroyed—

(a) the date of the destruction,

(b) the name and quantity of the substance destroyed,

(c) the pharmacist's name, professional registration number and signature,

(d) the authorised practitioner's name, professional registration number and signature.

150 Destruction of Schedule 8 substances at public health entities

(1) A pharmacist acting under the direction of a drug controller of a public health entity may destroy a Schedule 8 substance in the presence of one of the following (the ***witness***)—

(a) a medical practitioner, nurse practitioner, dentist or pharmacist,

(b) the nurse or midwife unit manager for a ward,

(c) a registered nurse or midwife authorised by written notice from the director of nursing at the public health entity.

(2) The pharmacist must ensure the following is recorded in the public health entity's drug register when a Schedule 8 substance is destroyed—

(a) the date of the destruction,

(b) the name and quantity of the substance destroyed,

(c) the pharmacist's name, professional registration number and signature,

(d) the witness's name, professional registration number and signature.

(3) This section does not apply to a substance destroyed under section 151.

(4) In this section—

drug controller, of a public health entity, means—

(a) the director of pharmacy, or

(b) if there is no director of pharmacy—the person responsible for controlling Schedule 8 substances for the public health entity, or

(c) a pharmacist appointed, by written notice, as the drug controller by—

(i) the director of pharmacy, or

(ii) the person responsible for controlling Schedule 8 substances for the public health entity.

151 Destruction of remaining Schedule 8 substances

(1) A member of staff of a public health entity must arrange for the remaining substance of a Schedule 8 substance to be destroyed in accordance with the approved guidelines.

(2) A member of staff of a private health facility must arrange for the remaining substance of a Schedule 8 substance to be destroyed in accordance with a procedure or policy of the facility.

(3) In this section—

remaining substance, of a Schedule 8 substance, means the part of the Schedule 8 substance that remains after part of the Schedule 8 substance has been administered to the patient.

152 Destruction of Schedule 8 substances by pharmacists at residential care facilities

(1) This section applies to a pharmacist in a pharmacy who is engaged in the supply of Schedule 8 substances to the following—

(a) a residential care facility,

(b) a patient in a residential care facility.

(2) The pharmacist may destroy a Schedule 8 substance in the presence of the authorised person for the residential care facility (the ***witness***).

(3) The substance must be destroyed at the residential care facility.

(4) The pharmacist must ensure the following is recorded in the residential care facility's drug register when a Schedule 8 substance is destroyed—

(a) the date of the destruction,

(b) the name and quantity of the substance destroyed,

(c) the pharmacist's name, professional registration number and signature,

(d) the witness's name and signature.

Maximum penalty—Tier 5 penalty.

153 Destruction of Schedule 8 substances in private health facilities and managed correctional centres

(1) The licensee of a private health facility or the management company for a managed correctional centre may arrange for a Schedule 8 substance to be destroyed by a responsible person in the presence of a medical practitioner, nurse practitioner, dentist or pharmacist (the ***witness***).

(2) The substance must be destroyed at the private health facility or managed correctional centre.

(3) The witness must be registered in a different health profession to the responsible person.

(4) The witness in a private health facility must not be the licensee of the private health facility or have a controlling interest in the private health facility.

(5) The responsible person must ensure the following is recorded in the drug register when a Schedule 8 substance is destroyed—

(a) the date of the destruction,

(b) the name and quantity of the substance destroyed,

(c) the responsible person's name, professional registration number and signature,

(d) the witness's name, professional registration number and signature.

(6) This section does not apply to the destruction of a Schedule 8 substance at a pharmacy at a private health facility or a managed correctional centre.

(7) In this section—

responsible person means the member of staff of a private health facility or managed correctional centre who is appointed, by written notice, by the private health facility or managed correctional centre, as the responsible person for this section and is—

(a) a pharmacist, or

(b) if there is no pharmacist on staff—an authorised practitioner, other than a veterinary practitioner, or registered nurse.

154 Destruction of prohibited substances, drugs and plants at research institutions, universities and laboratories

(1) The person in charge of a relevant research institution may destroy—

(a) a prohibited scheduled substance, prohibited drug or prohibited plant in accordance with an obtain licence that authorises the institution to obtain wholesale supply of that substance, drug or plant, or

(b) a prohibited scheduled substance, prohibited drug or prohibited plant in accordance with a DMT authority that authorises the institution to possess or otherwise deal with that substance or plant.

(2) In this section—

relevant research institution means the following—

(a) a research institution that is a member of the Association of Australian Medical Research Institutes,

(b) a university department or university laboratory,

(c) an approved analytical or research and development laboratory or department,

(d) an approved research institution.

155 Destruction of scheduled substances by NSW Health Pathology and Ambulance Service of NSW

(1) Despite another provision of this part, a member of staff of NSW Health Pathology must destroy a scheduled substance in accordance with the approved pathology standards.

Maximum penalty—Tier 5 penalty.

(2) Despite another provision of this part, a member of staff of, or a volunteer or student engaged by, the Ambulance Service of NSW must destroy a scheduled substance in accordance with the approved ambulance protocol.

Maximum penalty—Tier 5 penalty.

Part 17 Voluntary assisted dying substances

Division 1 Preliminary

156 Interpretation

In this part, the following terms have the same meaning as in the *Voluntary Assisted Dying Act 2022*—

(a) ***administering practitioner***,

(b) ***authorised disposer***,

(c) ***authorised supplier***,

(d) ***contact person***,

(e) ***coordinating practitioner***,

(f) ***health care establishment***,

(g) ***patient***,

(h) ***residential facility***,

(i) ***Voluntary Assisted Dying Board***,

(j) ***voluntary assisted dying substance***.

Note— See the *Voluntary Assisted Dying Act 2022*, section 7, which provides for the approval of a Schedule 4 or 8 substance as a voluntary assisted dying substance.

157 Application of part and regulation

(1) This part applies to—

(a) a prescription for a voluntary assisted dying substance for use under the *Voluntary Assisted Dying Act 2022*, and

(b) a voluntary assisted dying substance prescribed in accordance with the *Voluntary Assisted Dying Act 2022*.

(2) Parts 5, 6 and 12–16 do not apply to such a prescription or substance.

Division 2 Storage of voluntary assisted dying substances—the Act, ss 55 and 150

158 Storage by authorised supplier

(1) An authorised supplier in possession of a voluntary assisted dying substance that is a Schedule 4 substance must store the substance—

(a) apart from food intended for consumption by humans or animals, and

(b) in a room or enclosure to which the public does not have access, and

(c) in a way that, if the substance's container breaks or leaks, the substance cannot mix with or contaminate food intended for consumption by humans or animals.

Maximum penalty—Tier 5 penalty.

(2) An authorised supplier in possession of a voluntary assisted dying substance that is a Schedule 8 substance must store the substance in a receptacle that—

(a) is securely attached to a part of the premises, and

(b) is kept securely locked when not in immediate use, and

(c) is not used to store anything other than Schedule 4 or 8 substances.

Maximum penalty—Tier 5 penalty.

(3) An authorised supplier must ensure—

(a) for a safe that is unlocked by a key or other device—the key or device is kept safely and securely, and

(b) for a safe that is unlocked by a code or combination—the code or combination is not divulged to a person who is not an authorised supplier.

Maximum penalty—Tier 5 penalty.

159 Storage at residential facilities and health care establishments

(1) This section applies to a voluntary assisted dying substance stored at a residential facility or health care establishment on behalf of a patient.

Note— The *Voluntary Assisted Dying Act 2022*, section 89(2)(d) provides a residential facility or health care establishment may refuse to store a voluntary assisted dying substance.

(2) The locked box, in which the substance must be stored under the *Voluntary Assisted Dying Act 2022*, section 79, must be kept—

(a) in a room that is kept securely locked when not in immediate use, or

(b) in a receptacle that is—

(i) securely attached to a part of the premises, and

(ii) kept securely locked when not in immediate use.

160 Keys for storage boxes to be kept securely

A person who receives a voluntary assisted dying substance must ensure—

(a) if the locked box in which the substance must be stored by the *Voluntary Assisted Dying Act 2022*, section 79 is unlocked by a key or other device—the key or device is kept safely and securely, and

(b) if the locked box in which the substance must be stored by the *Voluntary Assisted Dying Act 2022*, section 79 is unlocked by a code or combination—the code or combination is not divulged to a person who is not an authorised supplier.

Maximum penalty—Tier 5 penalty.

Division 3 Records—the Act, s 55

161 Prescriptions to be kept

(1) A coordinating practitioner who issues a prescription for a voluntary assisted dying substance must keep a copy of the prescription.

Maximum penalty—Tier 5 penalty.

(2) An authorised supplier who supplies a voluntary assisted dying substance on prescription must keep the prescription or a copy of the prescription.

Maximum penalty—Tier 5 penalty.

162 Records to be kept by authorised supplier

(1) An authorised supplier must, in accordance with this section, keep a written record of a voluntary assisted dying substance supplied by the authorised supplier.

Maximum penalty—Tier 5 penalty.

(2) The record must include the following—

(a) the name of the substance,

(b) the date on which the substance was supplied,

(c) the name and address of the patient to whom the prescription for the substance was issued,

(d) the quantity of the substance supplied,

(e) the name of the person to whom the substance was supplied,

(f) the name of the coordinating practitioner who issued the prescription for the substance,

(g) the street address of the premises at which the substance was supplied,

(h) the date on which the record is made,

(i) the name and signature of the authorised supplier making the record.

(3) The record must be made as soon as practicable after the authorised supplier supplies the substance.

163 Records to be kept by administering practitioner

(1) An administering practitioner must, in accordance with this section, keep a written record of a voluntary assisted dying substance received, administered and disposed of by the administering practitioner.

Maximum penalty—20 penalty units.

(2) A record of the receipt of a voluntary assisted dying substance must—

(a) include the following—

(i) the name of the substance,

(ii) the date on which the substance was received,

(iii) the quantity of the substance received,

(iv) the name and address of the person from whom the substance was received,

(v) the name of the patient to whom the prescription for the substance was issued,

(vi) the date on which the record is made,

(vii) the name and signature of the administering practitioner making the record, and

(b) be made on the day on which the administering practitioner receives the substance.

(3) A record of the administration of a voluntary assisted dying substance must—

(a) include the following—

(i) the name of the substance,

(ii) the date on which the substance was administered,

(iii) the quantity of the substance administered,

(iv) the name of the patient to whom the substance was administered,

(v) the street address of the premises at which the substance was administered,

(vi) the date on which the record is made,

(vii) the name and signature of the administering practitioner making the record, and

(b) be made on the day on which the administering practitioner administers the substance.

(4) A record of the disposal of a voluntary assisted dying substance must—

(a) include the following—

(i) the name of the substance,
(ii) the date on which the substance was disposed of,
(iii) the quantity of the substance disposed of,
(iv) the means of disposal,
(v) if the substance is disposed of by destruction in accordance with section 166(2)—the name, registration number and signature of the relevant practitioner in whose presence the substance was destroyed,
(vi) the date on which the record is made,
(vii) the name and signature of the administering practitioner making the record, and

(b) be made on the day on which the administering practitioner disposes of the substance.

164 Records to be kept by authorised disposer

(1) An authorised disposer must, in accordance with this section, keep a written record of a voluntary assisted dying substance received for disposal and disposed of by the authorised disposer.

Maximum penalty—Tier 5 penalty.

(2) A record of the receipt of a voluntary assisted dying substance for disposal must—

(a) include the following—
(i) the name of the substance,
(ii) the date on which the substance was received for disposal,
(iii) the quantity of the substance received,
(iv) the name and address of the person from whom the substance was received,
(v) the name and street address of the patient to whom the prescription for the substance was issued,
(vi) the date on which the record is made,
(vii) the name and signature of the authorised disposer making the record, and

(b) be made on the day on which the authorised disposer receives the substance.

(3) A record of the disposal of a voluntary assisted dying substance must—

(a) include the following—
(i) the name of the substance,
(ii) the date on which the substance was disposed of,
(iii) the quantity of the substance disposed of,
(iv) the means of disposal,
(v) if the substance is disposed of by destruction in accordance with section 166(2)—the name, registration number and signature of the relevant practitioner in whose presence the substance was destroyed,
(vi) the date on which the record is made,
(vii) the name and signature of the authorised disposer making the record, and

(b) be made on the day on which the authorised disposer disposes of the substance.

Division 4 Miscellaneous

165 Prescriptions for voluntary assisted dying substances—the Act, ss 10 and 12 and Part 2.5

(1) A prescription for a voluntary assisted dying substance to be used for a purpose under the *Voluntary Assisted Dying Act 2022* must include the following—

(a) the date on which the prescription is issued,

(b) the patient's name, street address and date of birth,

(c) the identification number given to the patient by the Voluntary Assisted Dying Board,

(d) the name, strength and quantity of the voluntary assisted dying substance to be supplied,

(e) adequate directions for use of the voluntary assisted dying substance,

(f) the name, telephone number and practice of the coordinating practitioner who issued the prescription,

(g) the identification number given to the coordinating practitioner by the Voluntary Assisted Dying Board,

(h) the coordinating practitioner's signature.

Maximum penalty—Tier 5 penalty.

Note— The *Voluntary Assisted Dying Act 2022*, section 74 contains other requirements for prescriptions for voluntary assisted dying substances.

(2) Despite another provision of this regulation, if another substance is prescribed for a patient to assist in the administration of the voluntary assisted dying substance, the same prescription may be used for—

(a) the voluntary assisted dying substance, and

(b) the other substance.

166 Disposal of voluntary assisted dying substances—the Act, s 55

(1) An authorised disposer or administering practitioner must not dispose of a voluntary assisted dying substance in a place or in a way likely to constitute a risk to the public.

Maximum penalty—Tier 5 penalty.

(2) An authorised disposer or administering practitioner who destroys a voluntary assisted dying substance must destroy the substance in the presence of—

(a) a medical practitioner, or

(b) a pharmacist, or

(c) a registered nurse.

Maximum penalty—Tier 5 penalty.

Note— The *Voluntary Assisted Dying Act 2022*, sections 80–83 contain other requirements relating to the disposal of voluntary assisted dying substances.

167 Delivery of voluntary assisted dying substances by authorised suppliers—the Act, s 150

(1) A person who supplies a voluntary assisted dying substance must deliver the substance—

(a) personally, or

(b) by carrier.

Maximum penalty—Tier 5 penalty.

(2) An authorised supplier who delivers a voluntary assisted dying substance personally must obtain a signed and dated receipt from the person to whom the substance is supplied.

Maximum penalty—Tier 5 penalty.

(3) An authorised supplier who delivers a voluntary assisted dying substance by carrier must—

(a) obtain and keep written evidence of the consignment of the substance, and

(b) ensure the carrier—

(i) obtains a signed and dated receipt from the person to whom the substance is delivered, and

(ii) gives the receipt to the authorised supplier.

Maximum penalty—Tier 5 penalty.

168 Giving voluntary assisted dying substances to authorised disposers—the Act, s 150

(1) A contact person who gives a voluntary assisted dying substance to an authorised disposer must give the substance to the authorised disposer—

(a) personally, or

(b) by carrier.

Maximum penalty—Tier 5 penalty.

(2) A contact person who gives a voluntary assisted dying substance to an authorised disposer by carrier must—

(a) obtain and keep written evidence of the consignment of the substance, and

(b) ensure the carrier—

(i) obtains a signed and dated receipt from the person to whom the substance is delivered, and

(ii) gives the receipt to the contact person.

Maximum penalty—Tier 5 penalty.

169 Delivery of voluntary assisted dying substances by carriers—the Act, s 150

(1) A carrier is authorised to be in possession of a package containing a voluntary assisted dying substance only for the purpose of giving the substance to the person to whom it is addressed.

(2) An authorised supplier who delivers a voluntary assisted dying substance by carrier must ensure—

(a) the substance is contained in a package that has at least one opaque covering, and

(b) the package contains a document that—

(i) specifies the contents of the package, and

(ii) has the words "VOLUNTARY ASSISTED DYING SUBSTANCE—CHECK CAREFULLY" in bold face sans serif capital letters with a letter height of at least 12.5mm, and

(c) the outside of the package does not indicate that it contains a voluntary assisted dying substance or a Schedule 4 or 8 substance, and

(d) the package is properly addressed to the person to whom the substance is being supplied.

Maximum penalty—Tier 5 penalty.

(3) A contact person who delivers a voluntary assisted dying substance by carrier must ensure—

(a) the substance is contained in a package that has at least one opaque covering, and

(b) the outside of the package does not indicate that it contains a voluntary assisted dying substance or a Schedule 4 or 8 substance, and

(c) the package is properly addressed to the person to whom the substance is being supplied.

Maximum penalty—Tier 5 penalty.

Part 18 Database for activities involving certain Schedule 4 and 8 substances—the Act, ss 10, 12 and 150

170 Definitions

(1) In this part—

data source entity means—

(a) the Australian Health Practitioner Regulation Agency established under the Health Practitioner Regulation National Law, or

(b) a prescription exchange service prescribed by, or otherwise recognised for the purposes of, a law of the Commonwealth or another State or Territory, or

(c) an approved entity.

database means the database established under section 171.

monitored medicine means—

(a) a Schedule 8 substance, and

(b) a Schedule 4 substance specified in the following table—

Benzodiazepine derivative that is a Schedule 4 substance	Bromazepam	Chlordiazepoxide
Clobazam	Clonazepam	Clorazepate
Codeine that is a Schedule 4 substance	Diazepam	Flurazepam
Lorazepam	Medazepam	Midazolam
Nitrazepam	Oxazepam	Prazepam
Pregabalin	Quetiapine	Temazepam
Tramadol	Triazolam	Zolazepam
Zolpidem	Zopiclone	

(2) In this part, a reference to an authorised practitioner does not include a veterinary practitioner.

171 Establishment and purpose of database

(1) The Health Secretary must establish and maintain a database to record data about—

(a) the supply and issue of prescriptions for monitored medicines, and

(b) the supply, administration and issue of prescriptions for scheduled substances in circumstances where the activities require an approval or an OTP registration.

(2) The Health Secretary may enter into an agreement with a person, or a person who engages another person, to operate and maintain the database.

(3) The person may, subject to the terms of the agreement, exercise the functions of the Health Secretary under this part.

172 Recording of information for database by authorised practitioners

(1) This section applies to an authorised practitioner who uses an electronic prescribing system connected to a prescription exchange service operated by a data source entity (a ***prescriber***).

(2) A prescriber who issues a prescription for a monitored medicine must, for the purposes of the database, record the following information—

(a) the full name of the prescriber,

(b) the prescriber's registration number or code recorded in the National Register, as referred to in the Health Practitioner Regulation National Law, section 225(c),

(c) the healthcare identifier for the prescriber and the prescriber's practice, if available,

(d) the contact information for the prescriber and the prescriber's practice, including telephone number or email address,

(e) other approved information about the prescriber or the prescriber's practice,

(f) the date on which the prescription is issued,

(g) the information required to be included in the prescription under sections 50(1) and (2) and 54,

(h) the full name, sex, date of birth and street address of the person to whom the prescription is issued,

(i) other approved information about the person to whom the prescription is issued.

(3) A prescriber who issues a prescription for a monitored medicine may, for the purposes of the database, record the following information about the person to whom the prescription is issued—

(a) the healthcare identifier,

(b) other approved information.

173 Recording of information for database by pharmacists

(1) This section applies to a pharmacist who uses an electronic dispensing system connected to a prescription exchange service operated by a data source entity.

(2) A pharmacist who supplies a monitored medicine must, for the purposes of the database, record the following about the person to whom the monitored medicine is supplied—

(a) the person's full name, sex, date of birth and street address,

(b) other approved information.

(3) A pharmacist who supplies a monitored medicine may, for the purposes of the database, record the following—

(a) the following information about the person to whom the monitored medicine is supplied—

(i) the healthcare identifier,

(ii) other approved information,

(b) the following information about the pharmacist—

(i) full name,

(ii) the registration number or code recorded in the national register under the *Health Practitioner Regulation National Law (NSW)*, section 225(c),

(iii) the healthcare identifier, if available,

(iv) other contact information, including telephone number and email address,

(c) the following information about the healthcare provider organisation from which the monitored medicine was supplied—

(i) the healthcare identifier,

(ii) the organisation's name and address,

(iii) other approved information,

(d) the date on which the monitored medicine was supplied,

(e) the reference number for the prescription for the monitored medicine.

(4) In this section—

healthcare provider organisation has the same meaning as in the *Healthcare Identifiers Act 2010* of the Commonwealth.

174 Recording and including information in database by holders of approvals and OTP registrations

A person who applies for, or holds, an approval or OTP registration for the supply, administration or issue of a prescription for a scheduled substance may, for the purposes of the database, record or include in the database information about—

(a) an application for an approval or OTP registration, or

(b) the revocation of an approval or OTP registration by the Health Secretary.

175 Authority to transfer information

A data source entity is authorised to transfer the following information for inclusion in the database—

(a) information the data source entity receives from an authorised practitioner—

(i) under section 172, or

(ii) who is in another State or Territory when the authorised practitioner issues a prescription for a monitored medicine to a person ordinarily resident in New South Wales,

(b) information the data source entity receives from a pharmacist—

(i) under section 173, or

(ii) who is in another State or Territory if the pharmacist supplies a monitored medicine to a person ordinarily resident in New South Wales,

(c) information the data source entity receives from a person under section 174,

(d) other information received from an authorised practitioner or pharmacist if the information is reasonably required for the operation of the database.

176 Use and disclosure of information by Health Secretary

(1) The Health Secretary may include in the database any information obtained under the Act or this regulation that is relevant for the purposes of the database.

(2) The Health Secretary may use or disclose information in the database for the following purposes—

(a) to operate the database,

(b) to monitor the supply and issue of prescriptions for monitored medicines—

(i) by an authorised practitioner or pharmacist, or

(ii) generally, including Statewide,

(c) to regulate the supply, administration and issue of prescriptions for scheduled substances, in circumstances where the activities require an approval or OTP registration—

(i) by a holder of an approval or OTP registration, or

(ii) generally, including Statewide,

(d) to provide the information, whether directly or through a data source entity, to another State or Territory for inclusion in a database that—

(i) is established under a law of that State or Territory, and

(ii) serves substantially the same purpose as the database,

(e) to provide information to a regulatory authority if the information is reasonably required by the regulatory authority for the purposes of regulating—

(i) the supply, use and issue of prescriptions for monitored medicines, and

(ii) the supply, administration and issue of prescriptions for scheduled substances in circumstances where the activities require an approval or OTP registration,

(f) to provide information to a data source entity for purposes related to—

(i) the monitoring of supply and issue of prescriptions for monitored medicines, and

(ii) determining applications for approvals and OTP registrations and issuing approvals and OTP registrations for the supply, administration and issue of prescriptions for scheduled substances,

(g) to provide information to a public health and diseases register established under the *Public Health Act 2010*,

(h) other lawful purposes.

(3) In this section—

regulatory authority means an entity established under a law of New South Wales, another State or Territory or the Commonwealth with functions that include the regulation of monitored medicines or the regulation of health practitioners.

177 Use and disclosure of information by authorised practitioners and pharmacists

(1) A medical practitioner, nurse practitioner, registered nurse with an endorsement, pharmacist or dentist (a ***relevant person***) may access, use and disclose information in the database for the following purposes—

(a) to provide treatment to a patient by—

(i) reviewing the prescribing of monitored medicines to the patient by other authorised practitioners, and

(ii) reviewing the supply of monitored medicines to the patient by pharmacists,

(b) to provide advice to an authorised practitioner or pharmacist on the treatment of a patient.

(2) A relevant person other than a pharmacist may access, use and disclose information in the database as follows—

(a) for the purposes of applying for or reviewing an approval or OTP registration,

(b) in relation to the revocation of an approval or OTP registration by the Health Secretary.

(3) A pharmacist may access, use and disclose information in the database as follows—

(a) for the purposes of applying for or reviewing an approval or OTP registration that relates to the supply or administration of a scheduled substance by the pharmacist,

(b) in relation to the revocation of an approval or OTP registration that relates to the supply or administration of a scheduled substance by the pharmacist.

178 Unauthorised access to database

(1) A person must not, without lawful excuse, knowingly access, use or disclose information held in the database.

Maximum penalty—Tier 5 penalty.

(2) A lawful excuse includes, but is not limited to, if the person—

(a) is acting under the direction of a medical practitioner, nurse practitioner or dentist, and

(b) accesses, uses or discloses the information on the database in a way authorised under section 177(1) or (2).

Part 19 Applications and fees for licences, approvals and DMT authorities

179 Deemed refusal of applications for licences, approvals and DMT authorities

For the Act, sections 59(3), 70(3) and 77(3), the prescribed period is 90 days.

180 Form of licences and DMT authorities—the Act, s 150(d)

An obtain licence, wholesaler licence, retail licence and DMT authority must be in the approved form.

181 Fees for obtain licences and wholesaler licences—the Act, ss 59(2)(b), 62(1) and 85

The fees for the following are specified in Schedule 1—

(a) an application for an obtain licence or wholesaler licence,

(b) an amendment of an application for an obtain licence or wholesaler licence,

(c) an annual fee for an obtain licence or wholesaler licence,

(d) a variation of an obtain licence or wholesaler licence.

182 Fees for DMT authorities—the Act, ss 77(2)(b) and 85

(1) The fees for the following are specified in Schedule 1—

(a) an application for or renewal of a DMT authority,

(b) an amendment of an application for a DMT authority,

(c) a variation of a DMT authority.

(2) Despite subsection (1)(a), an application fee is not payable by a person or body referred to in section 24(2)(a)–(d).

183 Reduction, postponement, waiver and refund of fees—the Act, s 85(3)

The Health Secretary may reduce, postpone, waive or refund a fee payable under the Act or this regulation.

Part 20 Offences

184 Breaching therapeutic standards—the Act, ss 10, 12 and 150(b) and (c)

(1) An authorised practitioner or pharmacist must not supply a scheduled substance in a quantity, or for a purpose, that does not accord with—

(a) the recognised therapeutic standards of what is appropriate in the circumstances, or

(b) the purpose stated on its container, or

(c) the purpose for which it is normally used.

Maximum penalty—Tier 5 penalty.

(2) An authorised practitioner must not issue a prescription for a scheduled substance in a quantity, or for a purpose, that does not accord with—

(a) the recognised therapeutic standards of what is appropriate in the circumstances, or

(b) the purpose stated on its container, or

(c) the purpose for which it is normally used.

Maximum penalty—Tier 5 penalty.

(3) A person authorised under this regulation to administer a scheduled substance must not administer a Schedule 2, 3, 4 or 8 substance in a quantity, or for a purpose, that does not accord with—

(a) the recognised therapeutic standards of what is appropriate in the circumstances, or

(b) the purpose stated on its container, or

(c) the purpose for which it is normally used.

Maximum penalty—Tier 5 penalty.

185 Documents and records—the Act, s 55(f)

(1) A person who is required by this regulation to keep a record or register must not make an entry in the record or register that the person knows to be false or misleading in a material particular.

Maximum penalty—Tier 5 penalty.

(2) A person must not make an alteration, obliteration or cancellation in a record or register the person is required by this regulation to keep, but may correct a mistake in an entry by making a marginal note or footnote and by initialling and dating it.

Maximum penalty—Tier 5 penalty.

(3) A person who is required by this regulation to keep a document or make a record must keep it for a period of at least 2 years, and must make it available for inspection on demand by a police officer or an authorised officer during that period, commencing on the latest date on which—

(a) an entry was made in the document or record, or

(b) a substance was manufactured, received, supplied, administered or used in accordance with, or on the authority of, the document or record.

Maximum penalty—Tier 5 penalty.

186 Health practitioners must comply with labelling requirements about storage and safe use—the Act, ss 55 and 150(b)

(1) This section applies to scheduled substances or other therapeutic goods used by a health practitioner for the treatment of a person.

(2) The health practitioner must comply with the requirements for storage and safe use specified on the label of the substance or goods.

Maximum penalty—Tier 5 penalty.

187 Pentobarbital for use in animals—the Act, ss 55 and 150(c)

(1) This section applies to pentobarbital obtained by a local council or animal welfare organisation under section 21 for the destruction of an animal.

(2) A local council or animal welfare organisation that obtains pentobarbital must ensure—

(a) access to pentobarbital is only given to a nominated person, and

(b) records are kept regarding—

(i) the amount obtained, and

(ii) the name and street address of the person from whom it was obtained.

(3) A nominated person who uses pentobarbital must—

(a) keep the pentobarbital separately from all other goods in a receptacle that—

(i) is securely attached to a part of the premises of the office of the local council or animal welfare organisation, and

(ii) complies with the medicine storage standards, and

(b) record the following information—

(i) the date on which the record is made,

(ii) the amount of pentobarbital used,

(iii) the number and species of animals for which it was used,

(iv) the total quantity of pentobarbital in the possession of the nominated person after the record is made,

(v) the nominated person's name and signature.

Maximum penalty—Tier 5 penalty.

(4) A nominated person complies with subsection (3)(a)(i) by keeping pentobarbital, for emergency use, in a bag that is in a room or vehicle that is kept locked when not occupied by the person.

(5) In this section—

nominated person means—

(a) a veterinary practitioner employed or engaged by the local council or animal welfare organisation, or

(b) a person employed or engaged by the local council or animal welfare organisation who, in the opinion of the veterinary practitioner, demonstrates competency in the use of pentobarbital for the humane destruction of animals.

188 Medicines management in managed correctional centres—the Act, s 150(c)

(1) The management company for a managed correctional centre must ensure policies and procedures in relation to the following are maintained and implemented at the managed correctional centre—

(a) compliance with the Act and this regulation,

(b) obtaining wholesale supply of scheduled substances and therapeutic goods,

(c) prescribing and administering scheduled substances and therapeutic goods,

(d) ensuring safe and secure storage and access to scheduled substances and therapeutic goods,

(e) storage of medicines.

Maximum penalty—Tier 5 penalty.

(2) The policies and procedures must be approved by a committee established for the managed correctional centre.

(3) The committee for a managed correctional centre must consist of at least one medical practitioner who does not have a pecuniary interest in the management company for the managed correctional centre.

189 Medicines management in private health facilities—the Act, s 150(c)

(1) The licensee of a private health facility must ensure policies and procedures in relation to the following are maintained and implemented at the private health facility—

(a) compliance with the Act and this regulation,

(b) administering scheduled substances and therapeutic goods,

(c) ensuring safe and secure storage and access to scheduled substances and therapeutic goods,

(d) storage of medicines,

(e) compliance with approved standards in relation to the compounding and preparation of pharmaceutical and advanced therapeutic goods,

(f) the destruction of remaining substances.

Maximum penalty—Tier 5 penalty.

(2) The policies and procedures must be approved by the medical advisory committee appointed for the private health facility under the *Private Health Facilities Act 2007*, section 39.

190 Delivery of Schedule 8 or 9 substances—the Act, s 150(b)

(1) A person who supplies a Schedule 8 or 9 substance must deliver the substance—

(a) personally, or

(b) by registered mail, or

(c) by carrier.

Maximum penalty—Tier 5 penalty.

(2) A person who delivers a Schedule 8 or 9 substance personally must obtain a signed and dated receipt from the person to whom the substance is supplied.

Maximum penalty—Tier 5 penalty.

(3) A person who delivers a Schedule 8 or 9 substance by carrier must—

(a) obtain and keep written evidence of the consignment of the substance, and

(b) ensure the carrier—

(i) obtains a signed and dated receipt from the person to whom the substance is delivered, and

(ii) gives the receipt to the person who delivered the substance.

Maximum penalty—Tier 5 penalty.

191 Delivery of Schedule 8 or 9 substances by carriers—the Act, s 150(b)

(1) A carrier is authorised to be in possession of a package containing a Schedule 8 or 9 substance only for the purpose of giving the substance to the person to whom it is addressed.

(2) A person who delivers a Schedule 8 or 9 substance by carrier must ensure—

(a) the substance is contained in a package that has at least one opaque covering, and

(b) the package contains a document that—

(i) specifies the contents of the package, and

(ii) has the words "SCHEDULE 8/9—CHECK CAREFULLY" in bold face sans serif capital letters with a letter height of at least 12.5mm, and

(c) the outside of the package does not indicate that it contains a Schedule 8 or 9 substance, and

(d) the package is properly addressed to the person to whom the substance is being supplied.

Maximum penalty—Tier 5 penalty.

(3) This section does not prevent a person who delivers a Schedule 8 or 9 substance by carrier from supplying a Schedule 8 or 9 substance by means of a separately wrapped inner package within an outer package containing other goods so long as—

(a) a document listing the contents of the inner package is contained in the inner package, and

(b) the inner package is marked with the words "SCHEDULE 8/9—CHECK CAREFULLY" in bold face sans serif capital letters with a letter height of at least 12.5mm, and

(c) the outside of the outer package does not indicate that it contains a Schedule 8 or 9 substance, and

(d) the outer package is properly addressed to the person to whom the substance is being supplied.

Maximum penalty—Tier 5 penalty.

192 Restrictions on retail supply—the Act, s 150(b)

A person must not supply a scheduled substance—

(a) to a person in another State or a Territory, unless the person being supplied with the substance is authorised by a law of that State or Territory to obtain or supply the substance, or

(b) to a person outside Australia, unless the person supplying the substance is authorised to do so by a law of the Commonwealth.

Maximum penalty—Tier 5 penalty.

193 Restrictions on self-administration—the Act, s 150(c)

(1) An authorised practitioner must not issue a prescription for a Schedule 4D or 8 substance for the practitioner's own use.

Maximum penalty—Tier 5 penalty.

(2) An authorised practitioner must not obtain wholesale supply of a Schedule 4D or 8 substance for the practitioner's own use.

Maximum penalty—Tier 5 penalty.

194 Receipt of wholesale supply of Schedule 8 substances—the Act s 150(b)

(1) A person authorised to receive a Schedule 8 substance (an ***authorised person***), who orders and receives a Schedule 8 substance from a supplier, must give a written notice to the supplier of the receipt of the substance within 24 hours after the receipt.

Maximum penalty—Tier 5 penalty.

(2) The supplier must keep a copy of the notice and not supply any further Schedule 8 substances under that order.

Maximum penalty—Tier 5 penalty.

(3) If the supplier does not receive written notice under subsection (1) within 7 days after the drug being supplied, the supplier must notify the Health Secretary.

Maximum penalty—Tier 5 penalty.

195 Supplying or prescribing unregistered goods—the Act, s 12

(1) An authorised practitioner must not supply or prescribe scheduled substances that are not registered goods unless the authorised practitioner is a medical practitioner, nurse practitioner, dentist, podiatrist with an endorsement, or optometrist with an endorsement

Maximum penalty—Tier 5 penalty.

(2) A registered health practitioner must not administer scheduled substances that are not registered goods unless the registered health practitioner is—

(a) a medical practitioner, nurse practitioner, dentist, podiatrist with an endorsement or optometrist with an endorsement, or

(b) acting under the direction of a medical practitioner, nurse practitioner or dentist, or

(c) for a Schedule 2, 3 or 4 substance—acting under the direction of a podiatrist with an endorsement or optometrist with an endorsement.

(3) This section does not apply to a veterinary practitioner.

(4) In this section—

registered goods has the same meaning as in the Commonwealth Therapeutic Goods Act.

196 Penalty notice offences

(1) For the Act, section 121—

(a) each offence created by a provision specified in Schedule 2 is an offence for which a penalty notice may be issued, and

(b) the amount payable for the penalty notice is the amount specified opposite the provision.

(2) If the provision is qualified by words that restrict its operation to limited kinds of offences or to offences committed in limited circumstances, the penalty notice may be issued only for—

(a) that limited kind of offence, or

(b) an offence committed in those limited circumstances.

Part 21 Miscellaneous

197 Exemptions—the Act, s 10(2)(d)

(1) The Health Secretary may, by written order, exempt a person, or class of persons, from a provision of Part 2–8, 10–16 or 18 or section 195.

(2) An exemption may be given—

(a) unconditionally or subject to conditions, or

(b) in relation to a substance or class of substances.

(3) An exemption in force under a law of the Commonwealth or of another State or Territory corresponding to this section in relation to a provision of Part 14 has the same effect as an exemption under this section.

(4) The Health Secretary may, by order published in the Gazette, declare that subsection (3) does not apply to a specified exemption to a provision of Part 14.

198 Exceptions to offence of non-wholesale supply of unregistered or unlisted therapeutic goods

For the Act, section 44(2)(f), the supply and administration of the following is prescribed—

(a) therapeutic goods if—

(i) the registration or listing has been cancelled under the Commonwealth Therapeutic Goods Act, and

(ii) the Secretary under the Commonwealth Therapeutic Goods Act has not required the therapeutic goods to be recalled under that Act,

(b) therapeutic goods that are biologicals within the meaning of the Commonwealth Therapeutic Goods Act.

199 Modification of Commonwealth therapeutic goods laws relating to advertising—the Act, s 86

(1) The *Therapeutic Goods Regulations 1990* of the Commonwealth, Part 2 is modified in its application as a law of New South Wales to enable the Health Secretary, by written order, to exempt a person or substance, or a class of persons or substances, from a requirement of that part.

(2) An exemption may be given unconditionally or subject to conditions.

200 Forfeiture of seized things

It is a ground for the Act, section 107(2)(e) if the seized thing cannot lawfully be supplied or used by the owner of the seized thing.

201 Regulatory Advisory Committee

For the Act, section 127(7), qualifications and experience in toxicovigilance and the assessment and management of persons exposed to poisons and possible poisons are prescribed.

Schedule 1 Fees

sections 39, 181 and 182

Item	Matter for which fee is payable	Fee
1	Application for retail licence for Schedule 2 substance	$330
2	Application for retail licence for Schedule 7J substance	$330
3	Annual fee for retail licence for Schedule 2 substance	$330
4	Annual fee for retail licence for Schedule 7J substance	$330
5	Application for obtain licence for Schedule 2, 3 and 4 substances	$1,650
6	Application for obtain licence for Schedule 7J substance	$330
7	Application for obtain licence for Schedule 10 substance	$330
8	Application for obtain licence for Schedule 8 substance	$2,930
9	Application for obtain licence for Schedule 9 substance	$2,930
10	Annual fee for obtain licence for Schedule 2, 3 and 4 substances	$1,250
11	Annual fee for obtain licence for Schedule 7J substance	$330
12	Annual fee for obtain licence for Schedule 10 substance	$330
13	Annual fee for obtain licence for Schedule 8 substance	$2,520
14	Annual fee for obtain licence for Schedule 9 substance	$2,520
15	Application for wholesaler licence for Schedule 2, 3 and 4 substances	$1,650
16	Application for wholesaler licence for Schedule 7J substance	$770
17	Application for wholesaler licence for Schedule 10 substance	$770
18	Application for wholesaler licence for Schedule 8 substance	$2,930
19	Application for wholesaler licence for Schedule 9 substance	$2,930
20	Annual fee for wholesaler licence for Schedule 2, 3 and 4 substances	$1,250
21	Annual fee for wholesaler licence for Schedule 7J substance	$330
22	Annual fee for wholesaler licence for Schedule 10 substance	$330
23	Annual fee for wholesaler licence for Schedule 8 substance	$2,520
24	Annual fee for wholesaler licence for Schedule 9 substance	$2,520
25	Application for or renewal of DMT authority	$1,464
26	Amendment of application for retail licence, obtain licence, wholesaler licence or DMT authority	50% of application fee
27	Variation of retail licence, obtain licence or wholesaler licence	50% of annual fee
28	Variation of DMT authority	50% of application fee

Schedule 2 Penalty notice offences

section 196

Column 1 Provision	Column 2 Penalty for an individual	Column 3 Penalty for a corporation
Offences under the Act		
Section 45(1) (Offence—supply of expired therapeutic goods)	2 penalty units	10 penalty units
Section 54(3), in relation to a contravention of this regulation, section 91, 92 or 93(2) (Regulations about scheduled substances used for cosmetic purposes)	5 penalty units	50 penalty units
Section 60(3) (Conditions of licence)	2 penalty units	10 penalty units
Section 71(3) (Conditions of approval)	2 penalty units	10 penalty units
Section 79(3) (Conditions of DMT authority)	2 penalty units	10 penalty units
Section 115(6) (Compliance notices)	5 penalty units	25 penalty units
Offences under this regulation		
Section 33(2) (Non-wholesale supply by pharmacists without prescription)	2 penalty units	10 penalty units
Section 39(8) (Retail licences for Schedule 2 and 7J substances)	2 penalty units	10 penalty units
Section 46(1) (Issue of prescriptions by dentists)	2 penalty units	10 penalty units
Section 46(3) (Issue of prescriptions by dentists)	2 penalty units	10 penalty units
Section 48(1) (Schedule 4 and 8 substances must be supplied on proper prescription)	2 penalty units	10 penalty units
Section 49(1) (Expiry of prescriptions)	2 penalty units	10 penalty units
Section 49(2) (Expiry of prescriptions)	2 penalty units	10 penalty units
Section 57(1) (Pharmacists must keep copies of certain prescriptions)	2 penalty units	10 penalty units
Section 57(2) (Pharmacists must keep copies of certain prescriptions)	2 penalty units	10 penalty units
Section 109(1) (Drug registers for Schedule 8 substances)	2 penalty units	10 penalty units
Section 110(1) (Entries in drug registers for Schedule 8 substances)	2 penalty units	10 penalty units
Section 110(2) (Entries in drug registers for Schedule 8 substances)	2 penalty units	10 penalty units
Section 110(3) (Entries in drug registers for Schedule 8 substances)	2 penalty units	10 penalty units
Section 110(4) (Entries in drug registers for Schedule 8 substances)	2 penalty units	10 penalty units
Section 111(1) (Inventories of Schedule 8 substances)	2 penalty units	10 penalty units
Section 111(2) (Inventories of Schedule 8 substances)	2 penalty units	10 penalty units
Section 112 (Loss or destruction of drug registers for Schedule 8 substances)	2 penalty units	10 penalty units

Column 1	Column 2	Column 3
Provision	**Penalty for an individual**	**Penalty for a corporation**
Section 118(2) (Storage requirements generally)	2 penalty units	10 penalty units
Section 120(1) (Storage requirements for Schedule 6 substances)	2 penalty units	10 penalty units
Section 121 (Storage requirements for Schedule 7 substances)	2 penalty units	10 penalty units
Section 122(2) (Storage requirements for Schedule 8 substances in pharmacies)	2 penalty units	10 penalty units
Section 124(1) (Storage requirements for Schedule 8 substances in other places)	2 penalty units	10 penalty units
Section 133 (Misleading labelling of scheduled substances)	2 penalty units	10 penalty units
Section 134(2) (Additional requirements for authorised practitioners and pharmacists)	2 penalty units	10 penalty units
Section 135(1) (Additional requirements for Schedule 3 substances)	2 penalty units	10 penalty units
Section 135(2) (Additional requirements for Schedule 3 substances)	2 penalty units	10 penalty units
Section 136(1) (Additional requirements for dose administration aids)	2 penalty units	10 penalty units
Section 136(2) (Additional requirements for dose administration aids)	2 penalty units	10 penalty units
Section 136(3) (Additional requirements for dose administration aids)	2 penalty units	10 penalty units
Section 142(2) (Preparation and handling of exposed substances)	2 penalty units	10 penalty units
Section 142(3) (Preparation and handling of exposed substances)	2 penalty units	10 penalty units
Section 142(4) (Preparation and handling of exposed substances)	2 penalty units	10 penalty units
Section 144(1) (Animals and vermin)	2 penalty units	10 penalty units
Section 144(2) (Animals and vermin)	2 penalty units	10 penalty units
Section 185(2) (Documents and records)	2 penalty units	10 penalty units

Schedule 3 Savings, transitional and other provisions

Part 1 Provisions consequent on commencement of Act and regulation—the Act, Sch 2, s 1

1 Definitions

(1) In this part—

commencement date means the date on which this schedule commences.

former Act means the *Poisons and Therapeutic Goods Act 1966*.

former regulation means the *Poisons and Therapeutic Goods Regulation 2008*.

new Act means the *Medicines, Poisons and Therapeutic Goods Act 2022*.

(2) In this part, a reference to the Opioid Treatment Program includes a reference to the Opioid Treatment Program referred to in the former regulation, clause 166(4), in operation before the commencement date.

2 General savings

(1) A licence or authority that, immediately before the repeal of the former Act, was in force under the former Act remains in force, subject to any existing conditions under the former Act, until the earlier of the following—

(a) the licence or authority expires,

(b) the licence or authority is suspended or cancelled by the Health Secretary.

(2) Subsection (1) does not apply to a licence or authority otherwise dealt with by the this schedule or the Act, Schedule 2.

(3) This section is repealed 2 years after the commencement date.

3 Existing exemptions

An exemption granted under the former Act that, immediately before the repeal of the former Act, was in force under the former Act remains in force, subject to any existing conditions under the former Act, until the earlier of the following—

(a) 2 years after the commencement date,

(b) the exemption is revoked by the Health Secretary.

4 Existing prescriptions

(1) Despite section 49, a prescription issued under the former Act or former regulation may be validly dispensed for up to—

(a) for a Schedule 4 substance—12 months after the date of issue for the prescription, or

(b) for a Schedule 8 substance—6 months after the date of issue for the prescription.

(2) Subsection (1) does not apply if a shorter period of validity is specified on the prescription.

5 Existing retail licences for Schedule 2 substances

(1) This section applies to a person who, immediately before the commencement date, held a licence to supply a Schedule 2 substance from a retail shop under the former regulation, Part 8 (an ***existing licence***).

(2) The person is taken, on the commencement date, to hold a retail licence under this regulation that authorises the person to supply the Schedule 2 substance.

(3) The retail licence is subject to the same conditions, if any, of the existing licence.

(4) The retail licence remains in force until the earlier of the following—

(a) the end of the period specified in the existing licence, if any,

(b) the surrender of the retail licence by the holder,

(c) the revocation of the retail licence by the Health Secretary under this regulation.

6 Existing authorities under former Act, section 29

(1) A medical practitioner or nurse practitioner who, immediately before the commencement date, held an authority issued under the former Act, section 29 (an ***existing authority***) to supply or issue a prescription for a Schedule 8 substance, other than to a drug-dependent person as part of the Opioid Treatment Program, is taken, on the commencement date, to hold an approval under the new Act to supply, administer or issue a prescription for the same Schedule 8 substance to a patient.

(2) The approval is subject to the same conditions, if any, of the existing authority.

(3) The approval remains in force until the earlier of the following—

(a) the end of the period specified in the existing authority, if any,

(b) the surrender of the approval by the holder,

(c) the revocation of the approval by the Health Secretary under the new Act.

7 Existing authorities under former Act, section 29 for Opioid Treatment Program

(1) This section applies to a medical practitioner or nurse practitioner who, immediately before the commencement date, held an authority issued under the former Act, section 29 (an ***existing authority***) to supply or issue a prescription for a Schedule 8 substance to a drug-dependent person as part of the Opioid Treatment Program.

(2) The medical practitioner or nurse practitioner is taken, on the commencement date, to hold an OTP registration under the new Act to supply or issue a prescription for the same Schedule 8 substance.

(3) The OTP registration is subject to the same conditions, if any, of the existing authority.

(4) The OTP registration, and any conditions of the OTP registration, may be varied by the Health Secretary in accordance with this regulation.

(5) The OTP registration remains in force until the earlier of the following—

(a) the end of the period specified in the existing authority, if any,

(b) the surrender of the OTP registration by the holder,

(c) the suspension or revocation of the OTP registration by the Health Secretary under this regulation.

8 Existing DMT authorities

(1) This section applies to an authority issued under the following provisions of the *Drug Misuse and Trafficking Act 1985* (an ***existing DMT authority***) that, immediately before the commencement date, was in force under that Act—

(a) section 10(2)(b),

(b) section 11(2)(c),

(c) section 11(2)(d),
(d) section 11C(2)(b),
(e) section 13(2)(a),
(f) section 13(2)(b),
(g) section 18B(4)(b),
(h) section 23(4)(b),
(i) section 24(4)(b),
(j) section 24A(2)(b),
(k) section 25(4)(b),
(l) section 25A(9)(b).

(2) An existing DMT authority is, on and from the commencement date, taken to be a DMT authority issued under the new Act, Part 3.5.

(3) The DMT authority is subject to the conditions, if any, of the existing DMT authority.

(4) The DMT authority, and any conditions of the DMT authority, may be varied or revoked by the Health Secretary in accordance with the new Act and this regulation.

9 Possession of prohibited drugs

For the *Drug Misuse and Trafficking Act 1985*, section 10, a person licensed or authorised to have possession of the prohibited drug under the former Act is taken to be licensed or authorised to have possession of the prohibited drug under the new Act.

Schedule 4 Dictionary

section 3(1)

administering practitioner, for Part 17—see section 156.

animal welfare organisation means an approved charitable organisation within the meaning of the *Prevention of Cruelty to Animals Act 1979*.

approval exemption means an exemption from the requirement to have an approval for an activity, as referred to in section 77 or 79.

approved means approved by the Health Secretary from time to time and generally or in a particular case, unless otherwise indicated.

approved ambulance protocol means the protocol prepared by the Ambulance Service of NSW, approved by the Health Secretary from time to time.

approved pathology standards means the standards prepared by NSW Health Pathology, approved by the Health Secretary from time to time.

approved provider has the same meaning as in the *Aged Care Act 2024* of the Commonwealth.

authorised disposer, for Part 17—see section 156.

authorised person, for a residential care facility, has the same meaning as in the Act, section 23.

authorised supplier, for Part 17—see section 156.

conformant electronic prescription means an electronic prescription issued using an approved electronic prescribing system.

contact person, for Part 17—see section 156.

container, for Part 10—see section 95.

coordinating practitioner, for Part 17—see section 156.

cosmetic use substance, for Part 9—see section 86.

data source entity, for Part 18—see section 170.

database, for Part 18—see section 170.

dealer, for Part 10—see section 95.

Dental Schedule of Pharmaceutical Benefits means the items listed in the Schedule of Pharmaceutical Benefits that can be prescribed by an authorised dental practitioner under the *National Health Act 1953* of the Commonwealth.

dose administration aid or ***DAA*** means a device or packaging system for organising doses of medicine for a patient according to the time of administration to assist the management of the patient's medicine.

drug register means a register of Schedule 8 substances kept in accordance with Part 11.

endorsement means an endorsement on the registration of a health practitioner, of a kind specified in the Health Practitioner Regulation National Law, section 94.

exposed substance means a therapeutic good, or a substance used in the preparation of a therapeutic good, that is unpackaged or otherwise susceptible to contamination, but does not include a medical device.

family member has the same meaning as in the *Voluntary Assisted Dying Act 2022*.

first aid means immediate, acute treatment or care of a person who is suffering an illness or injury.

first aider means a person who—

(a) is a worker within the meaning of the *Work Health and Safety Act 2011*, and

(b) has been appointed by the person for whom they work to provide first aid.

food and drink related supply, for Part 10, Division 3—see section 102.

food business, for Part 10, Division 3—see section 102.

healthcare identifier means the healthcare identifier assigned to an individual healthcare provider, known as HPI-I, or a healthcare provider organisation, known as HPI-O, under the *Healthcare Identifiers Act 2010* of the Commonwealth.

health service has the same meaning as in the *Health Care Complaints Act 1993*.

licensee, of a private health facility, means the licensee of the private health facility under the *Private Health Facilities Act 2007*.

liquor licence, for Part 10, Division 3—see section 102.

medicine storage standards means approved standards relating to the storage of scheduled substances.

member of staff includes an employee or contractor.

monitored medicine, for Part 18—see section 170.

morphine equivalent maximum dose of morphine, oxycodone, fentanyl or hydromorphone means—

(a) 100mg oral morphine equivalent daily dose (oMEDD), or

(b) if the patient is being treated with more than one of morphine, oxycodone, fentanyl or hydromorphone—a dose that would in effect be equivalent to the dose in paragraph (a) when considered in combination with the other doses.

National Medical Stockpile means premises operated by or on behalf of the Commonwealth for the storage of scheduled substances and other therapeutic goods, including vaccines, and other medical or public health supplies, for the purposes of responding to a public health emergency, including an emergency arising from a natural disaster or terrorist incident.

nominated Schedule 4 substance means the following Schedule 4 substances—

acitretin, alefacept, ambrisentan, bexarotene, bosentan, clomifene, corifollitropin alfa, cyclofenil, dinoprost, dinoprostone, enzalutamide, etretinate, follitropin alpha, follitropin beta, follitropin delta, isotretinoin for oral use, lenalidomide, luteinising hormone, macitentan, riociguat, sitaxentan, teriparatide, thalidomide, tretinoin for oral use, urofollitropin.

NSW Health Pathology means the division of the Health Administration Corporation, constituted under the *Health Administration Act 1982*, section 9, known as NSW Health Pathology.

OTP clinic means a clinic or other facility, at which activities in the Opioid Treatment Program are carried out, operated by—

(a) a private OTP clinic, or

(b) a public OTP clinic.

partner, of a patient, includes the following—

(a) the patient's spouse or de facto partner,

(b) a person with whom the patient is or was in a sexual relationship.

patient, for Part 17—see section 156.

principal place of practice, for a person who is a registered health practitioner under the *Health Practitioner Regulation National Law (NSW)*, has the same meaning as in that Law.

private OTP clinic means an OTP clinic operated by a provider under the Opioid Treatment Program who is the holder of the obtain licence as referred to in the Act, section 57(2)(a)(i).

prohibited plant has the same meaning as in the *Drug Misuse and Trafficking Act 1985*.

public hospital pharmacy means a pharmacy in a public hospital within the meaning of the *Health Services Act 1997*.

public OTP clinic means an OTP clinic operated by a public health entity.

purchaser, for Part 10—see section 95.

receptacle includes a safe and a cupboard.

registered training organisation has the same meaning as in the *National Vocational Education and Training Regulator Act 2011* of the Commonwealth.

relevant place, for Part 11—see section 106.

relevant purpose has the same meaning as in the Act, section 76.

responsible person, for Part 11—see section 106.

responsible provider, for Part 9—see section 86.

retail licence—see section 39(1).

Schedule 7J substance means a Schedule 7 substance specified in Appendix J of the Commonwealth Poisons Standard.

Schedule 7J"a" substance means a Schedule 7 substance marked with "a" in column 2 of Appendix J of the Commonwealth Poisons Standard.

substance dependence, on a prohibited scheduled substance or prohibited drug, means—

(a) a substance dependence on a prohibited scheduled substance or prohibited drug according to the *International Classification of Diseases*, 11th revision, or

(b) a moderate to severe substance use disorder relating to a prohibited scheduled substance or prohibited drug according to the *Diagnostic and Statistical Manual of Mental Disorders*, 5th edition.

supplier means—

(a) for Part 13—see section 118, and

(b) for Part 14—see section 131.

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

veterinary hospital has the same meaning as in the *Veterinary Practice Act 2003*.

voluntary assisted dying substance, for Part 17—see section 156.