# Poisons and Therapeutic Goods Regulation 2008

[2008-392]

New South Wales

## Status Information

## Currency of version

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### Provisions in force

The provisions displayed in this version of the legislation have all commenced.

### Notes—

- **Staged repeal status**
  This legislation is currently due to be automatically repealed under the Subordinate Legislation Act 1989 on 1 September 2025

### Authorisation

This version of the legislation is compiled and maintained in a database of legislation by the Parliamentary Counsel's Office and published on the NSW legislation website, and is certified as the form of that legislation that is correct under section 45C of the Interpretation Act 1987.

File last modified 28 June 2024

# Poisons and Therapeutic Goods Regulation 2008

New South Wales

## Contents

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## Part 1 Preliminary

### 1 Name of Regulation

This Regulation is the *Poisons and Therapeutic Goods Regulation 2008*.

### 2 Commencement

This Regulation commences on 1 September 2008.

**Note—**

This Regulation replaces the *Poisons and Therapeutic Goods Regulation 2002* which is repealed on 1 September 2008 by section 10(2) of the *Subordinate Legislation Act 1989*.

### 3 Definitions

(1) In this Regulation—

***Ambulance Service of NSW*** has the same meaning as it has in the *Health Services Act 1997*.

***administering practitioner***, for Part 4A—see clause 128B.

***authorised disposer***, for Part 4A—see clause 128B.

***authorised practitioner*** means—

(a) in Part 4 (Drugs of addiction), a medical practitioner, nurse or midwife authorised under section 17A of the Act, dentist or veterinary practitioner, and

(b) in a Part other than Part 4, a medical practitioner, nurse or midwife authorised under section 17A of the Act, podiatrist, dentist, optometrist or veterinary practitioner.

***authorised supplier***, for Part 4A—see clause 128B.

***charitable organisation*** means an organisation or association that holds an authority under the *Charitable Fundraising Act 1991* or that is referred to in section 7 of that Act as an organisation or association to which that Act (section 48 excepted)

does not apply.

***Commonwealth Department of Health*** means the Commonwealth Department of Health.

***confer a function*** includes impose a duty.

***contact person***, for Part 4A—see clause 128B.

***coordinating practitioner***, for Part 4A—see clause 128B.

***correctional centre*** has the same meaning as in the *Crimes (Administration of Sentences) Act 1999*.

***current Poisons Standard*** has the same meaning as it has in the Commonwealth Act.

***dealer***, in relation to a substance, means a person who supplies the substance as a manufacturer, an importer or exporter or a wholesale or retail dealer, and includes an authorised practitioner or pharmacist in his or her capacity as a supplier of the substance.

***director of nursing*** means, in relation to a residential care facility, a registered nurse who is responsible for the care of the residents of the residential care facility.

***exercise*** a function includes perform a duty.

***function*** includes a power, authority and duty.

***hospital*** means a public hospital, public institution, private health facility or nursing home.

***inmate*** has the same meaning as in the *Crimes (Administration of Sentences) Act 1999*.

***inspector*** means a person authorised by the Secretary to exercise the powers conferred by section 43 of the Act.

***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.

***managed correctional centre*** has the same meaning as in the *Crimes (Administration of Sentences) Act 1999*.

**Note—**

A managed correctional centre is a kind of correctional centre.

***medication chart*** means a document, in a form that complies with the *National Health (Residential Medication Chart) Determination 2012* of the Commonwealth, that contains detailed information about an individual patient and the medication orders, administration record and other health care information related to that patient's care.

***medication chart prescription*** means a prescription included in a medication chart kept at a residential care facility in relation to a resident of that facility.

***nabiximols*** means a botanical extract of Cannabis sativa in a buccal spray for human therapeutic use—

(a) that includes the following cannabinoids—

(i) tetrahydrocannabinol,

(ii) cannabidiol,

(iii) cannabinol,

(iv) cannabigerol,

(v) cannabichromene,

(vi) cannabidiolic acid,

(vii) tetrahydrocannabinolic acid,

(viii) tetrahydrocannabivarol,

(ix) cannabidivarol, and

(b) in which tetrahydrocannabinol and cannabidiol (in approximately equal proportions) comprise not less than 90 per cent of the total cannabinoid content.

***nurse in charge***, in a managed correctional centre, means a nurse in charge of the medical treatment of inmates at the managed correctional centre.

***nursing home*** has the same meaning as in the *Public Health Act 1991*.

***patient***, for Part 4A—see clause 128B.

***practitioner of alternative medicine*** means a herbalist, nutritionist, naturopath, practitioner of Chinese medicine or homoeopathic practitioner.

***prescribed restricted substance***—see clause 61.

***prescription reference number*** means the unique reference number for the prescription recorded under clause 55 or 114.

***private health facility*** means a private health facility licensed under the *Private*

*Health Facilities Act 2007*.

***public health organisation*** has the same meaning as in the *Health Services Act 1997*, section 7.

***public hospital*** means a public hospital within the meaning of the *Health Services Act 1997*.

***residential care facility*** means a residential facility at which a person is provided with residential care, within the meaning of the *Aged Care Act 1997* of the Commonwealth, and includes a nursing home.

***residential care facility manager*** means the person (not being the director of nursing) employed at the residential care facility who is responsible for the management of that facility.

***responsible person***, in relation to a residential care facility, means—

(a) the director of nursing of the residential care facility, or

(b) in the case of a residential care facility for which there is no director of nursing—the residential care facility manager.

***retail dealer***, in relation to a substance, means a person who supplies the substance as a retailer, and not as a manufacturer, importer, exporter or wholesaler, and not as an authorised practitioner or pharmacist in his or her capacity as a supplier of the substance.

***retail pharmacist*** means a pharmacist who is employed in a retail pharmacy.

***retail pharmacy*** means premises included in the Register of Pharmacies kept under Schedule 5F of the *Health Practitioner Regulation National Law (NSW)*.

***scientifically qualified person*** means—

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

(b) a person who holds a degree or diploma approved for the time being by the Secretary, or

(c) a person approved for the time being by the Secretary.

***seized goods*** means regulated goods that have been seized under section 43 of the Act.

***special restricted substance*** means a substance included in Appendix B to this Regulation.

***the Act*** means the *Poisons and Therapeutic Goods Act 1966*.

***Therapeutic Goods Order No. 95*** means the *Therapeutic Goods Order No. 95 Child-resistant packaging requirements for medicines 2017*, as in force from time to time under the Commonwealth Act.

***therapeutic substances*** means substances that are therapeutic goods.

***type A drug of addiction*** means a drug of addiction prescribed by clause 122.

***type C drug of addiction*** has the meaning given by section 28(6) of the Act.

***type C unregistered drug of addiction*** means an unregistered drug of addiction other than an unregistered drug of addiction that is a type A drug of addiction.

***unregistered drug of addiction*** means any therapeutic good that consists of a Schedule 8 substance and that is not—

(a) a registered good, or

(b) a substance or good that has been excluded from this definition by an order made by the Secretary and published in the Gazette.

***voluntary assisted dying substance*** has the same meaning as in the *Voluntary Assisted Dying Act 2022*.

**Note—**

See the *Voluntary Assisted Dying Act 2022*, section 7, which provides for the approval of a Schedule 4 or 8 substance as a voluntary assisted dying substance.

***ward*** of a hospital includes any theatre, laboratory or department of the hospital, other than the pharmacy department.

**Note—**

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

(2) In this Regulation—

(a) expressions that are defined in the current Poisons Standard have the meanings given to them by that Standard, and

(b) expressions that are defined in the current Poisons Standard and that are also defined in the Act or in this Regulation have the meanings given to them by the Act or this Regulation, respectively, and

(c) a reference to a Schedule 1, 2, 3, 4, 5, 6, 7, 8 or 9 substance is a reference to a substance included in the correspondingly numbered Schedule of the Poisons List.

(3) Notes included in this Regulation do not form part of this Regulation.

**4–6 (Repealed)**

# Part 2 Poisons (S1, S2, S3, S5, S6, S7)

## Division 1 Packaging and labelling

### 7 Packaging and labelling generally

(1) A dealer who supplies a poison must ensure that the poison is packaged and labelled—

(a) in accordance with the relevant provisions of the current Poisons Standard, and

(b) in the case of a poison to which *Therapeutic Goods Order No. 95* applies, in accordance with that Order.

(2) This clause does not apply to the labelling of a substance that is supplied by an authorised practitioner or pharmacist so long as the substance is supplied in a package that is labelled in accordance with the requirements of Appendix A.

(3) A pharmacist who supplies any quantity of a Schedule 2 or 3 substance on prescription must ensure that the substance is supplied in a package that is labelled in accordance with the requirements of Appendix A instead of in accordance with the requirements of subclause (1).

(4) Despite subclause (1), an authorised practitioner or pharmacist who supplies a poison to a person who, in the opinion of the authorised practitioner or pharmacist, would suffer undue hardship through difficulty in opening a container that is packaged in accordance with *Therapeutic Goods Order No. 95*, is not required to package the poison in accordance with that Order.

Maximum penalty—10 penalty units.

### 8 Misleading labelling of substances as poisons

A dealer must not supply any substance in a container that has a label that states or implies that the substance is a poison, unless the substance is a poison.

Maximum penalty—10 penalty units.

### 9 Schedule 3 substances supplied by dealers

(1) A dealer must ensure that any Schedule 3 substance supplied by the dealer is labelled with the dealer's name and address.

Maximum penalty—2 penalty units.

(2) Subclause (1) does not apply to the supply of any Schedule 3 substance by wholesale.

### 10 Exemptions

(1) The Secretary may, by order in writing, exempt any person or substance, or any class

of persons or substances, from the requirements of this Division.

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

(3) Subject to subclause (4), any exemption in force under a law of the Commonwealth, or of another State or a Territory, corresponding to this clause has the same effect as an exemption under this clause.

(4) The Secretary may, by order published in the Gazette, declare that subclause (3) does not have effect with respect to an exemption specified in the order.

## Division 2 Storage

### 11 Storage generally

A dealer who has possession of any poison must keep the poison—

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

(b) in such a way that, if its container breaks or leaks, the poison cannot mix with or contaminate any food intended for consumption by humans or animals.

Maximum penalty—10 penalty units.

### 12 Schedule 3 or 7 substances

A dealer who has possession of any Schedule 3 or 7 substance must keep the substance in a room or enclosure to which the public does not have access.

Maximum penalty—10 penalty units.

### 13 Schedule 6 substances

(1) A dealer who has possession of any Schedule 6 substance must keep that substance—

(a) in a place to which the public does not have access, or

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

Maximum penalty—10 penalty units.

(2) This clause does not apply to any of the following—

(a) any therapeutic substance for internal use in animals,

(b) any substance in a container that is fitted with a child-resistant closure,

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

(d) any substance in a container that has a capacity of 5 litres or more or a weight (inclusive of its contents) of 5 kilograms or more,

(e) any hair dye in a container that has a capacity of 50 millilitres or less,

(f) any cockroach bait that is enclosed in a complex welded plastic structure.

(3) In this clause, ***child-resistant closure*** means—

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

(b) a closure of a design approved for the time being by the Secretary.

## Division 3 Prescriptions

### 14 Unauthorised persons not to prescribe Schedule 2 or 3 substances

(1) An authorised practitioner may issue a prescription for a Schedule 2 or 3 substance.

(2) A person must not issue a prescription for a Schedule 2 or 3 substance unless authorised to do so by this clause.

Maximum penalty—10 penalty units.

### 15 Prescription for pseudoephedrine

(1) A person who issues a prescription for pseudoephedrine must ensure that the prescription complies with Division 3 of Part 3 as if pseudoephedrine were a restricted substance.

Maximum penalty—10 penalty units.

(2) Subclause (1) applies to pseudoephedrine only in so far as it is a Schedule 3 substance.

### 16 Quantity and purpose of prescriptions to be appropriate

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

Maximum penalty—10 penalty units.

## Division 4 Supply

### 17 Schedule 2 and 3 substances may be supplied by authorised persons

A person who is not an authorised practitioner or a pharmacist may supply a Schedule 2 or 3 substance to another person if the supplier holds a licence or authority under Part 8 to supply the substance.

**18 Schedule 3 substances to be supplied personally by pharmacists**

(1) A pharmacist must not supply a Schedule 3 substance to any person unless the pharmacist—

(a) personally hands the substance to the person, and

(b) gives the person an opportunity to seek advice as to the use of the substance, including advice that the person may require in respect of the dosage, frequency of administration and general toxicity of the substance.

(2) This clause does not apply to the supply of any substance—

(a) to an authorised practitioner, or

(b) to any other person on the prescription of an authorised practitioner.

(3) This clause does not apply to the supply of salbutamol or terbutaline in metered aerosols for first aid purposes to a person who holds a current emergency asthma management certificate issued by an organisation approved by the Secretary for the purposes of this subclause.

(4) This clause does not apply to the supply to the responsible person for a residential care facility of any substance that is—

(a) in the manufacturer's original pack, and

(b) approved by the Secretary for urgent use in a residential care facility, and

(c) supplied in accordance with—

(i) any conditions of the approval, and

(ii) a written order signed by the responsible person.

(5) This clause does not apply to the supply of adrenaline for anaphylaxis first aid purposes if—

(a) the adrenaline is contained in single use automatic injectors that have been filled by the manufacturer and that deliver no more than 0.3 milligrams of adrenaline each, and

(b) the supply is to a person who holds a current first aid certificate issued after completion of a first aid course approved by the WorkCover Authority as referred to in regulations made under the *Occupational Health and Safety Act 2000*, and the person has received training on the symptoms and first aid management of anaphylaxis from—

(i) a first aid training organisation approved by the WorkCover Authority, or

(ii) any other organisation approved by the Secretary for the purposes of this paragraph.

Maximum penalty—10 penalty units.

**19 Prescriptions for Schedule 2 or 3 substances to be endorsed**

(1) A pharmacist who supplies a Schedule 2 or 3 substance on prescription must endorse the prescription for the substance in accordance with clause 41 as if the substance were a restricted substance.

Maximum penalty—10 penalty units.

(2) The Secretary may, by order in writing, exempt any person or substance, or any class of persons or substances, from any or all of the requirements of this clause.

(3) Such an exemption may be given unconditionally or subject to conditions.

**20 Certain Schedule 7 substances to be supplied and used only under an authority**

(1) A person must not obtain or use a Schedule 7 substance unless the person holds an authority under Part 8 to obtain or use the substance.

Maximum penalty—10 penalty units.

(2) A dealer must not supply a Schedule 7 substance to any other person unless—

(a) the dealer holds an authority under Part 8 to supply the substance, and

(b) the person being supplied holds an authority under Part 8 to obtain the substance.

Maximum penalty—10 penalty units.

(3) A person being supplied with a Schedule 7 substance must surrender to the dealer the person’s authority to obtain the substance.

Maximum penalty—10 penalty units.

(4) In the case of an authority—

(a) that authorises multiple supplies of a Schedule 7 substance, or

(b) that has been issued to a class of persons (as referred to in clause 170(4)),

it is sufficient compliance with subclause (3) if the person being supplied surrenders a copy of the authority to the dealer.

(5) The functions of the Secretary under Part 8 with respect to an authority under this clause may be exercised by the Permanent Head of the Commonwealth Department of Health.

(6) The Secretary may, by order in writing, exempt any person or substance, or any class of persons or substances, from any or all of the requirements of this clause.

(7) Such an exemption may be given unconditionally or subject to conditions.

(8) This clause does not apply to—

(a) the supply by wholesale of any Schedule 7 substance, or

(b) the use by a person of any Schedule 7 substance that is—

(i) a pesticide (within the meaning of the *Pesticides Act 1999*), or

(ii) a stock medicine (within the meaning of the *Stock Medicines Act 1989*),

or the supply to, or obtaining by, such a person of any such substance, or

(c) the use by a person in charge of an institution or facility for scientific research, instruction, analysis or study of any Schedule 7 substance for use in that institution or facility, or the supply to, or obtaining by, such a person of any such substance for use in that institution or facility, or

(d) the use by a person of any Schedule 7 substance (other than a highly dangerous substance) for non-domestic purposes, or the supply to, or obtaining by, a person of any such substance for use for non-domestic purposes.

(9) In subclause (8)(d), ***highly dangerous substance*** means any of the following substances—

arsenic

cyanides

fluoroacetamide

fluoroacetic acid

hydrocyanic acid

strychnine

thallium

**21 “Particular use” poisons may only be supplied in original containers**

(1) This clause applies to any Schedule 5, 6 or 7 substance that is specified in the Poisons List as being a substance that is manufactured or supplied for a particular use.

(2) A dealer (other than an authorised practitioner or pharmacist) who supplies a substance to which this clause applies must supply the substance, unopened, in the

container in which it was received by the dealer.

Maximum penalty—10 penalty units.

**22 Supply of art materials, toys, furniture and the like containing poisons**

(1) A person must not supply any pencil, crayon, finger colour, poster paint, school pastel or show card colour or other such article or substance if the article or substance contains a Schedule 2, 3, 5, 6 or 7 substance.

(2) Subclause (1) does not apply to the supply of artists' oil colours.

(3) A person must not supply any painted toy, furniture or other item of household goods if the paint contains a Schedule 6 or 7 substance.

Maximum penalty—10 penalty units.

**23 Quantity and purpose of supply to be appropriate**

An authorised practitioner, pharmacist or retail dealer must not supply any poison—

(a) in the case of a therapeutic substance, in a quantity, or for a purpose, that does not accord with the recognised therapeutic standard of what is appropriate in the circumstances, or

(b) in any other case, for a purpose other than that stated on its container or for a purpose other than that for which it is normally used.

Maximum penalty—20 penalty units or imprisonment for 3 months, or both.

## Division 5 Records of supply

**24 Supply of certain Schedule 2 or 3 substances to be recorded**

(1) A pharmacist who supplies pseudoephedrine on prescription must record details of the supply in accordance with clause 55 as if pseudoephedrine were a restricted substance.

Maximum penalty—20 penalty units or imprisonment for 3 months, or both.

(1A) A pharmacist who supplies pseudoephedrine to a person without a prescription must, at the time of the supply, record the following details in an electronic form approved by the Secretary—

(a) a unique reference number for the supply,

(b) the name of the person by whom the pseudoephedrine is supplied,

(c) the name and address of the person to whom the pseudoephedrine is supplied,

(d) the name, strength (if not readily apparent) and quantity of the pseudoephedrine supplied and the date on which it is supplied,

(e) if the pharmacist does not know the identity of the person to whom the pseudoephedrine is supplied, the unique reference number of a photo identification of the person and the type of that identification.

Maximum penalty—20 penalty units or imprisonment for 3 months, or both.

(2) Subclauses (1) and (1A) apply to pseudoephedrine only in so far as it is a Schedule 3 substance.

(2A) The operator of a residential care facility in which medication charts are used must ensure that an employee of the facility makes a record in the medication chart of a resident of the facility of the administration of any Schedule 2 or 3 substance to the resident.

Maximum penalty—10 penalty units.

(3) The Secretary may, by order in writing, exempt any person or any class of persons from the requirements of this clause.

(4) Such an exemption may be given unconditionally or subject to conditions.

(5) In this clause—

***photo identification*** means any of the following types of identification held by the person being supplied—

(a) an Australian driver licence that displays a photograph of the person, or

(b) a passport, or

(c) a NSW Photo Card issued under the *Photo Card Act 2005*, or

(d) a card issued under a law of the Commonwealth or another State or Territory for the purpose of proving the person's age which contains a photograph of the person in whose name the card is issued.

## Division 6 Miscellaneous

### 25 Poisons to be used or disposed of safely

A person must not use or dispose of a poison in any place or in any manner likely to constitute a risk to the public.

Maximum penalty—20 penalty units or imprisonment for 3 months, or both.

## Part 3 Restricted substances (S4)—the Act, s 17

## Division 1A Preliminary

### 25A Application of part

This part, other than clauses 61 and 67, does not apply to—

(a) a prescription for a voluntary assisted dying substance for use under the *Voluntary Assisted Dying Act 2022*, or

(b) a voluntary assisted dying substance prescribed in accordance with the *Voluntary Assisted Dying Act 2022*.

## Division 1 Packaging and labelling

### 26 Packaging and labelling generally

(1) A dealer who supplies a restricted substance must ensure that the substance is packaged and labelled—

(a) in accordance with the relevant provisions of the current Poisons Standard, and

(b) in the case of a substance to which *Therapeutic Goods Order No. 95* applies, in accordance with that Order.

(2) Despite subclause (1), an authorised practitioner who supplies a restricted substance must ensure that the substance is packaged in accordance with the requirements of subclause (1) but labelled in accordance with the requirements of Appendix A.

(3) Despite subclause (1), a pharmacist who supplies a restricted substance on prescription, or as referred to in clause 45, or who supplies the restricted substance benzylpenicillin as referred to in clause 48, must ensure that the substance is packaged and labelled in accordance with the requirements of Appendix A.

(4) Despite subclause (1), an authorised practitioner or pharmacist who supplies a restricted substance to a person who, in the opinion of the authorised practitioner or pharmacist, would suffer undue hardship through difficulty in opening a container that is packaged in accordance with *Therapeutic Goods Order No. 95*, is not required to package the substance in accordance with that Order.

Maximum penalty—10 penalty units.

### 27 Misleading labelling of substances as restricted substances

A dealer must not supply any substance in a container that has a label that states or implies that the substance is a restricted substance, unless the substance is such a substance.

Maximum penalty—10 penalty units.

**28 Exemptions**

(1) The Secretary may, by order in writing, exempt any person or substance, or any class of persons or substances, from the requirements of this Division.

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

(3) Subject to subclause (4), any exemption in force under a law of the Commonwealth, or of another State or a Territory, corresponding to this clause has the same effect as an exemption under this clause.

(4) The Secretary may, by order published in the Gazette, declare that subclause (3) does not have effect with respect to an exemption specified in the order.

## Division 2 Storage

**29 Storage generally**

A dealer who has possession of any restricted substance must keep the substance—

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

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

(c) in such a way that, if its container breaks or leaks, the substance cannot mix with or contaminate any food intended for consumption by humans or animals.

Maximum penalty—15 penalty units.

**30 Storage of prescribed restricted substances in hospital wards**

(1) Prescribed restricted substances that are kept in a hospital ward must be stored apart from all other goods (other than drugs of addiction or propofol) in a separate room, safe, cupboard or other receptacle securely attached to a part of the premises and kept securely locked when not in immediate use.

(2) This clause does not apply to the storage of prescribed restricted substances on an emergency trolley, anaesthetic trolley or operating theatre trolley.

(3) (Repealed)

Maximum penalty—20 penalty units.

**31 Responsibility for storage in hospitals**

(1) The chief pharmacist of a hospital is responsible for the storage of all restricted substances at the hospital other than those that have been supplied to a ward.

(2) In the case of a hospital for which there is no pharmacist, the responsibilities of a chief pharmacist under this clause are instead the responsibilities of—

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

(b) the medical superintendent of the hospital,

as the chief executive officer of the hospital may determine.

(3) The nurse or midwife in charge of a hospital ward is responsible for the storage of all restricted substances in the ward.

**31A Storage in managed correctional centres**

(1) The management company for a managed correctional centre must ensure that restricted substances at the managed correctional centre are stored—

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

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

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

(2) The management company for a managed correctional centre must ensure that prescribed restricted substances at the managed correctional centre are stored—

(a) apart from all other goods and substances, and

(b) in a separate room, safe, cupboard or other receptacle that is securely attached to a part of the premises and kept securely locked when not in immediate use.

(3) The management company for a managed correctional centre must appoint, by written instrument, a pharmacist employed at the managed correctional centre as the person responsible for the storage of restricted substances at the managed correctional centre.

(4) If there is no pharmacist employed at the managed correctional centre, an authorised practitioner or nurse in charge may be appointed.

(5) This clause does not apply to a restricted substance at a retail pharmacy located at a managed correctional centre.

(6) This clause does not prevent prescribed restricted substances from being stored with drugs of addiction.

(7) In this clause—

***authorised practitioner*** does not include a veterinary practitioner.

Maximum penalty—20 penalty units.

## Division 3 Prescriptions

### 32 Prescriptions for restricted substances

(1) A medical practitioner, dentist or veterinary practitioner may issue a prescription for a restricted substance.

(2) A person must not issue a prescription for a restricted substance unless authorised to do so by or under the Act (including by an authority under Part 8).

Maximum penalty—15 penalty units.

### 33 Prescriptions may be issued only for certain purposes

(1) A medical practitioner must not issue a prescription for a restricted substance otherwise than for medical treatment.

(2) A nurse practitioner must not issue a prescription for a restricted substance otherwise than in the course of practising as a nurse practitioner.

(3) A midwife practitioner must not issue a prescription for a restricted substance otherwise than in the course of practising as a midwife practitioner.

(4) A dentist must not issue a prescription for a restricted substance otherwise than for dental treatment, and must endorse any such prescription with the words “FOR DENTAL TREATMENT ONLY”.

(5) An optometrist must not issue a prescription for a restricted substance otherwise than in the course of practising as an optometrist, and must endorse any such prescription with the words “FOR OPTOMETRICAL TREATMENT ONLY”.

(6) A veterinary practitioner must not issue a prescription for a restricted substance otherwise than for veterinary treatment, and must endorse any such prescription with the words “FOR ANIMAL TREATMENT ONLY”.

(7) A podiatrist must not issue a prescription for a restricted substance otherwise than in the course of practising as a podiatrist, and must endorse any such prescription with the words “FOR PODIATRY TREATMENT ONLY”.

Maximum penalty—15 penalty units.

### 34 Quantity and purpose of prescriptions to be appropriate

An authorised practitioner must not issue a prescription for a restricted substance in a quantity, or for a purpose, that does not accord with the recognised therapeutic standard of what is appropriate in the circumstances.

Maximum penalty—20 penalty units or imprisonment for 6 months, or both.

**34A Medication chart prescriptions**

(1) The authority of a pharmacist to supply a restricted substance on prescription (other than for a special restricted substance or a substance listed in clause 37) extends, in the case of a medication chart prescription, to supply on a duplicate copy of the medication chart prescription.

(2) Accordingly, a reference in this Regulation to a prescription (in the context of the supply on prescription of a restricted substance by a pharmacist) is a reference, in the case of supply on a medication chart prescription, to a duplicate copy of the prescription.

**35 Form of prescription**

(1) A prescription for a restricted substance must include the following details—

(a) the date on which it is issued,

(b) if the treatment is for—

(i) a patient—the name, date of birth and address of the patient, or

(ii) an animal—the species of animal and the name and address of the animal's owner, or

(iii) a patient's partner and the prescription is for azithromycin for the treatment of chlamydia—the name and email address or mobile phone number of the partner,

(c) the name, strength (if not readily apparent) and quantity of the substance to be supplied,

(c1) the route of administration (if not readily apparent) of the substance to be supplied,

(d) adequate directions for use,

(e) the maximum number of times the substance may be supplied on the prescription,

(f) in the case of a prescription for a special restricted substance, the intervals at which the substance may be supplied on the prescription,

(g) if the prescription is issued at a hospital, the name and designation of the person by whom it is issued and the name, address and telephone number of the hospital,

(h) if the prescription is issued elsewhere than at a hospital, the name and designation of the person by whom it is issued and the address and telephone number of the premises at which it is issued.

(1A) As an alternative to complying with subclause (1), a medication chart prescription authorising the supply of a substance that is not a special restricted substance or a substance listed in clause 37 must include the following details—

(a) the date on which it is issued,

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

(c) the name and form (if not readily apparent) of the substance to be supplied,

(d) the strength (if not readily apparent) of the substance to be supplied,

(e) the route of administration (if not readily apparent) of the substance to be supplied,

(f) adequate directions for use,

(g) the frequency or times at which the substance is to be administered or used,

(h) the period during which the substance is to be used or administered (being a period that ends on a date that is no more than 4 months from the date of first use of the relevant chart for the resident),

(i) the name and designation of the person by whom it is issued,

(j) the name, address and telephone number of the relevant residential care facility.

(2) The details referred to in subclause (1A)(b) and (j) can be made out by any person.

(2A) The details referred to in subclause (1)(a)–(f) and (1A)(a) and (c)–(i) must be made out—

(a) in the handwriting of the person by whom the prescription is issued, or

(b) in such other manner as may be approved for the time being by the Secretary.

(2B) A prescription must be signed by the person by whom it is issued (whether it complies with subclause (1) or (1A)).

(3) The person by whom the prescription is issued must confirm any dose that could be regarded as being dangerous or unusual by underlining the part of the prescription that specifies the intended dose and by initialling the prescription in the margin.

(4) A person who issues a prescription for a restricted substance must ensure that the prescription complies with the requirements of this clause.

(5) The Secretary may, by order in writing, exempt any person or restricted substance, or any class of persons or restricted substances, from any or all of the requirements of this clause.

(6) Such an exemption may be given unconditionally or subject to conditions.

(7) In this clause—

***partner*** of a patient includes any of the following—

(a) the patient's spouse,

(b) the patient's de facto partner,

(c) a person with whom the patient is or was in a sexual relationship.

(8) (Repealed)

Maximum penalty—15 penalty units.

**36 Emergency prescriptions may be given by telephone or otherwise**

(1) In an emergency or other urgent circumstances, an authorised practitioner may direct the supply of a restricted substance orally, including by telephone, by electronic mail or by facsimile.

(2) A person who so directs the supply of a restricted substance—

(a) must immediately make out a prescription, and

(b) must send the prescription without delay (and in any case within 24 hours) to the person to whom the direction was given.

(3) A person who issues a prescription under this clause must ensure that the prescription is endorsed with words that indicate the prescription has been issued in confirmation of a direction under this clause.

(4) This clause does not apply to a direction given under clause 58.

Maximum penalty—15 penalty units.

**36A Special provisions for prescribing restricted substances—public health organisations**

(1) A medical practitioner or nurse practitioner may issue a prescription for a restricted substance by sending a prescription to a pharmacist employed in or engaged by a public health organisation in relation to carrying out functions in the course of that employment or engagement by email or facsimile.

(2) A medical practitioner or nurse practitioner who issues a prescription for a restricted substance in accordance with this clause must keep the prescription.

(3) A pharmacist to whom a prescription is sent under this clause must—

(a) print a copy of the prescription, and

(b) keep a printed copy.

(4) The copy of the prescription printed by the pharmacist is taken to be a prescription for the purposes of Division 4 of this Part.

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

(6) In this clause—

***restricted substance*** includes a prescribed restricted substance and a special restricted substance.

**36B Special provisions for prescribing restricted substances—private health facilities**

(1) This clause applies to a medical practitioner or nurse practitioner and a pharmacist—

(a) employed in or engaged by the same private health facility, and

(b) in relation to carrying out functions in the course of that employment or engagement.

(2) During the prescribed period, a medical practitioner or nurse practitioner may issue a prescription for a restricted substance by sending a prescription to a pharmacist by email or facsimile.

(3) A medical practitioner or nurse practitioner who issues a prescription for a restricted substance in accordance with this clause must keep the prescription.

(4) A pharmacist to whom a prescription is sent under this clause must—

(a) print a copy of the prescription, and

(b) keep a printed copy.

(5) The copy of the prescription printed by the pharmacist is taken to be a prescription for the purposes of Division 4 of this Part.

(6) This clause does not apply to a medication chart prescription.

(7) In this clause—

***prescribed period*** means the period commencing on the commencement of this clause and ending at the end of 31 March 2023.

***private health facility*** has the same meaning as in the *Private Health Facilities Act 2007*, section 4.

***restricted substance*** does not include a prescribed restricted substance or a special restricted substance.

**37 Authority required to prescribe certain restricted substances**

(1) This clause applies to the following restricted substances—

acitretin

clomiphene

cyclofenil

dinoprost

dinoprostone

etretinate

follitropin beta

hydroxychloroquine

isotretinoin for oral use

luteinising hormone

tretinoin for oral use

urofollitrophin (human follicle stimulating hormone)

(2) A person must not prescribe a restricted substance to which this clause applies unless the person holds an authority under Part 8 to prescribe the substance.

(3) This clause does not apply to the prescription of a substance—

(a) by a veterinary practitioner, or

(b) by a person who is authorised by the Permanent Head of the Commonwealth Department of Health to issue a prescription for the substance.

(4) A person who issues a prescription that authorises the supply of a substance to which this clause applies must ensure—

(a) in the case of a prescription that is issued in accordance with an authority under Part 8 that was granted to a particular person (by means of an instrument in writing given to the person), that the prescription is endorsed with the reference number shown on the authority, or

(b) in any other case, that the prescription is endorsed with words that clearly indicate that the prescription has been issued under this clause.

Maximum penalty—15 penalty units.

**38 Records to be kept of certain prescriptions**

(1) An authorised practitioner who prescribes a prescribed restricted substance must make a record of the following particulars—

(a) the name, strength and quantity of the substance prescribed and the date on which it was prescribed,

(b) if the substance is intended for the treatment of a person, the name and address of the person to be treated,

(c) if the substance is intended for the treatment of an animal, the species of animal and the name and address of the animal's owner,

(d) the maximum number of times the substance may be supplied on the prescription,

(e) in the case of a prescription for a special restricted substance, the intervals at which the substance may be supplied on the prescription,

(f) the directions for use, as shown on the prescription.

(2) The record must be kept at the surgery, hospital or office of the person prescribing the substance.

Maximum penalty—15 penalty units.

## Division 4 Supply

## Subdivision 1 Supply on prescription

**39 Prescriptions may be filled only if in proper form**

(1) A pharmacist must not supply a restricted substance on prescription unless the prescription is in the form required by Division 3.

(2) This clause does not prevent a pharmacist from supplying a restricted substance on a prescription that otherwise complies with clause 35(1) merely because—

(a) the prescription fails to specify the maximum number of times the substance may be supplied, or

(a1) the prescription fails to specify the patient's date of birth, or

(b) in the case of a prescription for a special restricted substance, the prescription fails to specify the intervals at which the substance may be supplied, or

(c) the address shown on the prescription indicates that it has been issued by a veterinary practitioner from some other State or a Territory.

(2A) This clause does not prevent a pharmacist from supplying a substance on a medication chart prescription that otherwise complies with clause 35(1A) merely because—

(a) the prescription fails to specify the maximum number of times the substance may be supplied, or

(b) the prescription fails to specify the patient's date of birth.

(3) A pharmacist must not supply a restricted substance on a prescription referred to in subclause (2)(a), (a1) or (b) if it appears to the pharmacist that the substance has previously been supplied on the prescription, regardless of how many times the prescription purports to authorise the supply of the substance.

(4) The Secretary may, by order in writing, exempt any person or restricted substance, or any class of persons or restricted substances, from any or all of the requirements of this clause.

(5) Such an exemption may be given unconditionally or subject to conditions.

Maximum penalty—15 penalty units.

**40 Certain prescriptions not to be filled**

(1) A pharmacist must not supply a restricted substance on prescription—

(a) if the prescription is marked "CANCELLED", or

(b) if the substance has already been supplied on the prescription the maximum number of times indicated by the prescription, or

(c) if the interval of time that has elapsed since the substance was last supplied on the prescription is less than that indicated by the prescription as the minimum interval that must elapse between successive supplies of the substance, or

(d) if the prescription is illegible or defaced, or

(e) if the prescription appears to have been forged or fraudulently obtained, or

(f) if the prescription appears to have been altered otherwise than by the authorised practitioner by whom it was issued, or

(g) if the prescription is dated—

(i) in the case of a medication chart prescription—more than 4 months before the date on which the supply is requested, or

(ii) in the case of a prescription, other than a medication chart prescription, for a prescribed restricted substance—more than 6 months before the date on

which the supply is requested, or

(iii) in any other case—more than 12 months before the date on which the supply is requested, or

(h) in the case of a medication chart prescription—where it appears to the pharmacist that a sufficient quantity of the substance has already been supplied to the resident for the period indicated on the prescription.

(2) Immediately on being requested to supply a prescribed restricted substance in either of the circumstances referred to in subclause (1)(e) or (f), a pharmacist must retain the prescription and cause notice of the request to be given to a police officer.

Maximum penalty—15 penalty units.

**41 Prescriptions to be endorsed**

(1) A pharmacist who supplies a restricted substance on prescription must (on each occasion the substance is supplied) endorse the following particulars (in ink) on the prescription—

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

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

(c) the prescription reference number.

Maximum penalty—15 penalty units.

(2) A person who supplies a substance on prescription must endorse (in ink) across the prescription the word “CANCELLED”—

(a) if the maximum number of times the prescription is to be dispensed is not clearly specified, or

(b) if (in the case of a prescription for a special restricted substance) the intervals at which the substance may be supplied are not clearly specified, or

(c) if the prescription has reached the last occasion on which it can be supplied according to the maximum number of times specified on it.

Maximum penalty—15 penalty units.

(3) The Secretary may, by order in writing, exempt any person or substance, or any class of persons or substances, from any or all of the requirements of this clause.

(4) Such an exemption may be given unconditionally or subject to conditions.

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

### 42 Prescriptions for certain substances to be kept

(1) A pharmacist who supplies a special restricted substance on prescription must keep the prescription, whether or not the prescription authorises more than one supply of the substance.

Maximum penalty—20 penalty units.

(2) A pharmacist must keep prescriptions for special restricted substances separate from other prescriptions (other than prescriptions for drugs of addiction).

Maximum penalty—20 penalty units.

(3) The Secretary may, by order in writing, exempt any person or substance, or any class of persons or substances, from any or all of the requirements of this clause.

(4) Such an exemption may be given unconditionally or subject to conditions.

### 42A (Repealed)

## Subdivision 2 Supply without prescription

### 43 Supply by certain health practitioners

(1) A medical practitioner must not supply a restricted substance to any person otherwise than for medical treatment.

(2) A nurse practitioner must not supply a restricted substance to any person otherwise than in the course of practising as a nurse practitioner.

(3) A midwife practitioner must not supply a restricted substance to any person otherwise than in the course of practising as a midwife practitioner.

(4) A dentist must not supply a restricted substance to any person otherwise than for dental treatment.

(5) An optometrist must not supply a restricted substance to any person otherwise than in the course of practising as an optometrist.

(6) A veterinary practitioner must not supply a restricted substance to any person otherwise than for veterinary treatment.

(7) A podiatrist must not supply a restricted substance to any person otherwise than in the course of practising as a podiatrist.

Maximum penalty—15 penalty units.

### 44 Emergency supply by pharmacists on direction of certain health practitioners

(1) A pharmacist may supply a person with a restricted substance (including a prescribed

restricted substance) in accordance with a direction given under clause 36.

(2) A prescription that is subsequently sent in confirmation of the direction must be dealt with in accordance with clauses 41 and 42, and details of the supply must be recorded in accordance with clause 55, in the same way as if the restricted substance had been supplied on prescription.

(3) If such a prescription is not received within 7 days after the substance is supplied, the pharmacist must report that fact to the Secretary.

Maximum penalty—15 penalty units.

**45 Emergency supply by pharmacists otherwise than on direction of health practitioner**

(1) A pharmacist may supply a person with a restricted substance (other than a prescribed restricted substance) if the pharmacist is satisfied—

(a) that the person is undergoing treatment essential to the person's well-being, and

(b) that the substance has previously been prescribed for the treatment, and

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

(d) that, in the circumstances, it is not practicable for the person to obtain a prescription for the substance from an authorised practitioner.

(2) A restricted substance may not be supplied to any person under this clause unless—

(a) the quantity supplied is no more than that required for 7 days' treatment, or

(b) in the case of a liquid, aerosol, cream, ointment or anovulant tablet that is contained in a standard pack, the standard pack is the smallest standard pack in which that kind of liquid, aerosol, cream, ointment or anovulant tablet is generally available.

Maximum penalty—15 penalty units.

**45A Supply by pharmacists in accordance with determination under National Health Act 1953 of Commonwealth**

(1) A pharmacist may supply a person with a restricted substance that is covered by the Continued Dispensing Determination under this clause if—

(a) the supply is made in accordance with conditions that are specified in that determination, and

(b) the supply is made in accordance with the document entitled *Guidelines for the Continued Dispensing of eligible prescribed medicines by pharmacists*, published by the Pharmaceutical Society of Australia in 2018 and as in force from time to

time, and

(c) the pharmacist is an approved pharmacist within the meaning of the *National Health Act 1953* of the Commonwealth, and

(d) the person is in immediate need of the substance for continuation of treatment.

(2) In this clause, ***Continued Dispensing Determination*** means the *National Health (Continued Dispensing) Determination 2022* of the Commonwealth, as in force from time to time.

**46 Supply by pharmacists to health practitioners for emergency use**

A pharmacist may supply an authorised practitioner with a restricted substance (including a prescribed restricted substance) for emergency use, but only on a written order signed and dated by the authorised practitioner.

**47 Supply by pharmacists to residential care facilities of stock for urgent use**

(1) The responsible person for a residential care facility is authorised to have possession of a restricted substance (including a prescribed restricted substance) that is approved by the Secretary for urgent use in a residential care facility.

(2) A retail pharmacist is authorised to supply a restricted substance (including a prescribed restricted substance) in the manufacturer's original pack to the responsible person for a residential care facility, but only if the substance is supplied—

(a) at the premises of, and in the course of carrying on the business of, the pharmacy, and

(b) in accordance with a written order signed by the responsible person.

(3) The responsible person for a residential care facility must not—

(a) sign an order under this clause for a restricted substance unless the substance is approved by the Secretary for urgent use in that residential care facility, or

(b) allow any restricted substance in his or her possession to be used otherwise than for administration to a resident of the residential care facility by a registered nurse in accordance with the direction of an authorised practitioner (other than a veterinary practitioner) or by an authorised practitioner (other than a veterinary practitioner).

Maximum penalty—15 penalty units.

(4) An approval under this clause—

(a) is to be by order in writing, and

(b) may apply generally or may be limited to a particular residential care facility or class of residential care facilities, and

(c) may apply generally or may be limited to a particular substance or class of substance, and

(d) may be given unconditionally or subject to conditions.

**48 Supply by pharmacists of benzylpenicillin for use in animals**

(1) This clause applies to benzylpenicillin, including procaine penicillin, in preparations for use by intramuscular injection in animals.

(2) A pharmacist may supply benzylpenicillin otherwise than on prescription to a person who satisfies the pharmacist that it is needed for the urgent treatment of an animal and that, under the circumstances, it is not practicable to obtain a prescription authorising its supply.

(3) A pharmacist must not supply benzylpenicillin—

(a) to any person who is under 18 years of age, or

(b) to any person who is unknown to the pharmacist.

(4) Subclause (3)(b) does not prevent a pharmacist from supplying benzylpenicillin to a person who is unknown to the pharmacist if it is supplied in the presence of a person who is known to the pharmacist and who satisfies the pharmacist that he or she knows the person being supplied.

**48A Supply by pharmacists of certain vaccines**

(1A)–(1C) (Repealed)

(1) A pharmacist who has authority to supply and administer a vaccine otherwise than on prescription must—

(a) before supplying and administering a vaccine, have completed a training course conducted by an education provider accredited by the Australian Pharmacy Council to provide the course, being a course that complies with standards for the accreditation of programs to support the administration of vaccines published by the Australian Pharmacy Council from time to time, and

(b) comply with standards approved by the Secretary.

(1AA) (Repealed)

(2) A pharmacist who, under an authority, supplies and administers a vaccine to a person in accordance with this clause must record the following details—

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

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

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

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

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

(f) the pharmacist's name, contact details and certificate of accreditation number,

(g) the address of the place at which the vaccination was administered,

(h) a unique reference number for the supply and administration.

Maximum penalty—15 penalty units.

## Subdivision 3 Supply in hospitals and managed correctional centres

### 49 Supply by pharmacists

A pharmacist employed at a hospital may supply a restricted substance—

(a) on a prescription issued in accordance with Division 3, or

(b) on the authorisation (whether in writing, by electronic mail, by facsimile or by any other form of electronic communication approved by the Secretary) of an authorised practitioner (other than a veterinary practitioner), where that authorisation is entered on a patient's medication chart, or

(c) on the requisition (whether in writing, by electronic mail, by facsimile or by any other form of electronic communication approved by the Secretary) of an authorised practitioner (other than a veterinary practitioner) or the nurse or midwife in charge of the ward in which the substance is to be used or stored.

### 49A Supply by pharmacists in managed correctional centres

(1) A pharmacist employed at a managed correctional centre may supply a restricted substance for the purposes of treating an inmate at the managed correctional centre—

(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.

Maximum penalty—20 penalty units.

(2) This clause does not limit the power of a pharmacist employed in a retail pharmacy located at a managed correctional centre to supply a restricted substance on

prescription in accordance with the Act or this Regulation.

(3) In this clause—

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

***authorised practitioner*** does not include a veterinary practitioner.

**50 Supply in original containers**

(1) A person who supplies a restricted substance to a patient in a hospital, or to an inmate in an institution, in accordance with section 10(4)(c) of the Act must supply the substance, unopened, in the container in which it was received by the person.

(2) This clause does not prevent the person from supplying an individual dose of the substance to the patient or inmate.

Maximum penalty—15 penalty units.

## Subdivision 4 Supply generally

**51 Research drugs**

(1) This clause applies to thalidomide other than as registered goods.

(2) A dealer must not supply thalidomide unless the person being supplied holds an authority under Part 8 to be supplied with thalidomide.

(3) This clause—

(a) does not prohibit a dealer from supplying thalidomide to a person who has the approval in writing of the Permanent Head of the Commonwealth Department of Health to import, buy, obtain or otherwise be supplied with thalidomide, and

(b) does not prohibit a person holding an authority under Part 8 to be supplied with thalidomide from supplying thalidomide to a person under his or her general supervision, for the purpose of enabling that other person to carry out medical diagnosis, or medical or scientific research or analysis (including the conduct of clinical trials), and

(c) does not prohibit a medical practitioner holding an authority under Part 8 to be supplied with thalidomide from supplying thalidomide to another person for the purpose of treating that other person in accordance with the authority.

(4) A person being supplied with thalidomide (otherwise than as referred to in subclause (3)(c)) must surrender his or her authority to the dealer.

(5) A dealer must keep any authority surrendered to the dealer under this clause.

Maximum penalty—15 penalty units.

**52 Authority required to supply certain restricted substances**

(1) This clause applies to the following substances—

acitretin

clomiphene

cyclofenil

dinoprost

dinoprostone

etretinate

follitropin beta

hydroxychloroquine

isotretinoin for oral use

luteinising hormone

tretinoin for oral use

urofollitropin (human follicle stimulating hormone)

(2) A person must not supply a substance to which this clause applies unless the person holds an authority under Part 8 to supply the substance.

(3) This clause does not apply to the supply of a substance—

(a) by wholesale, or

(b) by a veterinary practitioner, or

(c) by a pharmacist on the prescription of—

(i) a medical practitioner holding an authority under Part 8 to prescribe the substance, or

(ii) a veterinary practitioner, or

(d) by a person who is authorised by the Permanent Head of the Commonwealth Department of Health to supply the substance.

Maximum penalty—15 penalty units.

**53 Restricted substances may be supplied by authorised persons**

A person who is not an authorised practitioner may supply a restricted substance to another person if the person by whom the substance is supplied holds an authority under Part 8 to supply the substance.

**54 Quantity and purpose of supply to be appropriate**

An authorised practitioner or pharmacist must not supply any restricted substance in a quantity, or for a purpose, that does not accord with the recognised therapeutic standard of what is appropriate in the circumstances.

Maximum penalty—20 penalty units or imprisonment for 6 months, or both.

## Division 5 Records of supply

**55 Supply on prescription to be recorded**

(1) A pharmacist who supplies a restricted substance on prescription must record the following details in a manner approved by the Secretary—

(a) the details required by clause 35(1) to be included in the prescription,

(b) a unique reference number for the prescription,

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

(d) the name of the person by whom the substance was supplied.

Maximum penalty—15 penalty units.

(2) A prescription for the supply of a restricted substance in a hospital need not be recorded so long as the chief pharmacist of the hospital keeps the prescription or a copy of the prescription.

(3) The Secretary may, by order in writing, exempt any person or restricted substance, or any class of persons or restricted substances, from the requirements of this clause.

(4) Such an exemption may be given unconditionally or subject to conditions.

**55A Records relating to medication chart prescriptions**

(1) A pharmacist who supplies any substance to a person on a medication chart prescription must keep the prescription.

Maximum penalty—15 penalty units.

(2) A pharmacist who supplies any substance to a person on a medication chart prescription must endorse the following particulars (in ink) on the prescription on each occasion on which the substance is dispensed—

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

(b) the address of, or number identifying, the pharmacy from which the substance was supplied,

(c) the prescription reference number,

(d) the quantity supplied.

Maximum penalty—15 penalty units.

(3) The operator of a residential care facility in which medication charts are used must ensure that an employee of the facility makes a record in the medication chart of a resident of the facility of the administration of any restricted substance to the resident.

Maximum penalty—15 penalty units.

**56 Records to be kept of certain supply of restricted substances**

(1) An authorised practitioner who supplies a restricted substance—

(a) must record the name, strength and quantity of the substance supplied and the date on which it was supplied, and

(b) must record—

(i) if the supply of the restricted substance is for a patient—the name and address of the patient, or

(ii) if the supply of the restricted substance is for an animal—the species of the animal and the name and address of the animal's owner, or

(iii) if the restricted substance is azithromycin and the supply is for a patient's partner for the treatment of chlamydia—the name and email address or mobile phone number of the partner, and

(c) must keep the record of the supply of the substance at the hospital, surgery or office of the person supplying the substance.

Maximum penalty—20 penalty units or imprisonment for 6 months, or both.

(2) In this clause—

***partner*** of a patient includes any of the following—

(a) the patient's spouse,

(b) the patient's de facto partner,

(c) a person with whom the patient is or was in a sexual relationship.

(3) (Repealed)

**57 Certain supplies of restricted substances to be separately recorded**

(1) A pharmacist who supplies a restricted substance as referred to in clause 45, or who supplies the restricted substance benzylpenicillin as referred to in clause 48, must record the following details of the supply in a manner approved by the Secretary—

(a) a unique reference number for the supply,

(b) the name and address of the patient or (if the treatment is for an animal) the species of animal and the name and address of the animal's owner,

(c) the name, strength and quantity of the substance,

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

(e) in the case of a restricted substance supplied as referred to in clause 45, the name and address of the authorised practitioner by whom it appears to the pharmacist that the substance was last prescribed,

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

(g) the name of the person by whom the substance was supplied.

Maximum penalty—15 penalty units.

(2) A pharmacist who supplies a restricted substance as referred to in clause 46 or clause 47 must record the following details of the supply in a manner approved by the Secretary—

(a) a unique reference number for the supply,

(b) the name and address of the person supplied,

(c) the name, strength and quantity of the substance,

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

(e) the name of the person by whom the substance was supplied.

Maximum penalty—15 penalty units.

## Division 6 Administration

**58 Administration by persons employed at hospitals and managed correctional centres**

(1) A person employed at a hospital or managed correctional centre must not administer a restricted substance to a patient without a direction from an authorised practitioner.

(2) A direction must be—

(a) written and given in person, or

(b) given in another manner approved by the Secretary.

(3) However, a direction may be given in an emergency—

(a) by email or facsimile, or

(b) orally, including by telephone, or

(c) in another way approved by the Secretary.

(4) An authorised practitioner who gives a direction under subclause (3) must attend to review the patient as soon after giving the direction as the authorised practitioner considers appropriate in the circumstances.

(5) As soon as practicable and no later than 24 hours after giving a direction under subclause (3)(b), the authorised practitioner must confirm the direction by—

(a) signing an entry in the patient's medical history, or

(b) email or facsimile.

(6) If the authorised practitioner does not confirm the direction under subclause (5) within 7 days after the restricted substance is administered, the person who administered the substance must notify the Secretary.

(6A) Subclause (1) does not apply to a person employed at a hospital or managed correctional centre who holds an authority under Part 8 to administer the substance.

(7) Subclauses (4)–(6) do not apply to the administration of a restricted substance to a patient who is an inmate in a correctional centre if confirmation of the direction for the administration of the substance is given in accordance with the requirements of a protocol approved by the Secretary.

(8) In this clause—

***authorised practitioner*** does not include a veterinary practitioner.

***patient*** means—

(a) a patient in a hospital, or

(b) an inmate in a managed correctional centre.

Maximum penalty—15 penalty units.

**59 Administration of prescribed restricted substances**

(1) A person must not self-administer a prescribed restricted substance, or administer a prescribed restricted substance to any other person, otherwise than—

(a) for the purposes of medical treatment prescribed by a medical practitioner, or

(b) for the purposes of dental treatment prescribed by a dentist, or

(c) for the purposes of treatment prescribed by—

(i) a nurse practitioner in the course of practising as a nurse practitioner, or

(ii) a midwife practitioner in the course of practising as a midwife practitioner, or

(iii) an optometrist in the course of practising as an optometrist, or

(iv) a podiatrist in the course of practising as a podiatrist.

Maximum penalty—20 penalty units.

(2) For the purposes of subclause (1), it is sufficient if the treatment referred to in subclause (1)(a) or (b) in relation to the self-administration of a prescribed restricted substance has been prescribed by the person by whom the substance is being self-administered.

(3) This clause has effect for the purposes of Division 1 of Part 2 of the *Drug Misuse and Trafficking Act 1985* in relation to any prescribed restricted substance that is included in Schedule 1 to that Act.

**60 Authority required to administer certain restricted substances**

(1) This clause applies to the following restricted substances—

acitretin

clomiphene

cyclofenil

dinoprost

dinoprostone

etretinate

follitropin beta

hydroxychloroquine

isotretinoin for oral use

luteinising hormone

tretinoin for oral use

urofollitropin (human follicle stimulating hormone)

(2) A person must not administer a restricted substance to which this clause applies unless the person holds an authority under Part 8 to administer the substance.

(3) This clause does not apply to—

(a) the administration to a patient of a substance whose administration has been prescribed or directed by a medical practitioner holding an authority under Part 8 to prescribe the substance, or

(b) the administration of a substance to an animal by a veterinary practitioner or by a person acting under the general supervision of a veterinary practitioner.

Maximum penalty—15 penalty units.

## Division 7 Miscellaneous

### 61 Prescribed restricted substances

(1) For the purposes of section 16 of the Act, the substances specified in Appendix D are prescribed restricted substances.

(2) The substances specified in Appendix D are also restricted substances for the purposes of sections 9, 10, 11 and 18 of the Act, as referred to in paragraph (a) of the matter specified at the end of sections 9(1), 10(3), 11(1) and 18 of the Act with respect to penalties.

(3) For the purposes of section 18A(1) of the Act, the quantities specified in Appendix D are the prescribed quantities for the corresponding restricted substances specified in that Appendix.

### 62 Authorised persons

For the purposes of section 16(1)(e) of the Act, the following persons are authorised to obtain possession of prescribed restricted substances for the purposes of their profession or employment—

(a) the director of nursing of a hospital that does not employ a chief pharmacist,

(b) the nurse or midwife in charge of a ward in a public hospital,

(b1) the responsible person for a residential care facility,

(b2) a registered nurse at a residential care facility that is not a nursing home, but for the

purpose only of administering doses of such substances to individual residents of the residential care facility,

(c) a nurse or midwife who is approved for the time being by the Secretary for the purposes of this clause, or who belongs to a class of nurses or a class of midwives so approved,

(d) any other nurse or midwife, but for the purpose only of administering doses of such substances to individual patients in a hospital,

(e) an analyst, or a person acting under the direct personal supervision of an analyst.

**63 Disclosure of other prescribed restricted substances obtained or prescribed**

(1) A person who asks an authorised practitioner (other than a veterinary practitioner)—

(a) to supply the person with a prescribed restricted substance, or

(b) to give the person a prescription for a prescribed restricted substance,

must disclose to the authorised practitioner the quantity of that and any other prescribed restricted substance with which the person has been supplied, or for which the person has been given prescriptions, within the last 2 months.

(2) If the request is made on behalf of some other person, the person making the request is obliged only to furnish such information as is within that person's knowledge.

Maximum penalty—20 penalty units.

**64 Delivery by carrier**

A carrier is authorised to be in possession of a package containing a prescribed restricted substance, but for the purpose only of delivering it to the person to whom it is addressed.

**65 Pentobarbitone sodium**

(1) This clause applies to pentobarbitone sodium to the extent only to which it is a restricted substance, and not to the extent to which it is a drug of addiction.

(2) An authorised person who uses pentobarbitone sodium for the destruction of animals must ensure that the requirements of this clause are complied with.

(3) Pentobarbitone sodium must be kept separately from all other goods in a safe, cupboard or other receptacle—

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

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

(4) An authorised person must keep a separate register of all pentobarbitone sodium that

is obtained or used by the authorised person.

(5) On the day on which an authorised person obtains or uses any pentobarbitone sodium, the authorised person must enter in the register such of the following details as are relevant to the transaction—

(a) the quantity that was obtained or used,

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

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

(d) the total quantity held by the authorised person after the entry is made.

(6) Each entry must be dated and signed by the authorised person.

(7) In this clause, ***authorised person*** means—

(a) a person nominated by the council of a local government area, or

(b) an officer of an animal welfare organisation nominated by the organisation,

being in either case a person who is authorised under section 16(1)(d) of the Act to obtain possession of pentobarbitone sodium for the humane destruction of animals.

Maximum penalty—20 penalty units.

**66 Restricted substances to be used or disposed of safely**

A person must not use or dispose of a restricted substance in any place or in any manner likely to constitute a risk to the public.

Maximum penalty—15 penalty units.

**67 Loss or theft of prescribed restricted substances**

(1) A person must immediately notify the Secretary if the person loses a prescribed restricted substance or if a prescribed restricted substance is stolen from the person.

(2) This clause does not apply to the loss of any substance by, or the theft of any substance from, a person who has been supplied with the substance by, or on the prescription of, an authorised practitioner.

Maximum penalty—20 penalty units.

**68 Forfeiture of prescribed restricted substances**

The court before which a person is convicted of the illegal possession of a prescribed restricted substance may order that the substance be forfeited to the Crown, and may further order the forfeited substance to be destroyed or otherwise disposed of as the court thinks fit.

# Part 3A Restricted substances used for cosmetic and other purposes—the Act, Part 3, Div 1A

## Division 1 Preliminary

### 68A Definitions

In this Part—

***direction*** means a direction to a nurse to administer a relevant substance given by a medical practitioner or nurse practitioner in accordance with Division 2.

***relevant substance***—see clause 68B(1).

***responsible provider***, in relation to a relevant substance, means a person carrying on a business of administration of the relevant substance to which this Part applies, for fee or reward and whether or not for profit, but does not include an individual who is an employee or contractor of the business.

### 68B Application of Part

(1) This Part applies to the administration of the following substances (***relevant substances***) to a patient—

(a) a substance specified in the Act, section 18C(a) or (b),

(b) the following substances specified in Schedule 4 of the Poisons List that are prescribed for the purposes of the Act, section 18C(c)—

(i) calcium hydroxylapatite in preparations for injection or implantation for tissue augmentation or cosmetic use,

(ii) collagen in preparations for injection or implantation for tissue augmentation or cosmetic use,

(iii) deoxycholic acid,

(iv) polyacrylamide in preparations for injection or implantation for tissue augmentation or cosmetic use,

(v) polycaprolactone in preparations for injection or implantation for tissue augmentation or cosmetic use,

(vi) polylactic acid in preparations for injection or implantation for tissue augmentation or cosmetic use.

(2) This Part does not apply to the administration of a relevant substance to a patient by—

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

(b) a person employed at the hospital administering the relevant substance to a patient in a hospital on the direction of an authorised practitioner, other than a veterinary practitioner.

(3) This Part does not apply to the administration of a relevant substance to an animal by—

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

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

## Division 2 Administration

### 68C Nurse may administer relevant substance on direction of medical practitioner or nurse practitioner

(1) A person must not administer a relevant substance to a patient unless the person—

(a) is a nurse, and

(b) is acting in accordance with a direction of a medical practitioner or nurse practitioner.

(2) A nurse must not administer a relevant substance unless satisfied there is appropriate equipment available for use in a patient medical emergency.

(3) A nurse who administers a relevant substance in accordance with a direction must record the following information for each administration—

(a) the nurse's name,

(b) the date on which the relevant substance was administered,

(c) the batch number of the relevant substance,

(d) the information specified in clause 68E(1)(a)–(e) and (i).

(4) A nurse must give a copy of the record to the responsible provider.

### 68D Direction by medical practitioner or nurse practitioner

(1) A medical practitioner or nurse practitioner may give a direction to a nurse only if the practitioner has personally reviewed the patient in person or by audiovisual link.

(2) A direction must be written, signed by the medical practitioner or nurse practitioner and given to the nurse in person or by facsimile, email or other electronic means.

(3) However, if the medical practitioner or nurse practitioner is present when the relevant substance is administered by the nurse to whom the direction is given, the direction may be given orally.

(4) A direction has effect—

(a) for a written direction—for the period specified in the direction, not exceeding 6 months from the date on which the medical practitioner or nurse practitioner personally reviewed the patient under subclause (1), and

(b) for an oral direction—for the particular administration of the relevant substance to which the direction applies.

**68E Content of direction**

(1) A direction must include the following information—

(a) the patient's name,

(b) the patient's address,

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

(d) the address of the principal place of practice, within the meaning of the *Health Practitioner Regulation National Law (NSW)*, of the medical practitioner or nurse practitioner giving the direction,

(e) the address of the premises at which the relevant substance is to be administered,

(f) the responsible provider's name,

(g) the date on which the medical practitioner or nurse practitioner personally reviewed the patient under clause 68D(1),

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

(i) the number of times, and the intervals at which, the relevant substance is to be administered,

(j) for each administration of the relevant substance—

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

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

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

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

(2) If a direction is given orally, it is not required to include the information specified in subclause (1)(b)–(i).

**68F Records of directions**

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

(a) keep a copy of the direction, and

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

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

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

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

## Division 3 Miscellaneous

**68G Storage**

The person who occupies or has control of premises at which the administration of a relevant substance to which this Part applies occurs must ensure that the relevant substance is kept—

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

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

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

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

**68H Duties of responsible providers**

(1) A responsible provider must ensure the administration of a relevant substance to which this Part applies that occurs as part of the responsible provider's business is carried out in accordance with this Part.

(2) A responsible provider must ensure—

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

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

(c) each nurse administering a relevant substance is adequately trained for a patient

medical emergency.

(3) A responsible provider must ensure that a relevant substance is administered in the form of a therapeutic good that may, under the Commonwealth Act, be lawfully manufactured for use in Australia.

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

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

(b) each record made by a nurse under clause 68C that relates to the direction.

### 68I Category 1 and category 2 requirements—the Act, s 18D(2)

**Note—**

The Act, section 18D(2) provides that a person who contravenes a category 1 or category 2 requirement is guilty of an offence. The maximum penalty for a category 1 requirement is 1,000 penalty units for a corporation and 200 penalty units or imprisonment for 6 months, or both, for an individual. The maximum penalty for a category 2 requirement is 250 penalty units for a corporation and 50 penalty units for an individual.

(1) The following provisions are category 1 requirements—

(a) clause 68C(1) and (2),

(b) clause 68D(1),

(c) clause 68H(1)–(3).

(2) The following provisions are category 2 requirements—

(a) clause 68C(3) and (4),

(b) clause 68D(2),

(c) clause 68E(1),

(d) clause 68F,

(e) clause 68G,

(f) clause 68H(4).

## Part 4 Drugs of addiction (S8)—the Act, s 24

## Division 1A Preliminary

### 68J Application of part

This part, other than Division 5 and clause 124, does not apply to—

(a) a prescription for a voluntary assisted dying substance for use under the *Voluntary Assisted Dying Act 2022*, or

(b) a voluntary assisted dying substance prescribed in accordance with the *Voluntary Assisted Dying Act 2022*.

## Division 1 Packaging and labelling

### 69 Packaging and labelling generally

(1) A dealer who supplies a drug of addiction must ensure that the drug is packaged and labelled—

(a) in accordance with the relevant provisions of the current Poisons Standard, and

(b) in the case of a drug of addiction to which *Therapeutic Goods Order No. 95* applies, in accordance with that Order.

(2) Despite subclause (1), an authorised practitioner who supplies a drug of addiction must ensure that the drug is packaged in accordance with the requirements of that subclause but labelled in accordance with the requirements of Appendix A.

(3) A pharmacist who supplies any quantity of a drug of addiction on prescription must ensure that the drug is supplied in a package that is labelled in accordance with the requirements of Appendix A instead of in accordance with the requirements of subclause (1).

(4) Despite subclause (1), an authorised practitioner or pharmacist who supplies a drug of addiction to a person who, in the opinion of the authorised practitioner or pharmacist, would suffer undue hardship through difficulty in opening a container that is packaged in accordance with *Therapeutic Goods Order No. 95*, is not required to package the drug in accordance with that Order.

Maximum penalty—10 penalty units.

### 70 Misleading labelling of substances as drugs of addiction

A dealer must not supply any substance in a container that has a label that states or implies that the substance is a drug of addiction, unless the substance is such a drug.

Maximum penalty—10 penalty units.

### 71 Packages to be sealed so that broken seal is readily distinguishable

(1) A dealer who supplies any drug of addiction must ensure that the drug is packaged in such a way that—

(a) its container is so sealed that, when the seal is broken, it is readily distinguishable from sealed containers, and

(b) if several containers are enclosed in a single primary pack, the primary pack is so sealed that, when the seal is broken, it is readily distinguishable from sealed primary packs.

(2) This clause does not apply to the supply of a drug of addiction—

(a) by an authorised practitioner in the practice of his or her profession, or

(b) by a pharmacist on the prescription of an authorised practitioner, or

(c) by a pharmacist employed at a hospital, on the written requisition of an authorised practitioner (other than a veterinary practitioner) or the nurse or midwife in charge of the ward in which the drug is to be used or stored, or

(d) by a nurse or midwife on the direction in writing of an authorised practitioner (other than a veterinary practitioner).

Maximum penalty—20 penalty units.

### 72 Exemptions

(1) The Secretary may, by order in writing, exempt any person or substance, or any class of persons or substances, from the requirements of this Division.

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

(3) Subject to subclause (4), any exemption in force under a law of the Commonwealth, or of another State or a Territory, corresponding to this clause has the same effect as an exemption under this clause.

(4) The Secretary may, by order published in the Gazette, declare that subclause (3) does not have effect with respect to an exemption specified in the order.

## Division 2 Storage

### 73 Storage generally

(1) A person who is in possession of any drug of addiction must keep the drug—

(a) in his or her possession stored apart from all other goods (other than cash or documents) in a separate room, safe, cupboard or other receptacle securely attached to a part of the premises and kept securely locked when not in immediate use, or

(b) stored in any other manner approved by the Secretary for the particular person or class of persons to which the person belongs.

(2) A person who is an authorised practitioner or a person referred to in clause 101(1)(g) is taken to comply with subclause (1)(a) if he or she keeps any drug of addiction (for

use in an emergency only) in a bag that is in a room, or in a vehicle, kept locked when not occupied by the person.

Maximum penalty—20 penalty units.

**74 Responsibility for storage in hospitals**

(1) The chief pharmacist of a hospital is responsible for the storage of all drugs of addiction at a hospital other than those that have been supplied to a ward.

(2) In the case of a hospital for which there is no pharmacist, the responsibilities of a chief pharmacist under this clause are instead the responsibilities of—

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

(b) the medical superintendent of the hospital,

as the chief executive officer of the hospital may determine.

(3) The nurse or midwife in charge of a hospital ward is responsible for the storage of all drugs of addiction in the ward.

**75 Storage in hospital wards**

(1) Drugs of addiction that are kept in a hospital ward must be stored apart from all other goods (other than prescribed restricted substances or propofol) in a separate room, safe, cupboard or other receptacle securely attached to a part of the ward and kept securely locked when not in immediate use.

(2) The nurse or midwife in charge of a hospital ward must ensure that—

(a) the room, safe, cupboard or receptacle is kept securely locked when not in immediate use, and

(b) any key or other device by means of which the room, safe, cupboard or receptacle may be unlocked—

(i) is kept on the person of a nurse or midwife whenever it is in the ward, and is removed from the ward whenever there is no nurse or midwife in the ward, or

(ii) is kept in a separately locked safe to which only a nurse or midwife has access, and

(c) any code or combination that is required to unlock the room, safe, cupboard or receptacle is not divulged to any unauthorised person.

Maximum penalty—20 penalty units.

**76 Storage in pharmacies**

(1) The pharmacist for the time being in charge of a pharmacy must keep any drug of addiction stored apart from other substances or goods (other than cash or documents) in a separate safe.

(2) Unless otherwise approved for the time being by the Secretary, such a safe must comply with the following requirements—

(a) it must be made of black mild steel plate at least 9 millimetres thick with continuous welding along all edges,

(b) it must be fitted with a door made of mild steel plate at least 9 millimetres thick, the door being flush fitting with a clearance around the door of not more than 1.5 millimetres,

(c) it must have a fixed locking bar, welded to the inside face of the door near the hinged edge, that engages in a rebate in the safe body when the door is closed,

(d) it must be fitted with a five lever key lock (or a locking mechanism providing at least equivalent security) securely fixed to the rear face of the door,

(e) if mounted on a brick or concrete wall or floor, it must be attached to the wall or floor by means of suitably sized expanding bolts through holes 9 millimetres in diameter drilled in the rear or bottom of the safe,

(f) if mounted on a timber framed wall or floor, it must be attached to the wall or floor frame by means of suitably sized coach screws through holes 9 millimetres in diameter drilled in the rear or bottom of the safe,

(g) if mounted on any other kind of wall or floor, it must be attached to the wall or floor in a manner approved for the time being by the Secretary.

(3) The pharmacist must ensure that—

(a) the safe is kept securely locked when not in immediate use, and

(b) any key or other device by means of which the safe may be unlocked—

(i) is kept on the person of a pharmacist whenever it is on the same premises as the safe, and is removed from the premises whenever there is no pharmacist at those premises, or

(ii) is kept in a separately locked safe to which only a pharmacist has access, and

(c) any code or combination that is required to unlock the safe is not divulged to any unauthorised person.

(3A) Despite subclause (1), a drug of addiction that requires refrigeration may be kept in

a refrigerator rather than a safe if all of the following requirements are met—

(a) the refrigerator must be in a ***room*** (which includes a part of a room or an enclosure) to which the public does not have access,

(b) the refrigerator, or any cupboard or receptacle in which the refrigerator is kept, must be securely attached to a part of the premises,

(c) the refrigerator, or the room, cupboard or receptacle in which the refrigerator is kept, must be kept securely locked when not in immediate use,

(d) a device (including a key) that is used to securely lock anything under this subclause must—

(i) be kept on the person of a pharmacist who is at the premises, or

(ii) be securely locked in a safe that can be unlocked only by a pharmacist,

(e) a code or combination that is used to securely lock anything under this subclause must not be disclosed to any person who is not a pharmacist,

(f) the refrigerator must not be used to store any other item that is not a substance listed in Schedule 2, 3, 4 or 8 of the Poisons List or is not a therapeutic good.

(4) This clause applies to a hospital pharmacy as well as to a retail pharmacy.

Maximum penalty—20 penalty units.

**76A Storage in managed correctional centres**

(1) The management company for a managed correctional centre must ensure that drugs of addiction at the managed correctional centre are stored in a separate safe apart from other goods or substances.

(2) Unless otherwise approved for the time being by the Secretary, the safe must comply with the requirements specified in clause 76(2)(a)–(g).

(3) The management company for a managed correctional centre must ensure that—

(a) the safe is kept securely locked when not in immediate use, and

(b) a key or other device that unlocks the safe is—

(i) kept on the person of an appropriate person at the managed correctional centre, or

(ii) locked in a separate safe that can be unlocked only by an appropriate person, and

(c) a code or combination that is required to unlock the safe is not disclosed to a

person who is not an appropriate person.

(4) Despite subclause (1), a drug of addiction that requires refrigeration may be kept in a refrigerator instead of a safe if the following requirements are met—

(a) the refrigerator must be in a room, part of a room or an enclosure to which the public does not have access,

(b) the refrigerator, or a cupboard or receptacle in which the refrigerator is kept, must be securely attached to a part of the premises,

(c) the refrigerator, or the room, cupboard or receptacle in which the refrigerator is kept, must be kept securely locked when not in immediate use,

(d) a key or other device that unlocks the refrigerator, or the room, cupboard or receptacle in which the refrigerator is kept, must be—

(i) kept on the person of an appropriate person at the managed correctional centre, or

(ii) locked in a safe that can be unlocked only by an appropriate person,

(e) a code or combination that is required to unlock anything under this subclause must not be disclosed to a person who is not an appropriate person,

(f) the refrigerator must not be used to store an item that is not a Schedule 2, 3, 4 or 8 substance or a therapeutic good.

(5) The management company for a managed correctional centre must appoint, by written instrument, a pharmacist employed at the managed correctional centre as the person responsible for the storage of drugs of addiction at the managed correctional centre.

(6) If there is no pharmacist employed at the managed correctional centre, an authorised practitioner or nurse in charge may be appointed.

(7) This clause does not apply to drugs of addiction at a retail pharmacy located at a managed correctional centre.

(8) This clause does not prevent drugs of addiction from being stored with prescribed restricted substances.

(9) In this clause—

***appropriate person*** means—

(a) a person appointed under subclause (5) or (6), or

(b) an authorised practitioner, nurse, midwife or pharmacist appointed, by written

instrument, by the management company for the managed correctional centre for the purposes of this clause.

***authorised practitioner*** does not include a veterinary practitioner.

Maximum penalty—20 penalty units.

## Division 3 Prescriptions

### 77 Unauthorised persons not to prescribe drugs of addiction

(1) An authorised practitioner may issue a prescription for a drug of addiction.

(2) A person must not issue a prescription for a drug of addiction unless authorised to do so by this clause.

Maximum penalty—20 penalty units.

### 78 Prescriptions may be issued for certain purposes only

(1) A medical practitioner must not issue a prescription for a drug of addiction otherwise than for medical treatment (including in a clinical trial).

(2) A nurse practitioner must not issue a prescription for a drug of addiction otherwise than in the course of practising as a nurse practitioner.

(3) A midwife practitioner must not issue a prescription for a drug of addiction otherwise than in the course of practising as a midwife practitioner.

(4) A dentist must not issue a prescription for a drug of addiction otherwise than for the dental treatment (for a period not exceeding one month's continuous treatment) of a patient and must endorse any such prescription with the words "FOR DENTAL TREATMENT ONLY".

(5) If the patient is in a hospital, the dentist may issue a prescription for any drug of addiction.

(6) If the patient is not in a hospital, the dentist may issue a prescription only—

(a) for pentazocine, or

(b) for any drug of addiction included in the list of preparations that may be prescribed by participating dental practitioners for dental treatment only set out in the *Schedule of Pharmaceutical Benefits* issued by the Commonwealth Department of Health, as that Schedule is in force from time to time.

(7) A veterinary practitioner must not issue a prescription for a drug of addiction otherwise than for veterinary treatment, and must endorse any such prescription with the words "FOR ANIMAL TREATMENT ONLY".

Maximum penalty—20 penalty units.

**79 Quantity and purpose of prescriptions to be appropriate**

An authorised practitioner must not issue a prescription for a drug of addiction in a quantity, or for a purpose, that does not accord with the recognised therapeutic standard of what is appropriate in the circumstances.

Maximum penalty—20 penalty units or imprisonment for 6 months, or both.

**80 Form of prescription**

(1) A person who issues a prescription for a drug of addiction must ensure that the prescription includes the following details—

(a) the date on which it is issued,

(b) the name, date of birth and address of the patient or (if the treatment is for an animal) the species of animal and the name and address of the animal's owner,

(c) the name, strength and quantity (expressed in both words and figures) of the drug to be supplied,

(d) adequate directions for use,

(e) the maximum number of times the drug may be supplied on the prescription,

(f) the intervals at which the drug may be supplied on the prescription,

(g) if the prescription is issued at a hospital, the name and designation of the person by whom it is issued and the name, address and telephone number of the hospital,

(h) if the prescription is issued elsewhere than at a hospital, the name and designation of the person by whom it is issued and the address and telephone number of the premises at which it is issued,

(i) if the drug of addiction is a type A drug of addiction and the person holds an authority to issue the prescription under section 29 of the Act or Part 8 of this Regulation, the reference number of the authority.

(2) The details referred to in subclause (1)(a)–(f) must be made out—

(a) in the handwriting of the person by whom the prescription is issued, or

(b) in such other manner as may be approved for the time being by the Secretary,

and the prescription must be signed by the person by whom it is issued.

(3) The person by whom the prescription is issued must confirm any dose that could be regarded as being dangerous or unusual by underlining the part of the prescription

that specifies the intended dose and by initialling the prescription in the margin.

(4) A person must not issue a prescription that includes—

(a) more than one preparation containing a drug of addiction, or

(b) both a preparation containing a drug of addiction and another preparation.

(5) The Secretary may, by order in writing, exempt any person or drug of addiction, or any class of persons or drugs of addiction, from any or all of the requirements of this clause.

(6) Such an exemption may be given unconditionally or subject to conditions.

Maximum penalty—20 penalty units.

**81 Emergency prescriptions may be given by telephone or otherwise**

(1) In an emergency or other urgent circumstances, an authorised practitioner may direct the supply of a drug of addiction, other than an unregistered drug of addiction, orally, including by telephone, by electronic mail or by facsimile.

(2) A person who so directs the supply of a drug of addiction—

(a) must immediately make out a prescription, and

(b) must send the prescription without delay (and in any case within 24 hours) to the person to whom the direction was given.

(3) A person who issues a prescription under this clause must ensure that the prescription is endorsed with words that indicate the prescription has been issued in confirmation of a direction under this clause.

(4) This clause does not apply to a direction given under clause 120.

Maximum penalty—20 penalty units.

**81A Special provisions for prescribing drugs of addiction—public health organisations**

(1) This clause applies to a medical practitioner or nurse practitioner and a pharmacist—

(a) employed in or engaged by the same public health organisation, and

(b) in relation to carrying out functions in the course of that employment or engagement.

(2) A medical practitioner or nurse practitioner may issue a prescription for a drug of addiction by sending a prescription to a pharmacist by email or facsimile.

(3) A medical practitioner or nurse practitioner who issues a prescription for a drug of

addiction in accordance with this clause must keep the prescription.

(4) A pharmacist to whom a prescription is sent under this clause must—

(a) print a copy of the prescription, and

(b) keep a printed copy.

(5) The copy of the prescription printed by the pharmacist is taken to be a prescription for the purposes of Division 4 of this Part.

(6) This clause does not apply to a medication chart prescription.

**82 Records of prescriptions**

(1) An authorised practitioner who prescribes a drug of addiction must make a record of the following particulars—

(a) the name, strength and quantity of the drug prescribed and the date on which it was prescribed,

(b) if the drug is intended for the treatment of a person, the name and address of the person to be treated,

(c) if the drug is intended for the treatment of an animal, the species of animal and the name and address of the animal's owner,

(d) the maximum number of times the drug may be supplied on the prescription,

(e) the intervals at which the substance may be supplied on the prescription,

(f) the directions for use, as shown on the prescription.

(2) The record must be kept at the surgery, hospital or office of the person prescribing the substance.

Maximum penalty—20 penalty units.

**83 Exceptions to section 28—prescriptions generally**

(1) A medical practitioner or nurse practitioner is authorised to issue a prescription for a drug of addiction, other than an unregistered drug of addiction, for a person without an authority under section 29 of the Act if—

(a) the medical practitioner or nurse practitioner is of the opinion that the person requires the use of the drug in the course of treatment as an in-patient in a public hospital or private health facility, and

(b) the prescription is for a course of treatment for a period of not more than 14 days following the person's admission as an in-patient.

(2) A medical practitioner or nurse practitioner is authorised to prescribe methadone or buprenorphine for the treatment of a person without an authority under section 29 of the Act if—

(a) in the case of a medical practitioner, the medical practitioner is approved as a prescriber of drugs of addiction under section 28A of the Act and, in the case of a nurse practitioner, the nurse practitioner is authorised by the Secretary for the purposes of this clause, and

(b) at the time the prescription is issued the person is, or at some time during the preceding 21 days was, an inmate in a correctional centre, and

(c) the prescription is for methadone or buprenorphine for use by the person as a course of treatment—

(i) while an inmate, or

(ii) during a period of not more than 21 days after release, and

(d) immediately before the person became an inmate, a medical practitioner or nurse practitioner had an authority under section 29 of the Act to prescribe methadone or buprenorphine for the person, or to supply methadone or buprenorphine to the person, and

(e) the prescription is issued for the purpose of continuing the treatment that the person was receiving or was about to receive immediately before the person became an inmate.

(3) A medical practitioner or nurse practitioner is authorised to issue a prescription for a drug of addiction for a person without an authority under section 29 of the Act if—

(a) the person is the subject of such an authority, and

(b) the medical practitioner or nurse practitioner is practising at the same premises that the holder of the authority was practising at when the authority was issued, and

(c) the prescription is issued in accordance with any conditions to which that authority is subject.

(4) A medical practitioner is authorised to issue a prescription for a drug of addiction for a person without an authority under section 29 of the Act if—

(a) the prescription is issued for an in-patient in a public hospital or private health facility who was, immediately before the person’s admission to that hospital or facility, being treated with that drug of addiction, which was prescribed or supplied in accordance with the Act or this Regulation, and

(b) the prescription is issued for the purpose of continuing the person's treatment with that drug of addiction following the person's admission.

(5) A medical practitioner is authorised to issue a prescription for a drug of addiction for a person without an authority under section 29 of the Act if—

(a) the medical practitioner holds an authority under Division 4 of Part 8 of this Regulation that authorises the practitioner to issue a prescription for that drug of addiction for the purposes of a clinical trial, and

(b) the prescription is issued in accordance with the authority.

**84 Exceptions to section 28—prescriptions for type A drugs of addiction**

(1) (Repealed)

(2) A medical practitioner is authorised to issue a prescription for dexamphetamine, lisdexamfetamine or methylphenidate for a person without an authority under section 29 of the Act—

(a) for the purpose of testing the suitability of the person to undergo a course of medical treatment involving the use of such a substance, or

(b) for the purpose of treating the person for attention deficit disorder (ADD) or attention deficit hyperactivity disorder (ADHD),

so long as the medical practitioner holds an authority under Part 8 to prescribe such a substance.

(3) An authorised practitioner (other than a medical practitioner) must not issue a prescription for a type A drug of addiction.

Maximum penalty—20 penalty units.

**84A Authority required for prescriptions for clinical trials**

A medical practitioner must not issue a prescription for a type C unregistered drug of addiction for the purposes of a clinical trial unless—

(aa) (Repealed)

(a) the medical practitioner holds an authority under Division 4 of Part 8 of this Regulation that authorises the practitioner to issue a prescription for that type C unregistered drug of addiction for the purposes of a clinical trial, and

(b) the prescription is issued in accordance with the authority.

Maximum penalty—20 penalty units

**84B Restriction on prescriptions for clinical trials**

An authorised practitioner (other than a medical practitioner) must not issue a prescription for a type C unregistered drug of addiction for the purposes of a clinical trial.

Maximum penalty—20 penalty units

## Division 4 Supply

## Subdivision 1 Supply on prescription

**85 Pharmacists may supply drugs of addiction on prescription**

(1) A pharmacist may supply a drug of addiction on prescription if the prescription is in the form required by Division 3.

(2) This clause does not prevent a pharmacist from supplying a drug of addiction on prescription merely because—

(a) the prescription fails to specify the maximum number of times the drug may be supplied, or

(b) the prescription fails to specify the intervals at which the drug may be supplied, or

(c) the prescription fails to specify the patient's date of birth.

(3) A pharmacist must not supply a drug of addiction on a prescription referred to in subclause (2)(a) or (b) if it appears to the pharmacist that the drug has previously been supplied on the prescription, regardless of how many times the prescription purports to authorise the supply of the drug.

(4) The Secretary may, by order in writing, exempt any person or drug, or any class of persons or drugs, from any or all of the requirements of this clause.

(5) Such an exemption may be given unconditionally or subject to conditions.

Maximum penalty—20 penalty units.

**86 Certain prescriptions not to be filled**

(1) A pharmacist must not supply a drug of addiction on prescription—

(a) if the prescription is marked "CANCELLED", or

(b) if the drug has already been supplied on the prescription the maximum number of times indicated by the prescription, or

(c) if the interval of time that has elapsed since the drug was last supplied on the prescription is less than that indicated by the prescription as the minimum interval that must elapse between successive supplies of the drug, or

(d) if the prescription is illegible or defaced, or

(e) if the prescription is dated more than 6 months before the date on which the supply is being requested, or

(f) if the prescription appears to have been forged or fraudulently obtained, or

(g) if the prescription appears to have been altered otherwise than by the authorised practitioner by whom it was issued, or

(h) if notice of an order prohibiting the person by whom the prescription was issued from issuing such a prescription has been published in the Gazette, unless the prescription contains a direction for the supply of the drug more than once and it appears that the drug has been supplied on the basis of the prescription at least once before the notice was published.

(2) Immediately on being requested to supply a drug of addiction in any of the circumstances referred to in subclause (1)(f), (g) or (h), a pharmacist must retain the prescription and cause notice of the request to be given to a police officer.

Maximum penalty—15 penalty units.

(3) A pharmacist must not supply a drug of addiction on a prescription that includes—

(a) more than one preparation containing a drug of addiction, or

(b) both a preparation containing a drug of addiction and another preparation.

Maximum penalty—20 penalty units.

**87 Prescriptions require verification**

(1) A pharmacist must not supply a drug of addiction on prescription unless he or she—

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

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

(c) has verified that the person who is purported to have issued the prescription has actually issued the prescription.

(2) This clause does not prevent a pharmacist who is otherwise authorised to supply drugs of addiction from supplying a drug of addiction on prescription in a quantity sufficient for no more than 2 days' treatment.

Maximum penalty—20 penalty units.

**88 Prescriptions to be endorsed**

(1) A person who supplies a drug of addiction on prescription must (on each occasion the

drug is supplied) endorse the following particulars (in ink) on the prescription—

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

(b) the address of the place at which the drug was supplied,

(c) the prescription reference number.

Maximum penalty—20 penalty units.

(2) A person who supplies a drug of addiction on prescription must endorse (in ink) across the prescription the word “CANCELLED”—

(a) if the maximum number of times the prescription is to be dispensed is not clearly specified, or

(b) if the intervals at which the drug may be supplied are not clearly specified, or

(c) if the prescription has reached the last occasion on which it can be supplied according to the maximum number of times specified on it.

Maximum penalty—20 penalty units.

(3) The Secretary may, by order in writing, exempt any person or drug of addiction, or any class of persons or drugs of addiction, from any or all of the requirements of this clause.

(4) Such an exemption may be given unconditionally or subject to conditions.

**89 Prescriptions and orders to be kept**

(1) A pharmacist who supplies a drug of addiction on prescription, or by order under clause 97 or 103, must keep the prescription or order, whether or not the prescription or order authorises more than one supply of the drug.

Maximum penalty—20 penalty units.

(2) A pharmacist must keep prescriptions or orders for drugs of addiction separate from other prescriptions (other than prescriptions for special restricted substances).

Maximum penalty—20 penalty units.

(3) The Secretary may, by order in writing, exempt any person or drug of addiction, or any class of persons or drugs of addiction, from any or all of the requirements of this clause.

(4) Such an exemption may be given unconditionally or subject to conditions.

**90 Supply by pharmacists of type A drugs of addiction**

A pharmacist must not supply a type A drug of addiction on prescription unless—

(a) the reference number of the authority to issue the prescription (whether given under section 29 of the Act or Part 8 of this Regulation) is shown on the prescription, or

(b) the medical practitioner who issued the prescription was authorised to do so under clause 83(1)–(4).

Maximum penalty—20 penalty units.

**91 Records to be kept by pharmacists of methadone or buprenorphine prescriptions**

(1) A pharmacist at a retail pharmacy who supplies any person with methadone in oral liquid form or buprenorphine on a prescription for the treatment of drug dependence must keep a record of the supply in accordance with this clause.

Maximum penalty—20 penalty units.

(2) A record under this clause must contain the following particulars—

(a) the name of the person to whom the supply was made,

(b) the number of the prescription on which the supply was made,

(c) the name of the person who gave the prescription,

(d) the amount of methadone in oral liquid form or buprenorphine supplied,

(e) the date on which the supply occurred,

(f) if the whole or part of the methadone in oral liquid form or buprenorphine was supplied for consumption on a different day to that on which it was supplied, the day or days on which it is to be consumed and the amount to be consumed on that day or on each of those days.

(3) Records made under this clause in relation to a particular pharmacy are to be made in writing in a book in which all such records for the pharmacy are kept.

(4) The Secretary may from time to time approve the keeping of records under this clause in any other form.

(5) A record made under this clause must be kept for at least 2 years from the date on which it is made.

**92 Supply by pharmacists of liquid methadone or buprenorphine**

(1A) Despite clause 85, a pharmacist must not supply methadone in oral liquid form or buprenorphine on prescription for the treatment of drug dependence unless—

(a) the methadone or buprenorphine is supplied at the premises of, and in the course of carrying on the business of, a retail pharmacy, and

(b) the retail pharmacy is located on premises at which a pharmacist is approved to supply pharmaceutical benefits under section 90 of the *National Health Act 1953* of the Commonwealth.

Maximum penalty—20 penalty units.

(1) A pharmacist at a retail pharmacy must not, on any particular day, supply any person with methadone in oral liquid form or buprenorphine on a prescription for the treatment of drug dependence if that supply would result in more than 65 persons having been supplied with methadone in oral liquid form or buprenorphine on prescription at that pharmacy on that day.

Maximum penalty—20 penalty units.

(2) For the purposes of subclause (1), if an amount of methadone in oral liquid form or buprenorphine is supplied for consumption on a day other than the day on which it is supplied, the supply of that amount is taken to have occurred on the day on which the amount is to be consumed.

(3) A person is not to be counted for the purposes of subclause (1) if the person is supplied with an amount of methadone in oral liquid form or buprenorphine that is intended to last the person for at least one week and the person is supplied at that pharmacy with either of those drugs no more than once in any 7 day period.

(4) Subclause (1) does not apply to the supply of methadone in oral liquid form or buprenorphine at a pharmacy in accordance with—

(a) an exemption granted under clause 93, or

(b) a licence issued under Division 3 of Part 8.

**93 Exemptions relating to methadone or buprenorphine supply at pharmacies**

(1) The owner of a pharmacy may apply in writing to the Secretary for an exemption from clause 92(1A) or (1) in relation to the pharmacy.

(2) The Secretary may require the owner of the pharmacy to furnish such information as is necessary to enable the Secretary to determine the application.

(3) The Secretary may, by notice in writing served on the owner of the pharmacy, grant the exemption, if the Secretary is satisfied that exceptional circumstances exist that justify the granting of the exemption, or refuse to grant the exemption.

(4) An exemption is subject to such conditions as may be specified in the notice referred to in subclause (3) and to such further conditions as the Secretary may from time to time notify in writing to the holder of the exemption.

(5) The Secretary may from time to time vary or revoke any condition of an exemption by

notice in writing served on the holder of the exemption.

(6) An exemption remains in force until—

(a) the expiry date (if any) specified in the exemption, or

(b) it is surrendered or cancelled,

whichever occurs first.

(7) The Secretary may suspend or cancel an exemption by notice in writing served on the holder of the exemption.

(8) An exemption has no effect during any period of suspension.

(9) For the removal of doubt, an exemption is not a licence or authority for the purposes of this Regulation.

**94 Exceptions to section 28—supply**

(1) A medical practitioner or nurse practitioner is authorised to supply a drug of addiction, other than an unregistered drug of addiction, for a person without an authority under section 29 of the Act if—

(a) the medical practitioner or nurse practitioner is of the opinion that the person requires the use of the drug in the course of treatment as an in-patient in a public hospital or private health facility, and

(b) the supply is for a course of treatment for a period of not more than 14 days following the person's admission as an in-patient.

(2) A medical practitioner or nurse practitioner is authorised to supply methadone or buprenorphine to a person without an authority under section 29 of the Act if—

(a) in the case of a medical practitioner, the medical practitioner is approved as a prescriber of drugs of addiction under section 28A of the Act and in the case of a nurse practitioner, the nurse practitioner is authorised by the Secretary for the purposes of this clause, and

(b) the person is an inmate in a correctional centre, and

(c) the methadone or buprenorphine is supplied for use by the person as a course of treatment while an inmate, and

(d) immediately before the person became an inmate, a medical practitioner or nurse practitioner had an authority under section 29 of the Act to prescribe methadone or buprenorphine for the person, or supply methadone or buprenorphine to the person, and

(e) the methadone or buprenorphine is supplied for the purpose of continuing the treatment that the person was receiving or was about to receive immediately before the person became an inmate.

(3) A medical practitioner or nurse practitioner is authorised to supply a drug of addiction to a person without an authority under section 29 of the Act if—

(a) the person is the subject of such an authority, and

(b) the medical practitioner or nurse practitioner is practising at the same premises that the holder of the authority was practising at when the authority was issued, and

(c) the supply is in accordance with any conditions to which that authority is subject.

(4) A medical practitioner is authorised to supply a drug of addiction for a person without an authority under section 29 of the Act if—

(a) the person is an in-patient in a public hospital or private health facility who was, immediately before the person's admission to that hospital or facility, being treated with that drug of addiction, which was prescribed or supplied in accordance with the Act or this Regulation, and

(b) the drug of addiction is supplied for the purpose of continuing the person's treatment with that drug of addiction following the person's admission.

(5) A medical practitioner is authorised to supply a drug of addiction to a person without an authority under section 29 of the Act if—

(a) the medical practitioner holds an authority under Division 4 of Part 8 of this Regulation that authorises the practitioner to supply that drug of addiction for the purposes of a clinical trial, and

(b) the supply of the drug of addiction is in accordance with the authority.

**94AA Authority required for supply for clinical trials**

A medical practitioner must not supply a type C unregistered drug of addiction unless—

(aa) the prescription is for the purposes of a clinical trial, and

(a) the medical practitioner holds an authority under Division 4 of Part 8 of this Regulation that authorises the practitioner to supply that type C unregistered drug of addiction for the purposes of a clinical trial, and

(b) the supply of the unregistered drug is in accordance with the authority.

Maximum penalty—20 penalty units

**94AB Restriction on supply for clinical trials**

An authorised practitioner (other than a medical practitioner) must not supply a type C unregistered drug of addiction for the purposes of a clinical trial.

Maximum penalty—20 penalty units

**94A Supply of liquid methadone or buprenorphine by pharmacists—transitional provision**

Clause 92(1A) (as inserted by the *Poisons and Therapeutic Goods Amendment (Supply by Pharmacists) Regulation 2013*) does not operate to prevent a pharmacist who, before that insertion, supplied liquid methadone or buprenorphine on prescription for the treatment of drug dependence from continuing to supply methadone or buprenorphine after that insertion at the premises at which those drugs were provided by the pharmacist before that insertion.

## Subdivision 2 Supply without prescription

**95 Supply and receipt of drugs of addiction generally**

(1) A person who is authorised to supply drugs of addiction (whether by this Division or by an authority or licence under Part 8) may supply a drug of addiction to an ***authorised person***, being—

(a) any person who is authorised to have possession of such a drug of addiction, or

(b) any other person if the other person is in possession of a certificate, signed by a person so authorised, to the effect that the other person is authorised to obtain the drug of addiction on behalf of the person so authorised.

(2) A supplier may supply drugs of addiction under this clause on the basis of a written order signed by an authorised person or on the basis of an order received from an authorised person by telephone, electronic mail or facsimile.

(3) A person who orders and receives a drug of addiction must notify the supplier of the receipt of the drug within 24 hours after that receipt.

(4) The notice under subclause (3) must be in writing and must be dated and signed by an authorised person.

(5) If a supplier, who supplies a drug of addiction on the basis of an order, does not receive written notice of the order under subclause (3) within 7 days after the drug is supplied, the supplier must report that fact to the Secretary.

(6) A person who supplies a drug of addiction in accordance with this clause must—

(a) keep and cancel the relevant order, and

(b) keep the written notice under subclause (3) and (if the drug is supplied as referred

to in subclause (1)(b)) the relevant certificate.

Maximum penalty—20 penalty units.

**96 Emergency supply by pharmacists**

(1) A pharmacist may supply a person with a drug of addiction, other than an unregistered drug of addiction, in accordance with a direction given under clause 81.

(2) A pharmacist who supplies a drug of addiction in accordance with this clause—

(a) must keep and cancel the prescription that is subsequently sent in confirmation of the direction, or

(b) if such a prescription is not received within 7 days after the drug is supplied, must report that fact to the Secretary.

Maximum penalty—20 penalty units.

**97 Supply by pharmacists for emergency purposes**

A pharmacist may supply an authorised practitioner with a drug of addiction, other than an unregistered drug of addiction, for emergency use, but only on a written order signed and dated by the authorised practitioner.

**98 Supply of type A drugs of addiction**

(1) (Repealed)

(2) A medical practitioner does not require an authority under section 29 of the Act to supply dexamphetamine, lisdexamfetamine or methylphenidate to a person for the purpose of testing the suitability of the person to undergo a course of medical treatment involving the use of such a substance so long as the medical practitioner holds an authority under Part 8 to supply such a substance.

(3) A nurse practitioner, midwife practitioner, dentist or veterinary practitioner is not authorised to supply a type A drug of addiction.

(4) This clause does not prevent a veterinary practitioner from supplying methylphenidate in solid dosage form to a person for the treatment of an animal.

## Subdivision 3 Supply in hospitals and managed correctional centres

**99 Supply by pharmacists**

(1) A pharmacist employed at a hospital may supply a drug of addiction from the pharmacy department of the hospital—

(a) on a prescription issued in accordance with Division 3, or

(b) on the authorisation (whether in writing, by electronic mail, by facsimile or by any other form of electronic communication approved by the Secretary) of an authorised practitioner (other than a veterinary practitioner), where that authorisation is entered on a patient's medication chart, or

(c) on the requisition (whether in writing, by electronic mail, by facsimile or by any other form of electronic communication approved by the Secretary) of an authorised practitioner (other than a veterinary practitioner) or of the nurse or midwife in charge of the ward in which the drug is to be used or stored.

(2) The person delivering a drug of addiction to a ward from the pharmacy department of the hospital must obtain a receipt, dated and signed, from the person to whom the drug is delivered.

Maximum penalty—20 penalty units.

**99A Supply by pharmacists in managed correctional centres**

(1) A pharmacist employed at a managed correctional centre may supply a drug of addiction for the purposes of treating an inmate at the managed correctional centre—

(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.

Maximum penalty—20 penalty units.

(2) This clause does not limit the power of a pharmacist employed in a retail pharmacy located at a managed correctional centre to supply a drug of addiction on prescription in accordance with the Act or this Regulation.

(3) In this clause—

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

***authorised practitioner*** does not include a veterinary practitioner.

## Subdivision 4 Manufacture, possession and supply generally

**100 Unauthorised manufacture and supply of drugs of addiction prohibited**

(1) A person must not manufacture or supply a drug of addiction unless the person is authorised to do so by this Division or by an authority or licence under Part 8.

(2) This Division does not authorise a person to manufacture or supply drugs of addiction in contravention of any prohibition or restriction to which the person is otherwise

subject.

Maximum penalty—20 penalty units.

**101 Possession and supply of drugs of addiction**

(1) The following persons are authorised to have possession of, and to supply, drugs of addiction—

(a) an authorised practitioner,

(b) the chief pharmacist of, and any pharmacist employed in dispensing medicines at, any public hospital or other public institution,

(c) the director of nursing of a hospital in which a pharmacist is not employed,

(d) the nurse or midwife in charge of a ward in a public hospital,

(e) a nurse or midwife who is approved for the time being by the Secretary for the purposes of this clause, or who belongs to a class of nurses or a class of midwives so approved,

(f) any other nurse or midwife, but for the purpose only of administering doses of such drugs to individual patients in a hospital or individual inmates in a managed correctional centre,

(g) a person—

(i) who is employed in the Ambulance Service of NSW as an ambulance officer or as an air ambulance flight nurse, and

(ii) who is approved for the time being by the Secretary for the purposes of this clause,

(h) a pharmacist at a managed correctional centre, but for the purpose only of supplying the drugs for use by individual inmates in the managed correctional centre.

(2) The following persons are authorised to have possession of (but not to supply) drugs of addiction—

(a) a person in charge of a laboratory used for the purpose of analysis, research or instruction, who is, or who belongs to a class of persons who are, authorised for the time being by the Secretary for the purposes of this clause,

(b) an analyst,

(c) a person acting under the direct personal supervision of a person referred to in paragraph (a) or (b).

(3) This clause authorises a person referred to in subclause (1) or (2) to have possession of, or to supply, drugs of addiction for the purpose only of the lawful practice of the person's profession or occupation.

(4) For the purposes of the Act, section 4(1), the definition of ***Supply by wholesale***, a management company for a managed correctional centre is authorised to be supplied with wholesale quantities of drugs of addiction.

(4A) A management company for a managed correctional centre must appoint, by written instrument, a pharmacist employed at the managed correctional centre to receive the drugs of addiction authorised to be supplied to the management company.

(4B) If there is no pharmacist employed at the managed correctional centre, an authorised practitioner, other than a veterinary practitioner, or nurse in charge may be appointed.

(5) This clause does not authorise a nurse practitioner, midwife practitioner, dentist or veterinary practitioner to have possession of, or to supply, a type A drug of addiction (other than methylphenidate in solid dosage form, in the case of a veterinary practitioner).

**102 Possession and manufacture of drugs of addiction by retail pharmacists**

(1) A retail pharmacist is authorised—

(a) to have possession of drugs of addiction, and

(b) to manufacture drugs of addiction and any preparation, admixture or extract of a drug of addiction,

but only if he or she does so at the premises of, and in the course of carrying on a pharmacy business.

(2) (Repealed)

Maximum penalty—20 penalty units.

**103 Possession of drugs of addiction at private health facilities and residential care facilities**

(1) The following persons are authorised to have possession of ampoules of morphine sulphate in a quantity not exceeding 30 ampoules, each of 1 millilitre or less, at a concentration of 30 milligrams or less of morphine sulfate per millilitre—

(a) the director of nursing of a private health facility,

(b) the responsible person for a residential care facility,

(c) a registered nurse at a residential care facility, but for the purpose only of

administering doses of such drugs to individual residents of the residential care facility.

(2) The director of nursing of a private health facility is authorised to have possession of no more than 5 ampoules, each of 2 millilitres or less, of pethidine hydrochloride, at a concentration of 50 milligrams or less of pethidine hydrochloride per millilitre.

(3) **Order of Secretary—specified facilities** The Secretary may, by order in writing, authorise the possession of a drug of addiction specified in subclause (1) or (2), in a quantity that exceeds the limit specified in subclause (1) or (2), by the following persons—

(a) in the case of morphine sulphate—

(i) the director of nursing of a specified private health facility, or

(ii) the responsible person for a specified residential care facility,

(b) in the case of pethidine hydrochloride—the director of nursing of a specified private health facility.

(4) **Order of Secretary—specified classes of facilities** The Secretary may, by order published in the Gazette, authorise the possession of a drug of addiction specified in subclause (1) or (2), in a quantity that exceeds the limit specified in subclause (1) or (2), by the following persons—

(a) in the case of morphine sulphate—

(i) the director of nursing of a specified class of private health facilities, or

(ii) the responsible person for a specified class of residential care facilities,

(b) in the case of pethidine hydrochloride—the director of nursing of a specified class of private health facilities.

(5) A retail pharmacist is authorised to supply a drug of addiction to the director of nursing of a private health facility or residential care facility, or the residential care facility manager of a residential care facility, but only if the drug is supplied—

(a) at the premises of, and in the course of carrying on the business of, the pharmacy, and

(b) in accordance with a written order signed by the director of nursing or the residential care facility manager.

(6) The director of nursing or the residential care facility manager must not sign an order for any quantity of a drug of addiction if the quantity of that drug that will be in the possession of the director of nursing or the residential care facility manager as a result of the order being filled will be in excess of the maximum quantity allowed by this clause.

Maximum penalty—20 penalty units.

(7) The director of nursing of a private health facility must not allow any drug of addiction in his or her possession under subclause (1) or (2) to be used otherwise than for administration to a patient in accordance with the directions of an authorised practitioner (other than a veterinary practitioner) or by an authorised practitioner (other than a veterinary practitioner).

Maximum penalty—20 penalty units.

(8) The responsible person for a residential care facility must not allow any drug of addiction in his or her possession under subclause (1) to be used otherwise than for administration to a resident of the facility by a registered nurse in accordance with the directions of an authorised practitioner (other than a veterinary practitioner) or by an authorised practitioner (other than a veterinary practitioner).

Maximum penalty—20 penalty units.

(9) This clause does not limit the power of a director of nursing or a residential care facility manager to have possession of drugs of addiction, or to supply drugs of addiction to patients or residents, in accordance with the Act or this Regulation.

(10) A person does not commit an offence under this clause in relation to any pethidine hydrochloride that was lawfully in the person's possession before the commencement of this clause.

**104 Possession of drugs of addiction by masters of ships**

(1) The master of a ship is authorised to have possession of drugs of addiction that are required by law to be carried on the ship.

(2) A pharmacist may supply drugs of addiction to the master of a ship if the pharmacist is authorised to do so by an authority under Part 8.

(3) A person must not supply a drug of addiction to the master of a ship unless the person receives—

(a) a written order for the drug (in duplicate) signed by the master of the ship, and

(b) a written statement (in duplicate) signed by the master of the ship to the effect that the drug is required by law to be carried on the ship, and

(c) a certificate, issued by the ship's agent in New South Wales, to the effect that the signatures appearing on the order and statement are those of the master of the ship.

(4) A person who supplies a drug of addiction in accordance with this clause—

(a) must keep and cancel the relevant order and statement, and

(b) must cancel the duplicate copies of the order and statement and forward them to the Secretary, together with the certificate issued by the ship's agent, within 24 hours.

(5) (Repealed)

Maximum penalty—20 penalty units.

**105 (Repealed)**

**106 Authorities to possess and administer drugs of addiction**

(1) The following persons are authorised to have possession of drugs of addiction, but only if authorised to do so by an authority under Part 8—

(a) a person in an isolated locality,

(b) a person in charge of a first aid post,

(c) a person representing an organisation established for search and rescue,

(d) any other person the Minister may from time to time approve.

(2) A person who is so authorised to have possession of a drug of addiction is also authorised to administer the drug to another person in an emergency.

**107 Mode of delivery**

(1) A person who supplies drugs of addiction must do so personally, by registered mail or by carrier.

(2) A person who supplies a drug of addiction personally—

(a) must deliver it to the person being supplied at the premises of the supplier or at the premises of the person being supplied, and

(b) must obtain a receipt, dated and signed, from the person to whom it is delivered.

(3) A person who supplies a drug of addiction by registered mail must obtain and keep written evidence of postage of the drug.

(4) A person who supplies a drug of addiction by carrier must obtain and keep written evidence of the consignment of the drug.

(5) A person who supplies a drug of addiction must not deliver a drug of addiction by carrier otherwise than under an arrangement under which the carrier undertakes—

(a) to obtain a receipt, dated and signed, from the person to whom the drug is delivered, and

(b) to deliver the receipt to the supplier.

Maximum penalty—20 penalty units.

**108 Delivery by carrier**

(1) A carrier is authorised to be in possession of a package containing a drug of addiction, but for the purpose only of delivering it to the person to whom it is addressed.

(2) A dealer (other than an authorised practitioner or pharmacist) who supplies a drug of addiction by post or by carrier must ensure that—

(a) the drug is contained in a package that has at least one opaque covering, and

(b) no other goods are contained in the package, and

(c) the package contains a document—

(i) listing the contents of the package, and

(ii) bearing the words “SCHEDULE EIGHT—CHECK CAREFULLY” in bold face sans serif capital letters with a letter height of at least 12.5 millimetres, and

(d) the outside of the package does not indicate that it contains a drug of addiction, and

(e) the package is properly addressed to the person to whom the drug is being supplied.

(3) This clause does not prevent a dealer from supplying a drug of addiction by means of a separately wrapped inner package within an outer package containing other goods so long as—

(a) a document listing the contents of the inner package is contained in the inner package, and

(b) the inner package is marked with the words “SCHEDULE EIGHT—CHECK CAREFULLY” in bold face sans serif capital letters with a letter height of at least 12.5 millimetres, and

(c) the outside of the outer package does not indicate that it contains a drug of addiction, and

(d) the outer package is properly addressed to the person to whom the drug is being supplied.

Maximum penalty—20 penalty units.

**109 Quantity and purpose of supply to be appropriate**

An authorised practitioner or pharmacist must not supply any drug of addiction in a quantity, or for a purpose, that does not accord with the recognised therapeutic standard

of what is appropriate in the circumstances.

Maximum penalty—20 penalty units or imprisonment for 6 months, or both.

## Division 5 Records of supply

## Subdivision 1 Drug registers otherwise than for hospital wards

### 110 Application of Subdivision

(1) Except as provided by subclause (2), this Subdivision applies to drugs of addiction that are kept at any place (including the pharmacy of a hospital) for the purposes of manufacture, supply, research or testing.

(2) This Subdivision does not apply to drugs of addiction that are—

(a) kept in a hospital ward, or

(b) kept in a residential care facility, or

(c) in the possession of a carrier for the purpose of those drugs of addiction being delivered to the persons to whom they are addressed, or

(d) kept in a managed correctional centre.

### 111 Drug registers to be kept

(1) A person who has possession of drugs of addiction at any place must keep a separate register (a ***drug register***) at that place.

(2) A drug register is to be in the form of a book—

(a) that contains consecutively numbered pages, and

(b) that is so bound that the pages cannot be removed or replaced without trace, and

(c) that contains provision on each page for the inclusion of the particulars required to be entered in the book.

(3) Separate pages of the register must be used for each drug of addiction, and for each form and strength of the drug.

(4) The Secretary may from time to time approve the keeping of a drug register in any other form.

Maximum penalty—20 penalty units.

### 112 Entries in drug registers

(1) On the day on which a person manufactures, receives, supplies, administers or uses a

drug of addiction at any place, the person must enter in the drug register for that place such of the following details as are relevant to the transaction—

(a) the quantity of the drug manufactured, received, supplied, administered or used,

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

(c) in the case of a drug that has been administered to an animal or supplied for the treatment of an animal, the species of animal and the name and address of the animal's owner,

(d) in the case of a drug that is supplied or administered on prescription—

(i) the prescription reference number, and

(ii) the name of the authorised practitioner by whom the prescription was issued,

(e) in the case of a drug that has been administered to a patient, the name of the authorised practitioner (other than a veterinary practitioner) by whom, or under whose direct personal supervision, the drug was administered,

(f) in the case of a drug that has been administered to an animal, the name of the veterinary practitioner by whom, or under whose direct personal supervision, the drug was administered,

(g) in the case of a drug that has been administered by a person authorised to do so by an authority under Part 8, details of the circumstances requiring administration of the drug,

(h) in the case of a drug that has been used by a person who is in charge of a laboratory, or is an analyst, the purpose for which the drug was used,

(i) the quantity of drugs of addiction of that kind held at that place after the transaction takes place,

(j) any other details approved by the Secretary.

(2) Each entry in a drug register must be dated and signed by the person by whom it is made.

(3) The Secretary may, by order in writing, exempt any person or drug of addiction, or any class of persons or drugs of addiction, from any or all of the requirements of this clause.

(4) Such an exemption may be given unconditionally or subject to conditions.

Maximum penalty—20 penalty units or imprisonment for 6 months, or both.

### 113 Supply on prescription to be recorded

(1) A pharmacist who supplies a drug of addiction on prescription must record the following details in a manner approved by the Secretary—

(a) the details required by clause 80(1) to be included in the prescription,

(b) a unique reference number for the prescription,

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

(d) the name of the person by whom the substance was supplied.

Maximum penalty—20 penalty units.

(2) A prescription for the supply of a drug of addiction in a hospital need not be recorded so long as the chief pharmacist of the hospital keeps the prescription or a copy of the prescription.

(3) The Secretary may, by order in writing, exempt any person or drug of addiction, or any class of persons or drugs of addiction, from the requirements of this clause.

(4) Such an exemption may be given unconditionally or subject to conditions.

### 114 Emergency supply or supply to private health facility or residential care facility to be recorded

A pharmacist who supplies a drug of addiction in accordance with clause 97 or 103 must record the following details of the supply in a manner approved by the Secretary—

(a) a unique reference number for the supply,

(b) the name and address of the person supplied,

(c) the name, strength and quantity of the substance,

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

(e) the name of the person by whom the substance was supplied.

Maximum penalty—20 penalty units.

## Subdivision 2 Drug registers for hospital wards, residential care facilities and managed correctional centres

### 115 Application of Subdivision

This Subdivision applies to the following—

(a) drugs of addiction that are kept in a hospital ward other than drugs of addiction that are kept in a pharmacy at the hospital,

(b) drugs of addiction that are kept in a residential care facility that is a nursing home,

(c) drugs of addiction that are kept in a residential care facility that is not a nursing home and are possessed in accordance with clause 103,

(d) drugs of addiction that are kept in a managed correctional centre.

**116 Registers to be kept**

(1) The nurse or midwife in charge of a hospital ward must keep a register of the drugs of addiction kept in the ward.

(2) The responsible person for a residential care facility must keep a register of the drugs of addiction kept in the residential care facility.

(3) The responsible person for a managed correctional centre must keep a register of drugs of addiction kept in the managed correctional centre.

(4) A register must be in the form of a book that—

(a) contains consecutively numbered pages, and

(b) is bound so that the pages cannot be removed or replaced without trace, and

(c) contains provision on each page for the inclusion of the particulars required to be entered in the book.

(5) Separate pages of the register must be used for each drug of addiction and for each form and strength of the drug.

(6) The Secretary may from time to time approve the keeping of a register in another form.

(7) A management company for a managed correctional centre must appoint, by written instrument, a pharmacist employed at the managed correctional centre as the responsible person for the purposes of subclause (3).

(8) If there is no pharmacist employed at the managed correctional centre, an authorised practitioner, other than a veterinary practitioner, or nurse in charge may be appointed.

Maximum penalty—20 penalty units.

**117 Entries in registers**

(1) On the day on which a person receives, supplies or administers a drug of addiction in a ward, residential care facility or managed correctional centre, the person must enter the following details in the register—

(a) the quantity of the drug received, supplied or administered,

(b) the time of day when the drug was received, supplied or administered,

(c) in the case of a drug that is supplied or administered to a patient—

(i) the name of the patient to whom the drug was supplied or administered, and

(ii) the name of the person by whom the supply or administration of the drug was prescribed or directed,

(d) the quantity of drugs of addiction of that kind held in the ward, residential care facility or managed correctional centre after the transaction takes place,

(e) any other details approved by the Secretary.

(2) The entry must be dated and signed by the person by whom it is made and countersigned—

(a) in the case of an entry relating to the receipt of a drug of addiction, by a person who witnessed its receipt, or

(b) in the case of an entry relating to the supply or administration of a drug of addiction—

(i) by the person who supervised or directed its supply or administration, or

(ii) by a person who witnessed its supply or administration.

(2A) The person countersigning for the purposes of subclause (2) in a managed correctional centre must be an authorised practitioner, nurse, midwife or pharmacist appointed, by written instrument, by the management company for the managed correctional centre for the purposes of this clause.

(3) The Secretary may, by order in writing, exempt any person or drug of addiction, or any class of persons or drugs of addiction, from any or all of the requirements of this clause.

(4) Such an exemption may be given unconditionally or subject to conditions.

(5) In this clause—

***authorised practitioner*** does not include a veterinary practitioner.

Maximum penalty—20 penalty units.

## Subdivision 3 Records generally

### 118 Periodical inventory of stock of drugs of addiction

(1) The person responsible for maintaining a drug register at any place—

(a) must, during the prescribed periods, make an accurate inventory of all drugs of addiction at that place, and

(b) must endorse the relevant drug register, immediately under the last entry for each drug of addiction, with the quantity of each drug of addiction actually held and the date on which the inventory was made, and

(c) must sign each entry.

(2) The prescribed periods for the purposes of subclause (1)(a) are—

(a) March and September each year, or

(b) if the Secretary determines some other periods, either generally or in specified circumstances, the periods so determined.

(3) A person who assumes control for a period of one month or more over any place at which drugs of addiction are held must, immediately on assuming control, make an inventory and endorse the drug register as if the inventory were an inventory made under this clause.

Maximum penalty—20 penalty units.

**119 Loss or destruction of registers**

Immediately after a drug register is lost or destroyed, the person responsible for keeping the register—

(a) must give written notice to the Secretary of that fact and of the circumstances of the loss or destruction, and

(b) must make an accurate inventory of all drugs of addiction held at the premises concerned and enter, in a new drug register, the particulars of the drugs so held.

Maximum penalty—20 penalty units.

**119A Records relating to prescriptions for residents of residential care facilities**

The operator of a residential care facility in which medication charts are used must ensure that an employee of the facility makes a record in the medication chart of a resident of the facility of administration of any drug of addiction to the resident.

Maximum penalty—20 penalty units.

## Division 6 Administration

**120 Administration by persons employed at hospitals and managed correctional centres**

(1) A person employed at a hospital or managed correctional centre must not administer a drug of addiction to a patient without a direction from an authorised practitioner.

(2) A direction must be—

(a) written and given in person, or

(b) given in another manner approved by the Secretary.

(3) However, a direction may be given in an emergency—

(a) by email or facsimile, or

(b) orally, including by telephone, or

(c) in another way approved by the Secretary.

(4) An authorised practitioner who gives a direction under subclause (3) must attend to review the patient as soon after giving the direction as the authorised practitioner considers appropriate in the circumstances.

(5) As soon as practicable and no later than 24 hours after giving a direction under subclause (3)(b), the authorised practitioner must confirm the direction by—

(a) signing an entry in the patient's medical history, or

(b) email or facsimile.

(6) If the authorised practitioner does not confirm the direction under subclause (5) within 7 days after the drug of addiction is administered, the person who administered the substance must notify the Secretary.

(6A) Subclause (1) does not apply to a person employed at a hospital or managed correctional centre who holds an authority under Part 8 to administer the substance.

(7) Subclauses (4)–(6) do not apply to the administration of a drug of addiction to a patient who is an inmate in a correctional centre if confirmation of the direction for the administration of the drug is given in accordance with the requirements of a protocol approved by the Secretary.

(8) In this clause—

***authorised practitioner*** does not include a veterinary practitioner.

***patient*** means—

(a) a patient in a hospital, or

(b) an inmate in a managed correctional centre.

Maximum penalty—20 penalty units.

**121 Self-administration by medical practitioners and dentists**

(1) For the purposes of Division 1 of Part 2 of the *Drug Misuse and Trafficking Act 1985*—

(a) a medical practitioner is authorised to self-administer a drug of addiction, but only if the medical practitioner does so for the purposes of medical treatment, and

(b) a dentist is authorised to self-administer a drug of addiction, but only if the dentist does so for the purposes of dental treatment.

(2) Subclause (1) does not authorise a medical practitioner or dentist to self-administer a drug of addiction for more than 7 days.

(3) However, a medical practitioner may self-administer a drug of addiction for more than 7 days if the medical practitioner does so in accordance with an authority issued under Part 8.

(4) This clause does not authorise a medical practitioner or dentist to self-administer an unregistered drug of addiction.

## Division 7 Miscellaneous

**122 Prescribed type A drugs of addiction**

For the purposes of section 28 of the Act, each of the following is prescribed as a type A drug of addiction—

(a) amphetamine,

(a1) (Repealed)

(b) dexamphetamine,

(b1) N,?-dimethyl-3,4-(methylenedioxy)phenylethylamine (MDMA),

(b2) lisdexamfetamine,

(c) methylamphetamine,

(d) methylphenidate,

(d1) (Repealed)

(e) phendimetrazine,

(f) phenmetrazine,

(g) psilocybine,

(h) any unregistered drug of addiction that is extemporaneously compounded for a

particular person for therapeutic application to that person.

**123 Prescribed type B drugs of addiction**

For the purposes of section 28 of the Act, each of the following is prescribed as a type B drug of addiction—

(a) a drug of addiction that—

(i) does not contain cannabis or tetrahydrocannabinols (when included in Schedule 8 of the Poisons List) or nabiximols, and

(ii) is packaged and labelled in a manner that is consistent with the drug being intended for administration by injection, inhalation, spray or application to mucous membranes,

(a1) alprazolam,

(b) buprenorphine (other than in transdermal patches),

(c) dextromoramide,

(d) flunitrazepam,

(e) hydromorphone,

(f) methadone.

**124 Loss or theft of drugs of addiction**

A person who is authorised to be in possession of drugs of addiction must immediately notify the Secretary if the person loses a drug of addiction or if a drug of addiction is stolen from the person.

Maximum penalty—20 penalty units.

**125 Drugs of addiction not to be destroyed**

(1) A person who is authorised to be in possession of a drug of addiction must not wilfully destroy the drug or allow the drug to be destroyed.

(2) This clause does not apply to the destruction of a drug of addiction carried out—

(a) by or under the direct personal supervision of a police officer or an inspector or by or under the direct personal supervision of a person authorised, whether generally or in a particular case, by an authority under Part 8 held by the person, or

(b) by or under the direct personal supervision of a person who is in charge of a laboratory, or who is an analyst, but only if the destruction is carried out in accordance with an authority under Part 8 held by the person, or

(c) by a person to whom the drug has been supplied by, or in accordance with the prescription of, an authorised practitioner, or

(d) in accordance with clause 125A, 126, 126A, 127, 128 or 128A.

Maximum penalty—20 penalty units or imprisonment for 6 months, or both.

**125A Destruction of drugs of addiction by retail pharmacists**

(1) A pharmacist who practises at a retail pharmacy may destroy a drug of addiction at the pharmacy in the presence of an independent witness.

(2) A pharmacist who destroys a drug of addiction must ensure the following are recorded in the drug register kept at the pharmacy—

(a) the date of destruction,

(b) the name and quantity of the drug destroyed,

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

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

(3) In this clause—

***family member*** has the same meaning as in the *Voluntary Assisted Dying Act 2022*.

***independent witness*** means a medical practitioner, nurse practitioner or pharmacist who—

(a) is not employed or otherwise engaged to provide professional services at the pharmacy, and

(b) is not a family member of the pharmacist, and

(c) if the independent witness is a pharmacist—does not have a financial interest, within the meaning of the *Health Practitioner Regulation National Law (NSW)*, Schedule 5F, in the pharmacy.

**126 Destruction of unusable or unwanted drugs of addiction held by practitioners**

(1) A pharmacist who is engaged in the supply of restricted substances or drugs of addiction in a retail pharmacy and who has been notified by a relevant practitioner that a drug of addiction has become unusable or unwanted—

(a) may (but only in the presence of the relevant practitioner) destroy the drug of addiction, either at the retail pharmacy or at the premises at which the practitioner's practice is conducted, and

(b) in that event, must record the fact of the destruction of the drug in the relevant

practitioner's drug register.

(2) The entry must include the date and the name, professional registration number and signature of the pharmacist and the name and signature of the relevant practitioner.

Maximum penalty—20 penalty units.

(3) In this clause—

***relevant practitioner*** means a medical practitioner, a dentist or a veterinary practitioner.

**126A Destruction of unusable or unwanted drugs of addiction in public hospitals**

(1) The authorised director of a public hospital may destroy any unusable or unwanted drug of addiction at the hospital but only in the presence of—

(a) a pharmacist, or

(b) a registered medical practitioner, or

(c) an authorised midwife, or

(d) an authorised nurse, or

(e) a registered dentist.

(2) A person who destroys a drug of addiction in accordance with this clause—

(a) must record the fact of the destruction of the drug by an entry in the drug register maintained by the hospital, and

(b) must ensure that the entry includes the relevant date and the name, professional registration number and signature of that person and the person who witnessed the destruction of the drug.

Maximum penalty—20 penalty units.

(3) In this clause—

***authorised director***, in relation to a public hospital, means—

(a) the director of pharmacy at that hospital, or

(b) if no such position exists at that hospital, the person responsible for controlling drugs of addiction at that hospital, or

(c) a pharmacist authorised in writing for the purposes of this clause by the director of pharmacy or the person responsible for controlling drugs of addiction at the hospital.

***authorised midwife*** means a registered midwife who is in charge of a ward at a hospital or who is authorised by the director of nursing of a hospital to oversee the destruction of drugs at the hospital for the purposes of this clause.

***authorised nurse*** means a registered nurse who is in charge of a ward at the hospital or who is authorised by the director of nursing of a hospital to oversee the destruction of drugs at the hospital for the purposes of this clause.

**127 Destruction of unusable drugs of addiction in public hospital wards**

(1) The nurse or midwife in charge of a ward in a public hospital having responsibility for a drug of addiction that becomes unusable must immediately notify the chief pharmacist of the hospital of the fact and of the circumstances under which the drug became unusable.

(2) A pharmacist employed in a public hospital—

(a) may (but only in the presence of a nurse or midwife) destroy the drug of addiction, and

(b) in that event, must record the fact of the destruction of the drug in the ward register.

(3) The entry must include the date and the name, professional registration number and signature of the pharmacist and the name and signature of the nurse or midwife who witnessed the destruction of the drug.

(4) In the case of a public hospital for which there is no pharmacist, the functions of a chief pharmacist or pharmacist under this clause are instead the functions of—

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

(b) the medical superintendent of the hospital,

as the chief executive officer of the hospital may determine.

Maximum penalty—20 penalty units.

**128 Destruction of unwanted drugs of addiction in private health facilities or residential care facilities**

(1) A retail pharmacist who is engaged in the supply of restricted substances or drugs of addiction to any of the following—

(a) a private health facility,

(b) a residential care facility,

(c) a patient in a private health facility,

(d) a patient in a residential care facility that is a nursing home,

is, subject to subclauses (2) and (3), authorised to destroy any unwanted drug of addiction on the premises of that private health facility or residential care facility.

(2) A retail pharmacist is only authorised to destroy an unwanted drug of addiction on the premises of a residential care facility that is not a nursing home if that drug of addiction was supplied in accordance with clause 103.

(3) Subclause (1) applies only where the drug is destroyed in the presence of—

(a) if the private health facility or residential care facility is the holder of a licence under Division 2 of Part 8—the person who is named on the licence as being responsible for the storage of drugs of addiction, or

(b) in any other case—the director of nursing of the private health facility or residential care facility or the residential care facility manager.

(4) A pharmacist who destroys a drug of addiction in accordance with this clause—

(a) must record the fact of the destruction of the drug by an entry in the drug register maintained by the private health facility or residential care facility, and

(b) must ensure that the entry in the drug register includes the date and the name, professional registration number and signature of the pharmacist and the name and signature of person who witnessed the destruction of the drug.

Maximum penalty—20 penalty units.

**128A Destruction of unusable or unwanted drugs of addiction in managed correctional centres**

(1) The management company for a managed correctional centre may arrange for unusable or unwanted drugs of addiction at the managed correctional centre to be destroyed by a responsible person in the presence of another person who is—

(a) a pharmacist, or

(b) a medical practitioner, or

(c) a nurse practitioner, or

(d) a dentist.

(2) A responsible person who destroys a drug of addiction under this clause must make a record of the destruction in the managed correctional centre’s drug register that includes the following—

(a) the date of the destruction,

(b) the responsible person's name, signature and registration number under the *Health Practitioner Regulation National Law (NSW)*,

(c) the name, signature and registration number under the *Health Practitioner Regulation National Law (NSW)* of the person who witnessed the destruction,

(d) the quantity of the drug of addiction destroyed.

(3) A management company for a managed correctional centre must appoint, by written instrument, a pharmacist employed at the managed correctional centre as the responsible person for the purposes of this clause.

(4) If there is no pharmacist employed at the managed correctional centre, an authorised practitioner or nurse in charge may be appointed.

(5) This clause does not apply to the destruction of drugs of addiction at a retail pharmacy located at a managed correctional centre.

(6) In this clause—

***authorised practitioner*** does not include a veterinary practitioner.

***responsible person*** means a person appointed under subclause (3) or (4).

Maximum penalty—20 penalty units.

## Part 4A Voluntary assisted dying substances

**Note—**

See also the *Voluntary Assisted Dying Act 2022* and this regulation, clauses 61, 67 and 124 and Part 4, Division 5.

## Division 1 Preliminary

### 128B Definitions

In this part—

***administering practitioner*** has the same meaning as in the *Voluntary Assisted Dying Act 2022*.

***authorised disposer*** has the same meaning as in the *Voluntary Assisted Dying Act 2022*.

***authorised supplier*** has the same meaning as in the *Voluntary Assisted Dying Act 2022*.

***contact person***, for a patient, has the same meaning as in the *Voluntary Assisted Dying Act 2022*.

***coordinating practitioner*** has the same meaning as in the *Voluntary Assisted Dying Act*

*2022*.

***patient*** has the same meaning as in the *Voluntary Assisted Dying Act 2022*.

**128C Application of part**

This part applies to—

(a) a prescription for a voluntary assisted dying substance for use under the *Voluntary Assisted Dying Act 2022*, and

(b) a voluntary assisted dying substance prescribed in accordance with the *Voluntary Assisted Dying Act 2022*.

## Division 2 Storage

**128D Storage by authorised supplier**

(1) An authorised supplier who has possession of a voluntary assisted dying substance that is a restricted substance must keep the substance—

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

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

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

Maximum penalty—20 penalty units.

(2) An authorised supplier who has possession of a voluntary assisted dying substance that is a drug of addiction must keep the substance in a safe that is—

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

(b) securely locked when not in immediate use, and

(c) not used to store anything other than drugs of addiction or restricted substances.

Maximum penalty—20 penalty units.

(3) An authorised supplier must ensure—

(a) for a safe that is unlocked by a key or other device—the key or device is kept safely and securely, and

(b) for a safe that is unlocked by a code or combination—the code or combination is not revealed to an unauthorised person.

Maximum penalty—20 penalty units.

**128E Storage at health care establishments and residential facilities**

(1) If a voluntary assisted dying substance is kept at a health care establishment or residential facility on behalf of a patient, the substance must be stored in the steel box required by the *Voluntary Assisted Dying Act 2022*, section 79 and the box must be kept—

(a) in a storage room that is securely locked when not in immediate use, or

(b) in a safe, cupboard or other receptacle that is—

(i) securely attached to the establishment or facility, and

(ii) securely locked when not in immediate use.

**Note—**

See also the *Voluntary Assisted Dying Act 2022*, section 89(2)(d), which provides that a health care establishment or residential facility may refuse to store a voluntary assisted dying substance.

(2) In this clause—

***health care establishment*** has the same meaning as in the *Voluntary Assisted Dying Act 2022*.

***residential facility*** has the same meaning as in the *Voluntary Assisted Dying Act 2022*.

**128F Means to unlock storage box to be kept securely**

A person who receives a voluntary assisted dying substance must ensure—

(a) if the steel box in which the substance is required to be stored by the *Voluntary Assisted Dying Act 2022*, section 79 is unlocked by a key or other device—the key or device is kept safely and securely, and

(b) if the steel box in which the substance is required to be stored by the *Voluntary Assisted Dying Act 2022*, section 79 is unlocked by a code or combination—the code or combination is not revealed to an unauthorised person.

Maximum penalty—20 penalty units.

## Division 3 Records

**Note—**

See clause 176 regarding the keeping of records.

**128G Prescriptions to be kept**

(1) A coordinating practitioner who prescribes a voluntary assisted dying substance must keep a copy of the prescription for the substance.

Maximum penalty—20 penalty units.

(2) An authorised supplier who supplies a voluntary assisted dying substance must keep the prescription or a copy of the prescription for the substance.

Maximum penalty—20 penalty units.

**128H Records to be kept by authorised supplier**

(1) An authorised supplier must, in accordance with this clause, keep written records of voluntary assisted dying substances supplied by the authorised supplier.

Maximum penalty—20 penalty units.

(2) A record of the supply of a voluntary assisted dying substance must be made as soon as practicable after the substance is supplied and include the following—

(a) the name of the substance,

(b) the name and address of the patient for whom the substance was prescribed,

(c) the quantity supplied,

(d) the name of the person to whom the substance was supplied,

(e) the name of the coordinating practitioner who prescribed the substance,

(f) the address of the premises at which the substance was supplied,

(g) the date the substance was supplied and the record made,

(h) the name and signature of the person making the record.

**Note—**

A record kept under this clause may be kept in a drug register.

**128I Records to be kept by administering practitioner**

(1) An administering practitioner must, in accordance with this clause, keep written records of voluntary assisted dying substances received, administered and disposed of by the administering practitioner.

Maximum penalty—20 penalty units.

(2) A record of the receipt of a voluntary assisted dying substance must be made on the day the substance is received and include the following—

(a) the name of the substance,

(b) the quantity received,

(c) the name and address of the person from whom the substance was received,

(d) the name of the patient for whom the substance was prescribed,

(e) the date the substance was received and the record made,

(f) the name and signature of the person making the record.

(3) A record of the administration of a voluntary assisted dying substance must be made on the day the substance is administered and include the following—

(a) the name of the substance,

(b) the quantity administered,

(c) the name of the patient to whom the substance was administered,

(d) the date the substance was administered and the record made,

(e) the address of the premises at which the substance was administered,

(f) the name and signature of the person making the record.

(4) A record of the disposal of a voluntary assisted dying substance must be made on the day the substance is disposed of and include the following—

(a) the name of the substance,

(b) the quantity disposed of,

(c) the means of disposal,

(d) if the substance is disposed of by destruction in accordance with clause 128LA(2)—the name, registration number and signature of the relevant practitioner in whose presence the substance was destroyed,

(e) the date the substance was disposed of and the record made,

(f) the name and signature of the person making the record.

**Note—**

A record kept under this clause may be kept in a drug register.

### 128J Records to be kept by authorised disposer

(1) An authorised disposer must, in accordance with this clause, keep written records of voluntary assisted dying substances received for disposal and disposed of by the authorised disposer.

Maximum penalty—20 penalty units.

(2) A record of the receipt of a voluntary assisted dying substance must be made on the day the substance is received and include the following—

(a) the name of the substance,

(b) the quantity received,

(c) the name and address of the person from whom the substance was received,

(d) the name and address of the patient for whom the substance was prescribed,

(e) the date the substance was received for disposal and the record made,

(f) the name and signature of the person making the record.

(3) A record of the disposal of a voluntary assisted dying substance must be made on the day the substance is disposed of and include the following—

(a) the name of the substance,

(b) the quantity disposed of,

(c) the means of disposal,

(d) if the substance is disposed of by destruction in accordance with clause 128LA(2)—the name, registration number and signature of the relevant practitioner in whose presence the substance was destroyed,

(e) the date the substance was disposed of and the record made,

(f) the name and signature of the person making the record.

**Note—**

A record kept under this clause may be kept in a drug register.

### 128K Records may be kept electronically

A record under this division may be kept electronically.

## Division 4 Miscellaneous

### 128L Form and use of prescription

(1) A prescription for a voluntary assisted dying substance to be used for a purpose under the *Voluntary Assisted Dying Act 2022* must include—

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

(b) the following details for the patient—

(i) name,

(ii) date of birth,

(iii) address,

(iv) identification number, and

(c) the name, strength and quantity of the voluntary assisted dying substance to be supplied, and

(d) adequate directions for use of the voluntary assisted dying substance, and

(e) the following details for the coordinating practitioner who issued the prescription—

(i) name,

(ii) telephone number,

(iii) practice address,

(iv) identification number, and

(f) the coordinating practitioner's signature.

Maximum penalty—20 penalty units.

**Note—**

See also the *Voluntary Assisted Dying Act 2022*, section 74, which sets out certain mandatory matters for a prescription for a voluntary assisted dying substance.

(2) Despite another provision of this regulation, if other substances are prescribed for a patient to assist in the administration of the voluntary assisted dying substance, the same prescription may be used for—

(a) the voluntary assisted dying substance, and

(b) the other substances.

(3) In this clause—

***identification number*** means—

(a) for a coordinating practitioner—the identification number given to the practitioner by the Voluntary Assisted Dying Board, or

(b) for a patient—the identification number given to the patient by the Voluntary Assisted Dying Board.

***Voluntary Assisted Dying Board*** means the Voluntary Assisted Dying Board established by the *Voluntary Assisted Dying Act 2022*, section 134.

**128LA Disposal**

(1) An authorised disposer or administering practitioner must not dispose of a voluntary assisted dying substance in a place or in a way likely to constitute a risk to the public.

Maximum penalty—20 penalty units.

(2) An authorised disposer or administering practitioner who destroys a voluntary assisted dying substance must do so in the presence of a relevant practitioner.

Maximum penalty—20 penalty units.

(3) In this clause—

***relevant practitioner*** means the following—

(a) a medical practitioner,

(b) a pharmacist,

(c) a registered nurse.

**Note—**

See also the *Voluntary Assisted Dying Act 2022*, sections 80–83, which concern the disposal of voluntary assisted dying substances, including the recording and notifying of disposal.

**128LB Mode of delivery—authorised supplier**

(1) An authorised supplier who supplies a voluntary assisted dying substance must deliver the substance—

(a) personally, or

(b) by carrier.

Maximum penalty—20 penalty units.

(2) An authorised supplier who delivers a voluntary assisted dying substance personally must obtain a signed and dated receipt from the person to whom the substance is supplied.

Maximum penalty—20 penalty units.

(3) An authorised supplier who delivers a voluntary assisted dying substance by carrier must—

(a) obtain and keep written evidence of the consignment of the substance, and

(b) ensure the carrier—

(i) obtains a signed and dated receipt from the person to whom the substance is

delivered, and

(ii) gives the receipt to the authorised supplier.

Maximum penalty—20 penalty units.

**128LC Mode of delivery—contact person**

(1) A contact person who gives a voluntary assisted dying substance to an authorised disposer must deliver the substance—

(a) personally, or

(b) by carrier.

Maximum penalty—20 penalty units.

(2) A contact person who delivers a voluntary assisted dying substance to an authorised disposer by carrier must—

(a) obtain and keep written evidence of the consignment of the substance, and

(b) ensure the carrier—

(i) obtains a dated and signed receipt from the person to whom the substance is delivered, and

(ii) gives the receipt to the contact person.

Maximum penalty—20 penalty units.

**128LD Delivery by carrier**

(1) A carrier is authorised to be in possession of a package containing a voluntary assisted dying substance only for the purpose of delivering the substance to the person to whom it is addressed.

(2) An authorised supplier who delivers a voluntary assisted dying substance by carrier must ensure—

(a) the substance is contained in a package that has at least 1 opaque covering, and

(b) the package contains a document—

(i) listing the contents of the package, and

(ii) bearing the words “VOLUNTARY ASSISTED DYING SUBSTANCE—CHECK CAREFULLY” in bold face sans serif capital letters with a letter height of at least 12.5mm, and

(c) the outside of the package does not indicate that it contains a voluntary assisted

dying substance, a drug of addiction or a restricted substance, and

(d) the package is properly addressed to the person to whom the substance is being supplied.

Maximum penalty—20 penalty units.

(3) A contact person who delivers a voluntary assisted dying substance by carrier must ensure—

(a) the substance is contained in a package that has at least 1 opaque covering, and

(b) the outside of the package does not indicate that it contains a voluntary assisted dying substance, a drug of addiction or a restricted substance, and

(c) the package is properly addressed to the person to whom the substance is being supplied.

Maximum penalty—20 penalty units.

## Part 4B Etorphine

### 128M Obtaining etorphine

(1) A person must not obtain etorphine unless the person is authorised to do so by a licence or authority under Part 8.

Maximum penalty—20 penalty units.

(2) A reference in this clause to a licence or authority under Part 8 includes a reference to a licence or authority issued before the commencement of this Part for the purposes of clause 105 as then in force.

### 128N Prescribing and supplying etorphine

(1) A person must not prescribe or supply etorphine unless it is for the treatment of an animal.

Maximum penalty—20 penalty units.

(2) A veterinary practitioner must not prescribe or supply etorphine for the treatment of an animal unless the veterinary practitioner holds an authority under Part 8 authorising the practitioner to treat animals with the product.

Maximum penalty—20 penalty units.

(3) A reference in this clause to an authority under Part 8 includes a reference to an authority issued before the commencement of this Part.

### 128O Regulation applies as if etorphine were drug of addiction

This Regulation applies to etorphine as if it were a drug of addiction.

## Part 4C Schedule 10 substances

### 128P Schedule 10 substances

(1) A person must not manufacture, supply or use a Schedule 10 substance unless the person is authorised to do so by an authority under Part 8.

Maximum penalty—20 penalty units or imprisonment for 6 months, or both.

(2) In this clause—

(a) ***Schedule 10 substance*** means a substance specified in Schedule 10 of the current Poisons Standard, and

(b) for the purposes of determining whether a substance is so specified, the definitions, other interpretation provisions and Appendices of the current Poisons Standard apply.

## Part 5 Supply by wholesale and by holders of wholesaler's licences and authorities

### 129 Persons authorised to possess or use substances and to be supplied by holder of wholesaler's licence or authority—the Act, ss 10 and 11

(1) Each person specified in Appendix C is authorised to possess and use the substances specified in relation to that person in that Appendix subject to any conditions or qualifications that may be specified.

**Note—**

Section 11(1) of the Act creates an offence if the holder of a wholesaler's licence or wholesaler's authority supplies any Schedule 1, 2, 3 or 7 substance or any restricted substance to a person other than an authorised person. An authorised person includes a person who is authorised by or under the Act to use, or have possession of, the substance concerned.

(2) Each person who is specified in Appendix C as being authorised to possess and use a substance is, for the purposes of paragraph (d) of the definition of ***Supply by wholesale*** in section 4(1) of the Act, authorised to be supplied with wholesale quantities of the substance.

(3) For the purposes of section 10(2)(b) of the Act, the holder of a wholesaler's licence or wholesaler's authority is authorised to supply a Schedule 1, 2 or 3 substance otherwise than by wholesale to any person who is specified in Appendix C as being authorised to possess and use the substance.

**Note—**

Section 10(1) of the Act creates an offence of supplying a substance specified in Schedule 1, 2 or 3 of the

Poisons List otherwise than by wholesale except under a general supplier's licence or a general supplier's authority. Section 10(2) of the Act provides for exceptions to this offence.

(4) For the purposes of section 10(4)(d) of the Act, the holder of a wholesaler's licence or wholesaler's authority is authorised to supply a restricted substance otherwise than by wholesale to any person who is specified in Appendix C as being authorised to possess and use the substance.

**Note—**

Section 10(3) of the Act creates an offence of supplying a restricted substance otherwise than by wholesale. Section 10(4) of the Act provides for exceptions to this offence.

**130 Restrictions on supply by wholesale**

A person must not supply by wholesale any Schedule 2, 3 or 4 substance that is for therapeutic use—

(a) to any person in another State or a Territory, unless the person being supplied with the substance is authorised by a law of that State or Territory to obtain or supply the substance, or

(b) to any person outside Australia, unless the person supplying the substance is authorised to do so by a law of the Commonwealth.

Maximum penalty—15 penalty units.

**131 Records of supply by wholesale**

(1) A person who supplies by wholesale any regulated goods must issue an invoice to the person being supplied and must keep a copy of the invoice.

(2) Each invoice must show—

(a) the date of the supply, and

(b) the name and address of the person being supplied, and

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

(d) the name of the supplier and the address of the premises from which the goods were supplied.

Maximum penalty—20 penalty units.

**132 Distribution of free samples**

Any person—

(a) who is engaged in the manufacture, or supply by wholesale, of any poison or restricted substance for therapeutic use, or

(b) who is acting as an agent of a person so engaged,

must not supply any such poison or restricted substance by way of distribution of free samples otherwise than in a manner approved for the time being by the Secretary.

Maximum penalty—20 penalty units.

**133 Storage of therapeutic substances for human use**

(1) A person who is engaged in the supply by wholesale of therapeutic substances for human use must ensure that the recommendations and requirements of the Wholesaling Code of Practice are complied with.

Maximum penalty—20 penalty units.

(2) The Secretary may, by order in writing, exempt any person or substance, or any class of persons or substances, from any or all of the requirements of this clause.

(3) Such an exemption may be given unconditionally or subject to conditions.

(4) In this clause, ***Wholesaling Code of Practice*** means the Code of Practice entitled *Australian Code of Good Wholesaling Practice for Therapeutic Goods for Human Use*, published by the Commonwealth Government, as in force from time to time or a code of practice that replaces that Code.

**134 Pharmacists authorised to supply by wholesale in certain circumstances**

(1) A pharmacist is authorised to supply a substance by wholesale to another pharmacist if—

(a) the pharmacist is requested to do so in writing signed by the other pharmacist, and

(b) the other pharmacist is making the request to satisfy an order of a customer, and

(c) the pharmacist, as far as is reasonably practicable supplies to that other pharmacist only the minimum amount of the substance that is necessary to satisfy the order of that customer.

(2) A pharmacist is authorised to supply a substance by wholesale to another pharmacist if the pharmacist has previously been supplied an amount of the substance in accordance with subclause (1) and is supplying a similar amount of the substance as a replacement for that earlier supply.

(3) A pharmacist practising at a retail pharmacy is authorised to supply a poison or restricted substance by wholesale to a registered nurse or a midwife if the nurse or midwife—

(a) holds an authority under Part 8 to supply the poison or restricted substance for

the purpose of vaccination, and

(b) administers the poison or restricted substance in the pharmacy.

# Part 6 Preparation, handling, supply and labelling of therapeutic goods

## Division 1 Preparation and handling of exposed substances

### 135 Application of Division

This Division applies to all therapeutic goods, and all substances used in the preparation of therapeutic goods, that are unpackaged or otherwise susceptible to contamination (in this Division referred to as ***exposed substances***).

### 136 Preparation and handling generally

An authorised practitioner, pharmacist or practitioner of alternative medicine must ensure that—

(a) all exposed substances that are prepared or handled on his or her business premises are free from any contamination and from anything that is likely to render them harmful or to have an adverse effect on their efficacy, and

(b) all persons that he or she employs in the preparation or handling of exposed substances comply with the requirements of this Division.

Maximum penalty—20 penalty units.

### 137 Personal cleanliness

A person who is involved in the preparation or handling of exposed substances—

(a) must be clean and must wear clean clothing, and

(b) must clean his or her hands (by means of soap or detergent and water or by some other suitable cleaning process) before starting work and before resuming work after using the toilet.

Maximum penalty—10 penalty units.

### 138 Certain behaviour prohibited

A person who is involved in the preparation or handling of exposed substances, or who is in a place that is used for preparing or handling exposed substances, must not—

(a) urinate, defecate or spit on, or

(b) use, smoke or chew tobacco or any other similar substance in the vicinity of, or

(c) sit, walk, stand or lie on,

any surface used for the purpose of preparing or handling exposed substances.

Maximum penalty—10 penalty units.

**139 Contact with hands**

(1) A person who is involved in the preparation or handling of exposed substances—

(a) must not have any unnecessary human contact with any such substance, and

(b) must not handle any such substance with his or her fingers, but must use a suitable clean implement or disposable gloves to do so, and

(c) must not touch his or her mouth, eye, ear, nose or scalp while handling any such substance, and

(d) must not wipe his or her hands otherwise than with a clean towel, and

(e) must not place, so that it can come into contact with any such substance, any ticket, label or other article that is unclean or liable to contaminate any such substance or that has been in contact with the person's mouth, and

(f) must not place in his or her pockets any implement or gloves to be used in preparing or handling any such substance.

(2) A person who uses disposable gloves to handle an exposed substance must dispose of the gloves as soon as practicable.

Maximum penalty—10 penalty units.

**140 Contact with mouth**

A person who is involved in the preparation or handling of exposed substances must not apply to his or her mouth any implement used for preparing or handling any such substance.

Maximum penalty—10 penalty units.

**141 Bandages**

A person who is wearing an unclean bandage or a medicated or absorbent bandage must not prepare or handle exposed substances, or use any appliance, article or fitting for preparing or handling exposed substances, unless the bandage is protected and covered with a waterproof covering.

Maximum penalty—10 penalty units.

**142 Persons suffering from infectious diseases**

(1) A person who is suffering from an infectious disease, or who has any exposed cut, sore, wound or skin eruption, must not prepare or handle exposed substances, or use any appliance, article or fitting for preparing or handling exposed substances.

Maximum penalty—10 penalty units.

(2) This clause does not apply to an activity carried out by a person if the Secretary has certified in writing that the person may carry out that activity and the person complies with any conditions contained in the certificate.

**143 Appliances, articles, fittings and surfaces**

(1) A person who is involved in the preparation or handling of exposed substances must not use any appliance, article or fitting for preparing or handling any such substance unless the appliance, article or fitting—

(a) is designed and constructed so as to be easily cleaned, and

(b) is kept clean.

Maximum penalty—10 penalty units.

(2) A person who is involved in the preparation or handling of exposed substances must not cause or allow any such substance to come into contact with any surface used for preparing or handling any such substance unless the surface—

(a) is designed and constructed so as to be easily cleaned, and

(b) is kept clean.

Maximum penalty—10 penalty units.

## Division 2 Supply of therapeutic goods

**144 Premises to be free of vermin**

A person must not use any premises for preparing, handling or supplying therapeutic goods unless the premises are clean and free from vermin.

Maximum penalty—10 penalty units.

**145 Animals not permitted on premises**

(1) A person who uses any premises for preparing, handling or supplying therapeutic goods must not cause or permit any animal to be in those premises.

Maximum penalty—10 penalty units.

(2) This clause does not apply to the premises of a veterinary practitioner.

## Division 3 Labelling of unscheduled therapeutic substances

### 146 Labelling of unscheduled therapeutic substances

(1) This clause applies to all therapeutic goods that are not therapeutic devices and are not included in a Schedule of the Poisons List (in this clause referred to as ***unscheduled therapeutic substances***).

(2) An authorised practitioner, pharmacist or practitioner of alternative medicine must ensure that any unscheduled therapeutic substances that are supplied from his or her business premises for therapeutic use are labelled in accordance with the requirements of Appendix A.

Maximum penalty—10 penalty units.

(3) This clause does not apply to the supply of a substance by a person referred to in subclause (2) if—

(a) the substance is supplied, unopened, in the container in which it was received by the person, and

(b) the container is labelled in accordance with the requirements of the Commonwealth therapeutic goods laws.

# Part 7 Analysis and disposal of seized goods

## Division 1 Analysis of seized goods

### 147 Samples for analysis

(1) An inspector who seizes a portion or sample of regulated goods for analysis—

(a) must immediately notify the person from whom the portion or sample was taken of the inspector’s intention to submit it for analysis, and

(b) must divide the portion or sample into 3 parts and properly fasten and seal each part or (if that is impracticable) properly fasten and seal the whole portion or sample.

(2) If the portion or sample is divided into 3 parts, the inspector—

(a) must return one part to the person from whom it was taken, and

(b) must forward another part for analysis, and

(c) must retain the remaining part.

(3) If the portion or sample is not divided into 3 parts, the inspector must forward the whole of it for analysis.

(4) For the purposes of this clause, a portion or sample is properly fastened and sealed if—

(a) it is put into a container, and

(b) the container is marked with the name and address of the person from whom it was taken, and

(c) the container is fastened and sealed so as to prevent the container from being opened, or the name and address being removed, without the seal's being broken.

**148 Payment for sample**

Payment for a portion or sample of regulated goods that is seized for analysis is to be made by the State, at current market value—

(a) to the person from whom those goods were taken, or

(b) if the person was not the owner of those goods, to the owner.

## Division 2 Disposal of seized goods

**149 Release of seized goods**

(1) Seized goods are to be released at the end of the period of 6 months after they were seized unless, before the end of that period, a Magistrate makes an order under this Division directing them to be forfeited to the State.

(2) This clause does not prevent seized goods from being released before the expiration of that period.

(3) Seized goods may be released—

(a) by or at the direction of the inspector who seized them or by or at the direction of the Secretary, and

(b) to the owner of the goods or the person in whose possession, care, custody or control they were at the time of the seizure.

(4) This clause does not require the release of any goods that have been damaged or destroyed in the course of analysis.

(5) A Magistrate may, in any particular case, extend the period referred to in subclause (1).

**150 Order that seized goods be forfeited**

(1) A Magistrate may order that seized goods specified in the order be forfeited to the State on the expiration of any period so specified.

(2) Such an order does not have effect in respect of any goods that have been released under this Division.

(3) Before a Magistrate makes an order under this clause, the Magistrate may require such notice as he or she thinks fit to be given to such persons as he or she considers appropriate.

**151 Order that expenses be paid**

(1) A Magistrate may order that a person, from whom goods have been seized under section 43 of the Act and who has been convicted of an offence in connection with those goods, must pay to the Secretary such amount as the Magistrate considers appropriate to cover the reasonable costs of—

(a) seizing the goods, and

(b) dealing with them under this Division, and

(c) conducting any analysis for which they have been submitted.

(2) Before a Magistrate makes an order under this clause, the Magistrate may require such notice as he or she thinks fit to be given to such persons as he or she considers appropriate.

(3) An order under this clause operates as an order under the *Civil Procedure Act 2005*, and is enforceable as such an order under the provisions of that Act.

**152 Storage of and interference with seized goods**

(1) Subject to any direction of the Secretary, seized goods may be kept or stored—

(a) at the premises at which they were seized, or

(b) at such other place as the inspector who seized them considers appropriate.

(2) A person must not remove, alter or interfere in any way with seized goods without the authority of an inspector or the Secretary.

Maximum penalty—20 penalty units.

**153 Forfeiture of goods with consent**

If the owner of seized goods or the person in whose possession, care, custody or control they were at the time of their seizure consents in writing to their forfeiture, the goods are, by virtue of that consent, forfeited to the State.

**154 Disposal of forfeited goods**

Any goods forfeited under this Division may be disposed of in such manner as the Secretary may direct, either generally or in any particular case or class of cases.

# Part 8 Licences and authorities

## Division 1 Licences to supply Schedule 2 substances

### 155 Applications for licences

(1) Any person who conducts, or proposes to conduct, a retail shop may apply for a licence to supply Schedule 2 substances from the shop.

(2) The application—

(a) must be in the form approved by the Secretary, and

(b) must be accompanied by an application fee of $96, and

(c) must be lodged with the Secretary.

(3) The Secretary may require an applicant to furnish such further information as is necessary to enable the Secretary to determine the application.

### 156 Consideration of applications

(1) After considering an application under this Division, the Secretary may issue the licence for which the application is made or may refuse the application.

(2) In particular, the Secretary may refuse an application if of the opinion that the applicant is not a fit and proper person to hold the licence for which the application is made.

(3) A licence may not be issued or renewed unless—

(a) in the case of premises the subject of an existing licence issued before 7 April 1989 that is in force, the Secretary is satisfied that the premises to which the application relates are at least 6.5 kilometres (measured along the shortest practicable route) from the premises of the nearest retail pharmacist, or

(b) in any other case, the Secretary is satisfied that the premises to which the application relates are at least 20 kilometres (measured along the shortest practicable route) from the premises of the nearest retail pharmacist.

### 157 Licences

(1) A licence is to be in the form for the time being approved by the Secretary.

(2) A licence remains in force until suspended, cancelled or surrendered.

(3) A licence is not transferable.

### 158 Conditions of licences

(1) A licence is subject to such conditions as the Secretary may endorse on the licence and to such further conditions as the Secretary may from time to time impose by order in writing served on the holder of the licence.

(2) The Secretary may from time to time vary or revoke any condition of a licence by means of a further order in writing served on the holder of the licence.

(3) A licence is ineffective unless its conditions are complied with.

### 159 Annual licence fees

The holder of a licence under this Division must, on or before 31 March in each year following that in which the licence was issued, pay to the Secretary an annual licence fee of $96.

## Division 2 Licences to supply by wholesale poisons and restricted substances

### 160 Applications for licences

(1) Any person may apply to the Secretary for a licence to supply by wholesale any poisons or restricted substances.

(2) The application—

(a) must be in the form approved by the Secretary, and

(b) must be accompanied by the relevant application fee, and

(c) must be lodged with the Secretary.

(3) The relevant application fee is—

(a) $86, in the case of an application by a public institution, or

(b) $574, in any other case.

(4) The Secretary may require an applicant to furnish such further information as is necessary to enable the Secretary to determine the application.

### 161 Consideration of applications

(1) After considering an application under this Division, the Secretary may issue the licence for which the application is made or may refuse the application.

(2) In particular, the Secretary may refuse an application if of the opinion that the applicant is not a fit and proper person to hold the licence for which the application is made.

(3) A licence may not be issued unless the Secretary is satisfied that the premises to which the application relates are appropriate for the supply of the poisons or restricted substances concerned.

**162 Licences**

(1) A licence is to be in a form for the time being approved by the Secretary.

(2) A licence remains in force until suspended, cancelled or surrendered.

(3) A licence is not transferable.

**163 Conditions of licences**

(1) A licence is subject to such conditions as the Secretary may from time to time impose by order in writing served on the holder of the licence.

(2) The Secretary may from time to time vary or revoke any condition of a licence by means of a further order in writing served on the holder of the licence.

(3) A licence is ineffective unless its conditions are complied with.

**164 Annual licence fees**

The holder of a licence under this Division must, on or before 30 September in each year following that in which the licence was issued, pay to the Secretary an annual licence fee of—

(a) $86, if the holder is a public institution, or

(b) $574, in any other case.

## Division 3 Licences to manufacture or supply drugs of addiction

**165 Applications for licences**

(1) Any person may apply to the Secretary for a licence to manufacture drugs of addiction at, or to supply drugs of addiction from, any premises.

(2) The application—

(a) must be in the form approved by the Secretary, and

(b) must be accompanied by the relevant application fee, and

(c) must be lodged with the Secretary.

(3) The relevant application fee for a licence to manufacture drugs of addiction is—

(a) $86, in the case of an application by a public institution, or

(b) $765, in any other case.

(4) The relevant application fee for a licence to supply drugs of addiction is—

(a) $19, in the case of an application by a charitable organisation, or

(b) $86, in the case of an application by a public institution (other than a charitable organisation), or

(c) $383, in any other case.

(5) The Secretary may require an applicant to furnish such further information as is necessary to enable the Secretary to determine the application.

**166 Consideration of applications**

(1) After considering an application under this Division, the Secretary may issue the licence for which the application is made or may refuse the application.

(2) In particular, the Secretary may refuse an application if of the opinion that the applicant is not a fit and proper person to hold the licence for which the application is made.

(3) A licence may not be issued unless the Secretary is satisfied that the premises to which the application relates are appropriate for the manufacture or supply of drugs of addiction.

(4) The Secretary is not empowered to issue a licence under this Division for the supply, under the program known as the New South Wales Opioid Treatment Program, of methadone or buprenorphine to drug dependent persons (as defined in section 27 of the Act) unless—

(a) the licence is a replacement licence, or

(b) the application for the licence is made by or on behalf of an agency that—

(i) provides drug treatment services at premises under that Program to no more than 50 drug dependent persons who are resident at the premises while they are being treated, and

(ii) is a member of the Network of Alcohol and Other Drug Agencies Incorporated.

(5) To avoid doubt—

(a) subclause (4) does not affect the validity or operation of any licence to supply methadone or buprenorphine that was in force immediately before 30 June 2006, and

(b) the Secretary may—

(i) add conditions to, or vary or revoke the conditions of, such a licence, or

(ii) vary the premises to which such a licence relates, on the application of the licensee.

(6) In this clause—

***replacement licence*** means a licence to supply methadone or buprenorphine that replaces such a licence which is in force immediately before the replacement licence is issued.

**167 Licences**

(1) A licence is to be in the form for the time being approved by the Secretary.

(2) A licence to manufacture drugs of addiction authorises the manufacturer to supply drugs that are manufactured under the licence, subject to the conditions of the licence.

(3) A licence remains in force until suspended, cancelled or surrendered.

(4) A licence is not transferable.

**168 Conditions of licences**

(1) A licence is subject to such conditions as the Secretary may endorse on the licence and to such further conditions as the Secretary may from time to time impose by order in writing served on the holder of the licence.

(2) The Secretary may from time to time vary or revoke any condition of a licence by means of a further order in writing served on the holder of the licence.

(3) A licence is ineffective unless its conditions are complied with.

**169 Annual licence fees**

(1) The holder of a licence to manufacture drugs of addiction must, on or before 30 September in each year following that in which the licence was issued, pay to the Secretary an annual licence fee of—

(a) $86, if the holder is a public institution, or

(b) $765, in any other case.

(2) The holder of a licence to supply drugs of addiction must, on or before 30 September in each year following that in which the licence was issued, pay to the Secretary an annual licence fee of—

(a) $19, if the holder is a charitable organisation, or

(b) $86, if the holder is a public institution (other than a charitable organisation), or

(c) $383, in any other case.

## Division 4 Authorities

### 170 Authorities

(1) The Secretary may issue authorities for the purposes of the Act and this Regulation.

(2) The Secretary may require a person seeking an authority to furnish such information as is necessary to enable the Secretary to determine the issuing of the authority.

(3) The Secretary may refuse to issue an authority to a person if of the opinion that the person is not a fit and proper person to hold the authority.

(4) An authority may be issued to a particular person (by means of an instrument in writing given to the person) or to a specified class of persons (by means of an instrument published in a manner approved by the Secretary).

(5) An authority that is issued to a particular person remains in force until it is suspended, cancelled or surrendered.

(6) An authority that is issued to a particular person is not transferable.

(7) In this Regulation, a reference to a person who holds an authority under this Part includes a reference to a person who belongs to a class of persons specified in an instrument referred to in subclause (4).

### 171 Conditions of authorities

(1) The exercise of the functions conferred on a person by an authority is subject to such conditions as the Secretary may specify in the instrument by which the authority is issued and to such further conditions as the Secretary may from time to time impose by order in writing served on that person.

(2) The Secretary may from time to time vary or revoke any condition of an authority by means of a further order in writing served on the holder of the authority.

(3) An authority is ineffective unless its conditions are complied with.

## Division 5 Suspension and cancellation of licences and authorities

### 172 Grounds for suspension or cancellation

(1) The Secretary must suspend or cancel a licence or authority on the occurrence of one or more of the following—

(a) the holder of the licence or authority requests or agrees in writing to the

suspension or cancellation of the licence or authority,

(b) the holder of the licence or authority is convicted of a serious offence against the *Drug Misuse and Trafficking Act 1985* or any regulation in force under that Act,

(c) the Secretary forms the opinion that the holder of the licence or authority is no longer a fit and proper person to hold the licence or authority,

(d) in the case of a licence or authority to supply methadone or buprenorphine, the Secretary forms the opinion that the supply of methadone or buprenorphine has a significant adverse effect on the amenity of the area in which the premises from which it is being supplied are situated.

(2) The Secretary may, at the Secretary's discretion, suspend or cancel a licence or authority on any one or more of the following grounds—

(a) the holder of the licence or authority contravenes any condition of the licence or authority,

(b) the holder of the licence or authority is convicted of an offence against the Act or this Regulation, or of an offence (not being a serious offence) against the *Drug Misuse and Trafficking Act 1985* or any regulation in force under that Act,

(c) an order is made under section 10(1) of the *Crimes (Sentencing Procedure) Act 1999* relating to the holder of the licence or authority in respect of an offence against the Act or this Regulation, or an offence against the *Drug Misuse and Trafficking Act 1985* or any regulation in force under that Act,

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

(e) the annual fee for the licence is not duly paid.

(3) In this clause, ***serious offence*** means an offence that is punishable by imprisonment for a term of 5 years or more.

**173 Suspension or cancellation**

(1) Before suspending or cancelling a licence or authority (otherwise than at the request of its holder), the Secretary—

(a) must cause written notice of the proposed suspension or cancellation, and of the grounds for the proposed suspension or cancellation, to be served on the holder of the licence or authority, and

(b) must give the holder of the licence or authority a reasonable opportunity to make representations with respect to the proposed suspension or cancellation, and

(c) must take any such representations into consideration.

(2) Suspension or cancellation of a licence or authority takes effect on the date on which written notice of the suspension or cancellation is served on its holder or on such later date as is specified in the notice.

(3) The Secretary may, by a further notice in writing served on the holder of a licence or authority that is suspended, revoke the suspension or vary the period of the suspension.

## Division 6 Modification of applied provisions of Commonwealth therapeutic goods laws

### 174 Modification of applied provisions of Commonwealth therapeutic goods laws with respect to advertising

(1) Part 2 (Advertisements) of the *Therapeutic Goods Regulations 1990* of the Commonwealth is modified in its application as a law of New South Wales to the extent that the Secretary may, by order in writing, exempt any person or substance, or any class of persons or substances, from the requirements of that Part.

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

## Part 8A Real time prescription monitoring and authority management

### 174A Interpretation

In this Part—

***data source entity*** means—

(a) the Australian Health Practitioner Regulation Agency established by section 23 of the *Health Practitioner Regulation National Law (NSW)*, or

(b) eRx Script Exchange Pty Ltd, or

(c) Fred IT Group Pty Ltd, or

(d) Medication Knowledge Pty Ltd, or

(e) MediSecure Ltd, or

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

***database*** means the database established under clause 174C.

***healthcare identifier*** means the healthcare identifier assigned to a person or an organisation under the *Healthcare Identifiers Act 2010* of the Commonwealth.

***monitored medicine*** means a substance listed in Appendix E.

***prescriber*** means an authorised practitioner, other than a veterinary practitioner.

***regulatory authority*** means an entity—

(a) with functions that include the regulation of monitored medicines or the regulation of health practitioners, and

(b) that is established under a law of—

(i) New South Wales, or

(ii) another State or Territory, or

(iii) the Commonwealth.

**174B Objects**

The objects of this Part are to—

(a) establish a system for—

(i) the real time monitoring of the prescribing and supply of monitored medicines, and

(ii) managing the prescribing, supply and administration of substances that require an authority under the Act or this regulation, and

(b) require the establishment of a database of information about the—

(i) prescribing and supply of monitored medicines, and

(ii) prescribing, supply and administration of substances that require an authority under the Act or this regulation, and

(c) authorise the following persons to provide information for inclusion in the database—

(i) prescribers, pharmacists and data source entities,

(ii) other persons administering, supplying or issuing a prescription for a patient,

(iii) the Secretary, and

(d) allow for the use and disclosure of information in the database for purposes that include—

(i) monitoring the prescribing and supply of monitored medicines, and

(ii) regulating the prescribing, supply and administration of substances that require an authority under the Act or this regulation.

**174C Establishment and purpose of database**

(1) The Secretary must establish and keep a database to record data about the—

(a) prescribing and supply of monitored medicines, and

(b) prescribing, supply and administration of substances that require an authority under the Act or this regulation.

(2) The Secretary may enter into an agreement with the following to operate and maintain the database—

(a) a person,

(b) a person who engages another person to operate and maintain the database.

(3) The persons referred to in subclause (2)(a) or (b) may, subject to the terms of the agreement, carry out any of the Secretary's functions under this Part other than the power to give an exemption under clause 174J.

**174D Recording of information by prescribers**

(1) This clause applies to a prescriber who uses an electronic prescribing system that is connected to a prescription exchange service operated by a data source entity.

(2) A prescriber who issues a prescription for a monitored medicine may, for the purposes of the database, record the following information about the person who is prescribed the monitored medicine—

(a) full name,

(b) date of birth,

(c) gender,

(d) street address,

(e) healthcare identifier,

(f) other relevant information approved by the Secretary.

(3) A prescriber who issues a prescription for a monitored medicine is to record, for the purposes of the database, the following information—

(a) the following information about the prescriber—

(i) full name,

(ii) registration number or code recorded in the national register under section 225(c) of the *Health Practitioner Regulation National Law (NSW)*,

(iii) healthcare identifier, if available,

(iv) other relevant contact information, including telephone number and email address,

(b) the following additional information—

(i) for a monitored medicine that is included in Schedule 4 of the Poisons List—the information required by clause 35(1)(a)–(f),

(ii) for a monitored medicine that is included in Schedule 8 of the Poisons List—the information required by clause 80(1)(a)–(f),

(iii) the healthcare identifier for the practice if available,

(iv) practice name and address,

(v) other relevant practice information approved by the Secretary.

**174E Recording of information by pharmacists**

(1) This clause applies to a pharmacist who uses an electronic dispensing system that is connected to a prescription exchange service operated by a data source entity.

(1A) A pharmacist who supplies a monitored medicine must, for the purposes of the database, record the following information about the person who is supplied the medicine—

(a) full name,

(b) date of birth,

(c) street address.

(2) A pharmacist who supplies a monitored medicine may, for the purposes of the database, record—

(a) the following information about the person who is supplied a monitored medicine—

(i) gender,

(ii) healthcare identifier,

(iii) other relevant information approved by the Secretary,

(iv)–(v) (Repealed)

(b) the following information about the pharmacist—

(i) full name,

(ii) registration number or code recorded in the national register under section 225(c) of the *Health Practitioner Regulation National Law (NSW)*,

(iii) healthcare identifier,

(iv) other relevant contact information, including telephone number and email address,

(b1) the following information about the business from which the monitored medicine was supplied—

(i) healthcare identifier,

(ii) business name and address,

(iii) other relevant information approved by the Secretary,

(c) the following additional information—

(i) the date on which the monitored medicine was supplied,

(ii) (Repealed)

(iii) the prescription reference number for the prescription under which the monitored medicine was supplied.

**174EA Recording or including information on database for substances requiring authority**

A person who applies for, or holds, an authority required under the Act or this regulation for the purposes of prescribing, supplying or administering a substance may record for the purposes of the database, or include in the database, the following information—

(a) information relating to the person's application for the authority, or

(b) information relating to the cancellation of the authority.

**174EB Secretary may include information in database**

The Secretary may include in the database any information obtained under the Act or this regulation that is relevant for the purposes of the database.

**174F Authority to transfer information**

A data source entity is authorised to transfer the following information for inclusion in the database—

(a) information the entity receives from a prescriber—

(i) under clause 174D, or

(ii) who is in another State or Territory when the prescriber issues a prescription for a

monitored medicine to a person ordinarily resident in New South Wales,

(b) information the entity receives from a pharmacist—

(i) under clause 174E, or

(ii) who is in another State or Territory if the pharmacist supplies a monitored medicine to a person ordinarily resident in New South Wales,

(b1) information the entity receives from a person under clause 174EA,

(c) any other information received from a prescriber or pharmacist if that information is reasonably required for the operation of the database.

**174G Use and disclosure of information by Secretary**

Information in the database may be used or disclosed by the Secretary for the purposes of—

(a) operating, maintaining or improving the database, and

(b) monitoring the prescribing and supply of monitored medicines—

(i) by individual prescribers and pharmacists, or

(ii) on a more general, including State-wide, basis, and

(b1) regulating the prescribing, supply and administration of substances that require an authority under the Act or this regulation—

(i) by persons administering, supplying, or issuing a prescription, or

(ii) on a more general, including State-wide, basis, and

(c) providing that information, whether directly or via a data source entity, to another State or Territory for inclusion in a database established under a law of that State or Territory and serving substantially the same purpose as the database, and

(d) providing information to a regulatory authority where that information is reasonably required by the authority for the purpose of regulating—

(i) the prescribing, supply or use of monitored medicines, and

(ii) the prescribing, supply or administration of substances that require an authority under the Act or this regulation, and

(e) providing information to a data source entity for purposes connected to—

(i) monitoring the prescribing or supply of monitored medicines, and

(ii) managing applications and issuing authorities required for substances that require

an authority under the Act or this regulation, and

(f) for any other lawful purpose.

**174H Use of information by certain prescribers and by pharmacists**

(1) Information in the database may be used by a dentist, a medical practitioner, a nurse practitioner or a pharmacist for the purposes of—

(a) providing treatment to an individual patient by—

(i) reviewing the prescribing of monitored medicines to the patient by other prescribers, and

(ii) reviewing the supply of monitored medicines to the patient by pharmacists, and

(b) providing advice to a prescriber or a pharmacist on the treatment of an individual patient.

(2) Information in the database may be accessed, used or disclosed by a dentist, a medical practitioner or a nurse practitioner for the purposes of applying for, reviewing or applying to cancel an authority under the Act or this regulation.

(3) Information in the database may be accessed, used or disclosed by a pharmacist for the purpose of reviewing an authority for the prescribing or supply of a substance under the Act or this regulation.

**174I Unauthorised access to database**

(1) A person must not without lawful authority knowingly access, use or disclose information held in the database.

Maximum penalty—20 penalty units.

(2) For this clause, ***lawful authority*** includes the person acting—

(a) under the direction of a dentist, medical practitioner or nurse practitioner, and

(b) for a purpose under clause 174H(1) or (2).

**174J Exemption**

(1) The Secretary may, by written order, exempt any person, or any class of persons, from the requirements of this Part.

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

## Part 9 Miscellaneous

### 175 Secretary may restrict authorisations conferred by this Regulation

(1) The Secretary may, by order in writing served on any person, prohibit or restrict the person from doing anything authorised by this Regulation.

(2) Such an order may be made on any one or more of the following grounds—

(a) the person requests or agrees in writing to the making of the order,

(b) the person is convicted of an offence against the Act or this Regulation, or of an offence against the *Drug Misuse and Trafficking Act 1985* or any regulation in force under that Act, or an order is made against the person under section 10(1) of the *Crimes (Sentencing Procedure) Act 1999* in respect of such an offence,

(c) the person has, in the opinion of the Secretary, failed to comply with any restriction imposed on the person by an order under this clause,

(d) the person is, in the opinion of the Secretary, a person whose authorisation to do that thing should be withdrawn for the purpose of protecting the life, or the physical or mental health, of that or any other person (whether or not any other such person is identifiable).

(3) An order that restricts a person as referred to in subclause (1)—

(a) may be made unconditionally or subject to conditions, and

(b) may apply generally or be limited in its application by reference to specified exceptions or factors, and

(c) may apply differently according to different factors of a specified kind.

(4) An order under this clause must specify the grounds on which it is made including, if it is made on the grounds referred to in subclause (2)(d), the reasons for its withdrawal on those grounds.

(5) An order under this clause takes effect—

(a) in the case of an order made on the grounds referred to in subclause (2)(d), when the order is served on the person against whom it is made, or

(b) in any other case, the date specified in the order in that regard.

(6) Except in the case of an order that is made on the ground referred to in subclause (2)(a), the date referred to in subclause (5)(b) must be a date occurring not less than 14 days after the date on which the order is served on the person against whom it is made.

(7) On making an order that prohibits a person from doing all of the things authorised by Part 2, 3, 4 or 5 of this Regulation, or by any two or more of those Parts, the Secretary is to cause notice of—

(a) the name of the person, and

(b) the terms of the order, and

(c) the date on which the order took effect,

to be published in the Gazette.

(8) A person must not contravene any order in force under this clause.

Maximum penalty—20 penalty units or imprisonment for 6 months, or both.

**175A Exemption from storage requirements for goods requiring refrigeration**

(1) The Secretary may grant an exemption (which may be conditional) from a requirement of this Regulation relating to the storage of goods on the grounds that compliance with the requirement is not reasonably practicable because the goods require refrigeration.

(2) The exemption may be granted—

(a) to a person by written instrument on the application of the person, or

(b) for a class of goods or class of persons, by order published in the Gazette.

**176 Records generally**

(1) Except to the extent to which this Regulation otherwise provides, all documents required to be kept under this Regulation—

(a) must be kept in the form of legible instruments written indelibly in English, or

(b) must be kept in some other manner from which a legible instrument written indelibly in English is readily reproducible.

(2) A record required to be made of the manufacture, receipt, supply, administration or use of any substance at or from any premises must be kept at those premises.

(3) A person who is required by this Regulation to keep any document or make any record must keep it for a period of at least 2 years, commencing on the latest date on which—

(a) any entry was made in the document or record, or

(b) any substance was manufactured, received, supplied, administered or used in accordance with, or on the authority of, the document or record,

and must make it available for inspection on demand by a police officer or an inspector.

Maximum penalty—20 penalty units or imprisonment for 6 months, or both.

**177 False or misleading entries in records and registers**

(1) A person who is required by this Regulation to keep any record or register must not make any entry in the record or register that the person knows to be false or misleading in a material particular.

(2) A person must not make any alterations, obliterations or cancellations in a record or register required by this Regulation, but may correct any mistake in any entry by making a marginal note or footnote and by initialling and dating it.

Maximum penalty—20 penalty units or imprisonment for 6 months, or both.

**Note—**

Section 307A of the *Crimes Act 1900* creates the offence of providing false or misleading information in certain circumstances. The offence carries a maximum penalty imprisonment for 2 years, or 200 penalty units, or both.

**178 Service of notices**

A notice referred to in this Regulation may be served on a person—

(a) by delivering it to the person personally, or

(b) by leaving it at the person's place of residence last known to the Secretary with someone who apparently resides there, or

(c) by leaving it at the person's place of business or employment last known to the Secretary with someone who is apparently employed there, or

(d) by posting it to the person in an envelope addressed to the person at the place of his or her residence, business or employment last known to the Secretary.

**179 Applications for authorities under section 29**

Before determining an application referred to in section 29(1) of the Act, the Secretary may require the applicant to furnish such further information as the Secretary may require in relation to the application.

**180 Quorum for Poisons Advisory Committee**

The quorum for a meeting of the Advisory Committee referred to in clause 2 of Schedule 2 to the Act is 9.

**181 Saving**

Any act, matter or thing that, on the repeal of the *Poisons and Therapeutic Goods*

*Regulation 2002*, had effect under that Regulation continues to have effect under this Regulation.

**182 Licences and authorities for substance reclassified as type A drug of addiction**

(1) The reclassification of a substance from a designated non-ARTG product to a type A drug of addiction by the amending regulation does not affect any licence or authority under Part 8 of this Regulation that relates to the substance and that was in force immediately before that reclassification.

(2) Despite subclause (1), an authority referred to in that subsection that authorises the prescription or supply of a substance by a medical practitioner to treat a particular person, is taken, on the commencement of the amending regulation to be an authority of the Secretary issued under section 29 of the Act.

(3) In this clause—

***amending regulation*** means the *Poisons and Therapeutic Goods Amendment (Cannabis and Unregistered Drugs of Addiction) Regulation 2018*.

**183 Duty of governors of managed correctional centres—the Act, ss 17 and 24**

(1) A governor of a managed correctional centre must ensure the following are complied with in the managed correctional centre—

(a) the requirements of this Regulation that apply to the managed correctional centre,

(b) any standards approved by the Secretary relating to the management of poisons, restricted substances or drugs of addiction in a managed correctional centre.

(2) In this clause—

***governor*** of a correctional centre has the same meaning as in the *Crimes (Administration of Sentences) Act 1999*.

Maximum penalty—20 penalty units.

## Appendix A Labelling of therapeutic substances

(Clauses 7, 26, 69 and 146)

**Note—**

Although this Appendix refers to labels "on" a container, the information required by this Appendix may be shown by tags, brands, marks or statements in writing on the container itself (rather than on something affixed or attached to the container). See the definition of ***Label*** in section 4(1) of the Act.

**1 General**

(1) All details, words and other information that a label on a container of a therapeutic substance must carry must be in the English language (although it may also be in

another language).

(2) All symbols, numbers and words on a label must be in durable characters.

(3) The label on a container of a therapeutic substance must contain the following details—

(a) the name and address of the dealer supplying the substance,

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

(c) the substance's proprietary name (unless the substance is a preparation compounded in accordance with the dealer's own formula),

(d) adequate directions for use,

(e) the words "KEEP OUT OF REACH OF CHILDREN" in red on a white background,

(f) if the substance is intended for external use only, the word "POISON", or the words "FOR EXTERNAL USE ONLY", in red on a white background,

(g) if the substance is intended for the treatment of a person, the name of the person,

(h) if the substance is intended for the treatment of an animal, the species of animal and the name of the animal's owner,

(i) if the substance is supplied in the circumstances referred to in clause 45 or 48, the words "EMERGENCY SUPPLY".

**2 Additional labelling requirements for certain substances**

(1) The label on a container of a therapeutic substance that is supplied on prescription must also bear—

(a) the prescription reference number, and

(b) the date on which the prescription was supplied (unless that date is clear from the prescription reference number), and

(c) the directions for use set out in the prescription.

(2) The label on a container of a restricted substance that is supplied in the circumstances referred to in clause 45 or 48 must also bear—

(a) the unique reference number recorded under clause 57 with respect to the supply, and

(b) the date on which the substance was supplied, and

(c) the directions given by the pharmacist for the use of the substance.

**3 Warning: therapeutic substances for internal use**

The label on a container of a therapeutic substance specified in Appendix F to the current Poisons Standard must bear the warning specified in that Appendix in respect of that substance.

The label on a container of a therapeutic substance specified in Appendix K to the current Poisons Standard (being a therapeutic substance that is supplied on prescription and is intended for internal use in humans) must bear Warning Statement 39, 40 or 90 specified in Part 1 of Appendix F to that Standard. The warning must be immediately preceded by a symbol in the form of an open equilateral triangle at least 4.5 millimetres high in bold print, coloured red.

**4 Warning: quinine**

The label on a container of quinine must bear the words “WARNING—MAY BE FATAL TO CHILDREN”.

**5 Warning: other substances**

(1) This clause applies to the following substances—

amphetamine

chlorphentermine

dexamphetamine

diethylpropion

ephedrine

lisdexamfetamine

methylphenidate

phentermine

propylhexedrine

(2) The label on a container of such a substance (being a substance that is represented as being for oral use by a person other than a child under 16) must bear the words “THIS MEDICATION (MEDICINE) MAY AFFECT MENTAL ALERTNESS OR CO-ORDINATION OR BOTH. IF AFFECTED, DO NOT DRIVE A MOTOR VEHICLE OR OPERATE MACHINERY”.

(3) The warning must be immediately preceded by a symbol in the form of an open equilateral triangle at least 4.5 millimetres high in bold print, coloured red.

## Appendix B Special restricted substances

(Clause 3(1))

Amylobarbitone when included in Schedule 4 of the Poisons List
Anabolic and androgenic steroidal agents included in Schedule 4 of the Poisons List, except when referred to elsewhere in this Appendix
Drostanolone
Ethyloestrenol
Fluoxymesterone
Mesterolone
Methandienone
Methandriol
Methenolone
Methylandrostanolone
Methyltestosterone
Mibolerone
Nandrolone
Norethandrolone
Oxandrolone
Oxymesterone
Oxymetholone in preparations for therapeutic use
Pentobarbitone when included in Schedule 4 of the Poisons List
Stanolone
Stanozolol
Testosterone except when included in Schedule 6 of the Poisons List

## Appendix C Persons authorised to possess and use substances

(Clause 129)

**Note—**

Clause 129 provides that each person who is authorised by this Appendix to possess and use a substance is also authorised to be supplied with the substance, whether by wholesale or otherwise, by the holder of a wholesaler's licence or wholesaler's authority.

### 1 Medical superintendents of hospitals

The medical superintendent of a hospital is authorised to possess and, if the medical superintendent is an authorised practitioner, use any Schedule 2, 3 or 4 substance that is required for use in connection with the medical treatment of persons at the hospital.

### 2 (Repealed)

### 3 Podiatrists

A registered podiatrist is authorised to possess and use a Schedule 2, 3 or 4 substance that is a synthetic local anaesthetic if required for use in connection with the practice podiatry.

**4 Dental therapists or oral health therapists**

(1) A dental therapist or oral health therapist is authorised to possess and use the following substances if required for use in connection with dental therapy or oral health therapy—

benzocaine

lignocaine

mepivacaine

prilocaine

procaine

tetracycline (in preparations for treatment of dental pulp)

triamcinolone (in preparations for treatment of dental pulp)

(2) (Repealed)

**5 Dental hygienists**

(1) A dental hygienist is authorised to possess and use the following substances if required for use in connection with his or her practice as a dental hygienist—

(a) benzocaine,

(b) lignocaine,

(c) mepivacaine,

(d) prilocaine,

(e) procaine,

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

(2) (Repealed)

**6 Registered nurses involved in vaccination programs**

A person who is a registered nurse and who is employed in connection with a vaccination program carried out in a public institution or place of work is authorised to possess and use vaccines if required for use in vaccinating humans.

**7 Emergency medical treatment by ambulance officers**

A person—

(a) who is employed in the Ambulance Service of NSW as an ambulance officer or as an

air ambulance flight nurse, and

(b) who is approved for the time being by the Secretary for the purposes of this clause,

is authorised to possess and use any Schedule 2, 3 or 4 substance that is approved by the Secretary for use by such persons in the carrying out of emergency medical treatment.

**8 Emergency medical treatment of divers**

A person—

(a) who is a dive medical technician within the NSW Police Force, and

(b) whose duties include the carrying out (under the supervision of a medical practitioner who is qualified in underwater medicine) of emergency medical treatment on divers,

is authorised to possess and use any substance referred to in the Table to this clause if the substance is required for the emergency medical treatment of divers and the substance complies with the requirements as to form and strength set out in that Table opposite that substance.

**Table**

| Substance | Form | Strength |
|---|---|---|
| adrenaline | ampoule | not more than 0.01 per cent |
| amoxycillin with clavulanic acid | tablet | not more than 500 milligrams (amoxycillin) and 125 milligrams (clavulanic acid) |
| atropine | ampoule | not more then 600 micrograms per ampoule |
| dexamethasone with framycetin and gramicidin | ear drops | not more than 500 micrograms (dexamethasone), 5 milligrams (framycetin) and 50 micrograms (gramicidin) |
| diazepam | ampoule | not more than 10 milligrams per ampoule |
| diclofenac | tablet | not more than 50 milligrams |
| frusemide | ampoule | not more than 20 milligrams per ampoule |
| heparin | ampoule | not more than 25,000 units per 5 millilitres |
| lignocaine | ampoule | not more than 1 per cent |
| lignocaine with chlorhexidine | ampoule | not more than 2 per cent |
| metronidazole | tablet | not more than 200 milligrams |
| naloxone | ampoule | not more than 400 micrograms per ampoule |
| piroxicam | gel | not more than 0.5 per cent |

| | | |
|---|---|---|
| prochlorperazine | ampoule | not more than 12.5 milligrams per ampoule |
| prochlorperazine | tablet | not more than 5 milligrams |
| trimethoprim with sulfamethoxazole | tablet | not more than 160 milligrams (trimethoprim) and 800 milligrams (sulfamethaxozone) |

**9 General first aid**

A person who holds a current occupational first-aid certificate approved by the WorkCover Authority in accordance with the regulations under the *Occupational Health and Safety Act 2000* is authorised to possess and use methoxyflurane and nitrous oxide if required in connection with the carrying out of first aid.

**10 Industrial first aid**

A person who is in control of an industrial first aid post is authorised to possess and use any Schedule 2 substance that is required in connection with the carrying out of industrial first aid.

**11 First aid in mines**

A person who is trained and authorised to administer first aid at a mine (within the meaning of the *Work Health and Safety (Mines) Act 2013*) is authorised to possess and use methoxyflurane and nitrous oxide if required for use in connection with the carrying out of first aid at a mine.

**12 Asthma first aid**

A person who holds a current emergency asthma management certificate issued by an organisation approved by the Secretary for the purposes of clause 18(3) of this Regulation is authorised to possess and use salbutamol or terbutaline in metered aerosols if required in connection with the carrying out of first aid.

**13 Anaphylaxis first aid**

A person is authorised to possess and use adrenaline if—

(a) if the person requires the adrenaline for use in connection with the carrying out of anaphylaxis first aid, and

(b) the adrenaline is contained in single use automatic injectors that have been filled by the manufacturer and that deliver no more than 0.3 milligrams of adrenaline each, and

(c) the person holds a current first aid certificate issued after completion of a first aid course approved by the WorkCover Authority as referred to in regulations made under the *Occupational Health and Safety Act 2000*, and the person has received training on the symptoms and first aid management of anaphylaxis from—

(i) a first aid training organisation approved by the WorkCover Authority, or

(ii) any other organisation approved by the Secretary for the purposes of clause 18(5)(b)(ii) of this Regulation.

**14 Ski rescue**

A ski patroller who holds a valid first aid certificate issued by the Australian Ski Patrol Association for use in ski patrol duties is authorised to possess and use methoxyflurane, nitrous oxide and trichloroethylene if required for use in connection with the carrying out of ski rescues.

**15 Animal feedstuff production**

(1) A person who is authorised under this Regulation to obtain a Schedule 2, 3 or 4 substance is authorised to possess and use the substance if the substance is required for use in connection with the commercial production of animal feedstuff or feedstuff premixes.

(2) In this clause, a reference to an animal feedstuff or feedstuff premix is a reference to a feedstuff or feedstuff premix containing a Schedule 2, 3 or 4 substance at such a level, or in such a form—

(a) that Schedule 5 or 6 to the Poisons List applies to the substance, or

(b) that the substance is not a poison.

**16 Bee keeping**

(1) A registered beekeeper is authorised to possess and use oxytetracycline in the form of a stock medicine (within the meaning of the *Stock Medicines Act 1989*) if—

(a) required by the registered beekeeper for use in the treatment or prevention of European Foulbrood disease in bees, and

(b) the registered beekeeper holds a written authority (issued by the Secretary of the Department of Industry, Skills and Regional Development) recommending the use, by that person, of that substance for that purpose.

(2) In this clause—

***registered beekeeper*** means a person registered to keep bees under the *Biosecurity Act 2015*.

**17 Persons licensed to manufacture or supply drugs of addiction**

The holder of a licence under Part 8 to manufacture or supply drugs of addiction is authorised to possess and use any Schedule 2, 3 or 4 substance that the holder of the licence requires for use in accordance with that licence.

**18 Miscellaneous trades and industries**

A person who is engaged in any of the following activities is authorised to possess and use any Schedule 2 or 3 substance that is required for use in connection with that activity—

(a) jewellery manufacture,

(b) electroplating,

(c) paint manufacture,

(d) ferrous hardening,

(e) commercial pest control,

(f) mining gold or other precious metals,

(g) refining non-ferrous metals.

**19 Scientifically qualified persons**

A scientifically qualified person in charge of a laboratory or department, or a person acting under the direct personal supervision of such a person, is authorised to possess and use any Schedule 2, 3 or 4 substance that is required for the conduct of medical or scientific research or instruction or the conduct of quality control or analysis.

**20 Masters of ships**

The master of a ship is authorised to possess and use any Schedule 2, 3 or 4 substance that is required by law to be carried on the ship for use in connection with the medical treatment of persons on the ship.

**21 Responsible persons at managed correctional centres**

(1) A responsible person for a managed correctional centre is authorised to possess and, if the responsible person is an authorised practitioner, use a Schedule 2, 3 or 4 substance that is required in connection with the medical treatment of inmates at the managed correctional centre.

(2) A management company for a managed correctional centre must appoint, by written instrument, a pharmacist employed at the managed correctional centre as the responsible person for the purposes of this clause.

(3) If there is no pharmacist employed at the managed correctional centre, an authorised practitioner or nurse in charge may be appointed.

(4) In this clause—

***authorised practitioner*** does not include a veterinary practitioner.

***responsible person*** means a person appointed under subclause (2) or (3).

## Appendix D Prescribed restricted substances

(Clause 61)

| Substance | Prescribed quantity |
|---|---|
| Amylobarbitone when included in Schedule 4 of the Poisons List | 50.0 grams |
| Anabolic and androgenic steroidal agents included in Schedule 4 of the Poisons List, except when referred to elsewhere in this Appendix | 5.0 grams |
| Androisoxazole | 5.0 grams |
| AOD-9604 (CAS No. 221231-10-3) | 0.10 gram |
| Barbiturates included in Schedule 4 of the Poisons List, except when referred to elsewhere in this Appendix | 50.0 grams |
| Benzodiazepine derivatives included in Schedule 4 of the Poisons List, except when referred to elsewhere in this Appendix | 0.5 gram |
| Benzphetamine | 5.0 grams |
| Bolandiol | 5.0 grams |
| Bolasterone | 5.0 grams |
| Boldenone | 2.5 grams |
| Bolmantalate | 5.0 grams |
| Bromazepam | 5.0 grams |
| Calusterone | 30.0 grams |
| Cathine | 5.0 grams |
| Chlorandrostenolone | 5.0 grams |
| Chlordiazepoxide | 5.0 grams |
| Chloroxydienone | 5.0 grams |
| Chloroxymesterone | 5.0 grams |
| CJC-1295 (CAS No. 863288-34-0) | 0.50 gram |
| Clobazam | 2.5 grams |
| Clonazepam | 0.5 gram |
| Clorazepate | 3.0 grams |
| Clostebol | 2.0 grams |
| Darbepoetin | 0.015 grams |
| Dextropropoxyphene when included in Schedule 4 of the Poisons List | 15.0 grams |

| | |
|---|---|
| Diazepam | 2.5 grams |
| Diethylpropion | 5.0 grams |
| Dihydrolone | 5.0 grams |
| Dimethandrostanolone | 5.0 grams |
| Dimethazine | 5.0 grams |
| Doxapram | 2.0 grams |
| Drostanolone | 2.0 grams |
| Enobosarm | 0.3 grams |
| Ephedrine | 5.0 grams |
| Epoetins | 0.01 grams or 1,000,000 International Units |
| Erythropoietins (except when referred to elsewhere in this Appendix) | 1,000,000 International Units |
| Ethchlorvynol | 50.0 grams |
| Ethinamate | 50.0 grams |
| Ethyldienolone | 5.0 grams |
| Ethyloestrenol | 1.0 gram |
| Fencamfamin | 1.0 gram |
| Fenproporex | 1.0 gram |
| Fibroblast Growth Factors | 0.10 gram |
| Fluoxymesterone | 2.0 grams |
| Flurazepam | 10.0 grams |
| Follistatin | 0.1 grams |
| Formebolone | 1.0 gram |
| Formyldienolone | 1.0 gram |
| Furazabol | 0.5 gram |
| Glutethimide | 50.0 grams |
| Growth Hormone Releasing Hormones (GHRHs) including those separately specified in Schedule 4 of the Poisons List | 0.50 gram |
| Growth Hormone Releasing Peptide-6 (GHRP-6) | 0.50 gram |
| Growth Hormone Releasing Peptides (GHRPs) including those separately specified in Schedule 4 of the Poisons List | 0.50 gram |

| | |
|---|---|
| Growth Hormone Secretagogues including those separately specified in Schedule 4 of the Poisons List | 0.50 gram |
| Hexarelin | 0.50 gram |
| Hydroxystenozol | 5.0 grams |
| Ibutamoren | 0.50 gram |
| Insulin-like growth factors | 0.005 grams |
| Ipamorelin | 0.50 gram |
| Lorazepam | 1.0 gram |
| Mazindol | 0.5 gram |
| Medazepam | 2.5 grams |
| Mefenorex | 5.0 grams |
| Meprobamate | 100.0 grams |
| Mesabolone | 5.0 grams |
| Mestanolone | 5.0 grams |
| Mesterolone | 10.0 grams |
| Methandienone | 1.0 gram |
| Methandriol | 20.0 grams |
| Methenolone | 2.0 grams |
| Methylandrostanolone | 5.0 grams |
| Methylclostebol | 5.0 grams |
| Methylphenobarbitone | 50.0 grams |
| Methyltestosterone | 20.0 grams |
| Methyltrienolone | 5.0 grams |
| Methyprylone | 40.0 grams |
| Mibolerone | 0.01 gram |
| Midazolam | 0.5 gram |
| Nalbuphine | 0.5 gram |
| Nandrolone | 1.0 gram |
| Nitrazepam | 1.0 gram |
| Norandrostenolone | 1.0 gram |
| Norbolethone | 5.0 grams |

| | |
|---|---|
| Norethandrolone | 4.0 grams |
| Normethandrone | 0.5 gram |
| Oxabolone | 0.5 gram |
| Oxandrolone | 1.0 gram |
| Oxazepam | 10.0 grams |
| Oxymesterone | 4.0 grams |
| Oxymetholone | 40.0 grams |
| Paraldehyde | 250 millilitres |
| Pentobarbitone when included in Schedule 4 of the Poisons List | 50.0 grams |
| Perampanel for human use | 0.80 gram |
| Phenobarbitone | 50.0 grams |
| Phentermine | 10.0 grams |
| Pipradrol | 1.0 gram |
| Pralmorelin ((Growth Hormone Releasing Peptide-2) (GHRP-2)) | 0.50 gram |
| Prasterone | 1.0 gram |
| Prazepam | 2.5 grams |
| Pregabalin | 30.0 grams |
| Propylhexedrine | 5.0 grams |
| Pseudoephedrine when included in Schedule 4 of the Poisons List | 20.0 grams |
| Pyrovalerone | 1.0 gram |
| Quetiapine | 40.0 grams |
| Quinbolone | 3.0 grams |
| Selective androgen receptor modulators | 0.3 grams |
| Silandrone | 5.0 grams |
| Somatropin (human growth hormone) | 0.25 grams |
| Stanolone | 10.0 grams |
| Stanozolol | 2.0 grams |
| Stenabolic (SR9009) and other synthetic REV-ERB agonists | 2.0 grams |
| Stenbolone | 5.0 grams |
| TB-500 | 0.30 gram |
| Temazepam | 5.0 grams |

| | |
|---|---|
| Testolactone | 100.0 grams |
| Testosterone except when included in Schedule 6 of the Poisons List | 20.0 grams |
| Thiomesterone | 5.0 grams |
| Thymosin Beta 4 (THYMOSIN β4) | 0.30 gram |
| Tianeptine | 3.75 grams |
| Tramadol | 30.0 grams |
| Trenbolone except when included in Schedule 6 of the Poisons List | 5.0 grams |
| Trestolone | 5.0 grams |
| Triazolam | 0.05 gram |
| Zolazepam | 2.5 grams |
| Zolpidem | 1.0 gram |
| Zopiclone | 0.75 gram |

## Appendix E Monitored medicines

Clause 174A

**Substance**

All substances included in Schedule 8 of the Poisons List

Any benzodiazepine derivative included in Schedule 4 of the Poisons List

Bromazepam

Chlordiazepoxide

Clobazam

Clonazepam

Clorazepate

Codeine when included in Schedule 4 of the Poisons List

Diazepam

Flurazepam

Lorazepam

Medazepam

Midazolam

Nitrazepam

Oxazepam

Prazepam

Pregabalin

Quetiapine

Temazepam

Tramadol

Triazolam

Zolazepam

Zolpidem

Zopiclone