First print

New South Wales

Medicines, Poisons and Therapeutic Goods Bill 2022

Explanatory note

This explanatory note relates to this Bill as introduced into Parliament.

Overview of Bill

The objects of this Bill are as follows—

(a) to regulate activities involving substances specified in a Schedule of the NSW Poisons Schedules (***scheduled substances***) and other therapeutic goods to protect public health and safety,

(b) to use the Commonwealth Poisons Standard as the basis for classifying and regulating certain substances,

(c) to complement the Commonwealth laws that regulate therapeutic goods, including by providing for certain Commonwealth laws to apply as a law of New South Wales in relation to the activities of persons who are not corporations,

(d) to authorise certain activities involving scheduled substances and other therapeutic goods, including when the activities are prohibited under another law,

(e) to provide for effective administration and enforcement mechanisms in relation to scheduled substances and other therapeutic goods.

Outline of provisions

Chapter 1 Preliminary

Chapter 1 contains introductory and interpretative provisions.

Chapter 2 Regulation of supply, prescriptions and other activities

Chapter 2 deals with the following activities relating to scheduled substances and other therapeutic goods—

(a) wholesale supply,

(b) obtaining wholesale supply,

(c) non-wholesale supply,

(d) prescriptions,

(e) clinical trials.

Chapter 2 also creates various offences that relate to scheduled substances and other therapeutic goods.

Chapter 2 contains regulation-making powers that may be considered Henry VIII provisions.

Chapter 3 Licences, approvals and other authorisations

Chapter 3 deals with the following kinds of authorisations under the proposed Act—

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

(b) approvals for the supply and prescription of certain scheduled substances and other therapeutic goods by health practitioners,

(c) Opioid Treatment Program registrations,

(d) authorities that relate to the *Drug Misuse and Trafficking Act 1985*.

Chapter 4 Application of Commonwealth therapeutic goods laws

Chapter 4 provides for the application in New South Wales of the *Therapeutic Goods Act 1989* of the Commonwealth, and regulations, orders, manufacturing principles, specifications, determinations, rules, delegations and other instruments in force under that Act, including in relation to offences against that Act.

Chapter 5 Investigation functions

Chapter 5 gives various powers to authorised officers in relation to information gathering, entering premises and seizure.

Chapter 6 Enforcement

Chapter 6 deals with the following matters—

(a) the issue of compliance notices by the Secretary of the Ministry of Health (the ***Health Secretary***),

(b) the 5 tiers of penalties in the proposed Act,

(c) proceedings for offences against the proposed Act, including evidentiary provisions,

(d) the issue of penalty notices for offences against the proposed Act.

Chapter 7 Administration

Chapter 7 deals with the following matters—

(a) the Regulatory Advisory Committee and the Clinical Advisory Committee,

(b) authorised officers,

(c) analysts and analyses,

(d) public health risk authorisation orders made by the Health Secretary if there is a situation that presents a risk to the health or safety of humans or animals.

Chapter 8 Miscellaneous

Chapter 8 contains miscellaneous provisions.

Schedule 1 Members and procedures of Advisory Committees

Schedule 1 deals with the members and procedures of the Regulatory Advisory Committee and the Clinical Advisory Committee.

Schedule 2 Savings, transitional and other provisions

Schedule 2 contains savings, transitional and other provisions consequent on the enactment of the proposed Act.

Schedule 3 Dictionary

Schedule 3 defines words used in the proposed Act.

Schedule 4 Amendment of Drug Misuse and Trafficking Act 1985 No 226

Schedule 4 contains consequential amendments to the *Drug Misuse and Trafficking Act 1985*.

Schedule 5 Amendment of other legislation

Schedule 5 contains consequential amendments to various Acts and Regulations.

Table of concordance

In this Table—
PTGA means the *Poisons and Therapeutic Goods Act 1966*.
PTGR means the *Poisons and Therapeutic Goods Regulation 2008*.

Provisions of the proposed Act	Corresponding provisions of PTGA and PTGR
ss 1–3	—
ss 4 and 5	s 4 PTGA
s 6	s 8 PTGA
ss 7–13	—
ss 14 and 15	ss 9 and 11 PTGA
ss 16 and 17	—
s 18	cl 134 PTGR
ss 19–27	—
ss 28–30	s 10 PTGA

Provisions of the proposed Act	Corresponding provisions of PTGA and PTGR
s 31	cll 49 and 99 PTGR
s 32	cll 49A and 99A PTGR
s 33	s 23 PTGA
ss 34 and 35	—
s 36	cll 32 and 77 PTGR
s 37	cll 33 and 78 PTGR
ss 38 and 39	—
s 40	cll 67 and 124 PTGR
s 41	—
s 42	s 36 PTGA
s 43	s 34 PTGA
s 44	s 36A PTGA
s 45	s 36B PTGA
s 46	s 36AA PTGA
s 47	s 12 PTGA
s 48	cll 64 and 108 PTGR
ss 49–51	s 18AA PTGA and cl 175 PTGR
ss 52 and 53	—
s 54	ss 18B, 18C and 18D PTGA
ss 55 and 56	—
ss 57–61	cll 160–163 and 165–168 PTGR
s 62	cll 164 and 169 PTGR
ss 63–66	cll 172 and 173 PTGR
s 67	—
ss 68–73	ss 28, 28A and 29 PTGA
ss 74 and 75	—
ss 76–81	s 17D PTGA
ss 82–85	—
s 86	ss 31 and 32 PTGA
s 87	ss 33, 33A, 33B, 33C and 33D PTGA
s 88	ss 33E and 33F PTGA
s 89	ss 33G and 33H PTGA
s 90	s 33I PTGA
s 91	s 33J PTGA
s 92	s 33L PTGA
ss 93–98	—
ss 99, 101, 103 and 104	s 43 PTGA

Provisions of the proposed Act	Corresponding provisions of PTGA and PTGR
s 100	s 43A PTGA
s 102	—
s 105	—
ss 106–111	cll 149–154 PTGR
s 112	s 43 PTGA
ss 113–117	—
s 118	s 36D PTGA
s 119	—
s 120	s 45 PTGA
ss 121–123	—
s 124	s 39 PTGA
s 125	s 40 PTGA
s 126	s 18A PTGA
s 127	s 6 PTGA
s 128	s 30 PTGA
s 129	s 30AA PTGA
s 130	ss 6A and 30A PTGA
ss 131–133	s 42 PTGA
s 134	s 43 PTGA
s 135	—
s 136	s 43 PTGA
s 137	s 37A PTGA
ss 138 and 139	s 37B PTGA
ss 140–142	—
s 143	s 37 PTGA
ss 144–146	—
s 147	s 45D PTGA
s 148	—
ss 149 and 150	s 45C PTGA
s 151	—
Schedule 1	Schedules 1 and 2 PTGA

First print

New South Wales

Medicines, Poisons and Therapeutic Goods Bill 2022

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New South Wales

Medicines, Poisons and Therapeutic Goods Bill 2022

No , 2022

A Bill for

An Act to regulate activities involving scheduled substances and certain therapeutic goods to protect public health and safety; to repeal the *Poisons and Therapeutic Goods Act 1966* and certain instruments under that Act; and to make consequential amendments to other legislation.

Tabling copy

The Legislature of New South Wales enacts—

Chapter 1 Preliminary

1 Name of Act

This Act is the *Medicines, Poisons and Therapeutic Goods Act 2022*.

2 Commencement

This Act commences on a day or days to be appointed by proclamation.

3 Objects of Act

(1) The objects of this Act are as follows—

(a) to regulate activities involving scheduled substances and other prescribed therapeutic goods to protect public health and safety,

(b) to use the Commonwealth Poisons Standard as the basis for classifying and regulating certain substances,

(c) to complement the Commonwealth laws that regulate therapeutic goods, including by providing for certain Commonwealth laws to apply as a law of New South Wales in relation to the activities of persons who are not corporations,

(d) to authorise certain activities involving scheduled substances and other prescribed therapeutic goods, including when the activities are prohibited under another law,

(e) to provide for effective administration and enforcement mechanisms in relation to scheduled substances and other prescribed therapeutic goods.

(2) In the exercise of functions under this Act, the protection of public health and safety must be the paramount consideration.

4 Definitions

(1) The Dictionary in Schedule 3 defines words used in this Act.

Note— The *Interpretation Act 1987* contains definitions and other provisions affecting the interpretation and application of this Act.

(2) A reference in this Act to a substance using "Schedule" with a number is a reference to the substance specified in the Schedule with that number in the NSW Poisons Schedules.

Example— A Schedule 7 substance means a substance specified in Schedule 7 of the NSW Poisons Schedules.

5 Meaning of "supply" and "wholesale supply"

(1) In this Act, to ***supply*** scheduled substances and other prescribed therapeutic goods includes the following—

(a) to sell, dispense and distribute,

(b) to supply, whether for free or otherwise, as a sample or advertisement,

(c) to supply, whether for free or otherwise, for testing for safety or efficacy on humans or animals,

(d) to agree or offer to sell or distribute,

(e) to keep or possess for sale, dispensing or distribution,

(f) to send, forward, deliver or receive for sale, dispensing or distribution,

(g) to authorise, direct, cause or allow one or more of the above to be done.

(2) In this Act, to ***supply*** scheduled substances and other prescribed therapeutic goods does not include the following—

(a) to administer scheduled substances or other prescribed therapeutic goods,

(b) to supply scheduled substances or other prescribed therapeutic goods to a worker by a person for whom the worker works if—

(i) the person is authorised to obtain the substance or goods, and

(ii) the worker is authorised to supply, administer or use the substance or goods in connection with the worker's work,

(c) to supply scheduled substances or other prescribed therapeutic goods by an authorised practitioner to another authorised practitioner in the same practice for the purposes of supply or administration to patients of the practice,

(d) to supply in other prescribed circumstances, whether generally or in relation to prescribed scheduled substances or other prescribed therapeutic goods.

(3) In this Act, to ***wholesale supply*** scheduled substances and other prescribed therapeutic goods means to supply the substance or goods for the purposes of resupply.

(4) In this Act, to ***wholesale supply*** scheduled substances and other prescribed therapeutic goods does not include the following—

(a) to wholesale supply scheduled substances or other prescribed therapeutic goods to a worker by a person for whom the worker works if—

(i) the person is authorised to obtain the substance or goods, and

(ii) the worker is authorised to supply, administer or use the substance or goods in connection with the worker's work,

(b) to wholesale supply scheduled substances or other prescribed therapeutic goods by an authorised practitioner to another authorised practitioner in the same practice for the purposes of supply or administration to patients of the practice,

(c) to wholesale supply scheduled substances or other prescribed therapeutic goods by an authorised practitioner or pharmacist to an agent or carer of a patient or animal for the purposes of supply or administration to the patient or animal,

(d) to wholesale supply in other prescribed circumstances, generally or in relation to prescribed scheduled substances or other prescribed therapeutic goods.

(5) In this section—

worker means a person who does work for another person, whether as an employee, contractor or volunteer.

6 Meaning of "NSW Poisons Schedules"

(1) The Schedules to the Commonwealth Poisons Standard, as modified by the regulations—

(a) apply for the purposes of this Act, and

(b) are referred to in this Act as the ***NSW Poisons Schedules***.

(2) For the purposes of determining the Schedule to which a substance belongs, or the meaning of a reference to a scheduled substance in this Act, the following provisions of the Commonwealth Poisons Standard apply, as modified by the regulations—

(a) the definitions,

(b) other interpretation provisions,

(c) the Appendices.

(3) The regulations may modify the application of provisions of the Commonwealth Poisons Standard for the purposes of this Act, including by doing the following—

(a) adding a substance to or omitting a substance from—

(i) a Schedule, or

(ii) an Appendix, or

(iii) a class or subclass of substances,

(b) excluding the following from the NSW Poisons Schedule—

(i) a Schedule or part of a Schedule,

(ii) an Appendix or part of an Appendix,

(iii) a class or subclass of substances or part of a class or subclass of substances,

(c) relocating a substance from a Schedule or Appendix to another Schedule or Appendix,

(d) relocating a substance from a class or subclass of substances to another class or subclass, whether for the purposes of the same Schedule or Appendix or another Schedule or Appendix,

(e) renaming a Schedule, Appendix or class or subclass of substances,

(f) adding a Schedule, Appendix or class or subclass of substances,

(g) creating a category of substances for a Schedule or Appendix,

(h) modifying the interpretative provisions specified in subsection (2).

(4) To avoid doubt, the modifications that may be made by the regulations are not limited by the way in which the Commonwealth Poisons Standard does, or does not, classify or otherwise organise substances or classes or subclasses of substances.

(5) Without limiting subsections (3) and (4) or the *Interpretation Act 1987*, section 42, a modification may be limited in its application to—

(a) specified provisions of this Act or the regulations, or

(b) specified purposes or circumstances.

7 Effect of classification of substances

(1) This Act does not prevent a substance from being classified or subclassified as a scheduled substance and as a therapeutic good at the same time.

(2) If a substance is classified or subclassified as a scheduled substance or in a subclass of a scheduled substance, by reference to persons prevented, authorised or permitted to do activities involving the substance, the substance's classification or subclassification continues to apply for this Act in relation to activities carried out by other persons.

Chapter 2 Regulation of supply, prescriptions and other activities

Part 2.1 Introduction

8 Application of Chapter

(1) This Chapter makes it an offence to carry out the following activities unless authorised under this Act—

(a) wholesale supply of scheduled substances and other prescribed therapeutic goods—see Part 2.2,

(b) obtaining wholesale supply of scheduled substances and other prescribed therapeutic goods—see Part 2.3,

(c) non-wholesale supply of scheduled substances and other prescribed therapeutic goods—see Part 2.4,

(d) the issue of prescriptions for scheduled substances and other prescribed therapeutic goods—see Part 2.5.

(2) This Chapter does not limit the circumstances in which an activity that is prohibited under this Chapter may be authorised under another provision of this Act.

Note— Activities may also be authorised under the regulations or Chapter 3.

9 Authorisation of activities under other laws

(1) An activity referred to in Parts 2.2–2.6 is authorised for the purposes of this Act if the activity is carried out in accordance with a right, entitlement or authority conferred by a relevant law.

Example— The *Pesticides Act 1999* authorises the possession and use of certain Schedule 7 substances.

(2) The regulations may prescribe limitations or restrictions on the carrying out of activities authorised under subsection (1).

(3) To avoid doubt, it is not an offence under this Chapter to carry out an activity authorised under subsection (1).

10 Authorisation of activities by regulations

(1) The regulations may provide for the following in relation to activities—

(a) the persons or classes of persons who are authorised to carry out activities for the purposes of this Act,

(b) the circumstances in which activities are authorised for the purposes of this Act,

(c) the conditions, limitations, restrictions or other requirements for the carrying out of activities authorised for the purposes of this Act,

(d) exemptions from prescribed conditions, limitations, restrictions or other requirements.

(2) The regulations may provide for the Health Secretary to do the following, for the purposes of this Act, in relation to activities—

(a) authorise persons or classes of persons to carry out the activities,

(b) determine the circumstances in which activities are authorised,

(c) determine the conditions, limitations, restrictions or other requirements for the carrying out of authorised activities,

(d) exempt persons or classes of persons from prescribed conditions, limitations, restrictions or other requirements.

(3) Without limiting subsection (1) or (2), the regulations may provide for—

(a) the Health Secretary to issue licences to authorise the retail sale of prescribed Schedule 2 and 7 substances, and

(b) other matters relating to the licences, including applications for licences, determination of applications, licence conditions and licence fees.

(4) The regulations must not provide for the Health Secretary to authorise a person to issue prescriptions for scheduled substances and other therapeutic goods.

(5) Regulations may be made under this section in relation to an activity despite other provisions of this Act that regulate the activity.

11 Regulations about application of Parts 2.2–2.6

(1) The regulations may—

(a) exclude scheduled substances or other therapeutic goods from the operation of Parts 2.2–2.6, and

(b) apply Parts 2.2–2.6 to other scheduled substances or therapeutic goods.

(2) The regulations may exclude all or some substances in a NSW Poisons Schedule from the operation of Parts 2.2–2.6.

(3) A reference in a provision in Parts 2.2–2.6 to scheduled substances or other prescribed therapeutic goods is a reference to the scheduled substances and other prescribed therapeutic goods to which the provision applies.

(4) The regulations may prescribe a penalty, not exceeding a Tier 1 penalty, for the purposes of—

(a) paragraph (e) of the penalty provision in sections 14 and 28, and

(b) paragraph (d) of the penalty provision in section 36.

12 Regulations may prohibit or restrict authorised activities

(1) Despite any other provision of this Act, the regulations may—

(a) prohibit a person, or a class of persons, from carrying out an activity, or

(b) impose conditions, limitations, restrictions or other requirements on a person, or a class of persons, carrying out an activity.

(2) This section applies in relation to the carrying out of an activity by a person, or a class of persons, even if the person, or class of persons, is otherwise authorised to carry out the activity under this Act.

Part 2.2 Wholesale supply

13 Application of Part

(1) This Part applies to Schedule 2, 3, 4, 7, 8, 9 and 10 substances, subject to the regulations.

(2) This Part also applies to other prescribed therapeutic goods.

Note— Regulations under section 11 may—

(a) exclude scheduled substances or other therapeutic goods from the operation of this Part, and

(b) apply this Part to other scheduled substances or therapeutic goods.

14 Offence—unauthorised wholesale supply

A person must not wholesale supply, or cause or permit wholesale supply of, scheduled substances or other prescribed therapeutic goods unless—

(a) the wholesale supply is authorised under this Act, and

(b) the person receiving the substance or goods is authorised to obtain the substance or goods under Part 2.3.

Maximum penalty—

(a) for a Schedule 10 substance—Tier 1 penalty, or

(b) for a Schedule 7 substance—Tier 2 penalty, or

(c) for a Schedule 2 or 3 substance—Tier 3 penalty, or

(d) for a Schedule 4 substance other than a Schedule 4D substance—Tier 3 penalty, or

(e) otherwise—the prescribed penalty.

Note— The *Drug Misuse and Trafficking Act 1985* also prohibits the supply of prohibited drugs and prohibited scheduled substances. There is an exception for supply authorised under this Act.

15 Wholesale supply by licensed wholesalers

(1) Wholesale supply of scheduled substances and other prescribed therapeutic goods is authorised if the substance or goods are wholesale supplied by the holder of a wholesaler licence that authorises the holder to wholesale supply the substance or goods.

(2) This section does not apply to a Schedule 7 substance.

16 Wholesale supply of Schedule 7 substances

(1) Wholesale supply of Schedule 7 substances, other than prescribed Schedule 7 substances, is authorised if the wholesale supply is for—

(a) non-domestic use, or

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

(2) Wholesale supply of prescribed Schedule 7 substances is authorised if the substance is—

(a) supplied by the holder of a wholesaler licence that authorises the holder to wholesale supply the substance, or

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

17 Wholesale supply by public health entities

(1) Wholesale supply of Schedule 2, 3, 4 and 8 substances and other prescribed therapeutic goods by a public health entity to another public health entity is authorised.

(2) Wholesale supply of Schedule 2, 3, 4 and 8 substances and other prescribed therapeutic goods for the purposes of the State Vaccine Centre by the Health Secretary, or a person operating the State Vaccine Centre on the Health Secretary's behalf, is authorised.

18 Wholesale supply between pharmacists

Wholesale supply of Schedule 2, 3, 4 and 8 substances and other prescribed therapeutic goods by a pharmacist from a pharmacy (the ***supplying pharmacist***) to another pharmacist for a pharmacy (the ***receiving pharmacist***) is authorised if—

(a) the supplying pharmacist receives a written request in the approved form signed by the receiving pharmacist in the following circumstances—

(i) the receiving pharmacist is making the request to satisfy an order of a customer,

(ii) the supplying pharmacist, as far as reasonably practicable, supplies the receiving pharmacist only the minimum amount of the substance or goods necessary to satisfy the order of the customer, or

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

19 Return of wholesale supply

Wholesale supply of scheduled substances and other prescribed therapeutic goods is authorised if—

(a) the substance or goods were obtained by wholesale supply that is authorised under this Act, and

(b) the substance or goods are being returned to the holder of a wholesaler licence that authorises the holder to wholesale supply the substance or goods.

Part 2.3 Obtaining wholesale supply

Note— The *Drug Misuse and Trafficking Act 1985* also prohibits the possession of prohibited drugs and prohibited scheduled substances. There is an exception for possession authorised under this Act.

20 Application of Part

(1) This Part applies to Schedule 2, 3, 4, 7, 8, 9 and 10 substances, subject to the regulations.

(2) This Part also applies to other prescribed therapeutic goods.

Note— Regulations under section 11 may—

(a) exclude scheduled substances or other therapeutic goods from the operation of this Part, and

(b) apply this Part to other scheduled substances or therapeutic goods.

21 Obtaining wholesale supply by health practitioners and others

(1) Obtaining wholesale supply of Schedule 2, 3, 4 and 8 substances and other prescribed therapeutic goods by the following is authorised—

(a) a medical practitioner for medical treatment of a person,

(b) a nurse practitioner for treatment of a person,

(c) a dentist for dental treatment of a person,

(d) a veterinary practitioner for treatment of an animal,

(e) a nurse, midwife, podiatrist or optometrist if—

(i) the person's registration has an endorsement of a kind specified in the Health Practitioner Regulation National Law, section 94 that the person is qualified to possess, use or supply the substance or goods, and

(ii) the substance or goods are obtained for a purpose for which the person is qualified,

(f) a pharmacist for a pharmacy,

(g) a prescribed health practitioner for treatment of a person,

(h) a private health facility,

(i) the holder of a licence under the Commonwealth Therapeutic Goods Act, Part 3-3 or the Commonwealth Agvet Codes, Part 8.

(2) Subsection (1)(h) does not apply in relation to a Schedule 8 substance if the private health facility's licence under the *Private Health Facilities Act 2007* prohibits the supply of a Schedule 8 substance.

22 Obtaining wholesale supply by public health entities

Obtaining wholesale supply of Schedule 2, 3, 4 and 8 substances and other prescribed therapeutic goods by the following is authorised—

(a) a public hospital controlled by the Crown,

(b) a recognised establishment, within the meaning of the *Health Services Act 1997*, of an affiliated health organisation that is a hospital,

(c) a local health district,

(d) a prescribed statutory health corporation,

(e) the Health Secretary, or a person operating the State Vaccine Centre on the Health Secretary's behalf, for the purposes of the State Vaccine Centre,

(f) the Health Administration Corporation,

(g) another prescribed entity.

23 Obtaining wholesale supply in residential aged care facilities

(1) Obtaining wholesale supply of Schedule 2, 3, 4 and 8 substances and other prescribed therapeutic goods by an authorised person for a residential care facility for use in connection with the treatment of residents in the facility is authorised.

(2) In this section—

authorised person, for a residential care facility, means—

(a) the director of nursing for the facility, or

(b) if there is no director of nursing for the facility—a manager of the facility nominated by the approved provider, within the meaning of the *Aged Care Act 1997* of the Commonwealth, in relation to the facility, or

(c) another prescribed person or a person of a prescribed class.

24 Obtaining wholesale supply in correctional centres and detention centres

(1) Obtaining wholesale supply of Schedule 2, 3, 4 and 8 substances and other prescribed therapeutic goods by the following is authorised—

(a) an authorised person for a managed correctional centre for use in connection with the treatment of inmates in the centre,

(b) an authorised person for a detention centre for use in connection with the treatment of detainees in the centre,

(c) an authorised person for an immigration detention centre for use in connection with the treatment of detainees in the centre.

Note— Subsection (1) does not limit the authority of an authorised person to obtain wholesale supply of Schedule 2, 3, 4 and 8 substances and other prescribed therapeutic goods under another provision of this Division that authorises the person to obtain the substances or therapeutic goods.

(2) In this section—

authorised person means—

(a) for a managed correctional centre—

(i) a pharmacist employed or engaged by the management company for the managed correctional centre to receive wholesale supply of scheduled substances and prescribed therapeutic goods on behalf of the company, or

(ii) if there is no pharmacist as specified in subparagraph (i)—an authorised practitioner, or a registered nurse in charge of the medical treatment of inmates at the centre, appointed by the management company to receive the supply, and

(b) for a detention centre—a medical officer appointed for the detention centre, and

(c) for an immigration detention centre—

(i) a pharmacist employed or engaged by the centre to receive wholesale supply of scheduled substances and prescribed therapeutic goods on behalf of the centre, or

(ii) if there is no pharmacist as specified in subparagraph (i)—an authorised practitioner, or a registered nurse in charge of the medical treatment of detainees at the centre, appointed by the centre to receive the supply.

25 Obtaining wholesale supply by licence holders

Obtaining wholesale supply of Schedule 2, 3, 4, 8, 9 and 10 substances and other prescribed therapeutic goods is authorised if the substance or goods are obtained by—

(a) the holder of an obtain licence that authorises the holder to obtain the substance or goods, or

(b) the holder of a wholesaler licence that authorises the holder to wholesale supply the substance or goods.

26 Obtaining wholesale supply of Schedule 7 substances

(1) Obtaining wholesale supply of Schedule 7 substances, other than prescribed Schedule 7 substances, is authorised if the substance is obtained for—

(a) non-domestic use, or

(b) resupply to a person who is authorised to possess or use the Schedule 7 substance under the *Pesticides Act 1999*.

(2) Obtaining wholesale supply of prescribed Schedule 7 substances is authorised if the substance is obtained—

(a) by the holder of an obtain licence that authorises the holder to obtain the substance, or

(b) by the holder of a wholesaler licence that authorises the holder to wholesale supply the substance, or

(c) for resupply to a person authorised to possess or use the substance under the *Pesticides Act 1999*.

(3) Obtaining wholesale supply of a Schedule 7 substance is authorised if the person obtaining the substance is authorised to possess or use the substance under the *Pesticides Act 1999*.

Part 2.4 Non-wholesale supply

27 Application of Part

(1) This Part applies to Schedule 2, 3, 4, 7, 8, 9 and 10 substances, subject to the regulations.

(2) This Part also applies to other prescribed therapeutic goods.

(3) This Part does not apply in relation to wholesale supply.

Note— Regulations under section 11 may—

(a) exclude scheduled substances or other therapeutic goods from the operation of this Part, and

(b) apply this Part to other scheduled substances or therapeutic goods.

28 Offence—unauthorised non-wholesale supply

(1) A person must not supply, or cause or permit the supply of, scheduled substances or other prescribed therapeutic goods unless the supply is authorised under this Act.

Maximum penalty—

(a) for a Schedule 10 substance—Tier 2 penalty, or

(b) for a Schedule 7 substance—Tier 3 penalty, or

(c) for a Schedule 2 or 3 substance—Tier 4 penalty, or

(d) for a Schedule 4 substance other than a Schedule 4D substance—Tier 4 penalty, or

(e) otherwise—the prescribed penalty.

(2) It is not an offence under this section to supply, or cause or permit the supply of, a Schedule 7 substance to a person if the person is authorised to possess or use the Schedule 7 substance under the *Pesticides Act 1999*.

Note— The *Drug Misuse and Trafficking Act 1985* also prohibits the supply of prohibited drugs and prohibited scheduled substances. There is an exception for supply authorised under this Act.

29 Non-wholesale supply by health practitioners and veterinary practitioners

The supply of Schedule 2, 3, 4 and 8 substances and other prescribed therapeutic goods is authorised if the supply is by the following—

(a) a medical practitioner for medical treatment of a person,

(b) a nurse practitioner for treatment of a person,

(c) a dentist for dental treatment of a person,

(d) a veterinary practitioner for treatment of an animal,

(e) a nurse, midwife, podiatrist or optometrist if—

(i) the person's registration has an endorsement of a kind specified in the Health Practitioner Regulation National Law, section 94 that the person is qualified to possess, use, supply or prescribe the substance or goods, and

(ii) the substance or goods are obtained for a purpose for which the person is qualified,

(f) a prescribed health practitioner for treatment of a person.

30 Non-wholesale supply by pharmacists in pharmacies

(1) The supply of Schedule 2 and 3 substances and other prescribed therapeutic goods is authorised if the supply is by a pharmacist in a pharmacy.

(2) The supply of Schedule 2 substances is authorised if the supply is by a person employed or engaged by a pharmacy to a customer of the pharmacy.

(3) The supply of Schedule 4 and 8 substances and other prescribed therapeutic goods is authorised if the supply is—

(a) by a pharmacist in a pharmacy, and

(b) on a prescription that was authorised to be issued under section 37.

31 Non-wholesale supply by pharmacists in hospitals

(1) The supply of Schedule 2 and 3 substances and other prescribed therapeutic goods is authorised if the supply is by a pharmacist in—

(a) a public health entity, or

(b) a private health facility.

(2) The supply of Schedule 4 and 8 substances and other prescribed therapeutic goods is authorised if the supply is—

(a) by a pharmacist in—

(i) a public health entity, or

(ii) a private health facility, and

(b) on one of the following—

(i) a prescription that was authorised to be issued under section 37,

(ii) the written authorisation of an authorised practitioner, if the authorisation is entered on the patient's medication chart,

(iii) the written requisition of an appropriate person.

(3) In this section—

appropriate person means—

(a) an authorised practitioner, or

(b) a registered nurse or midwife in charge of the ward in which the substance is supplied.

authorised practitioner does not include a veterinary practitioner.

32 Non-wholesale supply by pharmacists in managed correctional centres

(1) The supply of Schedule 2, 3, 4 or 8 substances and other prescribed therapeutic goods is authorised if the supply is by a pharmacist employed or engaged by a managed correctional centre for the purposes of treating an inmate at the managed correctional centre.

(2) The supply of Schedule 4 or 8 substances and other prescribed therapeutic goods is authorised under subsection (1) only if the supply is—

(a) on the written authorisation of an authorised practitioner, if the authorisation is entered on the inmate's medication chart, or

(b) on the written requisition of an appropriate person.

(3) This section does not affect the supply of a scheduled substance or other prescribed therapeutic goods by a pharmacist employed or engaged by a pharmacy located at a managed correctional centre if the supply is otherwise authorised under this Act.

(4) In this section—

appropriate person means an authorised practitioner, registered nurse or midwife appointed, by written instrument, by the management company for the managed correctional centre for the purposes of this section.

authorised practitioner does not include a veterinary practitioner.

33 Non-wholesale supply by carers

The supply of Schedule 2, 3, 4 or 8 substances and other prescribed therapeutic goods by a carer of a person to the person is authorised if the substance or goods have been lawfully supplied to the carer for supply to the person for the person's therapeutic treatment.

34 Non-wholesale supply by State Vaccine Centre

The supply of scheduled substances and other prescribed therapeutic goods for the purposes of the State Vaccine Centre by the Health Secretary, or a person operating the State Vaccine Centre on the Health Secretary's behalf, is authorised.

Part 2.5 Prescriptions

35 Application of Part

(1) This Part applies to Schedule 2, 3, 4, 7, 8, 9 and 10 substances, subject to the regulations.

(2) This Part also applies to other prescribed therapeutic goods.

Note— Regulations under section 11 may—

(a) exclude scheduled substances or other therapeutic goods from the operation of this Part, and

(b) apply this Part to other scheduled substances or therapeutic goods.

36 Offence—unauthorised issue of prescription

A person must not issue a prescription for a Schedule 2, 3, 4, 7, 8, 9 or 10 substance unless the issue of the prescription is authorised under this Act.

Maximum penalty—

(a) for a Schedule 8, 9 or 10 substance—Tier 2 penalty, or

(b) for a Schedule 4D or 7 substance—Tier 3 penalty, or

(c) for a Schedule 2 or 3 substance or other Schedule 4 substance—Tier 4 penalty, or

(d) otherwise—the prescribed penalty.

Note— The *Drug Misuse and Trafficking Act 1985* also prohibits the supply of prohibited drugs and prohibited scheduled substances. There is an exception for supply authorised under this Act.

37 Prescriptions issued by health practitioners and veterinary practitioners

(1) This section applies to the issue of a prescription for a Schedule 2, 3, 4 or 8 substance.

(2) The issue of a prescription is authorised if it is issued by the following—

(a) a medical practitioner for medical treatment of a person,

(b) a nurse practitioner for treatment of a person,

(c) a dentist for dental treatment of a person,

(d) a veterinary practitioner for treatment of an animal,

(e) a nurse, midwife, podiatrist or optometrist if—

(i) the person's registration has an endorsement of a kind specified in the Health Practitioner Regulation National Law, section 94 that the person is qualified to prescribe the substance or goods, and

(ii) the prescription is issued for a purpose for which the person is qualified,

(f) a prescribed health practitioner for treatment of a person.

Part 2.6 Clinical trials

38 Application of Part

(1) This Part applies to prescribed Schedule 8 substances and Schedule 9 and 10 substances, subject to the regulations.

(2) This Part also applies to other prescribed therapeutic goods.

Note— Regulations under section 11 may—

(a) exclude scheduled substances or other therapeutic goods from the operation of this Part, and

(b) apply this Part to other scheduled substances or therapeutic goods.

39 Authorisation of clinical trials

(1) The Health Secretary may authorise a person, or a class of persons, to carry out an activity involving a scheduled substance or other prescribed therapeutic goods for the purposes of a clinical trial.

(2) The carrying out of the activity is authorised if it is carried out in accordance with—

(a) conditions imposed by the Health Secretary, and

(b) the prescribed requirements.

Part 2.7 Offences

40 Offence—loss or theft of Schedule 4D or 8 substances

(1) A person authorised under this Act to supply a Schedule 4D or 8 substance must notify the Health Secretary immediately after becoming aware that—

(a) the person has lost the substance, or

(b) the substance has been stolen, or

(c) a prescribed event involving the substance has occurred.

Maximum penalty—Tier 5 penalty.

(2) The regulations may provide for notifications under this section, including the circumstances in which notification is not required.

41 Offence—possessing Schedule 7 substances for domestic use

(1) A person must not possess a Schedule 7 substance for domestic use.

Maximum penalty—Tier 4 penalty.

(2) It is not an offence under this section if the possession or use of the Schedule 7 substance is authorised under the *Pesticides Act 1999*.

42 Offences—automatic machines for supplying certain therapeutic goods

(1) A person must not, in premises under the person's control or in or at another place—

(a) install an automatic machine for the supply of scheduled substances or therapeutic goods that do not contain a scheduled substance (***applicable goods***), or

(b) supply applicable goods using an automatic machine.

Maximum penalty—Tier 5 penalty.

(2) A person who occupies or controls premises is guilty of an offence if—

(a) an automatic machine for the supply of applicable goods is installed on the premises, or

(b) applicable goods are stored in an automatic machine installed on the premises, or

(c) applicable goods are supplied using an automatic machine.

Maximum penalty—Tier 5 penalty.

(3) Subsections (1) and (2) do not apply to the supply of applicable goods to or by an authorised practitioner for the treatment of a patient.

(4) The Health Secretary may, by order published in the Gazette, exempt a person or class of persons, or applicable goods or class of applicable goods, from the operation of subsection (1) or (2).

(5) An order under subsection (4) may be made with or without conditions.

(6) In this section—

automatic machine means a machine or mechanical device used, or capable of being used, for the purposes of supplying goods to members of the public without the personal manipulation or attention of the supplier or the supplier's employee or other agent at the time of supply.

43 Offence—supplying certain therapeutic goods at houses or in public places

(1) A person must not—

(a) go from house to house supplying scheduled substances or therapeutic goods that do not contain a scheduled substance (***applicable goods***), or

(b) supply applicable goods on a road or at another public place.

Maximum penalty—Tier 5 penalty.

(2) The Health Secretary may, by order published in the Gazette, exempt a person or class of persons, or applicable goods or class of applicable goods, from the operation of this section.

(3) An order under subsection (2) may be made with or without conditions.

(4) In this section—

house means premises where persons reside, whether or not permanently.

road means a road or road related area within the meaning of the *Road Transport Act 2013*.

44 Offence—administration or non-wholesale supply of unregistered or unlisted therapeutic goods

(1) A person must not administer or supply therapeutic goods for use in or on humans unless the goods are—

(a) registered goods, or

(b) listed goods, or

(c) subject to an approval, authority or exemption under the Commonwealth Therapeutic Goods Act, Chapter 3 or 4.

Maximum penalty—Tier 5 penalty.

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

(a) the supply of therapeutic goods that are medical devices, other than medical devices that contain scheduled substances,

(b) the administration or supply of therapeutic goods by a person who is a sponsor,

(c) the administration or supply of therapeutic goods by a carer of another person to the extent the goods are—

(i) a Schedule 2 or 3 substance, or

(ii) a Schedule 4 or 8 substance dispensed on a prescription by a pharmacist or supplied by an authorised practitioner for the other person,

(d) the self-administration of therapeutic goods by a person,

(e) the wholesale supply of therapeutic goods,

Note— See the Commonwealth Therapeutic Goods Act, section 21 for an offence relating to wholesale supply of unregistered or unlisted therapeutic goods.

(f) the administration or supply of prescribed therapeutic goods in prescribed circumstances,

(g) the administration or supply of therapeutic goods if—

(i) the registration or listing has been suspended 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.

(3) In this section—

listed goods, ***registered goods*** and ***sponsor*** have the same meaning as in the Commonwealth Therapeutic Goods Act.

45 Offence—supply of expired therapeutic goods

(1) A person must not, without reasonable excuse, supply scheduled substances or therapeutic goods that do not contain a scheduled substance (***applicable goods***) after the expiry date stated on or in relation to the applicable goods in accordance with a standard that applies to the applicable goods.

Maximum penalty—Tier 5 penalty.

(2) A standard applies to applicable goods for subsection (1) if the standard is—

(a) a standard specified in an order under the Commonwealth Therapeutic Goods Act that applies to the goods, or

(b) if no order applies to the goods under the Commonwealth Therapeutic Goods Act but there is a relevant monograph about the goods—a standard specified in the relevant monograph.

(3) This section applies only to a person who supplies applicable goods in the course of practising the person's profession or employment.

(4) In this section—

relevant monograph means—

(a) for applicable goods for use in or on humans—a monograph in the British, European or United States Pharmacopoeia, or

(b) for applicable goods for use in or on animals—a monograph in the British Pharmacopoeia (Veterinary) or United States Pharmacopoeia (Veterinary).

46 Offence—dispensing or compounding scheduled substances on prescription

A person must not dispense or compound a scheduled substance on a prescription issued by an authorised practitioner unless the person is a pharmacist.

Maximum penalty—Tier 4 penalty.

47 Offence—obtaining scheduled substances by false representation

(1) A person must not, by a representation the person knows, or ought reasonably to know, is false or misleading, obtain, or attempt to obtain, a scheduled substance from the following—

(a) an authorised practitioner,

(b) a pharmacist,

(c) a nurse, midwife, podiatrist or optometrist whose registration has an endorsement of a kind specified in the Health Practitioner Regulation National Law, section 94 that the person is qualified to possess, use or supply the scheduled substance,

(d) the holder of a wholesaler licence or obtain licence,

(e) another person authorised under this Act to obtain, supply or administer the scheduled substance.

Maximum penalty—Tier 5 penalty.

(2) This section does not apply to—

(a) a prohibited drug, or

(b) a prohibited scheduled substance.

48 Defence for delivering or transporting substances

This Act does not make it unlawful for a person to possess, supply or wholesale supply a scheduled substance or other prescribed therapeutic goods if—

(a) the person obtained the substance or goods from a person who is lawfully supplying or wholesale supplying the substance or goods (the ***lawful supplier***) to another person who is authorised to obtain the substance or goods (the ***recipient***), and

(b) the person is employed or engaged by the lawful supplier to deliver or transport the substance or goods to the recipient, and

(c) the possession or supply is only in connection with delivering or transporting the substance or goods to the recipient.

Part 2.8 Restriction orders

49 Health Secretary may make restriction orders

(1) The Health Secretary may, by written order (a ***restriction order***) given to a person, prohibit or restrict the person from carrying out an activity that the person is authorised to do under this Chapter, including possessing, supplying, wholesale supplying, obtaining wholesale supply, administering, dispensing, using, prescribing, manufacturing, storing or disposing of scheduled substances or other prescribed therapeutic goods.

(2) An activity is not authorised under this Act if it is carried out in contravention of a restriction order.

(3) A restriction order may, without limitation, prohibit or restrict an activity—

(a) by reference to specified therapeutic goods, circumstances, factors or exceptions, or

(b) unless it is carried out in a specified way, or

(c) generally or by reference to one or more classes or subclasses of activities.

(4) A restriction order may be made subject to conditions.

(5) A person must not contravene a restriction order applying to the person.

Maximum penalty for subsection (5)—Tier 3 penalty.

50 Grounds on which restriction orders may be made

(1) A restriction order may be made in relation to a person on one or more of the following grounds—

(a) the person has made a written request for the order,

(b) the person has been charged or convicted of an offence against—

(i) this Act or the regulations, or

(ii) the repealed *Poisons and Therapeutic Goods Act 1966*, or

(iii) a relevant law,

(c) the Health Secretary considers the person has previously contravened a restriction order,

(d) the person is a health practitioner who has given an undertaking under the Health Practitioner Regulation National Law or whose registration is subject to a condition or restriction under that Law,

(e) the person is a veterinary practitioner whose registration under the *Veterinary Practice Act 2003* is subject to a condition or limitation under that Act,

(f) the Health Secretary considers the person is someone who should be restricted or prohibited from carrying out the activity for the purposes of protecting the health or safety of the person or another person, whether or not the other person is identifiable,

(g) other prescribed grounds.

(2) A restriction order must specify the grounds on which the order is made.

51 Making restriction orders

(1) A restriction order must specify the day on which it takes effect.

(2) Unless earlier revoked, a restriction order has effect for the period, if any, specified in the order.

(3) A restriction order must be published in the Gazette as soon as practicable after the order is made.

(4) Failure to comply with subsection (3) does not invalidate the restriction order.

52 Restriction orders for health practitioners

(1) As soon as practicable after making a restriction order applying to a health practitioner, the Health Secretary must notify the Council under the *Health Practitioner Regulation National Law (NSW)* for the person's health profession.

(2) Before amending or revoking a restriction order applying to a health practitioner, the Health Secretary must consult with the Council under the *Health Practitioner Regulation National Law (NSW)* for the person's health profession.

(3) Subsection (1) does not apply to a restriction order made under section 50(1)(a).

53 Review of restriction orders

(1) A person to whom a restriction order applies may apply to the Health Secretary for a review of the decision to make the restriction order.

(2) The Health Secretary may refuse to review a decision to make a restriction order if the Health Secretary—

(a) has reviewed the decision within the previous 6 months, and

(b) is not satisfied there has been a material change in relevant circumstances.

Part 2.9 Miscellaneous

54 Regulations about scheduled substances used for cosmetic purposes

(1) The regulations may prescribe requirements about the possession, manufacture, supply, use, prescription, administration, storage and disposal of scheduled substances used for cosmetic purposes.

(2) Without limiting subsection (1), the regulations may provide that a prescribed requirement is a category 1 requirement or category 2 requirement.

(3) A person must not contravene a category 1 requirement or category 2 requirement.

Maximum penalty for subsection (3)—

(a) for a category 1 requirement—Tier 2 penalty, or

(b) for a category 2 requirement—Tier 4 penalty.

55 Regulations about activities involving certain therapeutic goods and preparations

(1) The regulations may provide for prohibiting or otherwise regulating activities in connection with the following—

(a) the manufacture, compounding, supply, administration, possession or use of the following (***applicable goods***)—

(i) scheduled substances,

(ii) therapeutic goods that are not scheduled substances,

(iii) sterile compounded preparations,

(b) the issue of prescriptions for applicable goods,

(c) the storage, labelling and packaging of applicable goods,

(d) the preparation and handling of applicable goods, including the use and condition of the premises used for the preparation and handling,

(e) the provision of access to applicable goods,

(f) record keeping in relation to applicable goods, including the keeping of registers for applicable goods,

(g) the destruction of applicable goods.

(2) Despite subsection (1), the regulations cannot prohibit the manufacture or compounding of applicable goods or sterile compounded preparations.

(3) The power to make regulations under this section is not limited by other provisions of this Chapter prohibiting or regulating, or authorising regulations to prohibit or regulate, activities of the kind specified in this section.

(4) In this section—

sterile compounded preparation means a compound of substances, whether or not containing scheduled substances, that is required to be kept sterile, and includes a preparation in—

(a) parenteral dosage form, other than an intradermal or subcutaneous injection of an allergen extract, and

(b) ophthalmic dosage form.

Chapter 3 Licences, approvals and other authorisations

Part 3.1 Introduction

56 Application of Chapter

(1) This Chapter provides for the following ***authorisations***—

(a) wholesaler licences,

(b) obtain licences,

(c) approvals,

(d) OTP registrations,

(e) DMT authorities.

(2) An activity is authorised under this Act if it is carried out in accordance with—

(a) an authorisation, and

(b) the terms and conditions, limitations and other restrictions that apply in relation to carrying out the activity.

Note— Activities may also be authorised under Chapter 2 or the regulations.

(3) An authorisation is not transferable.

(4) To avoid doubt, subsection (3) does not prevent a person from carrying out an activity relying on an authorisation granted to another person if another provision of this Act, or a provision of the regulations, authorises the reliance.

(5) An authorisation may apply, adopt or incorporate, wholly or in part and with or without modification, a standard, rule, code, specification, method or publication, as in force at a particular time or as in force from time to time, prescribed or published by an authority or body, whether or not it is a New South Wales authority or body.

Part 3.2 Licences for wholesale supply and obtaining wholesale supply of certain therapeutic goods

Division 1 Granting of wholesaler licences and obtain licences

57 Wholesaler licences and obtain licences

(1) The Health Secretary may, on application or the Health Secretary's own initiative, grant a licence (a ***wholesaler licence***) that authorises a person to wholesale supply specified scheduled substances or other prescribed therapeutic goods.

(2) The Health Secretary may, on application or the Health Secretary's own initiative, grant a licence (an ***obtain licence***) that authorises a person as follows—

(a) to obtain wholesale supply of specified scheduled substances or other prescribed therapeutic goods for use by one or more of the following—

(i) a provider under the Opioid Treatment Program,

(ii) a corporation that provides paramedical services,

(iii) a person providing ambulance transport with the consent of the Health Secretary under the *Health Services Act 1997*, section 67E,

(iv) a person engaged in the administration of a vaccination program for humans,

(v) a person on behalf of a university,

(vi) a person on behalf of a prescribed research institution, other than a university,

(vii) a person on behalf of an analytical or research and development laboratory,

(b) to obtain a prescribed Schedule 7 substance,

(c) to obtain a prescribed Schedule 10 substance that is not a prohibited drug,

(d) to obtain prescribed therapeutic goods for a prescribed purpose.

(3) In this Part—

licence means a wholesaler licence or an obtain licence.

58 Grounds for granting licence

(1) The Health Secretary may grant a licence if satisfied of all the following—

(a) the applicant is a fit and proper person to hold the licence,

(b) for an application for a licence for a Schedule 9 substance—the licence is intended for—

(i) medical or scientific research purposes, or

(ii) analysis, teaching or training purposes, or

(iii) a prescribed industrial purpose,

(c) for an application for a licence for a prescribed Schedule 7 substance—the licence is intended only for supply or obtaining supply for non-domestic use,

(d) for an application for a licence for a prescribed Schedule 7 substance marked with an "a" in the NSW Poisons List—the licence is intended only for supply or obtaining supply for an analytical or research purpose,

(e) for an application for a licence for a Schedule 9 substance, a prescribed Schedule 7 substance marked with a "p" in the NSW Poisons List or a Schedule 10 substance—the granting of the licence would not pose an unacceptable risk to public health,

(f) other prescribed matters, whether generally or for particular kinds of applications.

(2) The Health Secretary may grant a licence, even if the Health Secretary is not satisfied of all of the matters specified in subsection (1), if the Health Secretary considers it necessary to grant the licence to deal with urgent, emergency or unforeseen circumstances.

(3) To avoid doubt, the Health Secretary may refuse to grant a licence to an applicant even if the Health Secretary is satisfied of all the matters specified in subsection (1).

59 Application for licence

(1) A person may apply to the Health Secretary for a licence.

(2) An application must—

(a) be in an approved form, and

(b) be accompanied by the prescribed application fee, if any, and

(c) include or be accompanied by information or evidence the Health Secretary reasonably requires to assess the application.

Note— The *Crimes Act 1900*, Part 5A contains offences relating to the making of false or misleading applications or providing false or misleading information or documents. The offences have a maximum penalty of imprisonment for 2 years or a $22,000 fine, or both.

(3) The Health Secretary must give the person written notice of a decision to grant or refuse a licence within the prescribed period.

(4) If the Health Secretary fails to give notice within the prescribed period, the Health Secretary is taken to have refused to grant the licence.

Note— See also section 83, which enables the Health Secretary to require an applicant to provide further information in relation to an application. The Health Secretary may refuse to deal with the application until the information is provided and may reject the application after 6 months.

60 Conditions of licence

(1) A licence is subject to any conditions imposed by the Health Secretary—

(a) at the time of the grant of the licence, or

(b) at another time by variation of the licence.

(2) The conditions of a licence may provide that the licence does not take effect until—

(a) the end of a specified period, or

(b) a specified event happens, or

(c) a specified state of affairs occurs.

(3) A licence holder must not contravene a condition of the licence.

Maximum penalty for subsection (3)—Tier 5 penalty.

61 Variation of licence

(1) The Health Secretary may, by written notice to a licence holder, vary the licence, including the conditions of the licence.

(2) A variation of a licence includes the following—

(a) the imposition of a new licence condition,

(b) the substitution of a licence condition,

(c) the removal or amendment of a licence condition.

(3) The regulations may provide for—

(a) applications for variations of licences by licence holders, and

(b) the grounds for the variation of licences.

62 Annual fee for licence

(1) A licence holder must in each year, on or before 30 September or other date notified in writing by the Health Secretary to the licence holder, pay the prescribed annual fee, if any, to the Health Secretary.

(2) An annual fee is not payable for the year during which the licence was granted.

(3) The Health Secretary may accept payment of an annual fee up to 3 months after the date required under subsection (1), if an additional late fee of 50% of the annual fee is paid at the same time as the annual fee.

Division 2 Suspension or cancellation of wholesaler licences and obtain licences

63 Mandatory grounds for suspension or cancellation of licence

The Health Secretary must suspend or cancel a licence—

(a) if the licence holder requests or agrees to the suspension or cancellation, or

(b) if the licence holder is convicted of an offence against a relevant law that is punishable by imprisonment for 5 years or more, or

(c) if the Health Secretary considers the licence holder is no longer a fit and proper person to hold the licence, or

(d) on other prescribed grounds.

64 Discretionary grounds for suspension or cancellation of licence

The Health Secretary may suspend or cancel a licence on one or more of the following grounds—

(a) the licence holder contravenes a condition of the licence,

(b) the licence holder is charged with an offence against this Act, the regulations or a relevant law,

(c) the licence holder is convicted of an offence against this Act or the regulations,

(d) the licence holder is convicted of an offence against a relevant law, other than an offence that is punishable by imprisonment for 5 years or more,

(e) an order is made under the *Crimes (Sentencing Procedure) Act 1999*, section 10(1) relating to the licence holder for an offence against this Act, the regulations or a relevant law,

(f) the licence holder has made a representation in connection with the licence, including in connection with an application for the licence, that is false or misleading in a material particular,

(g) the prescribed annual fee, if any, and any late fee, for the licence has not been paid in accordance with section 62,

(h) other prescribed grounds.

65 Submissions about suspension or cancellation of licence on discretionary grounds

(1) Before suspending or cancelling a licence under section 64, the Health Secretary must give written notice to the licence holder of the Health Secretary's intention to suspend or cancel the licence and the proposed grounds for the suspension or cancellation.

(2) The notice must specify a period of at least 10 days in which the licence holder may make submissions to the Health Secretary about the proposed suspension or cancellation.

(3) Before suspending or cancelling a licence under section 64, the Health Secretary must consider any submissions made within the specified period.

(4) The Health Secretary is not required to comply with this section in relation to the suspension or cancellation of a licence if satisfied that—

(a) the time required to comply with this section would increase a risk to the health or safety of the public, or

(b) the suspension or cancellation is required for urgent or emergency reasons.

66 Notice of suspension or cancellation of licence

(1) The Health Secretary must give written notice to a licence holder of the suspension or cancellation of the licence.

(2) The notice must specify the following—

(a) the date or time from which the suspension or cancellation takes effect,

(b) the grounds for the suspension or cancellation,

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

Part 3.3 Approvals for supply and prescription of certain therapeutic goods by health practitioners

67 Application of Part

(1) This Part applies to prescribed Schedule 8 substances and other prescribed therapeutic goods.

(2) A reference in a provision in this Part to scheduled substances or therapeutic goods is a reference to the scheduled substances and prescribed therapeutic goods to which the provision applies.

68 Granting of approval

(1) The Health Secretary may, subject to the regulations, grant an approval that authorises—

(a) the supply or administration of scheduled substances or other prescribed therapeutic goods by a health practitioner or veterinary practitioner, or class of health practitioner or veterinary practitioner, specified in section 29, or

(b) the issue of a prescription for scheduled substances or other prescribed therapeutic goods by a health practitioner, or class of health practitioner, specified in section 37.

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

(3) An approval may be granted to authorise an activity referred to in subsection (1)(a) or (b) if—

(a) the activity is subject to prescribed restrictions, and

(b) the regulations require an approval for the activity to be authorised under this Act.

(4) The regulations may provide for the circumstances in which an approval, or kind of approval, may or must be granted or refused.

(5) An approval may be granted to a particular person or a class of persons.

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

(7) The Health Secretary must specify the term of an approval when granting the approval.

69 Offence—supplying or issuing prescriptions for therapeutic goods without approval

(1) A health practitioner must not in prescribed circumstances—

(a) supply or administer scheduled substances or other therapeutic goods without an approval, or

(b) issue a prescription for scheduled substances or other therapeutic goods without an approval.

Maximum penalty—Tier 5 penalty.

(2) This section does not apply to a health practitioner—

(a) acting under the direction of another health practitioner who is authorised under an approval, or

(b) carrying out an activity authorised under Part 2.6, or

(c) carrying out an activity under an OTP registration.

70 Application for approval

(1) A person may apply to the Health Secretary for an approval.

(2) An application must—

(a) be in an approved form, and

(b) include or be accompanied by information or evidence the Health Secretary reasonably requires to assess the application.

Note— The *Crimes Act 1900*, Part 5A contains offences relating to the making of false or misleading applications or providing false or misleading information or documents. The offences have a maximum penalty of imprisonment for 2 years or a $22,000 fine, or both.

(3) The Health Secretary must give the applicant written notice of a decision to grant or refuse an approval within the prescribed period.

(4) If the Health Secretary fails to give notice within the prescribed period, the Health Secretary is taken to have refused the application.

Note— Section 83 enables the Health Secretary to require an applicant to provide further information in relation to an application. The Health Secretary may refuse to deal with the application until the information is provided and may reject the application after 6 months.

71 Conditions of approval

(1) An approval is subject to conditions imposed by the Health Secretary—

(a) at the time of the grant of the approval, or

(b) at another time by variation of the approval.

(2) The conditions of an approval may provide that the approval does not take effect until—

(a) the end of a specified period, or

(b) a specified event happens, or

(c) a specified state of affairs occurs.

(3) An approval holder must not contravene a condition of the approval.

Maximum penalty for subsection (3)—Tier 5 penalty.

72 Variation of approval

(1) The Health Secretary may, by written notice, vary an approval, including the conditions of the approval.

(2) A variation of an approval includes the following—

(a) the imposition of a new approval condition,

(b) the substitution of an approval condition,

(c) the removal or amendment of an approval condition.

(3) The notice must be—

(a) for an approval granted to a particular person—given to the approval holder, or

(b) for an approval granted to a class of persons—published on the Ministry of Health's website.

(4) The regulations may provide for—

(a) applications for variations of approvals by approval holders, and

(b) the grounds for the variation of approvals.

73 Suspension or revocation of approval

(1) The Health Secretary may, subject to the regulations, suspend or revoke an approval for reasons the Health Secretary considers appropriate.

(2) The regulations may provide for the circumstances in which an approval, or kind of approval, may or must be suspended or revoked.

(3) An approval granted to a class of persons may be suspended or revoked in its application to—

(a) all the persons of the class, or

(b) specified persons of the class.

(4) Notice of the suspension or revocation of an approval 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.

(5) Notice of the suspension or revocation of an approval granted to a particular person must be given to the person.

(6) Notice of the suspension or revocation of an approval granted to a class of persons must be—

(a) if the suspension or revocation applies to all the persons of the class—published on the Ministry of Health's website, or

(b) if the suspension or revocation applies to a specified person of the class—given to the person.

Part 3.4 Opioid Treatment Program

74 Registration in Opioid Treatment Program

(1) The Health Secretary may, in accordance with the regulations, register a medical practitioner, nurse practitioner or pharmacy to carry out activities involving the following as part of the Opioid Treatment Program (an ***OTP registration***)—

(a) the supply or administration by a medical practitioner or nurse practitioner of a prescribed Schedule 8 substance or other prescribed scheduled substance,

(b) the issue of a prescription by a medical practitioner or nurse practitioner for a prescribed Schedule 8 substance or other prescribed scheduled substance,

(c) the dispensing of a prescribed Schedule 8 substance or other prescribed scheduled substance by a pharmacist at a pharmacy.

(2) An OTP registration for a pharmacy under subsection (1)(c) applies only to dispensing on a prescription issued by a medical practitioner or nurse practitioner with an OTP registration under subsection (1)(b).

(3) The regulations may provide for OTP registrations, including the following—

(a) the circumstances in which registrations, or kinds of registrations, may or must be granted or refused,

(b) the activities that medical practitioners, nurse practitioners, pharmacists and pharmacies are authorised to do under a registration,

(c) the variation, suspension or revocation of registrations,

(d) the provision of information about persons for the purposes of registrations, including information about whether persons are registrable,

(e) the keeping and publication of registers for registrations,

(f) the circumstances in which an OTP registration is not required, including in relation to particular medical practitioners, nurse practitioners, pharmacies, pharmacists and patients.

(4) The regulations may provide for standards that must be complied with by the following—

(a) a person who supplies, administers or issues prescriptions for a prescribed Schedule 8 substance or other prescribed scheduled substance under an OTP registration,

(b) a pharmacist who dispenses a prescribed Schedule 8 substance or other prescribed scheduled substance at a pharmacy under an OTP registration,

(c) a provider who is the holder of an obtain licence as referred to in section 57(2)(a)(i),

(d) another prescribed person.

75 Offence—supplying, dispensing or issuing prescriptions for certain scheduled substances without OTP registration

(1) A medical practitioner or nurse practitioner must not, without an OTP registration—

(a) supply or administer a prescribed Schedule 8 substance or other prescribed scheduled substance, or

(b) issue a prescription for a prescribed Schedule 8 substance or other prescribed scheduled substance.

Maximum penalty—Tier 5 penalty.

(2) Subsection (1) does not apply to a person acting under the direction of a medical practitioner or nurse practitioner who has an OTP registration.

(3) A pharmacist must not dispense a prescribed Schedule 8 substance or other prescribed scheduled substance from a pharmacy that does not have an OTP registration.

Maximum penalty—Tier 5 penalty.

Part 3.5 Authorities for Drug Misuse and Trafficking Act 1985

76 Granting of DMT authority

(1) The Health Secretary may, on application or the Health Secretary's own initiative, grant an authority to a person or class of persons for the purposes of the *Drug Misuse and Trafficking Act 1985* (a ***DMT authority***).

Note— The *Drug Misuse and Trafficking Act 1985* enables a person to carry out certain activities involving prohibited drugs or prohibited plants if carried out in accordance with a DMT authority.

(2) A DMT authority may authorise a person or class of persons to—

(a) do one or more of the following with a prohibited drug, prohibited scheduled substance or prohibited plant for a relevant purpose—

(i) possess the drug, substance or plant,

(ii) manufacture or produce the drug, substance or plant,

(iii) supply the drug, substance or plant,

(iv) administer the drug, substance or plant, and

(b) without limiting paragraph (a)—possess a prohibited drug, prohibited scheduled substance or prohibited plant for the purposes of the person's profession or employment.

(3) The Health Secretary must not grant a DMT authority in relation to the following—

(a) the possession, manufacture, production, cultivation or supply of low-THC hemp,

(b) the possession, manufacture, production, cultivation or supply of alkaloid poppies,

(c) the manufacture of a prohibited drug using alkaloid poppy material.

(4) A DMT authority may be granted to—

(a) a particular person, or

(b) a class of persons.

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

(6) In this section—

alkaloid poppy and ***alkaloid poppy material*** have the same meaning as in the *Poppy Industry Act 2016*.

low-THC hemp has the same meaning as in the *Hemp Industry Act 2008*.

prohibited plant has the same meaning as in the *Drug Misuse and Trafficking Act 1985*.

relevant purpose means the following purposes—

(a) medical or scientific research,

(b) analysis, teaching or training,

(c) a prescribed purpose.

77 Application for DMT authority

(1) A person may apply to the Health Secretary for a DMT authority.

(2) An application must—

(a) be in an approved form, and

(b) be accompanied by the prescribed application fee, if any, and

(c) include or be accompanied by information or evidence the Health Secretary reasonably requires to assess the application.

Note— The *Crimes Act 1900*, Part 5A contains offences relating to the making of false or misleading applications or providing false or misleading information or documents. The offences have a maximum penalty of imprisonment for 2 years or a $22,000 fine, or both.

(3) The Health Secretary must give the applicant written notice of a decision to grant or refuse a DMT authority within the prescribed period.

(4) If the Health Secretary fails to give notice within the prescribed period, the Health Secretary is taken to have refused the application.

Note— Section 83 enables the Health Secretary to require an applicant to provide further information in relation to an application. The Health Secretary may refuse to deal with the application until the information is provided and may reject the application after 6 months.

78 Duration of DMT authority

(1) A DMT authority has a term of 3 years unless the Health Secretary—

(a) specifies a different term when granting the DMT authority, or

(b) extends the term before the end of the term.

(2) A DMT authority remains in force until the DMT authority—

(a) expires, or

(b) is sooner revoked or surrendered.

(3) A DMT authority has no effect during a period in which the DMT authority is suspended.

79 Conditions of DMT authority

(1) A DMT authority is subject to—

(a) prescribed conditions, and

(b) conditions imposed by the Health Secretary—

(i) at the time of the grant of the DMT authority, or

(ii) at another time by variation of the DMT authority.

(2) The conditions of a DMT authority may provide the DMT authority does not take effect until—

(a) the end of a specified period, or

(b) a specified event happens, or

(c) a specified state of affairs occurs.

(3) The holder of a DMT authority must not contravene a condition of the DMT authority.

Maximum penalty for subsection (3)—Tier 5 penalty.

80 Variation of DMT authority

(1) The Health Secretary may, by written notice, vary a DMT authority, including any conditions imposed on the DMT authority by the Health Secretary.

(2) A variation of a DMT authority includes the following—

(a) the imposition of a new condition on the DMT authority,

(b) the substitution of a condition of the DMT authority,

(c) the removal or amendment of a condition of the DMT authority.

(3) The notice must be—

(a) for a DMT authority granted to a particular person—given to the holder of the DMT authority, or

(b) for a DMT authority granted to a class of persons—published on the Ministry of Health's website.

(4) The regulations may provide for—

(a) applications for variations of DMT authorities, and

(b) the grounds for variations of DMT authorities.

81 Suspension or revocation of DMT authority

(1) The Health Secretary may, subject to the regulations, suspend or revoke a DMT authority for reasons the Health Secretary considers appropriate.

(2) The regulations may provide for the circumstances in which a DMT authority, or kind of DMT authority, may or must be suspended or revoked.

(3) A DMT authority granted to a class of persons may be suspended or revoked in its application to—

(a) all the persons of the class, or

(b) specified persons of the class.

(4) Notice of a suspension or revocation of a DMT authority 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.

(5) Notice of a suspension or revocation of a DMT authority granted to a particular person must be given to the person.

(6) Notice of a suspension or revocation of a DMT authority granted to a class of persons must be—

(a) for a suspension or revocation applying to all the persons of the class—published on the Ministry of Health's website, or

(b) for a suspension or revocation applying to a specified person of the class—given to the person.

Part 3.6 Miscellaneous

Division 1 Investigation of applications for licences, approvals and DMT authorities

82 Application of Division

This Division applies to an application for the following—

(a) a wholesaler licence,

(b) an obtain licence,

(c) an approval,

(d) a DMT authority.

83 Information about applications for licences, approvals and DMT authorities

(1) The Health Secretary may, by written notice, require an applicant to do one or more of the following—

(a) provide relevant information that was not included in the application,

(b) provide documentary or other evidence in support of relevant information included in the application or later provided to the Health Secretary,

Example— A photograph of the applicant.

(c) authorise a person specified in the notice to provide the relevant information specified in the notice,

(d) authorise a person specified in the notice to—

(i) produce, in accordance with directions in the notice, relevant records specified in the notice, and

(ii) permit the examination of the records, the taking of extracts from the records and the making of copies of the records,

(e) provide the Health Secretary with the authorities and consents required by the Health Secretary for the purposes of enabling the Health Secretary to obtain relevant information, including financial and other confidential information, from other persons about the applicant.

(2) If a requirement made under this section is not complied with, the Health Secretary may—

(a) refuse to consider the application while the non-compliance continues, and

(b) if the non-compliance continues for 6 months or more—refuse the application without dealing with it further.

(3) A person who complies with a requirement of a notice under this section does not incur a liability to another person because of the compliance.

(4) In this section—

relevant, in relation to information or records, means information or records that are relevant to the Health Secretary's investigation of an application.

84 Investigation of applications for licences, approvals and DMT authorities

If the Health Secretary receives an application, the Health Secretary may—

(a) carry out, or arrange for the carrying out of, investigations and inquiries in relation to the application that the Health Secretary considers necessary for a proper consideration of the application, and

(b) seek information or advice from a person with functions under corresponding Australian legislation relating to the authorisation of persons to carry out activities to which the application relates, and

(c) refer an application, including supporting information, to the Regulatory Advisory Committee or Clinical Advisory Committee for advice.

Division 2 Fees

85 Fees for licences, approvals, OTP registrations and DMT authorities

(1) The regulations may provide for fees in connection with the following—

(a) wholesaler and obtain licences,

(b) approvals,

(c) OTP registrations,

(d) DMT authorities.

(2) Fees include the following—

(a) application fees,

(b) annual fees,

(c) fees for variations or extensions of licences, approvals, OTP registrations and DMT authorities.

(3) The regulations may provide for the reduction, postponement, waiver or refund of fees, including by providing for the Health Secretary to reduce, postpone, waive or refund the fees.

(4) The regulations may provide for fees to be not payable by specified persons or classes of persons.

Chapter 4 Application of Commonwealth therapeutic goods laws

86 Application of Commonwealth therapeutic goods laws

(1) The Commonwealth therapeutic goods laws, as in force from time to time and as modified by the regulations, apply as a law of New South Wales and are referred to in this Act as the ***applied provisions***.

(2) The Commonwealth therapeutic goods laws apply as a law of New South Wales as if the laws extended to things done or omitted to be done—

(a) by a person who is not a corporation, and

(b) during trade or commerce within the limits of New South Wales.

(3) The regulations under this Act may modify the Commonwealth therapeutic goods laws for the purposes of this section.

(4) The *Acts Interpretation Act 1901* and the *Legislation Act 2003* of the Commonwealth, as in force from time to time, apply—

(a) as laws of New South Wales in relation to the interpretation of the applied provisions, and

(b) as if the applied provisions were an Act of the Commonwealth or regulations or orders under an Act of the Commonwealth, as the case requires.

(5) The *Interpretation Act 1987* does not apply to the applied provisions.

87 Functions of Commonwealth Minister, Commonwealth Secretary and others

(1) The Commonwealth Minister has the same functions under the applied provisions as the Commonwealth Minister has under the Commonwealth therapeutic goods laws as the laws apply to the Commonwealth.

(2) The Commonwealth Secretary has the same functions under the applied provisions as the Commonwealth Secretary has under the Commonwealth therapeutic goods laws as the laws apply to the Commonwealth.

(3) Without limiting subsection (2), the Commonwealth Secretary has the function of including goods in the Australian Register of Therapeutic Goods kept under the applied provisions and is authorised to cancel the inclusion of goods in the Register in accordance with the applied provisions.

(4) An authorised person, authorised officer or official analyst appointed under the Commonwealth therapeutic goods laws has the same functions under the applied provisions as the person, officer or analyst has under the Commonwealth therapeutic goods laws as the laws apply to the Commonwealth.

(5) A delegation by the Commonwealth Minister or the Commonwealth Secretary under the Commonwealth therapeutic goods laws is taken to extend to, and have effect for the purposes of, the corresponding provision of the applied provisions.

(6) The appointment of a person to an office or position under a provision of the Commonwealth therapeutic goods laws is taken to extend to, and have effect for the purposes of, the applied provisions.

(7) In this section—

Commonwealth Minister means the Minister responsible for administering the Commonwealth therapeutic goods laws.

88 Application of Commonwealth administrative laws

(1) The Commonwealth administrative laws apply as a law of New South Wales to matters arising in relation to the applied provisions as if the applied provisions were laws of the Commonwealth and not a law of New South Wales.

(2) For the purposes of the law of New South Wales, a matter arising in relation to the applied provisions—

(a) is taken to be a matter arising in relation to the laws of the Commonwealth in the same way as if the applied provisions were laws of the Commonwealth, and

(b) is taken not to be a matter arising in relation to the law of New South Wales.

(3) Subsection (2) has effect for the purposes of the law of New South Wales except as provided for by the regulations.

(4) A provision of a Commonwealth administrative law applying because of this section purporting to confer jurisdiction on a federal court is taken not to have the effect.

(5) If a Commonwealth administrative law, which applies because of this section, confers a function on a Commonwealth officer or authority, the law also confers the same function on the officer or authority in relation to a matter arising in relation to the applied provisions.

(6) In exercising a function conferred by this section, the Commonwealth officer or authority must act as nearly as is practicable as the officer or authority would act in exercising the same function under the Commonwealth administrative law.

(7) A function conferred on a Commonwealth officer or authority because of this section must not be exercised by an officer or authority of New South Wales.

(8) In this section—

Commonwealth administrative laws means the following Acts of the Commonwealth and the regulations under the Acts—

(a) the *Administrative Appeals Tribunal Act 1975*,

(b) the *Freedom of Information Act 1982*,

(c) the *Ombudsman Act 1976*,

(d) the *Privacy Act 1988*.

89 Application of Commonwealth criminal laws

(1) An offence against the applied provisions must be treated as if it were an offence against a law of the Commonwealth.

(2) The purposes for which an offence against the applied provisions must be treated as an offence against a law of the Commonwealth include, without limitation, the following—

(a) the investigation and prosecution of offences,

(b) the arrest, custody, bail, trial and conviction of offenders or persons charged with offences,

(c) proceedings relating to a matter referred to in paragraph (a) or (b),

(d) appeals and reviews relating to criminal proceedings and to proceedings relating to a matter referred to in paragraph (a) or (b),

(e) the sentencing, punishment and release of persons convicted of offences,

(f) fines, penalties and forfeitures,

(g) liability to make reparation in connection with offences,

(h) proceeds of crime,

(i) spent convictions.

(3) The Commonwealth laws relating to the matters specified in subsection (2) apply as a law of New South Wales in relation to an offence against the applied provisions as if the applied provisions were laws of the Commonwealth and not a law of New South Wales.

(4) For the purposes of the law of New South Wales, an offence against the applied provisions—

(a) is taken to be an offence against the laws of the Commonwealth, as if the applied provisions were laws of the Commonwealth, and

(b) is taken not to be an offence against the law of New South Wales.

(5) Subsection (4) has effect for the purposes of the law of New South Wales except as provided by the regulations.

90 Functions of Commonwealth officers and authorities relating to offences

(1) If a Commonwealth law, which applies because of section 89, confers a function in relation to an offence against the Commonwealth therapeutic goods laws on a Commonwealth officer or authority, the law also confers the same function on the officer or authority in relation to an offence against the corresponding provision of the applied provisions.

(2) In exercising a function conferred by this section, the Commonwealth officer or authority must act as nearly as practicable as the officer or authority would act in exercising the same function in relation to an offence against the corresponding provision of the Commonwealth therapeutic goods laws.

91 No double jeopardy for offences against applied provisions

An offender is not liable to be punished for an offence against the applied provisions for an act or omission if—

(a) the act or omission is an offence against both the applied provisions and the Commonwealth therapeutic goods laws, and

(b) the offender has been punished for the offence under the Commonwealth therapeutic goods laws.

92 Commonwealth may keep fees paid to Commonwealth Secretary

The Commonwealth may keep fees paid to, or recovered by, the Commonwealth Secretary for the exercise of functions conferred on the Commonwealth Secretary by the applied provisions.

Chapter 5 Investigation functions

Part 5.1 Information gathering

93 Application of Part

A reference in this Part to an authorised officer does not include a police officer.

94 Powers to require information and records

(1) An authorised officer may, by written notice given to a person, require the person to provide the authorised officer with information or records, or both, that the authorised officer requires for ensuring compliance with this Act and the regulations, including compliance with the conditions of a licence, approval or DMT authority (referred to in this Chapter as ***compliance purposes***).

(2) A notice must specify—

(a) the way in which the information or records must be provided, and

(b) a reasonable time by which the information or records must be provided.

(3) A notice may only require a person to provide existing records that are—

(a) in the person's possession, or

(b) within the person's power to obtain lawfully.

(4) The authorised officer to whom records are provided under this section may make copies of the records.

(5) Records must be provided in written form, unless the notice otherwise provides.

95 Power to require answers

(1) An authorised officer may require a person to answer questions in relation to a relevant matter if the authorised officer suspects on reasonable grounds that the person has knowledge of the relevant matter.

(2) An authorised officer may, by written notice given to a corporation, require the corporation to nominate, within the time specified in the notice, one or more of the following, who has relevant knowledge about the corporation's activities, as the corporation's representative for the purposes of answering questions under this section—

(a) a director of the corporation,

(b) an officer of the corporation,

(c) a contractor.

(3) Answers given by a person nominated by the corporation bind the corporation.

(4) An authorised officer may, by written notice, require a person to attend at a specified place and time to answer questions if attendance at the place is reasonably required for the questions to be properly put and answered.

(5) The place and time at which a person may be required to attend under subsection (4) must be a place and time nominated by the authorised officer that is reasonable in the circumstances.

(6) In this section—

relevant matter means a matter in relation to which information is reasonably required for compliance purposes.

96 Recording of evidence

(1) An authorised officer may arrange for questions and answers to questions given under this Part to be recorded if the authorised officer has informed the person who will be questioned that a record will be made.

(2) A record may be made using—

(a) audio or audio visual equipment, or

(b) another method determined by the authorised officer.

(3) A copy of the record must be provided by the authorised officer to the person who is questioned as soon as practicable after the copy is made.

(4) A record may be made under this section despite the provisions of another law.

97 Power to require name and address

An authorised officer may require a person who the authorised officer suspects on reasonable grounds to have committed, or to be committing, an offence against this Act or the regulations to state the person's full name, date of birth and residential address.

98 Privilege against self-incrimination not affected

A requirement made under this Part does not affect the privilege against self-incrimination as it applies to an individual.

Part 5.2 Entering premises

99 Powers to enter premises

(1) An authorised officer may enter premises at a reasonable time for compliance purposes.

(2) Entry to premises may be effected under this Act—

(a) with the use of reasonable force, and

(b) with or without the authority of a search warrant.

(3) This Part does not empower an authorised officer to enter a part of premises used only for residential purposes without—

(a) the permission of the occupier, or

(b) the authority of a search warrant.

100 Search warrants

(1) An authorised officer may apply to an issuing officer for the issue of a search warrant for premises if the authorised officer believes on reasonable grounds—

(a) a requirement imposed by or under this Act is being or has been contravened at the premises, or

(b) there is, in or on the premises, a matter or thing connected with an offence under this Act or the regulations.

(2) An issuing officer to whom an application is made may, if satisfied there are reasonable grounds for doing so, issue a search warrant authorising an authorised officer named in the warrant—

(a) to enter the premises, and

(b) to exercise a function of an authorised officer under this Chapter.

(3) The *Law Enforcement (Powers and Responsibilities) Act 2002*, Part 5, Division 4 applies to a search warrant issued under this section.

(4) In this section—

issuing officer means an authorised officer within the meaning of the *Law Enforcement (Powers and Responsibilities) Act 2002*.

101 Powers permitted to be exercised on premises

(1) An authorised officer may, at premises lawfully entered, do anything the authorised officer considers necessary to be done for compliance purposes, including the following—

(a) search the premises,

(b) examine and inspect a thing, including open and examine a receptacle, container or package,

(c) take and remove samples of a thing, including for analysis,

(d) make examinations, inquiries or tests the authorised officer considers necessary,

(e) take photographs or other recordings the authorised officer considers necessary,

(f) require records or other documents to be produced for inspection,

(g) examine, inspect and remove records or other documents,

(h) copy records or other documents,

(i) seize a thing if the authorised officer has reasonable grounds for believing—

(i) the thing is connected with an offence against this Act or the regulations, or

(ii) the owner of the thing cannot readily be identified or determined,

(j) move a seized thing from the place where the thing is seized or leave the thing at the place where the thing is seized and take reasonable action to restrict access to the thing,

(k) direct the occupier of the premises where a thing is seized to keep the thing at the premises or at another place under the control of the occupier,

(l) require a person holding or required to hold a wholesaler licence, obtain licence, approval, OTP registration or DMT authority to produce it for inspection,

(m) anything else authorised by or under this Act.

(2) The power to examine and inspect a thing includes a power to use reasonable force to break open or otherwise access a container or other thing being used, or suspected of being used, to hold or contain another thing.

(3) The power to seize a thing connected with an offence includes a power to seize—

(a) a thing for or with which the offence has been committed, and

(b) a thing providing evidence of the commission of the offence, and

(c) a thing used for the purposes of committing the offence.

(4) The power to do a thing under this section—

(a) includes a power to require or arrange for the thing to be done, and

(b) may be exercised without the consent of the owner of the thing.

(5) In this section, a reference to an offence includes a reference to an offence there are reasonable grounds for believing has been committed.

102 Power to require name and address

An authorised officer may, at premises lawfully entered, require a person who the authorised officer suspects on reasonable grounds to have committed, or to be committing, an offence against this Act or the regulations to state the person's full name, date of birth and residential address.

103 Requiring assistance

(1) An authorised officer may require the owner or occupier of premises, or another person in or on premises, other than a public place, to provide the reasonable assistance the authorised officer specifies for the purposes of exercising the authorised officer's functions under this Part in relation to the premises.

(2) The requirement may be given—

(a) as a verbal direction to the person, or

(b) by written notice to the person.

104 Use of force

In exercising a power of entering or searching premises under this Part, or doing anything else on premises under this Act, an authorised officer must use no more force that is reasonably necessary to exercise the power.

Part 5.3 Seized things

105 Definition

In this Part—

seized thing means a thing seized by an authorised officer under Part 5.2.

106 Release of seized things

(1) A seized thing must be released at the end of the period of 6 months after the seizure (the ***return period***) unless, before the end of the return period, the thing is forfeited to the State under this Part.

(2) The Health Secretary may, by written notice given to the apparent owner, extend the return period for a particular seized thing.

(3) A seized thing may be released—

(a) by or at the direction of—

(i) the authorised officer who seized the thing, or

(ii) the Health Secretary, and

(b) to the owner of the thing or the person who had possession, care, custody or control of the thing at the time the thing was seized.

(4) This section does not—

(a) require the release of a seized thing that was damaged or destroyed during analysis, or

(b) prevent a seized thing from being released before the end of the return period.

107 Forfeiture of seized things by order

(1) A seized thing is forfeited to the State if the Health Secretary makes an order under this section declaring the forfeiture of the thing.

(2) The Health Secretary may, by written order, declare a seized thing to be forfeited to the State if satisfied that—

(a) a person has been convicted of an offence in connection with the seized thing, or

(b) the owner of the seized thing cannot be found despite inquiries being made that are reasonable in the circumstances, or

(c) the seized thing cannot be returned to the owner for other reasons despite efforts being made that are reasonable in the circumstances, or

(d) the return of the seized thing would pose an unacceptable risk to the health or safety of a human or animal, whether or not identifiable, or

(e) other prescribed grounds.

(3) At least 21 days before making an order, the Health Secretary must give written notice to the apparent owner of a seized thing of the intention to declare the seized thing to be forfeited.

(4) The notice must specify a period within which the apparent owner may make submissions to the Health Secretary before the order is made.

(5) The Health Secretary must consider any submissions made within the specified period.

(6) The Health Secretary is not required to give notice to the apparent owner of a seized thing if—

(a) an authorised officer has given a written certificate that the authorised officer is unable to return the seized thing to the owner, or

(b) the Health Secretary is satisfied that—

(i) the owner of the seized thing cannot be found despite inquiries being made that are reasonable in the circumstances, or

(ii) the seized thing cannot be returned to the owner for other reasons despite efforts being made that are reasonable in the circumstances.

108 Forfeiture of seized things with consent

(1) The owner of a seized thing, or the person who had possession, care, custody or control of the thing at the time the thing was seized, may give written consent for the forfeiture of the thing.

(2) The seized thing is forfeited to the State when the written consent is given.

109 Order for expenses to be paid

(1) If a person from whom a seized thing has been seized is convicted of an offence in connection with the seized thing, the Supreme Court or Local Court may order the person to pay the Health Secretary an amount the Court considers appropriate to cover the reasonable costs of—

(a) seizing the thing, and

(b) dealing with the thing under this Part, and

(c) conducting an analysis for which the thing is submitted.

(2) Before making an order, the Court may require specified notice to be given to specified persons, as the Court considers appropriate.

110 Storage of and interference with seized things

(1) Subject to the directions of the Health Secretary, a seized thing may be kept or stored at—

(a) the premises at which the thing was seized, or

(b) another place the authorised officer who seized the thing considers appropriate.

(2) A person must not remove, alter or interfere with a seized thing without the approval of an authorised officer or the Health Secretary.

Maximum penalty for subsection (2)—Tier 5 penalty.

111 Disposal of forfeited things

A seized thing forfeited under this Part may be disposed of in a way directed by the Health Secretary, whether generally or in a particular circumstance or class of circumstances.

Part 5.4 Miscellaneous

112 Offence—contravention of requirement made by authorised officer

(1) A person must not, without reasonable excuse, contravene a requirement made of the person by an authorised officer exercising a power under this Chapter.

Maximum penalty—Tier 4 penalty.

(2) A person is not guilty of an offence of failing to comply with a requirement to provide records or information or to answer a question unless the person was warned on the occasion that failure to comply is an offence.

113 Variation or revocation of notices

(1) The Health Secretary and an authorised officer may vary or revoke a notice given under this Chapter by a subsequent notice or notices.

(2) Without limiting subsection (1), a notice may be varied by extending the time for complying with the notice.

114 Destruction of things surrendered by enforcement agencies

(1) This section applies if a relevant enforcement agency—

(a) lawfully seizes a thing, and

(b) is not required under law to return the thing to the person from whom it was seized or to the owner.

(2) An authorised recipient may—

(a) agree to receive a thing that the relevant enforcement agency lawfully surrenders to the authorised recipient, and

(b) destroy, or authorise the destruction of, the thing if—

(i) a decision is made not to prosecute a person for an offence under this Act or another Act in connection with the thing, or

(ii) a decision is not made within 6 months of the surrender of the thing to prosecute a person for an offence under this Act or another Act in connection with the thing.

(3) Damages or other compensation is not payable to a person for the destruction of a thing in accordance with this section.

(4) In this section—

authorised recipient means the Health Secretary or a person authorised by the Health Secretary for the purposes of this section.

relevant enforcement agency means—

(a) the Australian Border Force, or

(b) another prescribed entity of an Australian jurisdiction with power to seize things that are or may be therapeutic goods.

Chapter 6 Enforcement

Part 6.1 Compliance notices

115 Compliance notices

(1) The Health Secretary may give a person a written notice (a ***compliance notice***) if the Health Secretary believes the person—

(a) is contravening—

(i) a provision of this Act or the regulations, or

(ii) a condition of a wholesaler licence, obtain licence, approval, OTP registration or DMT authority, or

(b) has contravened a provision or condition in circumstances making it likely the contravention will continue or be repeated.

(2) A compliance notice may require the person—

(a) to remedy the contravention, or

(b) to prevent a likely contravention from occurring, or

(c) to remedy the things or operations causing the contravention or likely contravention.

(3) A compliance notice must specify—

(a) the grounds on which the compliance notice is given, including the particular contravention on which the compliance notice is based, and

(b) the compliance period.

(4) A compliance notice may include directions about the measures to be taken to remedy the contravention or prevent the likely contravention.

(5) Before the end of the compliance period, the Health Secretary may, by written notice to the person, extend the compliance period for a compliance notice.

(6) A person must comply with the compliance notice within the compliance period.

Maximum penalty—Tier 4 penalty.

(7) The Health Secretary may vary or revoke a compliance notice.

(8) A compliance notice is not invalid only because of—

(a) a formal defect or irregularity in the compliance notice, unless the defect or irregularity causes or is likely to cause substantial injustice, or

(b) a failure to use the correct name of the person to whom the compliance notice is issued if the compliance notice—

(i) sufficiently identifies the person, and

(ii) is given to the person in accordance with this Act.

(9) In this section—

compliance period, for a compliance notice, means the period within which a person is required to comply with the compliance notice and includes the period as extended under subsection (5).

116 Review of compliance notices

(1) A person to whom a compliance notice is issued under section 115 may apply to the Health Secretary for a review of the decision to issue the compliance notice.

(2) An application must be—

(a) in an approved form, and

(b) made within the compliance period for the compliance notice under section 115.

(3) The Health Secretary may refuse to consider an application for review if the Health Secretary—

(a) has considered an application for review in relation to the same compliance notice within the previous 6 months, and

(b) is not satisfied there has been a material change in relevant circumstances.

(4) The Health Secretary must determine an application for review by—

(a) confirming the compliance notice, or

(b) varying the compliance notice, or

(c) revoking the compliance notice.

Part 6.2 Offences and penalties

117 Maximum penalty for Tier 1, 2, 3, 4 and 5 offences

The following table sets out the maximum penalties for offences against this Act or the regulations for Tiers 1, 2, 3, 4 and 5—

	Penalty for individuals		Penalty for corporations	
Tier	**Penalty**	**Additional penalty for each day of continuing offence**	**Penalty**	**Additional penalty for each day of continuing offence**
Tier 1	2 years' imprisonment or 400 penalty units, or both	200 penalty units	2,000 penalty units	1,000 penalty units
Tier 2	6 months' imprisonment or 200 penalty units, or both	100 penalty units	1,000 penalty units	500 penalty units
Tier 3	100 penalty units	50 penalty units	500 penalty units	250 penalty units
Tier 4	50 penalty units	25 penalty units	250 penalty units	125 penalty units
Tier 5	20 penalty units	10 penalty units	120 penalty units	60 penalty units

118 Contraventions by corporations

(1) If a corporation contravenes a provision of this Act or the regulations, each person who is a director of the corporation or who is concerned in the management of the corporation is taken to have contravened the same provision if the person knowingly authorised or permitted the contravention.

(2) A person may be proceeded against and convicted under a provision as provided by subsection (1) whether or not the corporation has been proceeded against or convicted under the provision.

(3) This section does not affect the liability imposed on a corporation for an offence committed by the corporation under this Act or the regulations.

119 Continuing offences

(1) This section applies to a provision of this Act or the regulations requiring a person to do, or stop doing, something (a ***continuing requirement provision***) regardless of whether—

(a) the requirement is imposed by a notice or in another way, or

(b) the person is required to do, or stop doing, something within a specified period.

(2) A person who is guilty of an offence because the person contravenes a continuing requirement provision—

(a) continues, until the requirement is complied with and despite the fact a specified period has expired or time has passed, to be liable to comply with the requirement, and

(b) is guilty of a continuing offence for each day the contravention continues.

(3) This section does not apply to an offence if the relevant provision of this Act or the regulations does not provide for a penalty for a continuing offence.

Note— A provision that has a Tier 1–5 penalty includes a penalty for a continuing offence.

(4) This section does not apply to the extent that a requirement imposed on a person is revoked.

120 Proceedings for offences

(1) Proceedings for an offence under this Act or the regulations may be dealt with—

(a) summarily before the Local Court, or

(b) summarily before the Supreme Court in its summary jurisdiction.

(2) Proceedings for an offence must be commenced not later than 2 years from when the offence was alleged to have been committed.

121 Penalty notices

(1) An authorised officer may issue a penalty notice to a person if it appears to the officer the person has committed a penalty notice offence.

(2) A penalty notice offence is an offence against this Act or the regulations prescribed by the regulations as a penalty notice offence.

(3) The *Fines Act 1996* applies to a penalty notice issued under this section.

Note— The *Fines Act 1996* provides that, if a person issued with a penalty notice does not wish to have the matter determined by a court, the person may pay the amount specified in the notice and is not liable to further proceedings for the alleged offence.

(4) The amount payable under a penalty notice issued under this section is the amount prescribed for the alleged offence by the regulations, not exceeding the maximum amount of penalty that could be imposed for the offence by a court.

(5) This section does not limit the operation of another provision of, or made under, this Act or another Act relating to proceedings that may be taken for offences.

122 Protection from personal liability

(1) A relevant person does not commit an offence against this Act or the regulations for an activity carried out in the exercise of functions under this Act or the regulations.

(2) A relevant person, or an individual acting under the direction of a relevant person, is not personally subject to civil liability for anything done or omitted to be done—

(a) in good faith, and

(b) for the purposes of exercising functions under this Act or the regulations.

(3) In this section—

civil liability includes an action, claim or demand.

relevant person means the following—

(a) the Health Secretary or a delegate of the Health Secretary,

(b) an authorised officer,

(c) a member of the Clinical Advisory Committee,

(d) a member of the Regulatory Advisory Committee.

123 Exclusion of civil liability of State and State authorities

(1) This section applies to civil proceedings for compensation brought against the State or an authority of the State.

(2) Compensation is not payable in civil proceedings to the extent the claim is based on alleged negligence, defamation or other breach of duty, including statutory duty, arising because of the exercise of, or the failure to exercise, functions under this Act or the regulations in good faith.

(3) In this section—

compensation includes damages and other forms of monetary compensation.

Part 6.3 Evidentiary matters

124 Certificates issued by Health Secretary

(1) A certificate purportedly issued by the Health Secretary or an authorised Health certifier stating a matter specified in subsection (2) was, or was not the case, at a specified time or during a specified period is—

(a) admissible in legal proceedings under this Act or another Act, and

(b) prima facie evidence of the matters stated.

(2) The following matters may be certified in a certificate issued under this section—

(a) a person had, or did not have, a particular authorisation,

(b) an authorisation was, or was not, subject to a particular condition, restriction, limitation or other requirement,

(c) a person was, or was not, an authorised officer or analyst,

(d) other prescribed matters relating to the enforcement or administration of this Act or the regulations.

(3) In this section—

authorisation includes an approval, exemption or other authority issued by the Health Secretary under this Act or the regulations.

authorised Health certifier means an employee of the Ministry of Health with written authorisation, whether generally or specifically, from the Health Secretary to issue a certificate under this section.

125 Certificates issued by analysts

(1) An analyst may give a certificate of the results of an analysis of a substance provided for analysis under this Act if the analyst—

(a) analysed the substance, or

(b) supervised or directed the analysis of the substance.

(2) A certificate purportedly issued by an analyst under this section about the results of an analysis is—

(a) admissible in legal proceedings under this Act or another Act, and

(b) prima facie evidence of the matters stated.

(3) A certificate purportedly issued by an interstate analyst under corresponding Australian legislation about the results of the analysis of a substance is—

(a) admissible in legal proceedings under this Act or another Act, and

(b) prima facie evidence of the matters stated.

(4) An analysis to which a certificate referred to in subsection (3) relates is taken to be an analysis of a substance provided under this Act.

(5) In this section—

interstate analyst means a person, however described, who analysed, or who supervised or directed the analysis of, a substance for the purposes of corresponding Australian legislation.

126 Presumptions

(1) This section applies to proceedings for a contravention of a provision of this Act or the regulations.

(2) Evidence that a substance or good is, for the purposes of supply or dispensing, represented as being or including a particular therapeutic good is prima facie evidence that the substance or good is or includes the particular therapeutic good.

(3) A substance or good is represented as being or including a particular therapeutic good for subsection (2) if —

(a) a name or description commonly used for the therapeutic good is also used for the substance or good, or

(b) the substance or good, or the container, is marked or labelled in the way that the therapeutic good or a thing including a therapeutic good, or the container, are required by the regulations to be marked or labelled, or

(c) the substance or good, or the container, is marked or labelled in another way to indicate it is, includes or may include the therapeutic good.

(4) In this section—

label includes to attach a tag, brand, mark or written statement to, or use a tag, brand, mark or written statement in connection with, a substance or good or a container or package containing the substance or good.

Chapter 7 Administration

Part 7.1 Regulatory Advisory Committee and Clinical Advisory Committee

127 Regulatory Advisory Committee

(1) The Regulatory Advisory Committee is established by this Act.

(2) The function of the Committee is to advise the Health Secretary on matters referred to it by the Health Secretary relating to the following—

(a) the operation, administration or amendment of this Act, the regulations and the NSW Poisons Schedules, including proposals to make, alter or repeal the regulations,

(b) therapeutic goods or stock medicines,

(c) the scheduling of substances under the Commonwealth Therapeutic Goods Act.

(3) The Committee also has other functions conferred or imposed on it by or under this Act or another Act.

(4) The Committee must consist of not less than 9, and not more than 15, members appointed by the Health Secretary.

(5) The Health Secretary must appoint the following—

(a) a person nominated by the Commissioner of Police,

(b) a person nominated by SafeWork NSW,

(c) a person nominated by the Australian Medical Association,

(d) a person nominated by the New South Wales branch of the Pharmacy Guild of Australia,

(e) a person nominated by the New South Wales branch of the Pharmaceutical Society of Australia.

(6) The Health Secretary may appoint persons who the Health Secretary considers have qualifications or experience in the following areas—

(a) medical, dental, nursing and midwifery,

(b) veterinary practice,

(c) industrial use of scheduled substances, including in primary industry,

(d) pharmacology,

(e) toxicology,

(f) the medicines manufacturing and distribution industries,

(g) the development of medicines and the regulation of scheduled substances, including their registration as therapeutic goods under the Commonwealth Therapeutic Goods Act,

(h) assessing the risk of harm to humans, animals or the environment arising in connection with therapeutic goods,

(i) as a consumer of therapeutic goods.

(7) The Health Secretary may also appoint persons who the Health Secretary considers have prescribed qualifications or experience.

(8) The Health Secretary must appoint a member of the Committee as Chairperson.

(9) Schedule 1 contains provisions relating to the members and procedure of the Committee.

128 Clinical Advisory Committee

(1) The Clinical Advisory Committee is established by this Act.

(2) The Committee has the following functions—

(a) to make recommendations to the Health Secretary about applications for approvals and existing approvals,

(b) to advise the Health Secretary on other matters referred to the Committee by the Health Secretary,

(c) prescribed functions.

(3) The Committee must consist of at least 6 members appointed by the Health Secretary.

(4) Each member must be a medical practitioner, nurse practitioner or other prescribed health practitioner.

(5) The Health Secretary must appoint a member of the Committee as Chairperson.

(6) Schedule 1 contains provisions relating to the members and procedure of the Committee.

129 Information required from Health Care Complaints Commission and certain health practitioner bodies

(1) For the purposes of exercising its function under section 128(2)(a), the Clinical Advisory Committee may, by written notice to a relevant body, require a relevant body to provide information that the Committee reasonably requires to exercise the function.

(2) A relevant body must comply with a requirement given under this section.

(3) This section applies despite any provision of the *Health Care Complaints Act 1993* or the *Health Practitioner Regulation National Law (NSW)*.

(4) In this section—

relevant body means the following—

(a) Health Care Complaints Commission,

(b) Medical Council of New South Wales,

(c) Medical Board of Australia,

(d) Nursing and Midwifery Council of New South Wales,

(e) Nursing and Midwifery Board of Australia.

130 Subcommittees

(1) The Regulatory Advisory Committee and the Clinical Advisory Committee may—

(a) establish subcommittees for the purposes of assisting the Committee in the exercise of the Committee's functions under this Act, and

(b) appoint as a member of a subcommittee a person the Committee considers to be qualified to be a member of the subcommittee.

(2) The members of a subcommittee do not need to be members of the Committee.

Part 7.2 Authorised officers

131 Appointment of authorised officers

(1) The Health Secretary may, by written instrument, appoint each of the following to be an authorised officer, either generally or in relation to a particular function exercisable by authorised officers under this Act or the regulations—

(a) an employee of the Ministry of Health,

(b) a member of the NSW Health Service,

(c) other prescribed persons or classes of persons.

(2) An appointment may apply to a specified person or to persons of a specified class.

(3) An appointment may be unconditional, or subject to conditions or limitations.

(4) An appointment has effect for the period specified in the instrument of appointment or, if no period is specified, until revoked by the Health Secretary.

(5) The Heath Secretary may, by written instrument, revoke or amend an appointment under this section.

(6) If an appointment of an authorised officer is made by reference to a particular office, the person appointed ceases to be an authorised officer if the person ceases to hold the office.

132 Police officers taken to be authorised officers

(1) A police officer is taken to be an authorised officer for this Act, other than for the purposes of Part 5.1.

(2) This Act does not limit the functions of a police officer under the *Law Enforcement (Powers and Responsibilities) Act 2002* or another law, including the functions of a police officer in relation to seized items.

133 Functions of authorised officers

Subject to the terms of an authorised officer's appointment, an authorised officer has the functions conferred or imposed on an authorised officer by or under this Act or another Act.

134 Certificate of authority for authorised officers

(1) The Health Secretary must ensure an authorised officer is issued with a certificate of authority.

(2) The certificate of authority must—

(a) specify it is issued under this Act, and

(b) give the name of the person to whom it is issued, and

(c) include a recent photograph of the person to whom it is issued, and

(d) describe the nature of the powers conferred and the source of the powers, and

(e) specify the date, if any, on which it expires, and

(f) describe the kind of premises to which the power extends, and

(g) be signed by the person issuing the certificate and specify the capacity in which the person is acting in issuing the certificate.

Note— A certificate of authority may be issued in the form of a card.

(3) A person who has ceased to be an authorised officer must not, without reasonable excuse, fail to return to the Health Secretary, within the period specified by the

Health Secretary in a request for the return of the certificate, a certificate of authority issued to the person by the Health Secretary.

Maximum penalty—Tier 5 penalty.

(4) An authorised officer must not exercise a function conferred by or under this Act unless a certificate of authority has been issued to the authorised officer.

(5) When exercising the functions of an authorised officer under this Act, the officer must, if requested to do so by a person affected by the exercise of the function, produce to the person the officer's certificate of authority.

(6) This section does not apply to—

(a) a power conferred by a search warrant, or

(b) an authorised officer who is a police officer.

135 Use of assistants

(1) An authorised officer exercising a function conferred by or under this Act may exercise the function with the assistance of another person that the authorised officer considers necessary.

(2) The person may accompany an authorised officer and take all reasonable steps to assist the authorised officer in the exercise of the authorised officer's functions under this Act.

136 Offences—obstruction or impersonation

(1) A person must not resist or obstruct an authorised officer in the exercise of the officer's functions under this Act.

Maximum penalty—Tier 3 penalty.

(2) A person must not assault, abuse or threaten an authorised officer or encourage another person to do so.

Maximum penalty—Tier 3 penalty.

(3) A person must not impersonate an authorised officer.

Maximum penalty—Tier 3 penalty.

Part 7.3 Analysts and analyses

137 Appointment of analysts

(1) The Health Secretary may, by written instrument, appoint a person as an analyst for the purposes of this Act.

Note— An analyst appointed for the purposes of this Act is also an analyst under the *Drug Misuse and Trafficking Act 1985*.

(2) An appointment may apply to a specified person or to persons of a specified class.

(3) An appointment may be unconditional, or subject to conditions or limitations.

(4) An appointment has effect for the period specified in the instrument of appointment or, if no period is specified, until revoked by the Health Secretary.

(5) The Health Secretary may, by written instrument, revoke or amend an appointment under this section.

(6) If an appointment of an analyst is made by reference to a particular office, the person appointed ceases to be an analyst if the person ceases to hold the office.

138 Conduct of analyses

(1) A person may submit for analysis under this section a substance or goods seized under this Act.

(2) An analyst must carry out or personally supervise the carrying out of an analysis of a substance or goods submitted to the analyst for analysis.

(3) An analyst who has carried out or personally supervised the carrying out of an analysis of the substance or goods may, and must on request, issue a certificate of analysis setting out the results of the analysis.

(4) The owner of the substance or goods, or the person in whose possession or under whose control the substance or goods were when they were seized, is entitled to be given a copy of the certificate of analysis relating to the substance or goods on payment of the prescribed fee, if any.

139 Offence—use of analysis for trade purposes or advertisement

A person must not, for trade purposes or advertisement, use—

(a) the results of an analysis carried out for the purposes of this Act, or

(b) a certificate of analysis issued under section 138(3).

Maximum penalty—Tier 5 penalty.

Part 7.4 Orders by Health Secretary

Division 1 Public health risk authorisation orders

140 Health Secretary may make public health risk authorisation orders

(1) The Health Secretary may make an order (a ***public health risk authorisation order***) that authorises a specified person or class of persons to possess, supply, wholesale supply, obtain wholesale supply, administer, dispense, use, prescribe, manufacture, store or dispose of therapeutic goods or stock medicines.

(2) The Health Secretary may make a public health risk authorisation order if the Health Secretary considers on reasonable grounds that—

(a) a situation presents, or is likely to present, a risk to the health or safety of humans or animals, and

(b) the order is necessary or convenient to deal with the risk and the possible consequences.

(3) A public health risk authorisation order must specify the following—

(a) the purpose of the order, including the risk being dealt with,

(b) the person or class of persons authorised by the order,

(c) the activity the person or class of persons specified in the order is authorised to do,

(d) the therapeutic goods or stock medicines in relation to which the person or class of persons is authorised to undertake the activity,

(e) other conditions to which the authorisation is subject.

(4) A public health risk authorisation order is not invalid just because the matter referred to in subsection (3)(a) is not specified in the order.

(5) A public health risk authorisation order must be published in the Gazette as soon as practicable after it is made.

(6) The Health Secretary must consult with the Secretary of the Department of Regional NSW before making a public health risk authorisation order that relates to, or affects, the health or safety of animals.

(7) Failure to comply with subsection (5) or (6) does not invalidate the public health risk authorisation order.

(8) The operation of a public health risk authorisation order may be extended by the making of a further order under this section on or before the expiry of the order.

(9) The regulations may prescribe other requirements to be complied with before a public health risk authorisation order may be made or extended.

141 Duration of public health risk authorisation orders

(1) A public health risk authorisation order commences on—

(a) the day specified in the order, or

(b) if no day is specified—the day on which the order is published in the Gazette.

(2) A public health risk authorisation order may commence on a day before the day it is published in the Gazette.

(3) Unless earlier revoked, a public health risk authorisation order expires at the end of—

(a) 90 days after it commences, or

(b) an earlier day specified in the order.

142 Effect of public health risk authorisation orders

(1) A person is not prevented from taking action authorised by a public health risk authorisation order by anything in this Act, the *Drug Misuse and Trafficking Act 1985* or the *Stock Medicines Act 1989*.

(2) To avoid doubt, a public health risk authorisation order authorises action, but it does not impose an obligation on a person.

Division 2 Supply prohibition orders

143 Health Secretary may make supply prohibition orders

(1) The Health Secretary may make an order (a ***supply prohibition order***) that prohibits the supply of a substance specified in the order if satisfied that the substance should not be supplied pending the evaluation of the toxic or deleterious properties of the substance.

(2) A supply prohibition order must be published in the Gazette as soon as practicable after it is made.

(3) Failure to comply with subsection (2) does not invalidate the supply prohibition order.

(4) A supply prohibition order commences on—

(a) the day specified in the order, or

(b) if no day is specified—the day on which the order is published in the Gazette.

(5) Unless earlier revoked, a supply prohibition order expires at the end of—

(a) 90 days after it commences, or

(b) an earlier day specified in the order.

(6) A person must not contravene a supply prohibition order.

Maximum penalty for subsection (6)—Tier 4 penalty.

Chapter 8 Miscellaneous

144 Health Secretary may recover fees and charges

(1) A fee or other charge payable under this Act, the regulations or the applied provisions may be recovered by the Health Secretary as a debt due to the Crown in a court of competent jurisdiction.

(2) The Health Secretary may refund, waive or postpone the whole or part of a fee or other charge payable under this Act, the regulations or the applied provisions.

145 Service of documents

(1) A document authorised or required by this Act or the regulations to be given to a person may be given by the following methods—

(a) for an individual—by personal delivery to the person,

(b) by post to the address specified by the person for the giving of documents of the kind,

(c) for an individual who does not have a specified address—by post to the residential or business address of the person last known to the person giving the document,

(d) for a corporation—by post to the registered office or other office of the corporation or by leaving it at the office with a person who is apparently more than 16 years of age,

(e) by email to an email address specified by the person for the giving of documents of the kind,

(f) by another method authorised by the regulations for the giving of documents of the kind.

(2) This section does not affect the operation of provisions of a law or of the rules of a court authorising a document to be given to or served on a person by another method.

146 Disclosure of information

A person must not disclose information obtained in connection with the administration or execution of this Act unless the disclosure is made—

(a) with the consent of the person from whom the information was obtained, or

(b) in connection with the administration or execution of this Act or the regulations, or

(c) for the purposes of legal proceedings arising out of this Act or the regulations, or

(d) in prescribed circumstances, or

(e) with other lawful excuse.

Maximum penalty—Tier 2 penalty.

147 Act to bind Crown

This Act binds the Crown in right of New South Wales and, to the extent the legislative power of the Parliament of New South Wales permits, the Crown in all its other capacities.

148 Review of Act

(1) The Minister must review this Act to determine whether—

(a) the policy objectives of the Act remain valid, and

(b) the terms of the Act remain appropriate for securing the objectives.

(2) The review must be undertaken as soon as possible after the period of 5 years from the commencement of this section.

(3) A report on the outcome of the review must be tabled in each House of Parliament within 12 months after the end of the period of 5 years.

149 Regulations

(1) The Governor may make regulations, not inconsistent with this Act, about—

(a) matters required or permitted to be prescribed by this Act, or

(b) matters necessary or convenient to be prescribed for carrying out or giving effect to this Act.

(2) Without limiting the *Interpretation Act 1987*, section 42, the regulations may—

(a) apply to—

(i) specified therapeutic goods or classes of therapeutic goods, or

(ii) specified persons or classes of persons, or

(iii) specified circumstances, and

(b) if made for the purposes of including or excluding a thing from a definition—apply generally or be limited to—

(i) specified provisions of this Act, or

(ii) specified activities, or

(iii) therapeutic goods for specified provisions of this Act.

(3) If the regulations may provide for the Health Secretary to determine a matter, the regulations may provide for the Health Secretary to determine the matter as follows—

(a) generally or limited to a particular person, premises or circumstances or class of persons, premises or circumstances,

(b) generally or limited to a particular scheduled substance or other therapeutic goods or class of scheduled substance or other therapeutic goods,

(c) unconditionally or subject to conditions.

(4) The regulations may apply, adopt or incorporate, wholly or in part and with or without modification, an Appendix of the Commonwealth Poisons Standard.

(5) The regulations may apply, adopt or incorporate, wholly or in part and with or without modification, a standard, rule, code, specification, method or publication, as in force at a particular time or as in force from time to time, prescribed or published by an authority or body, whether or not it is a New South Wales authority or body.

(6) The regulations may create offences, including continuing offences, punishable by a penalty not exceeding—

(a) for a corporation—100 penalty units, or

(b) for an individual—20 penalty units.

150 Specific regulation-making powers

Without limiting section 149, the regulations may provide for the following—

(a) the calculation for the purposes of the NSW Poisons Schedules of percentages for liquid preparations,

(b) preparing, supplying, storing, labelling, packaging, handling, carrying and delivering scheduled substances and therapeutic goods,

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

(d) wholesaler and obtain licences, approvals, OTP registrations and DMT authorities,

(e) sampling, examining, testing and analysing therapeutic goods,

(f) the quantities of Schedule 4D substances, or the determination of the quantities of Schedule 4D substances, for the purposes of a possession for deemed supply offence under the *Drug Misuse and Trafficking Act 1985*,

(g) conditions to be complied with when preparing, supplying, storing, packing, handling, carrying and delivering scheduled substances and other prescribed therapeutic goods,

(h) records required to be kept for the purposes of activities relating to scheduled substances or other prescribed therapeutic goods,

(i) the persons authorised to order or receive scheduled substances or other prescribed therapeutic goods on behalf of another person or body,

Example— employees at a residential aged care facility or a correctional centre

(j) the use of medical devices, including restrictions, conditions and offences,

(k) the loss, theft, altering or tampering of prescriptions,

(l) review of decisions made by the Health Secretary or other persons under this Act or the regulations, including the way in which reviews are to be conducted.

Example— a review of a restriction order and the way in which the review is to be conducted

151 Repeals

The following are repealed—

(a) the *Poisons and Therapeutic Goods Act 1966* No 31,

(b) the *Poisons and Therapeutic Goods (Poisons List) Proclamation 2016*,

(c) the *Poisons and Therapeutic Goods Regulation 2008*.

Schedule 1 Members and procedures of Advisory Committees

sections 127 and 128

1 Definition

In this Schedule—

Advisory Committee means—

(a) the Clinical Advisory Committee, or

(b) the Regulatory Advisory Committee.

2 Terms of office and remuneration

(1) A member of an Advisory Committee holds office for 3 years and is eligible, if otherwise qualified, for re-appointment.

(2) A member of an Advisory Committee is entitled to be paid remuneration, including travelling and subsistence allowances, as determined by the Health Secretary from time to time.

3 Acting members

(1) The Health Secretary may, from time to time, appoint a person to act in the office of a member of an Advisory Committee during the illness or absence of the member or vacancy in the office.

(2) While acting in the place of the member, the acting member has all the functions of the member and is taken to be a member.

(3) The Health Secretary may remove a person from the office to which the person was appointed under this section.

4 Vacancy in office of member

(1) The office of a member of an Advisory Committee becomes vacant if the member—

(a) dies, or

(b) completes a term of office and is not re-appointed, or

(c) resigns the office by written notice to the Health Secretary, or

(d) is removed from office by written order of the Health Secretary, or

(e) is absent from 4 consecutive meetings of the Committee of which reasonable notice has been given to the member personally or by post, except on leave granted by the Health Secretary or unless the member is excused by the Health Secretary for having been absent from the meetings, or

(f) becomes bankrupt, applies to take the benefit of a law for the relief of bankrupt or insolvent debtors, compounds with creditors or makes an assignment of the member's remuneration for the creditors' benefit, or

(g) becomes a mentally incapacitated person, or

(h) is convicted in New South Wales of an offence that is punishable by imprisonment for 12 months or more, or

(i) is convicted outside of New South Wales of an offence that, if committed in New South Wales, would be punishable by imprisonment for 12 months or more.

(2) If the office of a member of an Advisory Committee becomes vacant, a person must, subject to this Act, be appointed to fill the vacancy.

5 Chairperson

(1) The Chairperson of an Advisory Committee must preside at a meeting of Committee.

(2) If the Chairperson is absent from a meeting of the Committee, another member elected to chair the meeting must preside at the meeting.

(3) The presiding member has a deliberative vote and, if there is an equality of votes, has a second or casting vote.

(4) The Chairperson vacates office as Chairperson if the person—

(a) resigns the office by written instrument to the Health Secretary, or

(b) is removed from the office by the Health Secretary under this section, or

(c) ceases to be a member of the Committee.

(5) The Health Secretary may at any time remove the Chairperson from office as Chairperson.

6 Conduct of members

(1) A member of an Advisory Committee must—

(a) act honestly and exercise a reasonable degree of care and diligence in carrying out the member's functions, and

(b) act for a proper purpose in carrying out the member's functions, and

(c) not use the office of member for personal advantage, and

(d) not use the office of member to the detriment of the Committee, and

(e) disclose interests, whether pecuniary or otherwise, that could conflict with the proper performance of the member's functions and avoid exercising a function that could involve a conflict of interest.

(2) This section applies to a member of a subcommittee of an Advisory Committee in the same way as it applies to a member of the Committee.

7 Disclosure of pecuniary interests

(1) This section applies if—

(a) a member of an Advisory Committee has a direct or indirect pecuniary interest in a matter being considered or about to be considered at a meeting of the Committee, and

(b) the interest appears to raise a conflict with the proper performance of the member's duties in relation to the consideration of the matter.

(2) The member must, as soon as possible after the relevant facts have come to the member's knowledge, disclose the nature of the interest at a meeting of the Committee.

(3) It is sufficient disclosure of the nature of an interest relating to a specified company, body or person if the member has previously disclosed that the member—

(a) is a member, or is in the employment, of the company or body, or

(b) is a partner, or is in the employment, of the person, or

(c) has some other specified interest relating to the company, body or person.

(4) Particulars of a disclosure made under this section must be recorded by the Advisory Committee and made available to a person at all reasonable hours on payment of the fee determined by the Committee.

(5) After a member has disclosed the nature of an interest in a matter, the member must not, unless the Health Secretary or the Advisory Committee otherwise determines—

(a) be present during a deliberation of the Committee about the matter, or

(b) take part in a decision of the Committee about the matter.

(6) A member who has a direct or indirect pecuniary interest in a matter to which a disclosure relates must not—

(a) be present at the time the Committee is making a determination for the purposes of subsection (5), or

(b) take part in the making of the determination.

(7) A contravention of this section does not invalidate a decision of the Advisory Committee.

(8) This section applies to a member of a subcommittee of an Advisory Committee and the subcommittee in the same way as it applies to a member of the Committee and the Committee.

8 General procedure

(1) The procedure for the calling of meetings of an Advisory Committee and for the conduct of business at the meetings is, subject to this Act and the regulations, to be as determined by the Committee.

(2) The quorum for a meeting of an Advisory Committee is a majority of the members at the time of the meeting.

(3) A decision supported by a majority of the votes cast at a meeting of an Advisory Committee at which a quorum is present is the decision of the Committee.

(4) The Health Secretary may call the first meeting of an Advisory Committee in the way the Health Secretary thinks fit.

9 Transaction of business outside meetings or by telephone or other electronic means

(1) An Advisory Committee may, if it thinks fit, transact any of its business—

(a) by the circulation of papers, by email or other electronic means, among all members, or

(b) at a meeting at which all or some members participate by telephone, audio-visual link or other means, but only if a member who speaks on a matter at the meeting can be heard by the other members.

(2) If an Advisory Committee transacts its business by the circulation of papers under subsection (1)(a), a written resolution approved in writing by a majority of the members is taken to be a decision of the Advisory Committee made at an Advisory Committee meeting.

(3) For the purposes of a meeting held under subsection (1)(b) or the approval of a resolution under subsection (2), each member has the same voting rights as at an ordinary Advisory Committee meeting.

(4) A resolution approved under subsection (2) is, subject to the regulations, to be recorded in the minutes of the Advisory Committee meeting.

10 Application of Government Sector Employment Act 2013

The provisions of the *Government Sector Employment Act 2013* relating to the employment of Public Service employees do not apply to a member of an Advisory Committee.

11 Effect of other Acts

(1) This section applies if a provision under an Act—

(a) requires a person who is the holder of a specified office to devote the whole of the person's time to the duties of the office, or

(b) prohibits the person from engaging in employment outside the duties of the office.

(2) The provision does not operate to disqualify the person from—

(a) holding that office and also the office of a member, or

(b) accepting and keeping the remuneration payable to the person under this Act as a member.

Schedule 2 Savings, transitional and other provisions

Part 1 General

1 Regulations

(1) The regulations may contain provisions of a savings or transitional nature consequent on the commencement of—

(a) a provision of this Act, or

(b) a provision amending this Act.

(2) A savings or transitional provision consequent on the commencement of a provision must not be made more than 2 years after the commencement.

(3) A savings or transitional provision made consequent on the commencement of a provision is repealed 2 years after the commencement.

(4) A savings or transitional provision made consequent on the commencement of a provision may take effect before the commencement but not before—

(a) for a provision of this Act—the date of assent to this Act, or

(b) for a provision amending this Act—the date of assent to the amending Act.

(5) A savings or transitional provision taking effect before its publication on the NSW legislation website does not—

(a) affect the rights of a person existing before the publication in a way prejudicial to the person, or

(b) impose liabilities on a person for anything done or omitted to be done before the publication.

(6) In this section—

person does not include the State or an authority of the State.

Part 2 Provisions consequent on enactment of this Act

2 Definitions

In this Part—

commencement date means the date on which this Act commences.

existing wholesaler's licence means—

(a) a wholesaler's licence under the former Act, or

(b) a licence under the former Regulation, Part 8, Divisions 1–3 that authorises the wholesale supply of poisons, restricted substances or drugs of addiction under the former Act.

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*.

3 New obtain licences for existing wholesaler's licences

(1) This section applies to a person who, immediately before the commencement date, held an existing wholesaler's licence that authorised the person to wholesale supply a particular substance in the person's capacity as one of the following—

(a) a provider under the Opioid Treatment Program,

(b) a corporation providing paramedical services,

(c) a person providing ambulance transport with the consent of the Health Secretary under the *Health Services Act 1997*, section 67E,

(d) a person engaged in the administration of a vaccination program for humans.

(2) The person is taken, on the commencement date, to hold an obtain licence under the new Act that authorises the person to obtain wholesale supply of the particular substance.

(3) The obtain licence is subject to the same conditions, if any, of the existing wholesaler's licence, subject to the regulations.

(4) The obtain licence remains in force—

(a) for the period specified in the existing wholesaler's licence, if any, or

(b) until suspended or cancelled by the Health Secretary under the new Act, Part 3.2, Division 2.

4 New wholesaler licences for existing wholesaler's licences

(1) This section applies to a person—

(a) who, immediately before the commencement date, held an existing wholesaler's licence that authorised the person to wholesale supply a particular substance, and

(b) to whom this Schedule, section 3 does not apply.

(2) The person is taken, on the commencement date, to hold a wholesaler licence under the new Act that authorises the person to wholesale supply the particular substance.

(3) The wholesaler licence is subject to the same conditions, if any, of the existing wholesaler's licence, subject to the regulations.

(4) The wholesaler licence remains in force—

(a) for the period specified in the existing wholesaler's licence, if any, or

(b) until suspended or cancelled by the Health Secretary under the new Act, Part 3.2, Division 2.

5 Existing prohibition or restriction orders

(1) This section applies to a person who, immediately before the commencement date, was subject to an order under the former Act, section 18AA or the former Regulation, clause 175 (a ***former order***).

(2) The person is taken, on the commencement date, to be subject to a restriction order under the new Act, section 49.

(3) The restriction order is taken to—

(a) be in the same terms as the former order, and

(b) be subject to the same conditions, if any, of the former order, and

(c) have effect until revoked by the Health Secretary under the new Act.

(4) To avoid doubt, the new Act, Part 2.8, other than sections 50 and 52(1), applies in relation to the restriction order.

6 Exemptions for automatic machines that supply certain therapeutic goods

An order made by the Minister under the former Act, section 36(4) in force on the commencement date is taken, on the commencement date, to be an order made by the Health Secretary under this Act, section 42(4).

7 Existing inspectors

(1) A person who, immediately before the commencement date, was an inspector under the former Act is taken, on the commencement date, to be an authorised officer appointed by the Health Secretary under the new Act.

(2) Subsection (1) does not apply to a police officer who was taken to be a police officer under the former Act, section 42(6).

(3) To avoid doubt, the new Act, section 134 applies in relation to a person taken to be an authorised officer under this section.

8 Existing analysts

A person who, immediately before the commencement date, was an analyst under the former Act, is taken, on the commencement date, to be an analyst appointed by the Health Secretary under the new Act.

9 Existing certificates

(1) During the transition period, a reference in the new Act to a certificate issued under the new Act, section 124 includes a reference to a certificate given by the Health Secretary or a person employed in the Ministry of Health under the former Act, section 39.

(2) During the transition period, a reference in the new Act to a certificate given by an analyst under the new Act, section 125 includes a reference to a certificate given by an analyst under the former Act, section 40.

(3) In this section—

transition period means the period commencing on the commencement date and ending 2 years after the commencement date.

10 Existing licences to supply Schedule 2 substances

If regulations are made under the new Act, section 10(3)(a) in relation to licences that authorise the retail sale of prescribed Schedule 2 substances, the regulations may also provide for savings and transitional matters in relation to licences in force under the former Regulation, Part 8, Division 1, immediately before the commencement date.

Schedule 3 Dictionary

section 4

activity means an activity in relation to scheduled substances and other therapeutic goods, whether or not authorised under this Act or the regulations, and includes an omission.

administer, in relation to therapeutic goods—

(a) means—

(i) to introduce into, or apply to, the body of a human or animal by any means a dose of the goods, or

(ii) to give a dose of the goods to a human to be taken immediately, but not to give a dose to be taken at a later time, and

(b) does not include a prescribed thing.

Advisory Committee, for Schedule 1—see Schedule 1, section 1.

analyst means a person appointed by the Health Secretary under this Act as an analyst.

animal means a vertebrate or invertebrate animal, except a human being, at any stage of biological development.

another Australian jurisdiction means an Australian jurisdiction other than New South Wales.

applied provisions means the Commonwealth therapeutic goods laws that apply as laws of New South Wales because of section 86.

approval means an approval granted by the Health Secretary under section 68.

approved form means a form approved from time to time by the Health Secretary by written order for a particular provision of this Act or the regulations.

Australian jurisdiction means a State, a Territory or the Commonwealth.

authorisation means the following—

(a) a wholesaler licence,

(b) an obtain licence,

(c) an approval,

(d) an OTP registration,

(e) a DMT authority.

authorised officer means a person appointed by the Health Secretary under this Act as an authorised officer.

Note— A police officer is taken to be an authorised officer, other than for Part 5.1.

authorised practitioner—

(a) means the following—

(i) a medical practitioner,

(ii) a nurse practitioner,

(iii) a dentist,

(iv) a veterinary practitioner,

(v) a person of a prescribed class, and

(b) does not include a person of a prescribed class.

carer of a person means a parent, spouse, partner, other member of the person's family or other individual caring for the person, or assisting the person to care for the person, whether on a permanent or temporary basis.

Clinical Advisory Committee means the Clinical Advisory Committee established by section 128.

Commonwealth Agvet Codes means the Agvet Codes within the meaning of the *Agricultural and Veterinary Chemicals Act 1994* of the Commonwealth.

Commonwealth Poisons Standard means the current Poisons Standard within the meaning of the Commonwealth Therapeutic Goods Act, as in force from time to time.

Commonwealth Secretary means the Secretary of the Commonwealth Department of Health or other Commonwealth Department that is the relevant Department for the purposes of the Commonwealth therapeutic goods laws.

Commonwealth Therapeutic Goods Act means the *Therapeutic Goods Act 1989* of the Commonwealth.

Commonwealth therapeutic goods laws means—

(a) the Commonwealth Therapeutic Goods Act, and

(b) all regulations, orders, manufacturing principles, specifications, determinations, rules, delegations and other instruments in force under that Act.

compliance purposes, for Chapter 5—see section 94(1).

corresponding Australian legislation means—

(a) an Act or other legislation of another Australian jurisdiction regulating or prohibiting the use, possession, supply or dispensing of substances or goods that are scheduled substances, other therapeutic goods or stock medicines for the purposes of this Act, and

(b) a prescribed Act or other legislation of another Australian jurisdiction, whether prescribed generally or for particular provisions of this Act.

detention centre has the same meaning as in the *Children (Detention Centres) Act 1987*.

DMT authority means an authority granted by the Health Secretary under section 76.

domestic use, in relation to Schedule 7 substances, includes domestic garden use.

done, in relation to an omission, includes omitted to be done.

entity means the following, whether or not formed or located in New South Wales—

(a) a person,

(b) a body or group of persons, whether incorporated or unincorporated,

(c) a partnership or joint venture,

(d) the trustee, or if there is more than one trustee, the trustees together, of a trust,

(e) another legal, administrative or fiduciary arrangement or other organisational structure capable of deploying resources to achieve objectives.

exercise a function includes perform a duty.

function includes a power, authority or duty.

Health Administration Corporation means the Health Administration Corporation constituted by the *Health Administration Act 1982*.

health practitioner has the same meaning as in the *Health Practitioner Regulation National Law (NSW)*.

Health Practitioner Regulation National Law means—

(a) the Health Practitioner Regulation National Law—

(i) as in force from time to time, set out in the Schedule to the *Health Practitioner Regulation National Law Act 2009* of Queensland, and

(ii) as it applies, including with modifications, as a law of New South Wales or another State or Territory, or

(b) the law of another State or Territory that substantially corresponds to the law referred to in paragraph (a).

Health Secretary means the Secretary of the Ministry of Health.

holder of an authorisation granted to a particular person because of an application by the person means the person to whom the authorisation has been granted.

immigration detention centre means a detention centre established under the *Migration Act 1958* of the Commonwealth.

inmate has the same meaning as in *Crimes (Administration of Sentences) Act 1999*.

licence, for Part 3.2—see section 57.

local health district has the same meaning as in the *Health Services Act 1997*.

managed correctional centre has the same meaning as in the *Crimes (Administration of Sentences) Act 1999*.

management company, for a managed correctional centre, includes a submanagement company, within the meaning of the *Crimes (Administration of Sentences) Act 1999*, that provides health services to inmates at the correctional centre.

modify includes add, except, omit and substitute.

medical device has the same meaning as in the Commonwealth Therapeutic Goods Act.

non-domestic use, in relation to Schedule 7 substances, means use that is not domestic use.

NSW Poisons Schedules—see section 6.

nurse practitioner means a person registered under the Health Practitioner Regulation National Law to practise in the nursing profession whose registration is endorsed as being qualified to practise as a nurse practitioner.

obtain licence means a licence granted by the Health Secretary under section 57(2).

Opioid Treatment Program means the program known as the Opioid Treatment Program approved by the Health Secretary.

OTP registration means a registration by the Health Secretary under section 74.

patient means—

(a) in relation to an individual—the individual treated, and

(b) in relation to an animal—the animal treated.

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

premises includes land or a building, structure or vehicle or other place, whether built on or not.

prescription, in relation to therapeutic goods, means a written or electronic document or other authorisation issued to allow the goods to be supplied by a pharmacist for use by, or administration to, a human or animal for therapeutic purposes in a way specified by the document or authorisation.

private health facility means a private health facility licensed under the *Private Health Facilities Act 2007*.

prohibited drug has the same meaning as in the *Drug Misuse and Trafficking Act 1985*.

prohibited scheduled substance has the same meaning as in the *Drug Misuse and Trafficking Act 1985*.

public health entity means the following—

(a) a public hospital controlled by the Crown,

(b) a local health district,

(c) a prescribed statutory health corporation,

(d) the Health Secretary, or a person operating the State Vaccine Centre on the Health Secretary's behalf, for the purposes of the State Vaccine Centre,

(e) the Health Administration Corporation,

(f) another prescribed entity.

public health risk authorisation order means an order made by the Health Secretary under section 140.

public hospital has the same meaning as in the *Health Services Act 1997*.

public place means a place that the public, or a section of the public, is entitled to use or that is open to or used by the public or a section of the public, whether conditionally or unconditionally, but does not include—

(a) a shop, or

(b) premises where a health practitioner carries on the practice of the practitioner's profession.

Regulatory Advisory Committee means the Regulatory Advisory Committee established by section 127.

relevant law means the following—

(a) the Commonwealth Agvet Codes,

(b) the Commonwealth therapeutic goods laws,

(c) the *Narcotic Drugs Act 1967* of the Commonwealth,

(d) the *Drug Misuse and Trafficking Act 1985*,

(e) the *Hemp Industry Act 2008*,

(f) the *Pesticides Act 1999*,

(g) the *Poppy Industry Act 2016,*

(h) the *Stock Medicines Act 1989*,

(i) a regulation made under a law specified above,

(j) another prescribed law of New South Wales or another Australian jurisdiction.

representation means a verbal or written representation or a representation by conduct.

residential care facility means a residential facility at which residential care, within the meaning of the *Aged Care Act 1997* of the Commonwealth, is provided.

restriction order means an order made by the Health Secretary under section 49.

Schedule 4D substance means a prescribed substance that is in Schedule 4 of the NSW Poisons Schedules.

scheduled substance means a substance specified in a Schedule of the NSW Poisons Schedules, and includes a preparation, admixture, extract or other substance containing a scheduled substance.

seized thing, for Part 5.3—see section 105.

sell includes the following—

(a) sell by wholesale, retail, auction or tender,

(b) barter or exchange,

(c) supply for profit,

(d) offer for sale, receive for sale or expose for sale,

(e) consign or deliver for sale,

(f) have in possession for sale,

(g) cause or allow one or more of the above to be done.

State Vaccine Centre means premises operated by or on behalf of the Health Secretary for the storage and distribution of scheduled substances or prescribed therapeutic goods, including vaccines.

statutory health corporation has the same meaning as in the *Health Services Act 1997*.

stock medicine has the same meaning as in the *Stock Medicines Act 1989*.

substance includes an ingredient, compound, extract, salt or derivative of a substance.

supply scheduled substances or prescribed therapeutic goods—see section 5.

Tier 1, ***Tier 2***, ***Tier 3***, ***Tier 4*** or ***Tier 5 penalty***, in relation to an offence, indicates the maximum penalty a court may impose for the offence—see section 117 for the maximum penalties.

therapeutic goods has the same meaning as in the Commonwealth Therapeutic Goods Act.

Note— Scheduled substances are therapeutic goods.

vehicle includes a conveyance of any kind, whether or not self-propelled, and whether or not, at a material time, capable of being moved or operated, and includes the following—

(a) a caravan, trailer, truck, train or other land vehicle,

(b) a ship, hovercraft, boat, ferry, raft and pontoon or other watercraft,

(c) an aeroplane, helicopter, hot air balloon, drone or other aircraft.

veterinary practice has the same meaning as in the *Veterinary Practice Act 2003*.

veterinary practitioner has the same meaning as in the *Veterinary Practice Act 2003*.

wholesaler licence means a licence granted by the Health Secretary under section 57(1).

wholesale supply scheduled substances or prescribed therapeutic goods—see section 5.

Schedule 4 Amendment of Drug Misuse and Trafficking Act 1985 No 226

[1] Section 3 Definitions

Omit "*Poisons and Therapeutic Goods Act 1966*" from section 3(1), definition of ***analyst***, paragraph (b).

Insert instead "*Medicines, Poisons and Therapeutic Goods Act 2022*".

[2] Section 3(1)

Omit the definitions of ***Poisons List*** and ***Schedule 9 substance***.

Insert in alphabetical order—

Commonwealth drug legislation means the following—

(a) the Agvet Codes within the meaning of the *Agricultural and Veterinary Chemicals Act 1994* of the Commonwealth,

(b) the Commonwealth therapeutic goods laws within the meaning of the *Medicines, Poisons and Therapeutic Goods Act 2022*,

(c) the *Narcotic Drugs Act 1967* of the Commonwealth.

DMT authority has the same meaning as in the *Medicines, Poisons and Therapeutic Goods Act 2022*.

prohibited scheduled substance means a Schedule 4D, 8 or 9 substance within the meaning of the *Medicines, Poisons and Therapeutic Goods Act 2022* unless it is a prohibited drug.

[3] Section 7 Deemed possession of prohibited drug etc

Omit "Schedule 9 substance (not being a prohibited drug)".

Insert instead "prohibited scheduled substance".

[4] Section 8

Omit the section. Insert instead—

8 Relationship with Medicines, Poisons and Therapeutic Goods Act 2022

This Act does not—

(a) affect a provision of the *Medicines, Poisons and Therapeutic Goods Act 2022* or the regulations under that Act, or

(b) make unlawful an activity that is authorised under the *Medicines, Poisons and Therapeutic Goods Act 2022*.

[5] Section 10 Possession of prohibited drugs

Insert "the following" after "prohibited drug by" in section 10(2).

[6] Section 10(2)(a) and (b)

Omit section 10(2)(a) and (b). Insert instead—

(a) a person authorised to have possession of the prohibited drug under the *Medicines, Poisons and Therapeutic Goods Act 2022*, including under a DMT authority under that Act,

(b) a person who obtained the substance from a person specified in section 25(4)(a)(i)–(iii) who is lawfully supplying the substance (the ***lawful supplier***) to another person (the ***recipient***) if—

(i) the person is employed or engaged by the lawful supplier to deliver or transport the substance to the recipient, and

(ii) the possession is only in connection with delivering or transporting the substance to the recipient.

[7] Section 11 Possession of equipment for administration of prohibited drugs

Insert "the following" after "the possession of an item of equipment by" in section 11(2).

[8] Section 11(2)(c)

Omit section 11(2)(c) and (d). Insert instead—

(c) a person authorised under the *Medicines, Poisons and Therapeutic Goods Act 2022*, including under a DMT authority under that Act, to administer the prohibited drug using the item of equipment,

[9] Section 11C Possession of instructions for manufacture or production of prohibited drugs

Omit section 11C(2)(a) and (b). Insert instead—

(a) that the defendant is authorised under the *Medicines, Poisons and Therapeutic Goods Act 2022*, including under a DMT authority under that Act, to manufacture or produce the prohibited drug to which the instructions relate, or

(b) that the defendant is acting under the authority of a licence, permit, exemption or other authorisation under Commonwealth drug legislation to manufacture or produce the prohibited drug to which the instructions relate, or

[10] Section 13 Administration of prohibited drugs to others

Omit section 13(2)(a) and (b). Insert instead—

(a) a person administering or attempting to administer the prohibited drug in the course of practising the person's profession, or

(b) a person administering or attempting to administer the prohibited drug under the direction or control of a person authorised under the *Medicines, Poisons and Therapeutic Goods Act 2022*, including under a DMT authority under that Act, to administer the prohibited drug, or

(c) a person acting in accordance with a DMT authority authorising the administration of the prohibited drug.

[11] Section 15

Omit sections 15 and 16. Insert instead—

15 Forged, altered or illegally obtained prescriptions for prohibited drugs or prohibited scheduled substances

(1) A person must not knowingly forge, or fraudulently alter, a prescription for a prohibited drug or prohibited scheduled substance issued by an authorised practitioner.

Maximum penalty—

(a) for a corporation—250 penalty units, or

(b) for an individual—50 penalty units.

(2) A person must not, by a representation the person knows, or ought reasonably to know, is false or misleading—

(a) obtain, or attempt to obtain, from an authorised practitioner a prescription for a prohibited drug or prohibited scheduled substance, or

(b) induce, or attempt to induce, a pharmacist to dispense a prescription for a prohibited drug or prohibited scheduled substance if the person knows the prescription—

(i) was forged or fraudulently altered, or

(ii) was obtained in contravention of paragraph (a).

Maximum penalty—

(a) for a corporation—250 penalty units, or

(b) for an individual—50 penalty units.

(3) A person must not possess a prescription for a prohibited drug or prohibited scheduled substance if the person knows—

(a) the prescription was forged or fraudulently altered, or

(b) the prescription was obtained in contravention of subsection (2)(a).

Maximum penalty—

(a) for a corporation—250 penalty units, or

(b) for an individual—50 penalty units.

(4) In this section—

authorised practitioner and ***prescription*** have the same meaning as in the *Medicines, Poisons and Therapeutic Goods Act 2022*.

[12] Section 17, heading

Insert "**or prohibited scheduled substance**" after "**prohibited drug**".

[13] Section 17

Insert "or prohibited scheduled substance" after "prohibited drug".

[14] Sections 18B and 18C

Omit section 18B. Insert instead—

18B Manufacture, production, possession and supply of prohibited scheduled substances

(1) A person must not manufacture or produce, or knowingly take part in the manufacture or production of, a prohibited scheduled substance.

Maximum penalty—50 penalty units or imprisonment for 12 months, or both.

(2) A person must not possess a prohibited scheduled substance.

Maximum penalty—20 penalty units or imprisonment for 12 months, or both.

(3) A person must not supply, or knowingly take part in the supply of, a prohibited scheduled substance.

Maximum penalty—50 penalty units or imprisonment for 12 months, or both.

(4) This section does not make it unlawful for—

(a) a person to manufacture, produce, possess or supply a prohibited scheduled substance if authorised under the *Medicines, Poisons and Therapeutic Goods Act 2022*, or

(b) a person to manufacture, produce, possess or supply a prohibited scheduled substance under the authority of a licence, permit, exemption or other authorisation under Commonwealth drug legislation, or

(c) a person to take part in manufacturing, producing or supplying a prohibited scheduled substance along with a person specified in paragraph (a) or (b) or to possess the substance while taking part, or

(d) a person to possess a prohibited scheduled substance in the course of practising the person's profession, or

(e) a person to possess or supply a prohibited scheduled substance if the person is under the direction or control of a person authorised under the *Medicines, Poisons and Therapeutic Goods Act 2022*, including under a DMT authority under that Act, to possess or supply the prohibited scheduled substance, or

(f) a person to possess or supply a prohibited scheduled substance if—

(i) the person obtained the substance from a person specified in paragraph (a), (b), (c) or (d) who is lawfully supplying the substance (the ***lawful supplier***) to another person (the ***recipient***), and

(ii) the person is employed or engaged by the lawful supplier to deliver or transport the substance to the recipient, and

(iii) the possession or supply is only in connection with delivering or transporting the substance to the recipient, or

(g) a person to possess a prohibited scheduled substance that has been lawfully prescribed for, or supplied to, the person.

18C Possession of Schedule 4D substances taken to be for supply

(1) A person with actual possession of a Schedule 4D substance exceeding the prescribed quantity is, for the purposes of proceedings for an offence against section 18B involving the supply of a quantity of the substance, taken to have possession of the substance for the purposes of supply unless the person—

(a) proves the contrary, or

(b) proves the possession of the substance was obtained in accordance with a prescription for the substance and the issue of the prescription was authorised under the *Medicines, Poisons and Therapeutic Goods Act 2022*.

(2) A substance that, for the purposes of being supplied, is represented as being a particular Schedule 4D substance is taken to be the particular Schedule 4D substance for the purposes of proceedings for an offence against section 18B involving the supply of a Schedule 4D substance.

(3) In this section—

prescribed quantity, in relation to a Schedule 4D substance, means the quantity for the substance prescribed by, or determined in accordance with, the regulations under the *Medicines, Poisons and Therapeutic Goods Act 2022*.

Schedule 4D substance has the same meaning as in the *Medicines, Poisons and Therapeutic Goods Act 2022*.

Note— Schedule 4D substances are prescribed by the regulations under the *Medicines, Poisons and Therapeutic Goods Act 2022* and may differ from Schedule 4D of the current Poisons Standard under the *Therapeutic Goods Act 1989* of the Commonwealth.

[15] Section 24 Manufacture and production of prohibited drugs

Omit section 24(4). Insert instead—

(4) Nothing in this section renders the following unlawful—

(a) the manufacture or production of a prohibited drug by—

(i) a person authorised under the *Medicines, Poisons and Therapeutic Goods Act 2022*, including under a DMT authority under that Act, to manufacture or produce the prohibited drug, or

(ii) a person acting under the authority of a licence, permit, exemption or other authorisation under Commonwealth drug legislation, or

(iii) a person acting under a poppy licence under the *Poppy Industry Act 2016*,

(b) the taking part by any other person in the manufacture or production of a prohibited drug by a person to whom paragraph (a) applies.

[16] Section 24A Possession of precursors and certain apparatus for manufacture or production of prohibited drugs

Omit section 24A(2)(a)–(b). Insert instead—

(a) a person authorised under the *Medicines, Poisons and Therapeutic Goods Act 2022*, including under a DMT authority under that Act, to manufacture or produce the prohibited drug, or

(b) a person acting under the authority of a licence, permit, exemption or other authorisation under Commonwealth drug legislation, or

(c) a person acting under a poppy licence under the *Poppy Industry Act 2016*.

[17] Section 25 Supply of prohibited drugs

Omit section 25(4). Insert instead—

(4) Nothing in this section renders the following unlawful—

(a) the supply of a prohibited drug by—

(i) a person authorised to supply the prohibited drug under the *Medicines, Poisons and Therapeutic Goods Act 2022*, including under a DMT authority under that Act, or

(ii) a person acting in accordance with a direction given by the Commissioner of Police under section 39Q, or

(iii) a person who obtained the prohibited drug from a person specified in subparagraph (i) or (ii) who is lawfully supplying the substance (the ***lawful supplier***) to another person (the ***recipient***) if—

(A) the person is employed or engaged by the lawful supplier to deliver or transport the prohibited drug to the recipient, and

(B) the possession or supply is only in connection with delivering or transporting the prohibited drug to the recipient,

(b) the taking part by any other person in the supply of a prohibited drug by a person to whom paragraph (a) applies.

[18] Section 25A Offence of supplying prohibited drugs on an ongoing basis

Omit section 25A(9). Insert instead—

(9) **Exemption—lawful supply**

Nothing in this section renders unlawful the supply of a prohibited drug by a person authorised under the *Medicines, Poisons and Therapeutic Goods Act 2022*, including under a DMT authority under that Act, to supply the prohibited drug.

[19] Section 36ZE Substances to which this Part does not apply

Omit section 36ZE(1)(c). Insert instead—

(c) a Schedule 2, 3 or 4 substance within the meaning of the *Medicines, Poisons and Therapeutic Goods Act 2022* that is not a prohibited drug or prohibited scheduled substance,

(c1) a prohibited scheduled substance,

[20] Section 39A Application of Part

Omit section 39A(1)(c). Insert instead—

(c) a prohibited scheduled substance,

[21] Section 40 Effect of certain representations

Omit section 40(1A). Insert instead—

(1A) A substance that is not a prohibited scheduled substance represented for the purposes of supply, whether verbally, in writing or by conduct, as being a prohibited scheduled substance or particular prohibited scheduled substance is, for the purposes of this Act and the regulations, taken to be a prohibited scheduled substance or the particular prohibited scheduled substance.

[22] Sections 41 and 41A

Omit the sections.

Schedule 5 Amendment of other legislation

5.1 Children and Young Persons (Care and Protection) Act 1998 No 157

Section 175 Special medical treatment

Omit section 175(5), definition of ***special medical treatment***, paragraph (c1), including the note.

Insert instead—

(c1) any medical treatment that involves the administration of a Schedule 8 substance within the meaning of the *Medicines, Poisons and Therapeutic Goods Act 2022* over a period or periods totalling more than 10 days in any period of 30 days, or

5.2 Children (Detention Centres) Regulation 2015

Clause 3 Definitions

Omit clause 3(1), definition of ***drug***, paragraph (b). Insert instead—

(b) a Schedule 2, 3 or 4 substance or prohibited scheduled substance within the meaning of the *Medicines, Poisons and Therapeutic Goods Act 2022*, or

5.3 Community Gaming Regulation 2020

Clause 41 Prohibited prizes

Omit clause 41(1)(c). Insert instead—

(c) a prize involving the administration to a person of scheduled substances or therapeutic goods that are regulated under regulations under the *Medicines, Poisons and Therapeutic Goods Act 2022*, section 54,

5.4 Confiscation of Proceeds of Crime Act 1989 No 90

Section 7 Meaning of "serious offence" and "serious drug offence"

Omit the definition of ***serious offence***, paragraph (b). Insert instead—

(b) the offence of supplying a Schedule 4D substance under the *Drug Misuse and Trafficking Act 1985*, section 18B that arises under that Act, section 18C, or

5.5 Crimes Act 1900 No 40

[1] Section 25C Supply of drugs causing death

Omit section 25C(3). Insert instead—

(3) A person does not commit an offence under this section for supplying a prohibited drug if the person is authorised under the *Medicines, Poisons and Therapeutic Goods Act 2022* to supply the prohibited drug.

[2] Section 193A Definitions

Omit the definition of ***serious offence***, paragraph (b). Insert instead—

(b) the offence of supplying a Schedule 4D substance under the *Drug Misuse and Trafficking Act 1985*, section 18B that arises under that Act, section 18C, or

[3] Section 428A Definitions

Omit the definition of ***drug***. Insert instead—

drug means—

(a) a prohibited drug or prohibited scheduled substance within the meaning of the *Drug Misuse and Trafficking Act 1985*, and

(b) a Schedule 2, 3, 4, 5, 6, 7 or 8 substance within the meaning of the *Medicines, Poisons and Therapeutic Goods Act 2022* that is not a prohibited drug or prohibited scheduled substance.

5.6 Crimes (Administration of Sentences) Act 1999 No 93

[1] Section 236E Definitions

Omit section 236E(1), definition of ***steroid***. Insert instead—

steroid means an anabolic or androgenic steroidal agent that is a Schedule 4 substance within the meaning of the *Medicines, Poisons and Therapeutic Goods Act 2022*.

[2] Section 253C Trafficking

Omit "any poison listed in Appendix D of Schedule Four, or in Schedule Eight, of the Poisons List in force under the *Poisons and Therapeutic Goods Act 1966*" from section 253C(2).

Insert instead "a Schedule 4D or 8 substance within the meaning of the *Medicines, Poisons and Therapeutic Goods Act 2022*".

[3] Section 253C(3)

Omit "Section 40 of the *Poisons and Therapeutic Goods Act 1966*".

Insert instead "The *Medicines, Poisons and Therapeutic Goods Act 2022*, section 125".

5.7 Crimes (Administration of Sentences) Regulation 2014

Clause 3 Interpretation

Omit clause 3(3)(a) and (b). Insert instead—

(a) a Schedule 2, 3, 4 or 8 substance with the meaning of the *Medicines, Poisons and Therapeutic Goods Act 2022*,

(b) a derivative of—

(i) a prohibited drug, prohibited plant or prohibited scheduled substance within the meaning of the *Drug Misuse and Trafficking Act 1985*, or

(ii) a substance referred to in paragraph (a),

5.8 Criminal Procedure Regulation 2017

[1] Clause 24 Offences for which briefs of evidence not required

Insert after section 24(e)—

(e1) proceedings for an offence under the *Drug Misuse and Trafficking Act 1985*, section 18B(2) in relation to possession of a Schedule 4D substance,

[2] Clause 24(f)

Omit "section 16 (1) of the *Poisons and Therapeutic Goods Act 1966*".

Insert instead "the *Medicines, Poisons and Therapeutic Goods Act 2022*, Part 2.2–2.5".

5.9 Drug Misuse and Trafficking Regulation 2021

Section 5 Sales and storage of Schedule 1 precursors—the Act, s 45(2A)

Omit "*Poisons and Therapeutic Goods Act 1966*" from section 5(7), definition of ***relevant therapeutic goods laws***, paragraph (a).

Insert instead "*Medicines, Poisons and Therapeutic Goods Act 2022*".

5.10 Electronic Transactions Regulation 2017

Clauses 4(e) and 7(e)

Omit the paragraphs.

5.11 Fair Trading Act 1987 No 68

Schedule 1 Paramount legislation

Omit "*Poisons and Therapeutic Goods Act 1966*".

Insert instead "*Medicines, Poisons and Therapeutic Goods Act 2022*".

5.12 Firearms Regulation 2017

Clauses 5(1)(b), (2)(b) and (3)(b) and 42(1)(b), (2)(b) and (3)(b)

Omit "prescribed restricted substance within the meaning of the *Poisons and Therapeutic Goods Regulation 2008*" wherever occurring.

Insert instead "prohibited scheduled substance within the meaning of the *Medicines, Poisons and Therapeutic Goods Act 2022*".

5.13 Government Information (Public Access) Regulation 2018

Schedule 3 Agencies declared to be part of other agencies

Omit the matter relating to the Medical Committee constituted under the *Poisons and Therapeutic Goods Act 1966*.

Insert in appropriate order—

Clinical Advisory Committee constituted under the *Medicines, Poisons and Therapeutic Goods Act 2022*	Ministry of Health
Regulatory Advisory Committee constituted under the *Medicines, Poisons and Therapeutic Goods Act 2022*	Ministry of Health

5.14 Guardianship Regulation 2016

[1] Clause 3 Definitions

Omit clause 3(1), definition of ***restricted substance***.

Insert in alphabetical order—

Schedule 4 substance has the same meaning as in the *Medicines, Poisons and Therapeutic Goods Act 2022*.

[2] Clause 10 Major medical treatment

Omit "restricted substance" from clause 10(1)(e). Insert instead "Schedule 4 substance".

[3] Clause 14 Experimental special medical treatment to which Tribunal may consent

Omit "restricted substances" wherever occurring in clause 14(a).

Insert instead "Schedule 4 substances".

5.15 Health Administration Act 1982 No 135

Section 23A Exchange of information between health officials

Omit "*Poisons and Therapeutic Goods Act 1966*" from section 23A(4), definition of ***health official***, paragraph (d).

Insert instead "*Medicines, Poisons and Therapeutic Goods Act 2022*".

5.16 Health Care Complaints Act 1993 No 105

Section 25 Notification of certain complaints to Health Secretary

Omit the matter relating to the *Poisons and Therapeutic Goods Act 1966* from section 25(1).

Insert in appropriate order—

- *Medicines, Poisons and Therapeutic Goods Act 2022*

5.17 Health Practitioner Regulation (Adoption of National Law) Act 2009 No 86

[1] Schedule 1 Modification of Health Practitioner Regulation National Law

Omit Schedule 1[13], section 138(1), definition of ***drug related offence***, paragraph (b).

Insert instead—

(b) the *Medicines, Poisons and Therapeutic Goods Act 2022* or the repealed *Poisons and Therapeutic Goods Act 1966* or regulations under either Act.

[2] Schedule 1[25], Schedule 5F, clause 1, definition of "pharmacy business"

Omit "any substance specified in the Poisons List proclaimed under section 8 of the *Poisons and Therapeutic Goods Act 1966*".

Insert instead "a scheduled substance within the meaning of the *Medicines, Poisons and Therapeutic Goods Act 2022*".

5.18 Health Practitioner Regulation (New South Wales) Regulation 2016

[1] Schedule 5 Equipment and publications required for pharmacy premises

Omit the following from clause 2—

the *Poisons and Therapeutic Goods Act 1966* and the regulations under that Act

the Poisons List proclaimed under section 8 of the *Poisons and Therapeutic Goods Act 1966* or the latest edition, and all published amendments or supplements to that edition, of the *Guide to the New South Wales Medicines and Poisons Schedules* published by the Pharmacy Guild of Australia (New South Wales Branch)

Insert instead—

the *Medicines, Poisons and Therapeutic Goods Act 2022* and the regulations under that Act

the NSW Poisons Schedules within the meaning of the *Medicines, Poisons and Therapeutic Goods Act 2022* or the latest edition, and all published amendments or supplements to that edition, of the *Guide to the New South Wales Medicines and Poisons Schedules* published by the Pharmacy Guild of Australia (New South Wales Branch)

[2] Schedule 6 Publications required for professional services room premises

Omit the following—

the *Poisons and Therapeutic Goods Act 1966* and the regulations under that Act

the Poisons List proclaimed under section 8 of the *Poisons and Therapeutic Goods Act 1966* or the latest edition, and all published amendments or supplements to that edition, of the *Guide to the New South Wales Medicines and Poisons Schedules* published by the Pharmacy Guild of Australia (New South Wales Branch)

Insert instead—

the *Medicines, Poisons and Therapeutic Goods Act 2022* and the regulations under that Act

the NSW Poisons Schedules within the meaning of the *Medicines, Poisons and Therapeutic Goods Act 2022* or the latest edition, and all published amendments or supplements to that edition, of the *Guide to the New South Wales Medicines and Poisons Schedules* published by the Pharmacy Guild of Australia (New South Wales Branch)

5.19 Health Professionals (Special Events Exemption) Act 1997 No 90

[1] Section 3 Definitions

Omit the definitions of ***drug of addiction***, ***Poisons List***, ***restricted substance*** and ***supply***.

Insert in alphabetical order—

Schedule 4 substance has the same meaning as in the *Medicines, Poisons and Therapeutic Goods Act 2022*.

Schedule 8 substance has the same meaning as in the *Medicines, Poisons and Therapeutic Goods Act 2022*.

supply has the same meaning as in the *Medicines, Poisons and Therapeutic Goods Act 2022*.

[2] Sections 9(4), 10(2)(d) and 11(1)–(3)

Omit "*Poisons and Therapeutic Goods Act 1966*" wherever occurring.

Insert instead "*Medicines, Poisons and Therapeutic Goods Act 2022*".

[3] Section 10(1) and (2)(a) and (b) and 11(3)(a)

Omit "restricted substance or drug of addiction" wherever occurring.

Insert instead "Schedule 4 substance or Schedule 8 substance".

5.20 Law Enforcement (Powers and Responsibilities) Act 2002 No 103

[1] Section 21 Power to search persons and seize and detain things without warrant

Omit section 21(1)(d). Insert instead—

(d) the person has in the person's possession or under the person's control—

(i) a prohibited plant or prohibited drug in contravention of the *Drug Misuse and Trafficking Act 1985*, or

(ii) a Schedule 4D substance, within the meaning of the *Medicines, Poisons and Therapeutic Goods Act 2022*, in contravention of that Act.

[2] Section 46A Searchable offences

Insert "repealed" after "an offence under the" in section 46A(2), definition of ***narcotics offence***, paragraph (a).

[3] Section 46A(2), definition of "narcotics offence"

Insert after paragraph (a)—

(a1) an offence under the *Medicines, Poisons and Therapeutic Goods Act 2022*, or a regulation made under that Act, that is committed in respect of a Schedule 4D or 8 substance within the meaning of that Act, or

[4] Schedule 2 Search warrants under other Acts

Omit "*Poisons and Therapeutic Goods Act 1966*, section 43A".

Insert in alphabetical order—

Medicines, Poisons and Therapeutic Goods Act 2022, section 100

5.21 Mental Health Act 2007 No 8

Section 81 Transport of persons to and from mental health facilities and other health facilities

Omit "*Poisons and Therapeutic Goods Act 1966*" from section 81(3), note.

Insert instead "*Medicines, Poisons and Therapeutic Goods Act 2022*".

5.22 Police Act 1990 No 47

Section 211AA Testing of officers for steroids

Omit section 211AA(4), definition of ***steroid***. Insert instead—

steroid means an anabolic or androgenic steroidal agent that is a Schedule 4 substance within the meaning of the *Medicines, Poisons and Therapeutic Goods Act 2022*.

5.23 Police Regulation 2015

Clause 77 Definitions

Omit the definition of ***steroid***. Insert instead—

steroid has the same meaning as in the Act, section 211AA.

5.24 Poppy Industry Act 2016 No 37

[1] Section 4 Definitions

Omit "*Poisons and Therapeutic Goods Act 1966*" from section 4(1), definition of ***manufacturing, export or research licence***, paragraph (c).

Insert instead "*Medicines, Poisons and Therapeutic Goods Act 2022*".

[2] Section 5 Fit and proper person

Omit "*Poisons and Therapeutic Goods Act 1966* or regulations under that Act" from section 5(5)(c)(ii).

Insert instead "*Medicines, Poisons and Therapeutic Goods Act 2022* or the repealed *Poisons and Therapeutic Goods Act 1966* or regulations under either Act".

5.25 Poppy Industry Regulation 2016

[1] Clause 8 Checks and requirements for person employed or engaged

Insert "repealed" after "against the" in clause 8(f)(iii).

[2] Clause 8(f)(iiia)

Insert after clause 8(f)(iii)—

(iiia) an offence against the *Medicines, Poisons and Therapeutic Goods Act 2022* or regulations under that Act or against a corresponding law of another jurisdiction,

5.26 Prevention of Cruelty to Animals Act 1979 No 200

Section 15 Poisons not to be administered to animals

Omit section 15(1)(a). Insert instead—

(a) a scheduled substance within the meaning of the *Medicines, Poisons and Therapeutic Goods Act 2022* or a substance including a scheduled substance, or

5.27 Public Health (Tobacco) Act 2008 No 94

[1] Section 22 Sale of tobacco and non-tobacco smoking products or e-cigarettes and e-cigarette accessories to minors

Omit "*Poisons and Therapeutic Goods Act 1966*" from section 22(2A), note.

Insert instead "*Medicines, Poisons and Therapeutic Goods Act 2022*".

[2] Section 22(4), definition of "authorised product", paragraph (b)

Omit the paragraph. Insert instead—

(b) authorised under the *Medicines, Poisons and Therapeutic Goods Act 2022* to be supplied.

5.28 Road Transport Act 2013 No 18

Schedule 3 Testing for alcohol and drug use

Omit "*Poisons and Therapeutic Goods Act 1966*" from clause 1(1), definition of ***analyst***, paragraph (b).

Insert instead "*Medicines, Poisons and Therapeutic Goods Act 2022*".

5.29 Security Industry Regulation 2016

Clause 15 Offences and civil penalties that disqualify applicants

Omit "prescribed restricted substance within the meaning of the *Poisons and Therapeutic Goods Regulation 2008*" from clause 15(1)(b).

Insert instead "Schedule 4D substance within the meaning of the *Medicines, Poisons and Therapeutic Goods Act 2022*".

5.30 Stock Medicines Act 1989 No 182

[1] Section 3 Definitions

Omit "*Poisons and Therapeutic Goods Act 1966* to supply a restricted substance" from section 3(1), definition of ***prescribe***, paragraph (b).

Insert instead "*Medicines, Poisons and Therapeutic Goods Act 2022* to supply a scheduled substance".

[2] Section 6

Omit the section. Insert instead—

6 Activities authorised under Medicines, Poisons and Therapeutic Goods Act 2022

A person does not commit an offence against this Act if the act or omission that would, but for this section, constitute the offence is authorised to be done or omitted to be done under the *Medicines, Poisons and Therapeutic Goods Act 2022*.

[3] Section 39D Instructions to be provided by veterinary practitioners

Omit section 39D(1)(c). Insert instead—

(c) prescribes or supplies a Schedule 2, 3, 4 or 8 substance within the meaning of the *Medicines, Poisons and Therapeutic Goods Act 2022* for use on stock of a major food producing species, or uses a Schedule 2, 3, 4 or 8 substance on the stock.

[4] Section 39E Records to be kept by veterinary practitioners

Omit section 39E(1)(c). Insert instead—

(c) the prescription or supply of a registered stock medicine that is a Schedule 2, 3, 4 or 8 substance within the meaning of the *Medicines, Poisons and Therapeutic Goods Act 2022* for use on stock of a major food producing species and the use by the veterinary practitioner on the stock.

5.31 Stock Medicines Regulation 2019

Clause 7 Advertising etc

Omit clause 7(1). Insert instead—

(1) This clause applies to a stock medicine that is a Schedule 3, 4 or 8 substance within the meaning of the *Medicines, Poisons and Therapeutic Goods Act 2022*.

5.32 Subordinate Legislation Act 1989 No 146

Schedule 5 Further postponement of repeal of certain statutory rules

Omit "1 September 2024, unless sooner repealed" from clause 1.

Insert instead "the *Poisons, Therapeutic Goods Act 1966* is repealed by the *Medicines, Poisons and Therapeutic Goods Act 2022*".

5.33 Veterinary Practice Act 2003 No 87

[1] Section 4 Definitions

Insert in alphabetical order in section 4(1)—

relevant law means the following—

(a) the *Prevention of Cruelty to Animals Act 1979*,

(b) the *Biosecurity Act 2015*,

(c) the repealed *Poisons and Therapeutic Goods Act 1966*,

(d) the *Medicines, Poisons and Therapeutic Goods Act 2022*,

(e) a relevant law within the meaning of the *Medicines, Poisons and Therapeutic Goods Act 2022*,

(f) the *Export Control Act 2020* of the Commonwealth.

[2] Section 18 Refusal of registration

Omit section 18(b)(i). Insert instead—

(i) an offence under this Act or the regulations,

(ia) an offence under a relevant law or regulations under a relevant law,

[3] Section 19 Conditions of registration

Omit "poisons and therapeutic substances" from section 19(4)(b)(ii).

Insert instead "scheduled substances within the meaning of the *Medicines, Poisons and Therapeutic Goods Act 2022*".

[4] Section 27 Removal of person's name from Register

Omit section 27(2)(c)(i). Insert instead—

(i) an offence under this Act or the regulations,

(ia) an offence under a relevant law or regulations under a relevant law,

[5] Section 33 Annual return to be submitted

Omit section 33(1)(a)(i). Insert instead—

(i) an offence under this Act or the regulations,

(ia) an offence under a relevant law or regulations under a relevant law,

5.34 Veterinary Practice Regulation 2013

[1] Clause 4 Restricted acts of veterinary science

Omit "specified in Schedule Four or Schedule Eight to the Poisons List proclaimed under the *Poisons and Therapeutic Goods Act 1966*" from clause 4(3), definition of ***anaesthetic agent***.

Insert instead "a Schedule 4 or 8 substance within the meaning of the *Medicines, Poisons and Therapeutic Goods Act 2022*.

[2] Schedule 2 Veterinary practitioners code of professional conduct

Omit "**restricted substances**" from clause 20, heading.

Insert instead "**Schedule 4 or 8 substances**".

[3] Schedule 2, clause 20(1)

Omit "restricted". Insert instead "Schedule 4 or 8".

[4] Schedule 2, clause 20(2)

Omit "restricted substance medications".

Insert instead "Schedule 4 or 8 substances".

[5] Schedule 2, clause 20(3)

Omit the subclause. Insert instead—

(3) In this clause—

Schedule 4 or 8 substance means a Schedule 4 or 8 substance within the meaning of the *Medicines, Poisons and Therapeutic Goods Act 2022*.

5.35 Voluntary Assisted Dying Act 2022 No 17

[1] Section 14, heading

Omit "**Poisons and Therapeutic Goods Act 1966**".

Insert instead "**Medicine, Poisons and Therapeutic Goods Act 2022**".

[2] Section 14

Omit "*Poisons and Therapeutic Goods Act 1966*".

Insert instead "*Medicines, Poisons and Therapeutic Goods Act 2022*".

[3] Section 74 Prescription for substance

Omit "*Poisons and Therapeutic Goods Act 1966*" from Note 1, paragraph (a) and Note 2.

Insert instead "*Medicines, Poisons and Therapeutic Goods Act 2022*".

[4] Sections 77(1), 80(4) and 82(7)

Omit "*Poisons and Therapeutic Goods Act 1966*" wherever occurring.

Insert instead "*Medicines, Poisons and Therapeutic Goods Act 2022*".

[5] Section 128

Omit the section. Insert instead—

128 Application of Medicines, Poisons and Therapeutic Goods Act 2022

(1) The *Medicines, Poisons and Therapeutic Goods Act 2022*, Chapters 5 and 6 and Parts 7.2 and 7.3 (the ***applied provisions***) apply, for the purposes of the enforcement of this Act, with—

(a) the modifications prescribed by the regulations, and

(b) necessary modifications.

(2) A definition in the *Medicines, Poisons and Therapeutic Goods Act 2022* of a term used in the applied provisions also applies for the purposes of the application of the provisions under subsection (1).

[6] Schedule 1 Dictionary

Omit the definitions of ***medicine***, ***prescription***, ***Schedule 4 poison***, ***Schedule 8 poison*** and ***supply***.

Insert instead—

medicine means—

(a) a scheduled substance within the meaning of the *Medicines, Poisons and Therapeutic Goods Act 2022*, and

(b) therapeutic goods, within the meaning of the *Therapeutic Goods Act 1989* of the Commonwealth, that are not scheduled substances.

NSW Poisons Schedule has the same meaning as in the *Medicines, Poisons and Therapeutic Goods Act 2022*.

prescription, in relation to a voluntary assisted dying substance, means a prescription issued in accordance with the *Medicines, Poisons and Therapeutic Goods Act 2022* for the voluntary assisted dying substance.

Schedule 4 poison means a substance specified in Schedule 4 of the NSW Poisons Schedule.

Schedule 8 poison means a substance specified in Schedule 8 of the NSW Poisons Schedule.

supply, in relation to a voluntary assisted dying substance, includes the following—

(a) sell, dispense and distribute,

(b) supply, whether free of charge or otherwise, by way of sample or advertisement,

(c) supply, whether free of charge or otherwise, in the course of testing for safety or efficacy on persons or animals,

(d) agree or offer to sell or distribute,

(e) keep or have in possession for sale, dispensing or distribution,

(f) send, forward, deliver or receive for sale, dispensing or distribution,

(g) authorise, direct, cause, suffer, permit or attempt an act specified in paragraphs (a)–(f).

5.36 Weapons Prohibition Regulation 2017

[1] Clause 5 Offences that disqualify applicants

Omit "or prohibited drug within the meaning of the *Drug Misuse and Trafficking Act 1985* or a prescribed restricted substance within the meaning of the *Poisons and Therapeutic Goods Regulation 2008*" from clause 5(1)(b).

Insert instead ", prohibited drug or prohibited scheduled substance".

[2] Clause 5(2)(b) and (3)(b)

Omit "or prohibited drug within the meaning of the *Drug Misuse and Trafficking Act 1985*, or a prescribed restricted substance within the meaning of the *Poisons and Therapeutic Goods Regulation 2008*," wherever occurring.

Insert instead ", prohibited drug or prohibited scheduled substance".

[3] Clause 5(4)

Insert after clause 5(3)—

(4) In this clause—

prohibited drug and ***prohibited scheduled substance*** have the same meaning as in the *Drug Misuse and Trafficking Act 1985*.