New South Wales

Medicines, Poisons and Therapeutic Goods Regulation 2023

under the

Medicines, Poisons and Therapeutic Goods Act 2022

[*The following enacting formula will be included if this regulation is made*—]

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*.

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 regulation is made under the provisions of the *Medicines, Poisons and Therapeutic Goods Act 2022* specified throughout the regulation.

Contents

Page

Part 1 Preliminary

1 Name of regulation 8
2 Commencement 8
3 Definitions 8
4 Public health entities 8
5 Schedule 4D substances 9
6 Veterinary practitioners and etorphine—the Act, s 6 13
7 References to publications in force from time to time 13

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

Division 1 Wholesale supply by pharmacists

8 Wholesale supply by pharmacy businesses 14
9 Wholesale supply between pharmacists 14
10 Wholesale supply by pharmacists for urgent use in residential care facilities 15
11 Wholesale supply by pharmacists to authorised practitioners 15
12 Wholesale supply by pharmacists to registered nurses and midwives providing vaccines in pharmacies 15
13 Wholesale supply by pharmacists to first aiders 15
14 Wholesale supply by pharmacists to masters of vessels 16

Division 2 Other wholesale supply

15 Wholesale supply by National Medical Stockpile 17
16 Unauthorised wholesale supply of samples 17
17 Wholesale supply by certain affiliated health organisations to public health entities 18

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

Division 1 Obtaining wholesale supply generally

18 Obtaining wholesale supply by health practitioners 19
19 Obtaining wholesale supply by various persons and bodies 19
20 Obtaining wholesale supply by first aiders 20

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

21 Obtain licences for Schedule 4D, 8 and 9 substances required for certain research institutions 21
22 Obtaining wholesale supply by research institutions, universities and laboratories 21

Division 3 Other

23 Health Secretary may authorise obtaining wholesale supply—the Act, s 10(2) 22

Page

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

Division 1 Non-wholesale supply generally

24 Non-wholesale supply under direction 23
25 Non-wholesale supply of buprenorphine and methadone at OTP clinics 23
26 Non-wholesale supply of Schedule 7 substances 24
27 Non-wholesale supply by midwife practitioners 24
28 Non-wholesale supply by dentists 24

Division 2 Non-wholesale supply by pharmacists

29 Non-wholesale supply by pharmacists without prescription 24
30 Non-wholesale supply by pharmacists in emergencies and urgent circumstances 24
31 Non-wholesale supply by pharmacists approved under Commonwealth National Health Act 1953 without prescription 25

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

32 Retail sale of Schedule 2 and 7J substances 25
33 Retail licences for Schedule 2 and 7J substances 25
34 Restriction on retail licences for Schedule 2 substances 26

Division 4 Other

35 Restriction on non-wholesale supply of certain Schedule 4 and 8 substances 26
36 Health Secretary may authorise non-wholesale supply—the Act, s 10(2) 27

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

Division 1 General

37 Midwife practitioners may issue prescriptions 29
38 Restriction on issue of prescriptions for certain Schedule 4 and 8 substances 29
39 Issue of prescriptions by dentists 29

Division 2 General requirements for prescriptions

40 Types of prescriptions 30
41 Schedule 4 and 8 substances must be supplied on proper prescription 30
42 Schedule 4 and 8 substances must be supplied on proper medication chart prescription 30
43 Expiry of prescriptions 30

Division 3 Form and content of prescriptions

44 Information to be specified in prescriptions 31
45 Requirements for paper prescriptions 31
46 Requirements for printed electronic prescriptions 31
47 Requirements for conformant electronic prescriptions 32

Division 4 Additional requirements for prescriptions

48 Prescriptions for high or unusual doses 32

Page

49 Prescriptions issued by dentists, optometrists, podiatrists and veterinary practitioners 32
50 Approval number for prescriptions for certain Schedule 4 and 8 substances 33
51 Prescriptions for azithromycin for treatment of chlamydia 33
52 Prescriptions issued by veterinary practitioners 33

Division 5 Email and facsimile prescriptions

53 Email and facsimile prescriptions 33
54 Email, facsimile and photocopies of medication chart prescriptions 34

Division 6 Records and verification of prescriptions

55 Pharmacists must verify prescriptions for Schedule 8 substances 34
56 Pharmacists must keep certain prescriptions 34
57 Information about supply to be recorded on prescriptions 34
58 Records of prescriptions 35

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

59 Unauthorised administration of scheduled substances 36
60 Administration by registered health practitioners 36
61 Administration by health practitioners 36
62 Administration by staff at public health entities, private health facilities and other places 36
63 Administration by first aiders 37
64 Administration by carers 37
65 Administration at schools and child care facilities 37
66 Administration by Ambulance Service of NSW staff 37
67 Administration by Royal Flying Doctor Service 37
68 Administration of buprenorphine and methadone at OTP clinics 38
69 Administration of vaccines by pharmacists 38
70 Administration by NSW Police Force dive medical technicians 38
71 Administration of Schedule 8 substances by dentists 38
72 Restriction on administration of certain Schedule 4 and 8 substances 38
73 Health Secretary may authorise administration—the Act, s 10(2) 39

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

74 Schedule 4 and 8 substances that require approvals—the Act, s 67(1) 41
75 Approvals required for activities involving Schedule 4 substances—the Act, s 69(1) 41
76 Approvals for Schedule 4 substances not required in certain circumstances—the Act, s 69(1) 41
77 Approvals required for activities involving Schedule 8 substances—the Act, s 69(1) 42
78 Approvals for Schedule 8 substances not required in certain circumstances—the Act, s 69(1) 43

Part 8 Compounding of Schedule 4D and 8 substances—the Act, s 55

79 Compounding of Schedule 4D and 8 substances 45
80 Health Secretary may authorise compounding of Schedule 4D and 8 substances—the Act, s10(2) 45

Page

Part 9 Opioid Treatment Program—the Act, Part 3.4

81 Substances under Opioid Treatment Program 46
82 Compliance standards for Opioid Treatment Program 46
83 Circumstances in which OTP registration is not required 46
84 Suspension and revocation of OTP registrations—the Act, s74(3)(c) 47

Part 10 Cosmetic use substances—the Act, s 54

85 Definitions 48
86 Administration of cosmetic use substances 48
87 Administration by nurses under direction of medical practitioners and nurse practitioners 48
88 Content of directions 49
89 Records of directions 49
90 Storage 50
91 Duties of responsible providers 50
92 Category 1 and category 2 requirements 50

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

93 Definitions 51
94 Application of part to storage of Schedule 8 substances at certain places 51
95 Persons responsible for drug registers 51
96 Drug registers for Schedule 8 substances 52
97 Entries in drug registers for Schedule 8 substances 52
98 Inventories of Schedule 8 substances 53
99 Loss or destruction of drug registers for Schedule 8 substances 54

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

100 Records of supply by authorised practitioners 55
101 Records of supply by pharmacists on prescription 55
102 Records of supply by pharmacists on medication chart prescriptions 55
103 Records of supply by pharmacists in emergencies and urgent circumstances 55
104 Records of supply and administration on medication charts at residential care facilities 56
105 Records of supply and administration on medication charts at managed correctional centres 56

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

Division 1 Storage requirements

106 Storage requirements generally 57
107 Storage requirements for Schedule 8 substances in pharmacies 57
108 Storage requirements for Schedule 4D and 8 substances in hospitals and other places 58
109 Storage requirements for Schedule 8 substances in other places 59

Division 2 Responsibilities for storage

110 Responsibility for storage in public hospitals and private health facilities 60

Page

111 Responsibility for storage in OTP clinics 60
112 Responsibility for storage in residential care facilities 60
113 Responsibility for storage in managed correctional centres 60

Division 3 Other

114 Wholesaler licence holders must comply with Commonwealth Code of Practice 61

Part 14 Labelling of scheduled substances—the Act, ss 55 and 150

Division 1 Labelling requirements for suppliers of scheduled substances

115 Application of division 62
116 Labelling of scheduled substances 62
117 Misleading labelling of scheduled substances 62
118 Additional requirements for authorised practitioners and pharmacists 62
119 Additional requirements for Schedule 3 substances 62

Division 2 Dose administration aids

120 Additional requirements for dose administration aids 63
121 Third party DAA manufacturing services 63

Division 3 Labelling of unscheduled therapeutic goods

122 Labelling of unscheduled therapeutic goods 64

Part 15 Preparation and handling of scheduled substances—the Act, ss 55 and 150

123 Preparation and handling of exposed substances 65
124 Personal cleanliness and contact with hands 65
125 Animals and vermin 65
126 Responsibilities of health service providers 66

Part 16 Destruction of scheduled substances—the Act, s 55

127 Disposal of scheduled substances generally 67
128 Destruction of Schedule 8 substances 67
129 Destruction of Schedule 8 substances at pharmacies 67
130 Destruction of Schedule 8 substances by pharmacists on request of authorised practitioners 68
131 Destruction of Schedule 8 substances at public health entities 68
132 Destruction of Schedule 8 substances in public hospital wards 69
133 Destruction of Schedule 8 substances by pharmacists at private health facilities and residential care facilities 69
134 Destruction of Schedule 8 substances in private health facilities and managed correctional centres 70
135 Destruction of prohibited substances, drugs and plants at research institutions, universities and laboratories 70

Part 17 Database for activities involving certain Schedule 4 and 8 substances—the Act, ss 10, 12 and 150

136 Definitions 72
137 Establishment and purpose of database 72

Page

138 Recording of information for database by authorised practitioners 73
139 Recording of information for database by pharmacists 73
140 Recording and including information on database by holders of approvals and OTP registrations 74
141 Authority to transfer information 74
142 Use and disclosure of information by Health Secretary 74
143 Use and disclosure of information by authorised practitioners and pharmacists 75
144 Unauthorised access to database 76

Part 18 Applications and fees for licences, approvals and DMT authorities

145 Deemed refusal of applications for licences, approvals and DMT authorities 77
146 Fees for obtain licences and wholesaler licences—the Act, ss 59(2)(a), 62(1) and 85 77
147 Fees for DMT authorities—the Act, ss 77(2)(b) and 85 77
148 Reduction, postponement, waiver and refund of fees—the Act, s 85(3) 77

Part 19 Offences

149 Breaching therapeutic standards—the Act, ss 10, 12 and 150 78
150 Documents and records must be kept for 5 years—the Act, s 55 78
151 Health practitioners must comply with labelling requirements about storage and safe use—the Act, ss 55 and 150 78
152 Sterile compounded preparations—the Act, s 55 78
153 Pentobarbital for use in animals—the Act, ss 55 and 150 79
154 Medication management in managed correctional centres—the Act, s 150 79
155 Medication management in private health facilities—the Act, s 150 80
156 Tier 6 penalties 80
157 Penalty notice offences 80

Part 20 Miscellaneous

158 Exemptions—the Act, s 10(2)(d) 81
159 Exceptions to offence of non-wholesale supply of unregistered or unlisted therapeutic goods 81
160 Modification of Commonwealth therapeutic goods laws relating to advertising—the Act, s 86 81
161 Forfeiture of seized things 81
162 Regulatory Advisory Committee 81

Schedule 1 Fees 82
Schedule 2 Penalty notice offences 83
Schedule 3 Savings, transitional and other provisions 84
Schedule 4 Dictionary 86

Medicines, Poisons and Therapeutic Goods Regulation 2023

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 2023*.

2 Commencement

This regulation commences on [to be confirmed].

3 Definitions

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

(3) 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 that 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.

(4) Despite subsection (3), nurses, midwives, podiatrists and optometrists with an endorsement are not prescribed as an authorised practitioner for the Act, section 24.

4 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), the recognised establishments and recognised services of the following affiliated health organisations under the *Health Services Act 1997* are prescribed—

(a) Calvary Health Care (Newcastle) Limited,

(b) Calvary Health Care Sydney Limited,

(c) Hammondcare Health and Hospitals Limited,

(d) Mercy Hospitals NSW Ltd,

(e) Royal Rehab,

(f) St Vincent's Hospital Sydney Limited,

(g) Uniting Church in Australia.

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

(3) The quantity specified in Column 2 is the nominal weight 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	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

Column 1	Column 2
Substance	**Prescribed quantity for DMT Act**
Clonazepam	0.5g
Clorazepate	3g
Clostebol	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, 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	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
Pentobarbitone 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	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	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	5g
Thymosin Beta 4 (thymosin β4)	0.3g
Tianeptine	3.75g
Tramadol	30g
Trenbolone that is a Schedule 4 substance	5g
Trestolone	5g
Triazolam	0.05g

Column 1	Column 2
Substance	**Prescribed quantity for DMT Act**
Zolazepam	2.5g
Zolpidem	1g
Zopiclone	0.75g

6 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 23 or 36.

7 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

8 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 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) a 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) The supplying pharmacy business and receiving pharmacy business must keep a record of Schedule 2, 3, 4 or 8 substances wholesale supplied under this section.

Maximum penalty—Tier 6 penalty.

(5) In this section—

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

9 Wholesale supply between pharmacists

(1) For the Act, section 14(a), wholesale supply of a Schedule 2, 3, 4 and 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 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 a 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—

(a) in the approved form, or

(b) signed by the receiving pharmacist.

Maximum penalty—Tier 6 penalty.

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

Maximum penalty—Tier 6 penalty.

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

(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 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 the supply is—

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

(b) in the manufacturer's original pack.

Maximum penalty—Tier 6 penalty.

(3) The pharmacist must keep a record of Schedule 2, 3, 4 or 8 substances wholesale supplied under this section.

Maximum penalty—Tier 6 penalty.

11 Wholesale supply by pharmacists to authorised practitioners

(1) For the Act, section 14(a), wholesale supply of a Schedule 4 or 8 substance by a pharmacist to an authorised practitioner for emergency use is authorised if the supply is in accordance with a written order of the authorised practitioner.

(2) This section does not apply to the following Schedule 4 or 8 substances—

(a) for all authorised practitioners—a Schedule 4 or 8 substance that is not a registered good, and

(b) for a veterinary practitioner—a Schedule 4 or 8 substance that is not registered under the Commonwealth Agvet Codes.

(3) The pharmacist must keep a record of Schedule 4 or 8 substances wholesale supplied under this section.

Maximum penalty—Tier 6 penalty.

12 Wholesale supply by pharmacists to registered nurses and midwives providing vaccines in pharmacies

For the Act, section 14(a), wholesale supply of a Schedule 2, 3 or 4 substance by a pharmacist to a registered nurse or midwife is authorised if the registered nurse or midwife has an authority to administer the substance in a pharmacy granted by the Health Secretary under section 73.

13 Wholesale supply by pharmacists to first aiders

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

Column 1	Column 2
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 for a unit of competency in the use and administration, including access and preparation, of the substance for first aid
Adrenaline	Person with a current certificate in the use and administration of adrenaline in emergency first aid issued by an approved person
Naloxone	Person with a current certificate in the use and administration of naloxone in emergency first aid issued by an approved person
Salbutamol	Person with a current certificate in the use and administration of salbutamol in emergency asthma management issued by an approved person
Terbutaline	Person with a current certificate in the use and administration of terbutaline in emergency asthma management issued by an approved person

(2) The pharmacist must keep a copy of the person's first aid qualification.

Maximum penalty—Tier 6 penalty.

14 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 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—Part C of the *National Standard for Commercial Vessels* 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) 2015* 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)(i) or (ii), 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) Part 1 of the *Special Regulations* 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—

(i) the regulations referred to in paragraph (a)(i), or

(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 scheduled substance under subsection (1) unless the pharmacist has a copy of the following—

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

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

Maximum penalty—Tier 6 penalty.

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

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

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

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

Maximum penalty—Tier 6 penalty.

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

Maximum penalty— Tier 6 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

15 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.

16 Unauthorised wholesale supply of samples

(1) A person must not wholesale supply, whether for free or otherwise, a Schedule 4D or 8 substance as a sample.

Maximum penalty—Tier 6 penalty.

(2) A person must not wholesale supply, whether for free or otherwise, a Schedule 2, 3 or 4 substance as a sample to a health practitioner or veterinary practitioner other than in accordance with a written order from the health practitioner or veterinary practitioner in the approved form.

Maximum penalty—Tier 6 penalty.

(3) Subsection (2) does not apply to a Schedule 4D substance.

17 Wholesale supply by certain affiliated health organisations to public health entities

A public health entity prescribed under section 4(2) must ensure that wholesale supply carried out under the Act, section 17 is carried out in accordance with the approved guidelines.

Maximum penalty—Tier 6 penalty.

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

Division 1 Obtaining wholesale supply generally

18 Obtaining wholesale supply by health practitioners

For the Act, section 21(1)(g), the following are prescribed as health practitioners who are authorised to obtain wholesale supply—

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

(b) 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,

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

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

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

Note— Podiatrists and optometrists may also be authorised to obtain wholesale supply under the Act, section 21 if they have an endorsement.

19 Obtaining wholesale supply by various persons and bodies

(1) 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.

(2) Obtaining wholesale supply by a person under subsection (1) is authorised only if—

(a) the person 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* St John Ambulance Australia (NSW)	—
Schedule 2, 3, 4 or 8 substance	Superintendent of veterinary hospital licensed under the *Veterinary Practice Act 2003* who is a veterinary practitioner	—
Schedule 2, 3 or 4 substance	National Measurement Institute	—

Column 1	Column 2	Column 3
Scheduled substance	**Person**	**Purpose**
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	National Measurement Institute Health Administration Corporation	—
Schedule 2, 3, 4 or 8 substance	Operator of National Medical Stockpile	—
Schedule 2, 3 or 4 substance, approved Schedule 8 substance	Royal Flying Doctor Service of Australia	—
Schedule 2 or 7J substance	Holder of a retail licence for the Schedule 2 or 7J substance	—
Adrenaline, glucagon, glyceryl trinitrate, methoxyflurane, naloxone, nitrous oxide, salbutamol, terbutaline	Principal of a government or non-government school under the *Education Act 1990*	—
Prohibited scheduled substance, prohibited drug or prohibited plant	Holder of a DMT authority for the prohibited scheduled substance, prohibited drug or prohibited plant	—
Schedule 2 or 3 substance	Person engaged in jewellery manufacture, electroplating, paint manufacture, ferrous hardening, commercial pest control, mining gold or other precious metals or refining non-ferrous metals	For use in an activity specified in Column 2

20 Obtaining wholesale supply by first aiders

(1) For the Act, Part 2.3, obtaining wholesale supply of a scheduled substance specified in Column 1 of the table to this subsection by a person specified opposite in Column 2 is authorised if the person is authorised to administer the scheduled substance under section 63.

Column 1	Column 2
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 for a unit of competency in the use and administration, including access and preparation, of the substance for first aid
Adrenaline	Person with a current certificate in the use and administration of adrenaline in emergency first aid issued by an approved person
Naloxone	Person with a current certificate in the use and administration of naloxone in emergency first aid issued by an approved person
Salbutamol	Person with a current certificate in the use and administration of salbutamol in emergency asthma management issued by an approved person

Column 1	Column 2
Scheduled substance	**Person**
Terbutaline	Person with a current certificate in the use and administration of terbutaline in emergency asthma management issued by an approved person

(2) A person specified in Column 2 must give a copy of the person's first aid qualification to the person wholesale supplying the substance to the person.

Maximum penalty—Tier 6 penalty.

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

21 Obtain licences for Schedule 4D, 8 and 9 substances required for certain research institutions

For the Act, section 57(2)(vi), the following research institutions are prescribed for Schedule 4D, 8 and 9 substances—

(a) the Garvan Institute of Medical Research,

(b) the Heart Research Institute Ltd,

(c) the Victor Chang Cardiac Research Institute Limited.

Note— The research institutions are authorised to obtain prohibited scheduled substances and prohibited drugs without an obtain licence in certain circumstances. See section 22.

22 Obtaining wholesale supply by research institutions, universities and laboratories

(1) This section applies to the following—

(a) a Schedule 2, 3 or 4 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, the following are authorised to obtain wholesale supply of a substance or drug to which this section applies—

(a) the Garvan Institute of Medical Research,

(b) the Heart Research Institute Ltd,

(c) the Victor Chang Cardiac Research Institute Limited,

(d) the person in charge of a university department or university laboratory,

(e) a qualified person in charge of a laboratory, department or research institution at which medical or scientific research, analysis, teaching or training or quality control is carried out,

(f) a person acting under the direct personal supervision of a person specified in paragraph (d) or (e),

(g) an approved analytical or research and development laboratory or department.

(3) In this section—

qualified person means the following—

(a) a medical practitioner, dentist, veterinary practitioner or pharmacist,

(b) a person who holds an approved academic qualification,

(c) an approved person.

Division 3 Other

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

(1) The Health Secretary may grant an authority that authorises the 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 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 provide 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 in its application to—

(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

24 Non-wholesale supply under direction

(1) For the Act, section 28(1), non-wholesale supply of a Schedule 2, 3, 4 or 8 substance to a person 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 midwife practitioner acting in the course of practice,

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

(e) a veterinary practitioner acting in the course of practice.

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

(a) in writing, or

(b) in an approved electronic 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) A person who gives an emergency oral direction must attend to review the patient as soon as practicable after giving the direction as the person considers appropriate in the circumstances.

Maximum penalty—Tier 6 penalty.

(5) 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 6 penalty.

(6) If a person who gives an emergency oral direction does not confirm the direction under subsection (5) within 7 days after the substance is supplied, the person who supplied the substance must notify the Health Secretary.

Maximum penalty—Tier 6 penalty.

(7) This section does not apply to non-wholesale supply by a pharmacist.

25 Non-wholesale supply of buprenorphine and methadone at OTP clinics

For the Act, section 28(1), non-wholesale supply of buprenorphine or methadone to a patient at an OTP clinic is authorised if the person supplying the substance is acting under the written direction 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 this regulation, section 83.

26 Non-wholesale supply of Schedule 7 substances

For the Act, section 28(1), non-wholesale supply of a Schedule 7 substance, other than a Schedule 7J substance, is authorised if the supply is—

(a) for non-domestic use, or

(b) to a person who is authorised to possess or use the substance under the *Pesticides Act 1999*.

27 Non-wholesale supply by midwife practitioners

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

28 Non-wholesale supply by dentists

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

Maximum penalty—Tier 6 penalty.

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

(3) A dentist must not non-wholesale supply a scheduled substance to a patient for a period that, together with all other periods for which any 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 1 month.

Maximum penalty—Tier 6 penalty.

Division 2 Non-wholesale supply by pharmacists

29 Non-wholesale supply by pharmacists without prescription

(1) For the Act, section 28(1), non-wholesale supply of a Schedule 4 substance, other than a Schedule 4D substance, by a pharmacist 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.

(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 6 penalty.

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

(1) For the Act, section 28(1), non-wholesale 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) immediately 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—provide the prescription to the pharmacist.

Maximum penalty—Tier 6 penalty.

(3) The pharmacist must—

(a) keep and cancel the prescription provided to the pharmacist under subsection (2)(b), and

(b) if a prescription is not received within 7 days after the substance is supplied—notify the Health Secretary.

Maximum penalty—Tier 6 penalty.

(4) The pharmacist is not required to cancel a prescription under subsection (3)(a) if the prescription is a conformant electronic prescription.

(5) This section does not apply to a Schedule 4 or 8 substance that is not a registered good.

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

(1) For the Act, section 28(1), non-wholesale 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 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 6 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.

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

32 Retail sale of Schedule 2 and 7J substances

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

33 Retail licences for Schedule 2 and 7J substances

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

(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 provide additional information 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 6 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 (10), 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.

34 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 (2) is to 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

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

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

(a) a nominated Schedule 4 substance,

(b) a compounded Schedule 4D substance for non-topical use,

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

(d) dexamfetamine, lisdexamfetamine or methylphenidate,

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

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

(g) a compounded Schedule 8 substance,

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

Maximum penalty—Tier 6 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 non-wholesale supply the following—

(a) a compounded Schedule 4D substance for non-topical use,

(b) a compounded Schedule 8 substance,

(c) dexamfetamine or lisdexamfetamine,

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

Maximum penalty—Tier 6 penalty.

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

(4) Subsections (1) and (2)(a) and (b) do not apply to a person who is non-wholesale supplying the substance in accordance with an approval or approval exemption.

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

(1) The Health Secretary may grant an authority that authorises the non-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 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 provide 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 in its application to—

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

Division 1 General

37 Midwife practitioners may issue prescriptions

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

38 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 compounded Schedule 4D substance for non-topical use,

(c) 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,

(d) dexamfetamine, lisdexamfetamine or methylphenidate,

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

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

(g) a compounded Schedule 8 substance,

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

Maximum penalty—Tier 6 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) a compounded Schedule 4D substance for non-topical use,

(b) a compounded Schedule 8 substance,

(c) dexamfetamine, lisdexamfetamine or methylphenidate,

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

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

(4) Subsections (1) and (2)(a) and (b) do not apply to a person who issues the prescription in accordance with an approval or approval exemption.

39 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 6 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 any other period for which any 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 1 month.

Maximum penalty—Tier 6 penalty.

Division 2 General requirements for prescriptions

40 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) a medication chart prescription.

Maximum penalty—Tier 6 penalty.

41 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, other than a medication chart prescription, unless the prescription complies with the requirements of this part.

Maximum penalty—Tier 6 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.

(3) Subsection (2) does 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.

42 Schedule 4 and 8 substances must be supplied on proper medication chart prescription

A person must not supply a Schedule 4 or 8 substance on a medication chart prescription, unless the prescription is in the approved form.

Maximum penalty—Tier 6 penalty.

43 Expiry of prescriptions

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

Maximum penalty—Tier 6 penalty.

(2) A pharmacist must not supply a Schedule 4D or 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 6 penalty.

Division 3 Form and content of prescriptions

44 Information to be specified in prescriptions

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

(a) the name of the substance,

(b) the strength and form of the substance,

(c) adequate directions for the administration of the substance, including, if not readily apparent, the route, frequency and times for administration,

(d) the amount of the substance to be supplied,

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

(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 amount in subsection (1)(d) must be expressed in words and numbers if the substance is a Schedule 8 substance.

(4) This section does not apply to a medication chart prescription.

45 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 prescription must specify—

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

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

(3) The information required to be specified in the prescription under subsection (2) must be—

(a) written by hand by the person issuing the prescription, or

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

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

(5) If the prescription is issued at a public health entity or private health facility, the prescription must specify—

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

(b) the name, address and telephone number of the public health entity or private health facility.

(6) If the prescription is not issued at a public health entity or private health facility, the prescription must specify—

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

(b) the address and telephone number of the person's principal place of practice.

(7) If the prescription authorises the supply of a Schedule 8 substance, the prescription must not authorise the supply of any other scheduled substance.

46 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 the following—

(a) a unique reference number for the prescription or for each Schedule 4 or 8 substance,

(b) the address and telephone number of the principal place of practice of the person issuing the prescription,

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

(d) the patient's name, date of birth and address.

(3) The information required under section 44(1)(a), (b), (d) and (e) and (2) must be handwritten on the prescription for a Schedule 8 substance.

(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 any other scheduled substance.

47 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) the healthcare identifier for the practice or organisation at which the prescription is issued,

(c) the healthcare identifier for the person issuing the prescription,

(d) a unique reference number for the prescription,

(e) the address and telephone number of the person's principal place of practice,

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

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

(h) a digitally encrypted signature of the person issuing the prescription.

Division 4 Additional requirements for prescriptions

48 Prescriptions for high or unusual doses

(1) This section applies to a prescription for a Schedule 4 or 8 substance, other than a conformant electronic prescription or medication chart prescription.

(2) If the strength or form, the amount of the substance to be supplied or the number of times an amount of the substance may be supplied on the prescription could be regarded as high or unusual, the person issuing the prescription must underline and initial that part of the prescription.

49 Prescriptions issued by dentists, optometrists, podiatrists and veterinary practitioners

(1) A prescription for a Schedule 4 or 8 substance issued by a dentist must include the words "FOR DENTAL TREATMENT ONLY".

(2) A prescription for a Schedule 4 or 8 substance issued by an optometrist must include the words "FOR OPTOMETRICAL TREATMENT ONLY".

(3) A prescription for a Schedule 4 or 8 substance issued by a podiatrist must include the words "FOR PODIATRIC TREATMENT ONLY".

(4) A prescription for a Schedule 4 or 8 substance issued by a veterinary practitioner must include the words "FOR ANIMAL TREATMENT ONLY".

(5) This section does not apply to a medication chart prescription.

50 Approval number for prescriptions for certain Schedule 4 and 8 substances

(1) A prescription for the following substances issued by a person must specify the number of the person's approval to issue the prescription—

(a) a nominated Schedule 4 substance,

(b) a compounded Schedule 4D substance for non-topical use,

(c) a compounded Schedule 8 substance,

(d) dexamfetamine, lisdexamfetamine or methylphenidate,

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

(2) If the prescription is issued by a person in accordance with an approval exemption, the prescription must specify that the person has an "approval exemption".

(3) This section does not apply to a medication chart prescription.

51 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 any other provision of this Part, the prescription is not required to specify the partner's date of birth or address and may instead specify the partner's email address or telephone number.

52 Prescriptions issued by veterinary practitioners

For a prescription issued by a veterinary practitioner, a reference in this Part to a patient's name, address and date of birth is a reference to the species of animal and the owner's name and street address.

Division 5 Email and facsimile prescriptions

53 Email and facsimile prescriptions

(1) A medical practitioner or nurse practitioner may issue a prescription for a Schedule 4 substance by sending the prescription by email or facsimile to a pharmacist who is a member of staff of a public health entity.

(2) A medical practitioner or nurse practitioner who issues a prescription under subsection (1) must keep the prescription or a reproducible digital image of the prescription.

(3) A medical practitioner or nurse practitioner who is a member of staff of a public health entity may issue a prescription for a Schedule 8 substance by sending the prescription by email or facsimile to a pharmacist who is a member of staff of the public health entity.

(4) A medical practitioner or nurse practitioner who issues a prescription under subsection (3) must ensure that the prescription or a reproducible digital image of the prescription is kept at the public health entity.

(5) A pharmacist to whom a prescription is emailed under this section must print a copy of the prescription.

(6) A pharmacist to whom a prescription is emailed or sent by facsimile must keep a printed copy of the prescription.

(7) The printed copy of a prescription kept by a pharmacist is taken to be a prescription for the Act and this regulation.

(8) This section does not apply to a medication chart prescription.

54 Email, facsimile and photocopies of medication chart prescriptions

A facsimile or email copy or a photocopy of a medication chart prescription may be used for the Act and this regulation.

Division 6 Records and verification of prescriptions

55 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—

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

(b) knows the person for whom the substance is prescribed, or

(c) has verified that the prescription has been issued by the person purported to have issued the prescription.

Maximum penalty—Tier 6 penalty.

(2) Subsection (1)(a) does not apply to a conformant electronic prescription.

56 Pharmacists must keep 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 the prescription, whether or not the prescription authorises more than one supply of the substance.

Maximum penalty—Tier 6 penalty.

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

Maximum penalty—Tier 6 penalty.

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

57 Information about supply 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 street address of the place at which the substance is supplied,

(c) the reference number for the prescription.

Maximum penalty—Tier 6 penalty.

(2) A pharmacist who supplies a Schedule 2, 3, 4 or 8 substance on prescription 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) for a Schedule 4D or 8 substance—the intervals at which an amount of the substance may be supplied are not specified on the prescription, or

(c) 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 it.

Maximum penalty—Tier 6 penalty.

(3) This section does not apply to a medication chart prescription.

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

58 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 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 patient—the patient'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 6 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 6 penalty.

(3) Subsection (1)(f) does not apply to a medication chart prescription.

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

59 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 6 penalty.

60 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.

61 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 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 midwife, with an endorsement that qualifies the midwife to administer the scheduled substance, acting in the course of practice.

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

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

(2) Subsection (1)(b) 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 section 62 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.

62 Administration by staff 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 is authorised to administer a Schedule 4 or 8 substance to a person 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 midwife practitioner acting in the course of practice,

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

(2) The direction must be given—

(a) in writing, or

(b) in an approved electronic way.

Maximum penalty—Tier 6 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 6 penalty.

(5) If a person who gives an emergency oral direction does not confirm the direction under subsection (4) within 7 days after the substance is administered, the person who administered the substance must notify the Health Secretary.

Maximum penalty—Tier 6 penalty.

(6) 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.

63 Administration by first aiders

(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 for a unit of competency in the use and administration, including access and preparation, of the substance for first aid.

64 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.

65 Administration at schools and child care facilities

A person employed or engaged at a school or childcare facility is authorised to administer a Schedule 2, 3, 4 or 8 substance to a child at the school or childcare facility if—

(a) the administration is in accordance with the label of the substance, and

(b) the substance was supplied to the school or childcare facility by the child's parent or guardian.

66 Administration by Ambulance Service of NSW staff

An approved member of staff of the Ambulance Service of NSW is authorised to administer a Schedule 2, 3, 4 or 8 substance to a person.

67 Administration by Royal Flying Doctor Service

A patient transport officer employed or engaged by the Royal Flying Doctor Service of Australia is authorised to administer a Schedule 2 or 3 substance to a patient.

68 Administration of buprenorphine and methadone at OTP clinics

A member of staff of an OTP clinic is authorised to administer buprenorphine or methadone to a patient at the OTP clinic in accordance with a written direction lawfully given by a medical practitioner or nurse practitioner in relation to the patient.

69 Administration of vaccines by pharmacists

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

(a) has an authority to administer the vaccine granted by the Health Secretary under section 73, and

(b) has completed a recognised training course, and

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

(2) The pharmacist must record the following details—

(a) the person's name, street address, date of birth and other contact details,

(b) the name and contact details of the person's primary medical practitioner,

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

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

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

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

(g) a reference number for the administration,

(h) the pharmacist's name and contact details,

(i) evidence of the completion of the recognised training course.

Maximum penalty—Tier 6 penalty.

(3) In this section—

recognised training course means a course that—

(a) is provided by an education provider accredited by the Australian Pharmacy Council, and

(b) complies with standards for the accreditation of programs to support the administration of vaccines published by the Australian Pharmacy Council.

70 Administration by NSW Police Force dive medical technicians

A dive medical technician employed or engaged by 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.

71 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) Subsection (1) does not apply to the administration by a dentist to a patient in a public health entity or private health facility.

72 Restriction on administration of certain Schedule 4 and 8 substances

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

(a) a nominated Schedule 4 substance,

(b) a compounded Schedule 4D substance for non-topical use,

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

(d) dexamfetamine, lisdexamfetamine or methylphenidate,

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

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

(g) a compounded Schedule 8 substance,

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

Maximum penalty—Tier 6 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) a compounded Schedule 4D substance for non-topical use,

(b) a compounded Schedule 8 substance,

(c) dexamfetamine or lisdexamfetamine,

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

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

(4) Subsections (1) and (2)(a) and (b) do not apply to a person who administers the substance in accordance with an approval or approval exemption.

73 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 provide 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 in its application to—

(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, prescription and administration of certain Schedule 4 and 8 substances—the Act, Part 3.3

74 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) compounded Schedule 4D substances for non-topical use,

(c) Schedule 8 substances.

75 Approvals required for activities involving 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 or compounded Schedule 4D substance for non-topical use without an approval.

76 Approvals for 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 for an activity specified in section 75.

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 an activity carried out in a public health entity or private health facility for the purposes of the treatment of a patient.

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

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

Column 1	Column 2
Nominated Schedule 4 substance	**Specialist registration**
Acitretin	Dermatology Physician
Alefacept	Dermatology
Bexarotene	Dermatology Haematology Medical oncology Physician
Clomifene	Obstetrics and gynaecology Endocrinology
Corifollitropin alfa	Obstetrics and gynaecology
Cyclofenil	Obstetrics and gynaecology Endocrinology
Dinoprost	Obstetrics and gynaecology
Dinoprostone	Obstetrics and gynaecology

Column 1	Column 2
Nominated Schedule 4 substance	**Specialist registration**
Etretinate	Dermatology Physician
Folitropin alfa	Obstetrics and gynaecology
Folitropin beta	Obstetrics and gynaecology Endocrinology
Folitropin delta	Obstetrics and gynaecology
Hydroxychloroquine	Dermatology Emergency medicine Intensive care medicine Paediatrics and child health Physician
Isotretinoin for oral use	Dermatology Physician
Luteinising hormone	Obstetrics and gynaecology Endocrinology
Riociguat	Physician
Teriparatide	Medical oncology Haematology
Tretinoin for oral use	Dermatology Haematology
Urofollitropin (human follicle stimulating hormone)	Obstetrics and gynaecology Endocrinology

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

(1) A medical practitioner or nurse practitioner 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) N,α-dimethyl-3,4-(methylenedioxy)phenylethylamine (MDMA) or psilocybine,

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

(d) the Schedule 8 substance is compounded,

(e) the Schedule 8 substance is in an injectable or intranasal preparation or alprazolam, flunitrazepam or methadone (a ***relevant substance***), if the supply, administration or issue of a prescription would result in supply for a period that, 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, would result in one or more relevant substances

being supplied for continuous therapeutic use by the patient for more than 3 months.

(2) A veterinary practitioner must not supply, administer or issue a prescription for a compounded Schedule 8 substance without an approval.

78 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 nurse practitioner does not require an approval for an activity specified in section 77(1).

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

(2) A medical practitioner or nurse practitioner 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 who is physically present in 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 that the person was receiving immediately before the person became an inmate.

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

(a) the medical practitioner or nurse practitioner carries out the activity on behalf of another medical practitioner or nurse 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) practices 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 specialist registration in palliative medicine, paediatric palliative medicine, medical oncology or paediatric medical oncology.

(5) A medical practitioner or nurse practitioner does not require an approval for the activity specified in section 77(1)(a), (c) or (e) 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.

(6) A medical practitioner does not require an approval for the activity specified in section 77(1)(b)(i) or (d) in relation to dexamfetamine, lisdexamfetamine or methylphenidate if—

(a) the medical practitioner has a specialist registration in psychiatry, paediatrics and child health, neurology or respiratory and sleep medicine, and

(b) the activity does not involve more than the maximum amount of the substance specified by the Health Secretary in an order published on the Ministry of Health's website.

(7) In this section—

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 Compounding of Schedule 4D and 8 substances—the Act, s 55

79 Compounding of Schedule 4D and 8 substances

(1) For the Act, section 55(1), a medical practitioner, dentist or veterinary practitioner must not compound a Schedule 4D substance for non-topical use or a Schedule 8 substance unless the person is acting in accordance with an authority granted by the Health Secretary under section 80.

Maximum penalty—Tier 6 penalty.

(2) Subsection (1) does not apply to compounding at a public health entity or private health facility for the purposes of the treatment of a patient.

(3) A reference to a private health facility in subsection (2) does not include a pharmacy at a private health facility.

80 Health Secretary may authorise compounding of Schedule 4D and 8 substances—the Act, s10(2)

(1) The Health Secretary may grant an authority that authorises a medical practitioner, dentist or veterinary practitioner to compound a Schedule 4D substance for non-topical use or a Schedule 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 provide 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 in its application to—

(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 9 Opioid Treatment Program—the Act, Part 3.4

81 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.

82 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 6 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 6 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 6 penalty.

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

Maximum penalty—Tier 6 penalty.

(5) For the Act, section 74(4)(d), a person carrying out an activity for which an OTP registration is not required under this regulation, section 83(a) 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 6 penalty.

(6) In this section—

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

83 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 who is physically present in a public health entity, other than a public OTP clinic, or private health facility,

(b) the treatment of a patient on behalf of a medical practitioner or nurse practitioner with an OTP registration (the ***original practitioner***) for the purposes of continuing the treatment that the patient was receiving from the original practitioner if—

(i) the activity is carried out at the premises at which the original practitioner carried out the activity, or

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

(c) the treatment of an inmate in a correctional centre on behalf of a medical practitioner or nurse practitioner with an OTP registration (the ***original practitioner***) for the purposes of continuing the treatment that the patient was receiving from the original practitioner in a correctional centre,

(d) the treatment of a person for 21 days after the person was released from a correctional centre and ceased to be an inmate.

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.

84 Suspension and revocation of OTP registrations—the Act, s74(3)(c)

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

(2) Notice of the suspension or revocation of an OTP registration must—

(a) be written, and

(b) specify the following—

(i) the date or time from which the suspension or revocation takes effect,

(ii) the grounds for the suspension or revocation,

(iii) for a suspension—the period of suspension.

Part 10 Cosmetic use substances—the Act, s 54

85 Definitions

In this part—

cosmetic use substance means the following Schedule 4 substances—

(a) botulinum toxins,

(b) hyaluronic acid and its polymers,

(c) calcium hydroxylapatite,

(d) collagen,

(e) deoxycholic acid,

(f) polyacrylamide,

(g) polycaprolactone,

(h) polylactic acid.

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

86 Administration of cosmetic use substances

A person must not administer a cosmetic use substance to a patient unless the person is—

(a) an authorised practitioner acting in the course of practice, or

(b) a member of staff of a public health entity or private health facility acting under the direction of an authorised practitioner, other than a veterinary practitioner, or

(c) a nurse acting under the direction of a medical practitioner or nurse practitioner, or

(d) a person administering the substance to an animal under the direction of a veterinary practitioner.

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

(1) A medical practitioner or nurse practitioner giving a direction for the purposes of section 86(c) 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, 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.

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

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

(b) 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 88(1)(a)–(e) and (i), and

(c) give a copy of the written record to the relevant medical practitioner or nurse practitioner and to the responsible provider.

88 Content of directions

(1) A written direction given under section 87(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 is to 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 87(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 is to 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 87(2) must include the information specified in subsection (1)(a) and (j).

89 Records of directions

(1) A medical practitioner or nurse practitioner who gives a written direction under section 87(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 87(1) must—

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

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

90 Storage

The person who occupies or has control of premises at which a cosmetic use substance is stored or administered must ensure that the substance is stored in accordance with the requirements of this regulation for storage.

91 Duties of responsible providers

(1) A responsible 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) any cosmetic use substance administered to a patient in the course of the provider's business has been lawfully supplied or prescribed for the patient,

(c) any cosmetic use substance administered in the course of the provider's business is administered in the form of a therapeutic good that may, under the Commonwealth therapeutic goods laws, be lawfully manufactured for use in Australia,

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

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

(f) 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 87(6).

92 Category 1 and category 2 requirements

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.

(1) The following provisions are category 1 requirements—

(a) section 86,

(b) section 87(1)(a) and (6)(a),

(c) section 91(1).

(2) The following provisions are category 2 requirements—

(a) section 87(1)(b) and (c) and (6)(b) and (c),

(b) section 88,

(c) section 89,

(d) section 90,

(e) section 91(2).

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

93 Definitions

In this part—

relevant place —see section 94.

responsible person, for a relevant place—see section 95.

94 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 pharmacy in a public hospital,

(c) a dispensary in a private health facility,

(d) a residential care facility,

(e) a managed correctional centre,

(f) an OTP clinic,

(g) a pharmacy,

(h) a veterinary hospital licensed under the *Veterinary Practice Act 2003*,

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

95 Persons responsible for drug registers

(1) In this part, the ***responsible person*** for each relevant place is as follows—

(a) for a hospital ward in a public health entity or private health facility—the nurse or midwife unit manager for the ward,

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

(c) for a dispensary in a private health facility—the licensee of the private health facility,

(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 (3),

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

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

(h) 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,

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

(j) for another place referred to in section 94(i)—

(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 23, 36 or 73, or

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

(2) 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 of the hospital to have the responsibilities of the responsible person under this part.

(3) 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.

(4) 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.

96 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 6 penalty.

(2) A drug register must 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 trace, and

(iii) specifies the particulars required to be entered under section 97(1), or

(b) in an approved electronic form.

(3) A separate page of a drug register in the form of a book, as referred to in subsection (2)(a), must be used for each Schedule 8 substance and for each form and strength of the Schedule 8 substance.

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

97 Entries in drug registers for Schedule 8 substances

(1) On the day on which a person manufactures, receives, supplies, administers or uses a Schedule 8 substance at a relevant place, the person must enter the following in the drug register at the relevant place—

(a) the quantity of the Schedule 8 substance manufactured, received, supplied, administered or used,

(b) the name and street address of the person to, from or by whom the Schedule 8 substance was manufactured, received, supplied, administered or used,

(c) for a Schedule 8 substance supplied or administered to an individual—the name of the person—

(i) who supplied or administered the substance, or

(ii) under whose direction or direct personal supervision the substance was supplied or administered,

(d) for a Schedule 8 substance supplied or administered on prescription—

(i) the reference number for the prescription, and

(ii) the name of the person who issued the prescription,

(e) for a Schedule 8 substance kept in a hospital ward, residential care facility or managed correctional centre—the time of day the substance was received, supplied or administered,

(f) for a Schedule 8 substance supplied or administered by a person under an authority granted by the Health Secretary under section 36 or 73—the details of the circumstances requiring supply or administration of the substance,

(g) for a Schedule 8 substance used by a person in charge of a laboratory or an analyst—the purpose for which the substance was used,

(h) for a Schedule 8 substance supplied or administered to a patient in a hospital ward, residential care facility or managed correctional centre—the name of the patient,

(i) for a Schedule 8 substance administered to an animal or supplied for the treatment of an animal—the species and owner's name and street address,

(j) for a Schedule 8 substance administered to an animal—the name of the veterinary practitioner—

(i) who administered the substance, or

(ii) under whose direction or direct personal supervision the substance was administered,

(k) the actual quantity of Schedule 8 substances of the same kind that remains at the relevant place after the event,

(l) other approved information.

Maximum penalty—Tier 6 penalty.

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

Maximum penalty—Tier 6 penalty.

(3) A person making an entry in the drug register in a hospital ward, residential care facility or managed correctional centre for the receipt of a Schedule 8 substance must ensure the entry is countersigned by a person who witnessed the receipt.

Maximum penalty—Tier 6 penalty.

(4) A person making an entry in the drug register in a hospital ward, residential care facility or managed correctional centre 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.

Maximum penalty—Tier 6 penalty.

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

98 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—

(a) each month, and

(b) at other approved times.

Maximum penalty—Tier 6 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 substance actually kept at the relevant place, and

(ii) the date on which the inventory was made, and

(c) sign the entry in the drug register.

Maximum penalty—Tier 6 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 6 penalty.

99 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 6 penalty.

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

100 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 patient'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 6 penalty.

101 Records of supply by pharmacists on prescription

A pharmacist 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,

(d) the reference number for the prescription.

Maximum penalty—Tier 6 penalty.

102 Records of supply by pharmacists on medication chart prescriptions

A pharmacist who supplies a scheduled substance to a person on a medication chart prescription must record the following information on the medication chart each time the substance is supplied—

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

(b) the quantity of the substance supplied,

(c) the street address of the pharmacy from which the substance was supplied,

(d) the reference number for the prescription,

Maximum penalty—Tier 6 penalty.

103 Records of supply by pharmacists in emergencies and urgent circumstances

(1) A pharmacist who supplies a substance under section 29 or 30 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 is supplied,

(d) the name of the pharmacist,

(e) the reference number for the supply.

Maximum penalty—Tier 6 penalty.

(2) A pharmacist who supplies a substance under section 29 must also record the following—

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

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

Maximum penalty—Tier 6 penalty.

(3) The pharmacist must make the records in an approved way.

Maximum penalty—Tier 6 penalty.

104 Records of supply and administration on medication charts at residential care facilities

If a Schedule 2, 3, 4 or 8 substance is supplied or administered to a resident of a residential care facility under a medication chart, the approved provider for the residential care facility must ensure a contemporaneous record of the supply or administration is made in the resident's medication chart.

Maximum penalty—Tier 6 penalty.

105 Records of supply and administration on medication charts at managed correctional centres

If a Schedule 2, 3, 4 or 8 substance is supplied or administered to an inmate under a medication chart at a managed correctional centre, the management company for the managed correctional centre must ensure a contemporaneous record of the supply or administration is made in the inmate's medication chart.

Maximum penalty—Tier 6 penalty.

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

Division 1 Storage requirements

106 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 keep the substance apart from food intended for consumption by humans or animals.

Maximum penalty—Tier 6 penalty.

(3) 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 6 penalty.

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

(a) in a way that prevents access by a child, 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 6 penalty.

(5) 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 person employed or engaged by 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 person employed or engaged by the supplier.

Maximum penalty—Tier 6 penalty.

(6) In this section—

child means a person who is under the age of 16 years.

107 Storage requirements for Schedule 8 substances in pharmacies

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

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

Maximum penalty—Tier 6.

(3) The substance must be stored—

(a) apart from all other goods, and

(b) in a dedicated room or receptacle.

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

(5) A receptacle 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 medication storage standards, including in relation to the receptacle.

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

(a) kept on the person of a pharmacist when a pharmacist is at the pharmacy or removed from the pharmacist 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 or receptacle must not be divulged to a person who is not a pharmacist.

(9) A Schedule 8 substance that requires refrigeration must be stored in a refrigerator that contains no other thing.

108 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,

(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) apart from all other goods, and

(b) in a dedicated room or receptacle.

(3) A Schedule 8 substance that requires refrigeration must be stored in a refrigerator that contains no other thing.

(4) Schedule 4D substances and Schedule 8 substances must be stored separately.

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

(6) A receptacle must—

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

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

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

(8) A key or other device that unlocks the dedicated room or receptacle 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.

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

(10) 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 107 applies.

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

(12) In this section—

appointed person, for a managed correctional centre, means—

(a) a pharmacist who is employed or engaged by the management company for a managed correctional centre, 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—a registered nurse in charge of the medical treatment of inmates at the managed correctional centre or an authorised practitioner, other than a dentist or veterinary practitioner, 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—the nurse or midwife unit manager for the ward,

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

(c) for a managed correctional centre—the appointed person for the managed correctional centre,

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

109 Storage requirements for Schedule 8 substances in other places

(1) A person in possession of a Schedule 8 substance to which section 107 or 108 does not apply must ensure the Schedule 8 substance is stored in accordance with this section.

Maximum penalty—Tier 6 penalty.

(2) The substance must be stored—

(a) apart from all other goods, and

(b) in a dedicated room or receptacle.

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

(4) A receptacle 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 medication 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 a vehicle that is kept locked when not occupied by the person.

(7) This section does not apply to a person in possession of a Schedule 8 substance if the substance was lawfully supplied to the person from an authorised practitioner or pharmacist.

Division 2 Responsibilities for storage

110 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 nurse or midwife unit manager for a ward must ensure scheduled substances are stored in the ward in accordance with this part.

Maximum penalty—Tier 6 penalty.

111 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 6 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 6 penalty.

112 Responsibility for storage in residential care facilities

(1) The authorised person for a residential care facility must ensure that scheduled substances are stored at the residential care facility in accordance with this part.

Maximum penalty—Tier 6 penalty.

(2) The approved provider for a residential care facility must ensure that scheduled substances are stored at the residential care facility in accordance with this part.

Maximum penalty—Tier 6 penalty.

113 Responsibility for storage in managed correctional centres

(1) The relevant person for a managed correctional centre under section 108 must ensure that scheduled substances are stored at the managed correctional centre in accordance with this part.

Maximum penalty—Tier 6 penalty.

(2) The management company for a managed correctional centre must ensure that scheduled substances are stored at the managed correctional centre in accordance with this part.

Maximum penalty—Tier 6 penalty.

Division 3 Other

114 Wholesaler licence holders must comply with Commonwealth Code of Practice

(1) A holder of a wholesaler licence authorising the wholesale supply of a scheduled substance for human use must ensure that the Wholesaling Code of Practice is complied with.

Maximum penalty—Tier 6.

(2) In this section—

Wholesaling Code of Practice means the *Australian Code of Good Wholesaling Practice for Therapeutic Goods for Human Use*, published by the Commonwealth Government or a code of practice that replaces that code.

Part 14 Labelling of scheduled substances—the Act, ss 55 and 150

Division 1 Labelling requirements for suppliers of scheduled substances

115 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.

116 Labelling of scheduled substances

A supplier who supplies a scheduled substance must ensure the substance is packaged and labelled in accordance with the Commonwealth Poisons Standard, Part 2, Division 2.

Maximum penalty—Tier 6 penalty.

117 Misleading labelling of scheduled substances

A supplier must not supply a substance in a container with a label that states or implies that the substance is a particular scheduled substance, unless the substance is that particular scheduled substance.

Maximum penalty—Tier 6 penalty.

118 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, Appendix L.

Maximum penalty—Tier 6 penalty.

(3) The requirement in the Commonwealth Poisons Standard, Appendix L 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 24 to a person for the non-wholesale supply of a Schedule 2, 3, 4 or 8 substance by the person.

119 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 6 penalty.

(2) A pharmacist 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 6 penalty.

Division 2 Dose administration aids

120 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) a reference number that links the DAA, the manufacturing instructions for the DAA and the prescriptions or medication charts for the substances included in the DAA,

(d) the date on which the DAA was supplied to the patient,

(e) the patient's date of birth.

Maximum penalty—Tier 6 penalty.

(2) If the Commonwealth Poisons Standard, Appendix L requires the label to include information about a substance included in a container, the requirement applies to the substance included in a DAA.

(3) If a substance is supplied in a DAA to a residential care facility for a resident of the facility, the DAA is not required to be labelled with the warnings required by the Commonwealth Poisons Standard, Appendix L, Part 2 and the warnings may instead be entered on the resident's medication chart.

(4) 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 6 penalty.

(5) 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 6 penalty.

121 Third party DAA manufacturing services

(1) This section applies if a pharmacist engages a licensed third party to prepare a DAA on the pharmacist's behalf for the pharmacist to supply to a patient.

(2) The pharmacist must ensure that the instructions given to the licensed third party are in accordance with—

(a) the prescription given to the pharmacist, and

(b) other directions from the person who issued the prescription in relation to administration.

Maximum penalty—Tier 6 penalty.

(3) The licensed third party must ensure the DAA is prepared in accordance with the instructions given to the licensed third party by the pharmacist.

Maximum penalty—Tier 6 penalty.

(4) In this section—

licensed third party means a third party licensed to manufacture DAAs under the Commonwealth therapeutic goods laws.

Division 3 Labelling of unscheduled therapeutic goods

122 Labelling of unscheduled therapeutic goods

(1) A person providing a health service must ensure that an unscheduled therapeutic good supplied to a patient for therapeutic use at the person's place of practice is labelled as required by the Commonwealth Poisons Standard, Appendix L.

Maximum penalty—Tier 6 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.

Part 15 Preparation and handling of scheduled substances—the Act, ss 55 and 150

123 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 that 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 6 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 6 penalty.

(4) The person must ensure that 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 6 penalty.

124 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 6 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 6 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 6 penalty.

125 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 6 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.

Maximum penalty—Tier 6 penalty.

(3) Subsection (2) does not apply to—

(a) a veterinary practitioner in the course of practice, or

(b) an assistance animal referred to in the *Disability Discrimination Act 1992* of the Commonwealth, section 9.

126 Responsibilities of health service providers

(1) A person providing a health service must ensure that 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 6 penalty.

(2) A person providing a health service must ensure that 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 6 penalty.

Part 16 Destruction of scheduled substances—the Act, s 55

127 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 6 penalty.

128 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 129–135.

Maximum penalty—Tier 6 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 by an authorised practitioner for the treatment of the person, or

(c) 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.

129 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—

(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 following must be recorded in the pharmacist's drug register—

(a) the date of the destruction,

(b) the 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.

130 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 following must be recorded in the applicable drug register—

(a) the date of the destruction,

(b) the 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.

(5) In this section—

applicable drug register means—

(a) if the substance is destroyed at the pharmacist's pharmacy—the pharmacist's drug register, or

(b) if the substance is destroyed at the authorised practitioner's place of practice—the authorised practitioner's drug register.

131 Destruction of Schedule 8 substances at public health entities

(1) The drug controller of a public health entity may destroy a Schedule 8 substance in the presence of—

(a) a medical practitioner, nurse practitioner, dentist or pharmacist, or

(b) the nurse or midwife unit manager for a ward, or

(c) a registered nurse or midwife authorised by written notice from the director of nursing at the public health entity.

(2) The drug controller must record the following in the public health entity's drug register—

(a) the date of destruction,

(b) the quantity of the substance destroyed,

(c) the drug controller's name, professional registration number and signature,

(d) the witness's name, professional registration number and signature.

(3) 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.

132 Destruction of Schedule 8 substances in public hospital wards

(1) The nurse or midwife unit manager for a ward in a public hospital must immediately notify the drug controller of the hospital if a Schedule 8 substance on the ward becomes unusable.

(2) After being notified under subsection (1), the drug controller may arrange for the substance to be destroyed by—

(a) a pharmacist employed at the hospital, or

(b) if there is no pharmacist employed at the hospital—

(i) the director of nursing of the hospital, or

(ii) the medical superintendent of the hospital.

(3) The substance must be destroyed in the presence of a nurse or midwife.

(4) The person who destroys the substance must record the following information about the destruction of the substance in the ward's drug register—

(a) the date of destruction,

(b) the quantity of the substance destroyed,

(c) the person's name, professional registration number and signature,

(d) the witness's name, professional registration number and signature.

133 Destruction of Schedule 8 substances by pharmacists at private health facilities and 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 private health facility,

(b) a residential care facility,

(c) a patient in a private health facility,

(d) a patient in a residential care facility.

(2) The pharmacist may destroy a Schedule 8 substance in the presence of—

(a) if the private health facility or residential care facility is authorised to non-wholesale supply a Schedule 8 substance—the person responsible for the storage of Schedule 8 substances at the facility, or

(b) for a private health facility—the director of nursing, or

(c) for a residential care facility—the authorised person for the residential care facility.

(3) The substance must be destroyed at the private health facility or residential care facility.

(4) The pharmacist must record the following in the private health facility's or residential care facility's drug register—

(a) the date of destruction,

(b) the pharmacist's name, professional registration number and signature,

(c) the witness's name.

Maximum penalty—Tier 6 penalty.

(5) The person in whose presence the substance was destroyed must sign the drug register and the responsible person must confirm in the drug register that the person has signed the drug register.

134 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.

(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) A responsible person who destroys a Schedule 8 substance under this section must record the following information about the destruction of the substance in the drug register—

(a) the date of the destruction,

(b) the quantity of the substance destroyed,

(c) the responsible person's name, professional registration number and signature,

(d) the witness's name and professional registration number.

(6) The witness must sign the drug register and the responsible person must confirm in the drug register that the witness has signed the drug register.

(7) 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.

(8) In this section—

responsible person means—

(a) a pharmacist employed or engaged by the private health facility or managed correctional centre and appointed, by written notice, by the private health facility or managed correctional centre as the responsible person for this section, or

(b) if there is no pharmacist employed or engaged by the private health facility or managed correctional centre—an authorised practitioner, other than a veterinary practitioner, or registered nurse appointed, by written notice, by the private health facility or managed correctional centre as the responsible person for this section.

135 Destruction of prohibited substances, drugs and plants at research institutions, universities and laboratories

(1) This section applies to the following institutions if a relevant authority authorises the destruction of a prohibited scheduled substance, prohibited drug or prohibited plant by the institution—

(a) the Garvan Institute of Medical Research,

(b) the Heart Research Institute Ltd,

(c) the Victor Chang Cardiac Research Institute Limited,

(d) a university department or university laboratory,

(e) an approved analytical or research and development laboratory or department,

(f) an approved research institution.

(2) The accountable person for an institution to which this section applies may destroy the drug, plant or substance in accordance with the relevant authority.

(3) In this section—

accountable person, for an institution to which this section applies, means the person in charge of the particular laboratory or department of the institution.

relevant authority means—

(a) an obtain licence that authorises the institution to obtain wholesale supply of a prohibited scheduled substance, prohibited drug or prohibited plant, or

(b) a DMT authority that authorises the institution to possess or otherwise deal with a prohibited scheduled substance, prohibited drug substance or prohibited plant.

Part 17 Database for activities involving certain Schedule 4 and 8 substances—the Act, ss 10, 12 and 150

136 Definitions

(1) In this part—

data source entity means the following—

(a) the Australian Health Practitioner Regulation Agency established under the Health Practitioner Regulation National Law,

(b) eRx Script Exchange Pty Ltd,

(c) Fred IT Group Pty Ltd,

(d) Medication Knowledge Pty Ltd,

(e) MediSecure Ltd,

(f) a prescription exchange service prescribed by, or otherwise recognised for the purposes of, a law of the Commonwealth or another State or Territory.

database means the database established under section 137.

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.

137 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 (the ***database operator***) to establish and maintain the database.

(3) The database operator may, subject to the terms of the agreement, exercise the functions of the Health Secretary under this part, other than the function of granting an exemption from a provision of this Part under section 158.

138 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—

(a) the following information about the prescriber—

(i) the full name of the prescriber,

(ii) 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),

(iii) the healthcare identifier for the prescriber and the prescriber's practice, if available,

(iv) the contact information for the prescriber and the prescriber's practice, including telephone number or email address,

(v) other approved information about the prescriber or the prescriber's practice,

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

(c) the information required to be included in the prescription under sections 44(1) and (2) and 51,

(d) the full name, gender, date of birth and street address of the person to whom the prescription is issued,

(e) 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.

139 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, gender, 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 street 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.

140 Recording and including information on 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.

141 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 138, or

(ii) who is in another State or Territory when an 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 139, 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 140,

(d) other information received from an authorised practitioner or pharmacist if the information is reasonably required for the operation of the database.

142 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 or maintain 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 State-wide,

(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 State-wide,

(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) 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.

143 Use and disclosure of information by authorised practitioners and pharmacists

(1) A medical practitioner, nurse practitioner, pharmacist or dentist 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 medical practitioner, nurse practitioner or dentist may access, use and disclose information in the database for the purposes of applying for, reviewing or revoking an approval or OTP registration.

(3) A pharmacist may access, use and disclose information in the database for the purposes of applying for, reviewing or revoking an approval or OTP registration that relates to the supply or administration of a scheduled substance by the pharmacist.

144 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 6 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 143(1) or (2).

Part 18 Applications and fees for licences, approvals and DMT authorities

145 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.

146 Fees for obtain licences and wholesaler licences—the Act, ss 59(2)(a), 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.

147 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 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 22(2)(a)–(d).

148 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 19 Offences

149 Breaching therapeutic standards—the Act, ss 10, 12 and 150

(1) An authorised practitioner or pharmacist must not non-wholesale supply a Schedule 2, 3, 4 or 8 substance in a quantity, or for a purpose, that does not accord with the recognised therapeutic standards of what is appropriate in the circumstances.

Maximum penalty—Tier 6 penalty.

(2) An authorised practitioner must not issue a prescription for a Schedule 2, 3, 4 or 8 substance in a quantity, or for a purpose, that does not accord with the recognised therapeutic standards of what is appropriate in the circumstances.

Maximum penalty—Tier 6 penalty.

(3) A person authorised under this regulation to administer a Schedule 2, 3, 4 or 8 substance must not administer a Schedule 2, 3, 4 or 8 substance in a quantity, or for a purpose, that does not accord with the recognised therapeutic standards of what is appropriate in the circumstances.

Maximum penalty—Tier 6 penalty.

150 Documents and records must be kept for 5 years—the Act, s 55

A person required under the Act or this regulation to keep a document or record must keep the document or record for 5 years.

Maximum penalty—Tier 6 penalty.

151 Health practitioners must comply with labelling requirements about storage and safe use—the Act, ss 55 and 150

(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 6 penalty.

152 Sterile compounded preparations—the Act, s 55

(1) A person compounding a sterile compounded preparation must comply with the requirements specified in *Compounded medicines and good manufacturing practice (GMP), Guide to the interpretation of the PIC/S Guide to GMP for compounded medicinal products*, published by the Therapeutic Goods Administration.

Maximum penalty—Tier 6 penalty.

(2) This section does not apply to a person compounding a substance—

(a) at a public health entity, for the purposes of the treatment of a patient at the public health entity, or

(b) at a private health facility, for the purposes of the treatment of a patient at the private health facility.

(3) A reference to a private health facility in subsection (2)(b) does not include a pharmacy at a private health facility.

(4) In this section—

sterile compounded preparation has the same meaning as in the Act, section 55.

153 Pentobarbital for use in animals—the Act, ss 55 and 150

(1) This section applies to pentobarbital obtained or used by a nominated person for the destruction of an animal.

(2) A nominated person who obtains or uses pentobarbital must keep the pentobarbital separately from all other goods in a receptacle that is—

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

(b) kept securely locked except when in immediate use.

Maximum penalty—Tier 6 penalty.

(3) A nominated person who obtains or uses pentobarbital must record the following information in a separate register—

(a) the date on which the record is made,

(b) for obtaining pentobarbital—

(i) the amount obtained, and

(ii) the name and street address of the person from whom it was obtained,

(c) for using pentobarbital—

(i) the amount used, and

(ii) the number and species of animals for which it was used,

(d) the total quantity of pentobarbital in the possession of the nominated person after the record is made,

(e) the nominated person's name and signature.

Maximum penalty—Tier 6 penalty.

(4) In this section—

nominated person means a person who—

(a) has an authority to non-wholesale supply pentobarbital for the humane destruction of animals granted by the Health Secretary under section 36, and

(b) is nominated by the council of a local government area or an animal welfare organisation for this section.

154 Medication management in managed correctional centres—the Act, s 150

(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 medications.

Maximum penalty—Tier 6 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 1 medical practitioner who does not have a pecuniary interest in the management company for the managed correctional centre.

155 Medication management in private health facilities—the Act, s 150

(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 medications,

(e) compliance with approved standards in relation to the compounding and preparation of pharmaceutical and advanced therapeutic goods.

Maximum penalty—Tier 6 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.

156 Tier 6 penalties

In this regulation, a ***Tier 6 penalty*** for an offence is—

(a) for an individual—

(i) 20 penalty units, and

(ii) an additional 10 penalty units for each day of a continuing offence, and

(b) for a corporation—

(i) 100 penalty units, and

(ii) an additional 50 penalty units for each day a continuing offence.

Note— See the Act, section 119 in relation to continuing offences against the Act or this regulation.

157 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 20 Miscellaneous

158 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 5, 11, 12, 13, 14 or 17.

(2) An exemption may be given unconditionally or subject to conditions.

(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.

159 Exceptions to offence of non-wholesale supply of unregistered or unlisted therapeutic goods

For the Act, section 44(2)(f), the non-wholesale 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.

160 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.

161 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.

162 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 33, 145, 147

Item	Matter for which fee is payable	Fee
1	Application for retail licence	$330
2	Annual fee for retail licence	$330
3	Application for obtain licence for Schedule 2, 3 or 4 substance	$1,650
4	Application for obtain licence for Schedule 7J substance	$330
5	Application for obtain licence for Schedule 8 or 9 substance	$2,930
6	Annual fee for obtain licence for Schedule 2, 3 or 4 substance	$1,250
7	Annual fee for obtain licence for Schedule 7J substance	$330
8	Annual fee for obtain licence for Schedule 8 or 9 substance	$2,520
9	Application for wholesaler licence for Schedule 2, 3 or 4 substance	$1,250
10	Application for wholesaler licence for Schedule 7J substance	$770
11	Application for wholesaler licence for Schedule 8 substance	$2,930
12	Annual fee for wholesaler licence for Schedule 2, 3 or 4 substance	$1,250
13	Annual fee for wholesaler licence for Schedule 7J substance	$330
14	Annual fee for wholesaler licence for Schedule 8 substance	$2,520
15	Application or renewal of DMT authority	$1464
16	Amendment of application for retail licence, obtain licence, wholesaler licence or DMT authority	50% of application fee
17	Variation of retail licence, obtain licence, wholesaler licence or DMT authority	50% of annual fee

Schedule 2 Penalty notice offences

section 157

Column 1 Provision	Column 2 Penalty for an individual	Column 3 Penalty for a corporation
Offences under the Act		
Section 45(1)	2 penalty units	10 penalty units
Section 54(3), in relation to a contravention of this regulation, section 90	2 penalty units	10 penalty units
Section 60(3)	2 penalty units	10 penalty units
Section 71(3)	2 penalty units	10 penalty units
Section 79(3)	2 penalty units	10 penalty units
Section 115(6)	2 penalty units	10 penalty units
Offences under this regulation		
Section 29(2)	2 penalty units	10 penalty units
Section 33(8)	2 penalty units	10 penalty units
Section 39(1) and (3)	2 penalty units	10 penalty units
Section 39(3)	2 penalty units	10 penalty units
Section 43(1) and (2)	2 penalty units	10 penalty units
Section 56(1) and (2)	2 penalty units	10 penalty units
Section 82(1)–(5)	2 penalty units	10 penalty units
Section 96(1)	2 penalty units	10 penalty units
Section 97(1)–(4)	2 penalty units	10 penalty units
Section 98(1) and (2)	2 penalty units	10 penalty units
Section 106(2)	2 penalty units	10 penalty units
Section 116	2 penalty units	10 penalty units
Section 118(2)	2 penalty units	10 penalty units
Section 119(1) and (2)	2 penalty units	10 penalty units
Section 120(1) and (5)	2 penalty units	10 penalty units
Section 123(2)–(4)	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 day on which this schedule commences.

existing authority means an authority under the former Act, section 29.

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 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 non-wholesale 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—

(a) the end of the period specified in the existing approval, if any, or

(b) the surrender of the retail licence by the holder, or

(c) the revocation of the retail licence by the Health Secretary under this regulation.

3 Existing authorities under former Act, section 29

(1) A medical practitioner or nurse practitioner who, immediately before the commencement date, held an existing authority to supply or issue a prescription for a Schedule 8 substance to a drug dependent person, other than as part of the Opioid Treatment Program, is taken, on the commencement date, to hold an approval under the new Act to supply or issue a prescription for the same Schedule 8 substance to a patient who has a substance dependence on a prohibited scheduled substance or prohibited drug.

(2) A medical practitioner or nurse practitioner who, immediately before the commencement date, held an existing authority for the following activities is taken, on the commencement date, to hold an approval under the new Act for the same activity—

(a) supply or issue a prescription for dexamfetamine, lisdexamfetamine or methylphenidate,

(b) supply or issue a prescription for N,α-dimethyl-3,4-(methylenedioxy)phenylethylamine (MDMA) or psilocybine.

(3) The approval is subject to the same conditions, if any, of the existing authority.

(4) The approval remains in force until the earlier of—

(a) the end of the period specified in the existing authority, if any, or

(b) the surrender of the approval by the holder, or

(c) the revocation of the approval by the Health Secretary under the new Act.

4 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 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 remains in force until the earlier of—

(a) the end of the period specified in the existing authority, if any, or

(b) the surrender of the OTP registration by the holder, or

(c) the revocation of the OTP registration by the Health Secretary under this regulation.

Schedule 4 Dictionary

section 3

approval exemption means an exemption from the requirement to have an approval for an activity, as referred to in section 76 or 78.

approved means approved by the Health Secretary from time to time and generally or in a particular case, unless otherwise indicated.

approved provider, for a residential care facility, has the same meaning as the *Aged Care Act 1997* of the Commonwealth.

authorised person, for a residential care facility, has the same meaning as in the Act, section 23.

conformant electronic prescription means an electronic prescription issued using an approved electronic prescribing system.

cosmetic use substance, for Part 10—see section 85.

data source entity, for Part 17—see section 136.

database, for Part 17—see section 136.

Dental Schedule of Pharmaceutical Benefits means the Dental Schedule of Pharmaceutical Benefits under the *National Health Act 1953* of the Commonwealth.

dose administration aid or ***DAA*** means a device or packaging system for organising doses of medicines for a patient according to the time of administration, to assist the management of the patient's medication.

drug register means a register of Schedule 8 substances kept in accordance with Part 13*.

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 therapeutic goods, or a substance used in the preparation of therapeutic goods, that are unpackaged or otherwise susceptible to contamination, but does not include a medical device.

family member, of a person, 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 as defined in the *Work Health and Safety Act 2011*, and

(b) has been appointed by the person for whom they work to provide first aid.

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*.

maximum dose of morphine, oxycodone, fentanyl or hydromorphone means—

(a) 100mg oral morphine equivalent daily dose, known as oMEDD, or

(b) if the patient is being treated with more than 1 of morphine, oxycodone, fentanyl or hydromorphone—a dose that would have an effect equivalent to the dose in paragraph (a), when considered in combination with the other doses.

medication chart, for a person, means a document used for the management of the therapeutic goods used to treat the person that contains—

(a) the orders for medication for the person and the name of the person issuing the orders, and

(b) detailed information about the person's treatment and care.

medication chart prescription means a prescription included on a medication chart.

medication storage standards means approved standards relating to the storage of scheduled substances.

monitored medicine, for Part 17—see section 136.

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 Schedule 4 substances specified in the following table—

Acitretin	Alefacept	Bexarotene	Clomifene
Corifollitropin alfa	Cyclofenil	Dinoprost	Dinoprostone
Etretinate	Folitropin alpha	Folitropin beta	Folitropin delta
Luteinising hormone	Hydroxychloroquine	Isotretinoin for oral use	Riociguat
Teriparatide	Tretinoin for oral use	Urofollitropin (human follicle stimulating hormone)	

OTP clinic means a clinic or other facility, at which activities in the Opioid Treatment Program are carried out, operated by—

(a) a provider under the Opioid Treatment Program who is the holder of an obtain licence as referred to in the Act, section 57(2)(a)(i) (a ***private OTP clinic***), or

(b) a public health entity (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.

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 OTP clinic means an OTP clinic operated by a public health entity.

receptacle includes a safe and a cupboard.

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

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 93.

responsible person, for a relevant place, for Part 11—see section 93.

responsible provider, for Part 10—see section 85.

retail licence means a licence granted by the Health Secretary to authorise the non-wholesale supply of a Schedule 2 or Schedule 7J substance by retail sale.

Schedule 7J substance means a Schedule 7 substance specified in Appendix J of the Commonwealth Poisons Standard.

substance dependence, on a prohibited scheduled substance or prohibited drug, means a substance dependence on a prohibited scheduled substance or prohibited drug according to the *International Classification of Diseases*, 11th edition.

supplier means—

(a) for Part 13—see section 106, and

(b) for Part 14—see section 115.

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

Tier 6 penalty—see section 156.