I certify that this is a copy of the authorised version of this Statutory Rule as at 14 March 2023, and that it incorporates all amendments, if any, made before and in force as at that date and any reprint changes made under any Act, in force before the commencement of the *Legislation Publication Act 1996*, authorising the reprint of Acts and statutory rules or permitted under the *Legislation Publication Act 1996* and made before 14 March 2023.

K Woodward Acting Chief Parliamentary Counsel Dated 14 March 2023

#### **TASMANIA**

\_\_\_\_

### POISONS REGULATIONS 2018 STATUTORY RULES 2018, No. 79

### CONTENTS

#### **PART 1 – PRELIMINARY**

- 1. Short title
- 2. Commencement
- 3. Interpretation
- 4. Preparations containing substances listed in two or more Schedules to Poisons List

#### **PART 2 – ADMINISTRATION**

- 5. Manufacturing chemists and wholesale chemists
- 6. Granting of permits by Minister
- 7. Authorised health professionals
- 8. Administration of listed substances by optometrists
- 9. Administration of listed substances by podiatrists
- 10. Prescribed substances for certain first-aid services

#### PART 3 – NARCOTIC SUBSTANCES AND PROHIBITED PLANTS

#### Division 1 – Licences in respect of narcotic substances and prohibited plants

- 11. Licences to manufacture, &c., narcotic substances for scientific purposes
- 12. Licences to manufacture, &c., prohibited substances for scientific purposes
- Fees

#### Division 2 – Possession of narcotic substances

14. Possession of narcotic substances for purposes of profession, &c.

#### Division 3 – Supply of narcotic substances

- 15. Inquiries, &c., before supplying narcotic substance to patient
- 16. Supply of narcotic substances
- 17. Conveyance of narcotic substances

#### Division 4 – Records and returns as to narcotic substances

- 18. Narcotic substances register to be kept by certain persons
- 19. Retaining of records

#### Division 5 – Prescriptions for narcotic substances

- 20. Prescribing and supplying narcotic substances
- 21. Electronic prescriptions for narcotic substances
- 22. Record of prescribing and supplying narcotic substances
- 23. Emergency prescribing and dispensing of narcotic substances
- 24. Prescription for certain narcotic substances to be issued only on authority of Secretary
- 25. Supply of certain narcotic substances without prior authority of Secretary
- 26. Minister's authorisation for possession and supply of narcotic substance

#### Division 6 – Dispensing of narcotic substances

- 27. Dispensing of narcotic substances (S8)
- 28. Restriction on dispensing of narcotic substances

#### Division 7 – Storage of narcotic substances and prohibited substances

29. Storage of narcotic substances and prohibited substances

#### Division 8 – Storage and supply of narcotic substances in medical institutions

- 30. Authorised officer to store, supply, &c., narcotic substances in medical institution
- 31. Supply of narcotic substances in medical institution
- 32. Receipt for supply of narcotic substance in medical institution
- 33. Storage and control of narcotic substances in wards of medical institutions

34.	Administration	of	narcotic	substances	(S8)	in	medical
	institutions						

#### Division 9 – Storage and use of narcotic substances in special cases

- 35. Minister may grant nurse's authority in certain circumstances
- 36. Narcotic substances on vessels
- 37. Narcotic substances for first aid use

#### Division 10 – Destruction, disposal and loss, &c., of narcotic substances

- 38. Destruction of narcotic substances prohibited
- 39. Procedures in case of loss, &c., of narcotic substances

#### Division 11 – General

- 40. Miscellaneous duties of licence holder
- 41. Self-administration of narcotic substances prohibited
- 42. Control of narcotic substances within Ambulance Service

#### PART 4 – POISONS AND RESTRICTED SUBSTANCES

#### Division 1 – Storage of poisons, &c.

43. Storage of poisons, &c.

### Division 2 – Advertising, prescribing, sale, supply and dispensing of restricted substances

- 44. Restriction on advertising of restricted substances
- 45. Prescriptions for restricted substances
- 46. Electronic prescriptions for restricted substances
- 47. Emergency prescribing and dispensing of restricted substances
- 48. Continued dispensing without prescription in specified circumstances
- 49. Records of prescribing of declared restricted substances
- 50. Sale or supply of restricted substances
- 51. Dispensing prescriptions for restricted substances (S4)
- 52. Specified psychotropic substances
- 53. Emergency supply of restricted substances other than specified psychotropic substances
- [53A. *Rescinded*]
- 54. Supply of restricted substance in medical institution

54B.	Dental assistant may administer sodium fluoride varnish				
55.	Information about drugs				
Division 3 -	Advertising, sale, supply, dispensing and recording of potent substances				
56.	Interpretation of Division				
57.	Advertising of potent substances				
58.	Supply of potent substances by pharmacists				
59.	Administration of salbutamol (S3)				
60.	Administration of adrenaline (S3)				
61.	Obtaining potent substances through misrepresentation				
Division 3A –	Advertising of narcotic substances				
61A.	Restriction on advertising of narcotic substances				
Division 4 – U	Ise, &c., of restricted substances in medical institutions				
62.	Authorised officer to store, &c., restricted substances				
63.	Supply of restricted substances to patients				
64.	Storage of declared restricted substances in wards of medical institutions				
65.	Administration of restricted substances (S4) in medical institutions				
Division 5 – A	Administration of substances by nurses				
66.	Enrolled nurse may administer certain substances				
67.	Administration of restricted substances by registered nurses in certain circumstances				
68.	Minister's authorisation for possession and supply of restricted substance				
Division 5A –	Non-application of section 59C				
68A.	Non-application of section 59C				
Division 6 -	Possession and supply of nitrous oxide and methoxyflurane at relevant workplaces				

Possession and supply of nitrous oxide at workplace

Possession and supply of methoxyflurane at workplace

Administration of certain vaccines

54A.

69.

70.

71.

Interpretation of Division

70	D 1 C 14 ' '	1 11''' 11 1	
,,	Records of obtaining	clinnia and administration to he kei	$\mathbf{a}$
72.	Necolus of obtaining.	supply and administration to be ker	.,

### Division 7 – Possession, &c., of nitrous oxide and methoxyflurane by relevant first-aiders

- 73. Interpretation of Division
- 74. Possession, &c., of nitrous oxide by relevant first-aiders
- 75. Possession, &c., of methoxyflurane by relevant first-aiders
- 76. Records of possession and supply to be kept

#### Division 8 – Possession and supply of salbutamol (S4)

- 77. Interpretation of Division
- 78. Possession and supply of salbutamol (S4), for nebulisation, by relevant person
- 79. Records of obtaining and supplying to be kept

### Division 8A – Possession and supply of naloxone by needle and syringe services

- 79A. Interpretation of Division
- 79B. Possession, &c., of naloxone by certified person at permitted premises
- 79C. Records of possession, supply and administration to be kept

#### Division 9 – Miscellaneous

- 80. Prescribed form of various certificates, applications and licences
- 81. Aboriginal health worker may administer certain substances
- 82. Prescribed persons for section 38(1)(i) of Act
- 83. Restrictions on purchase, &c., of certain pesticidal substances
- 84. Veterinary use of chloramphenicol
- 85. Restriction on possession, &c., of diazepam
- 86. Restriction on sale, &c., of clozapine
- 87. Prescription, &c., of certain substances prohibited, unless authorised by Secretary
- 88. Precautions in prescribing substances capable of producing birth defects
- 89. Restrictions on use of certain poisons and restricted substances
- 90. Restriction of possession of certain substances
- 91. Authorisation to manufacture, &c., certain dangerous poisons

- 92. Restrictions applying to veterinary medicines
- 93. Wholesale dealing
- 94. Retaining of records
- 95. Supply of clinical samples

#### PART 4A – MONITORED MEDICINES DATABASE

- 95A. Interpretation
- 95B. Prescribed monitored medicines
- 95C. Prescribed dispenser
- 95D. Prescribed prescriber
- 95E. Prescribed manner and prescribed form of providing information to monitored medicines database
- 95F. Prescribed information provided to, or collected and stored in, the monitored medicines database
- 95G. Prescriber or dispenser not required to check monitored medicines database

# PART 5 – STANDING ORDERS FOR ADMINISTRATION OF RESTRICTED SUBSTANCES AND NARCOTIC SUBSTANCES

- 96. Interpretation
- 97. Drugs and Therapeutics Committee
- 98. Application for authorisation of issue of standing order
- 99. Determination of application
- 100. Standing orders issued by Director of Public Health in public health emergencies or for treatment of notifiable diseases
- 101. Standing orders issued by medical practitioners for persons treated in public hospitals or day-treatment
- 102. Standing orders issued by medical practitioner for patients of medical practitioner treated in private hospitals or private day-treatment centres
- 103. Standing orders issued by medical practitioners for persons treated in community health centres
- 104. Standing orders issued by medical practitioners for persons treated in remote areas
- 105. Form of standing orders

106. Authorisation by standing orders 107. Offences relating to standing orders 108. Revocation of standing orders PART 6 - PACKAGING AND LABELLING OF SCHEDULED **SUBSTANCES** Division 1 – Application of provisions of Uniform Standard 109. Application of provisions of Uniform Standard Division 2 – Packaging of scheduled substances 110. Special provisions as to containers for narcotic substances 111. Child-resistant packaging of certain medicines Division 3 – Labelling of scheduled substances 112. Labelling of poisons in poisons book 113.

- Labelling prohibitions
- 114. Labelling of dispensed medicines

#### PART 7 – MISCELLANEOUS

- 115. Revocation of licence to be published
- Offence to act if right suspended or revoked 116.
- 117. Duration of licence or authority
- 118. Surrender of licence or authority
- 119. Application to extend suspension
- 120. Prescribed authorities
- 121. **Exemptions**
- 122. Supply of medicine chests by RFDS
- 123. Emergency use of medicine chest
- 124. Reporting of acquisition and disposal of relevant substances
- 125. Transport by drone prohibited
- 126. Administration of drugs by midwives under general orders
- 127. Administration of certain substances by disability service workers
- 128. Disability service workers may assist with self-administration
- 129. Administration of certain substances by school staff

- 130. Administration of certain substances by TasTAFE employees
- 131. Administration of certain substances by child carers, &c.
- 132. Administration of certain substances by foster-parents
- 133. Administration of certain substances by aged-care workers in residential care services
- 134. Administration of certain substances by aged-care workers in community care services
- 135. Administration of certain substances by carers
- 136. Administration of certain substances to detainees
- 137. Administration of certain substances to animals
- 138. Possession of pseudoephedrine
- 139. Savings provision
- 140. Infringement offences

[SCHEDULE 1 – Rescinded]

[SCHEDULE 2 – Rescinded]

SCHEDULE 3 – SPECIFIED PSYCHOTROPIC SUBSTANCES

SCHEDULE 4 – SUBSTANCES NOT TO BE SUPPLIED WITHOUT APPROVED INFORMATION SHEET

SCHEDULE 5 – SPECIFIED POTENT SUBSTANCES

SCHEDULE 6 – PROCEDURES TO BE FOLLOWED IN A MEDICAL INSTITUTION IN CASE OF LOSS, SPILLAGE, BREAKAGE OR UNINTENTIONAL DESTRUCTION OF NARCOTIC SUBSTANCES

**SCHEDULE 7 – FEES** 

SCHEDULE 8 – INFRINGEMENT NOTICE OFFENCES

#### **POISONS REGULATIONS 2018**

I, the Governor in and over the State of Tasmania and its Dependencies in the Commonwealth of Australia, acting with the advice of the Executive Council, make the following regulations under the *Poisons Act 1971*.

Dated 17 December 2018.

C. WARNER Governor

By Her Excellency's Command,

MICHAEL DARREL JOSEPH FERGUSON
Minister for Health

#### PART 1 – PRELIMINARY

#### 1. Short title

These regulations may be cited as the *Poisons Regulations 2018*.

#### 2. Commencement

These regulations take effect on the day on which their making is notified in the *Gazette*.

#### 3. Interpretation

- (1) In these regulations, unless the contrary intention appears
  - Aboriginal health worker means a person who holds a Certificate III, or equivalent, in Aboriginal Primary Health Care from a registered training organisation;

Act means the Poisons Act 1971;

- Ambulance Service means Ambulance Tasmania established under the Ambulance Service Act 1982;
- approved name, in relation to a poison, restricted substance or narcotic substance means the name for that poison, restricted substance or narcotic substance determined in a manner approved by the Minister;
- approved recording system means a system or method approved by the Secretary for the keeping of records of prescriptions;
- authorised nurse means a nurse who holds a nurse's authority granted under regulation 35;
- authorised officer, in relation to a medical
  institution, means -
  - (a) a pharmacist employed as such in that institution or, where more

- than one pharmacist is employed, the chief pharmacist; or
- (b) where no pharmacist is employed in that institution, the medical practitioner in charge of that institution; or
- (c) where no pharmacist is employed in that institution and there is no medical practitioner in charge thereof, the registered nurse in charge of that institution;
- authorised person means a person to whom responsibility for the storage and security of a medicine chest has been given under regulation 122(3);

#### chemist means –

- (a) a pharmacist; or
- (b) a manufacturing chemist or wholesale chemist licensed under section 16 of the Act;
- children and youth services facility means a children and youth services facility approved by the Secretary for the purposes of these regulations;
- Commonwealth Department means the Department of State of the Commonwealth responsible for the administration of the Therapeutic Goods Act 1989 of the Commonwealth or of

- such Act that from time to time has effect in substitution for that Act;
- correctional health facility means a correctional health facility approved by the Secretary for the purposes of these regulations;
- day book means any continuous written record kept by a medical practitioner indicating the medicines or narcotic substances supplied to patients;
- day-treatment centre means a centre at which a person is admitted and discharged on the same day for medical, surgical or other treatment:
- declared restricted substance means a restricted substance that, in accordance with an order in force under section 36 of the Act, is a substance to which that section applies;
- dental therapist means a person registered under the Health Practitioner Regulation National Law (Tasmania) in the dental profession as a dental therapist;
- detainee means a person who is being lawfully detained in a detention centre;
- detention centre means a detention centre established under section 123 of the *Youth Justice Act 1997*;

- *Director of Public Health* means the Director of Public Health appointed under the *Public Health Act 1997*;
- disability has the same meaning as in the Disability Services Act 2011;
- dispensary means the room or area, within a pharmacy or other premises, that a pharmacist uses for the dispensing or preparation of prescriptions, medicines or drugs;
- **drug** means a poison intended for human therapeutic use or animal therapeutic use;
- drug therapy chart means a document prepared by a medical practitioner, dentist, authorised health professional or authorised nurse practitioner authorising the administration of a scheduled substance to a person;
- employ means employ for payment or other reward and includes engage the services of, whether as an employee or an independent contractor or otherwise;
- funding agreement has the same meaning as in the Disability Services Act 2011;

#### *health professional* means –

- (a) a dentist; and
- (b) a medical practitioner; and
- (c) a pharmacist; and

- (d) a registered nurse; and
- (e) a midwife; and
- (f) an authorised nurse practitioner; and
- (g) a veterinary surgeon; and
- (h) an authorised health professional;

#### immediate wrapper means –

- (a) any material used as the first wrapper for a single tablet, pastille, capsule or product unit; or
- (b) strip packaging when used in connection with some form of primary pack;
- internal use, in respect of a substance, means administration orally, parenterally or by way of a body orifice but does not include the administration of topical preparations for use in the nose, eyes, ears, mouth or throat or douches for rectal, vaginal or urethral use;
- medical institution means an institution the sole or main object, or one of the main objects, of which is, or is held out to be, the provision of accommodation (whether with or without medical or other treatment) for —

- (a) persons suffering from any illness, injury, infirmity or mental disorder; or
- (b) pregnant women or women immediately after childbirth; or
- (c) persons who are substantially and permanently handicapped by illness, injury or congenital deformity, or by any other disability; or
- (d) persons who are aged;

#### *medication chart* means –

- (a) a medication chart in a format formulated by the Australian Commission on Safety and Quality in Health Care established under section 8 of the *National Health Reform Act 2011* of the Commonwealth; and
- (b) a medication chart maintained at a correctional health facility; and
- (c) a medication chart maintained at a children and youth services facility;

*medicine chest* means a medicine chest supplied under regulation 122;

nurse practitioner treatment means treatment carried out by a nurse practitioner in

accordance with an authorisation under section 25B of the Act;

- Nursing and Midwifery Board of Australia means the Nursing and Midwifery Board of Australia established under the Health Practitioner Regulation National Law (Tasmania);
- optometrist means a person registered under the Health Practitioner Regulation National Law (Tasmania) in the optometry profession;
- Optometry Board of Australia means the Optometry Board of Australia established under the Health Practitioner Regulation National Law (Tasmania);
- oral health therapist means a person registered under the Health Practitioner Regulation National Law (Tasmania) in the dental profession as an oral health therapist;
- patient means, when used in relation to a medical practitioner, dentist, podiatrist, therapist, registered midwife, authorised nurse practitioner, optometrist, authorised health professional or enrolled nurse, a person upon whom that medical practitioner, dentist, podiatrist, dental therapist, registered nurse, midwife, authorised nurse practitioner, optometrist, authorised health professional or enrolled

- nurse attends in the exercise of his or her practice, profession or calling as such;
- PBS medication chart has the same meaning as medication chart in regulation 41(4) of the National Health (Pharmaceutical Benefits) Regulations 2017 of the Commonwealth:
- pharmacy means a shop or other place, or a
   part of a shop or other place, in which a
   person practises as a pharmacist;
- podiatric surgeon means a person registered under the Health Practitioner RegulationNational Law (Tasmania) in the speciality of podiatric surgery;
- podiatrist means a person registered under theHealth Practitioner Regulation NationalLaw (Tasmania) in the podiatry profession;
- Podiatry Board of Australia means the Podiatry Board of Australia established under the Health Practitioner Regulation National Law (Tasmania);
- primary pack means the package, other than any wrapping, bag, carton or similar article, in which any poison or restricted substance is placed for the purposes of delivery to a person after sale;
- private hospital means a private hospital within the meaning of the Health Service Establishments Act 2006;

- registered training organisation means a registered training organisation within the meaning of the National Vocational Education and Training Regulator Act 2011 of the Commonwealth;
- Registrar of Chemical Products means the Registrar of Chemical Products appointed under the Agricultural and Veterinary Chemicals (Control of Use) Act 1995;

#### *selected container* means –

- (a) a single-use syringe; or
- (b) any other container having a capacity not exceeding 10 millilitres;
- service provider, in relation to a disability, has the same meaning as disability services provider has in the Disability Services Act 2011;
- specified potent substance means a substance that, in accordance with regulation 56, is a specified potent substance for the purposes of Division 3 of Part 4;
- specified psychotropic substance means a restricted substance that, in accordance with regulation 52, is a specified psychotropic substance for the purposes of section 38(1)(b) of the Act;
- speech pathologist means a person who –

- (a) has successfully completed an accredited course of study in speech pathology at a tertiary institution, or holds qualifications and experience deemed by Speech Pathology Australia to be equivalent to such a course; and
- (b) is eligible for membership of Speech Pathology Australia;
- **TasTAFE** means TasTAFE as continued by the *TasTAFE* (Skills and Training Business) Act 2021;
- TasTAFE CEO has the same meaning as in the TasTAFE (Skills and Training Business) Act 2021;
- VAD substance has the same meaning as in the End-of-Life Choices (Voluntary Assisted Dying) Act 2021.
- (2) A reference in these regulations to a substance includes, unless specifically exempted
  - (a) the substance prepared from natural sources or artificially; and
  - (b) if the substance is a plant, other than a plant included in Schedule 8 to the Poisons List or a prohibited plant, that plant or any part of it when packed or prepared for therapeutic use; and
  - (c) any salt, active principle or derivative of the substance, including esters and

- ethers, and any salt of the active principle or derivative; and
- (d) any alkaloid of the substance and any salt of the alkaloid; and
- (e) any stereo-isomer of the substance and any salt of the stereo-isomer, except if the substance is levomethorphan or levorphanol; and
- (f) any preparation or admixture containing any proportion of the substance or of any other substance included in paragraph (a), (b), (c), (d) or (e).
- If a poison is present in a substance (3) or preparation as a salt, active principle or any concentration, derivative, strength or quantity in respect of that substance or preparation is to be calculated concentration, strength or quantity of the poison in the form in which it is named in the Poisons List.
- (4) A reference in these regulations to a substance by name followed, in parentheses, by a capital letter "S" and a number is a reference to that substance when included in the correspondingly numbered Schedule to the Poisons List.

## 4. Preparations containing substances listed in two or more Schedules to Poisons List

(1) Subject to subregulation (2), where a preparation contains 2 or more scheduled substances, that

preparation, unless the contrary intention appears, is to be taken to be included in each of the Schedules to the Poisons List in which those substances are included.

- (2) Where, in relation to a preparation referred to in subregulation (1), it is not possible to comply both with a requirement of the Act applicable to that preparation by reason of its inclusion in one Schedule to the Poisons List and with such a requirement applicable to it by reason of its inclusion in another such Schedule, unless the preparation, contrary intention appears, is to be taken for the purposes of the Act to be included in the more restrictive of those Schedules.
- (3) For the purposes of subregulation (2), the comparative restrictiveness of the Schedules to the Poisons List, in descending order, is 8, 4, 7, 1, 3, 2, 6, 5.

#### **PART 2 – ADMINISTRATION**

#### 5. Manufacturing chemists and wholesale chemists

- (1) An application for a licence
  - (a) to carry on business as a manufacturing chemist or to make, refine or prepare a narcotic substance is to be made by a qualified person and accompanied by the relevant fee specified in item 1 of Schedule 7: and
  - (b) to carry on business as a wholesale chemist is to be accompanied by the relevant fee specified in item 2 of Schedule 7.
- (2) In subregulation (1)(a) –

#### qualified person means –

- (a) a medical practitioner, pharmacist, dentist or veterinary surgeon; or
- (b) a person who holds a degree or diploma approved by the Minister; or
- (c) a person approved by the Secretary; or
- (d) a person who is, or is eligible to be –

- (i) a Fellow or Associate of the Royal Australian Chemical Institute; or
- (ii) a Fellow, Associate or Licentiate of the Royal Institute of Chemistry; or
- (e) where the carrying out of a process involving a prohibited plant is only preparatory to the use of that plant for the manufacture of a narcotic substance, a person approved by the Minister.

#### 6. Granting of permits by Minister

- (1) The Minister may, on the application of a person and on payment of the fee (if any) specified in Schedule 7, grant a permit under this regulation.
- (2) A permit under subregulation (1) authorises the person to whom it is issued to purchase from a licensed manufacturing chemist or a licensed wholesale chemist any of the substances specified in Schedule 1, 2, 3 or 4 to the Poisons List in such quantities and on such conditions, limitations and restrictions as the Minister may determine and as may be specified in the permit for use by the person for industrial, educational, advisory or research purposes.
- (3) A permit issued under subregulation (1) remains in force until it is cancelled, suspended or revoked by the Minister.

#### 7. Authorised health professionals

- (1) For the purposes of paragraph (a) of the definition of *authorised health professional* in section 3(1) of the Act, the following classes of health professionals are prescribed:
  - (a) optometrists whose registration is endorsed under section 94 of the Health Practitioner Regulation National Law (Tasmania);
  - (b) podiatric surgeons whose registration is endorsed under section 94 of the Health Practitioner Regulation National Law (Tasmania);
  - (c) podiatrists whose registration is endorsed under section 94 of the Health Practitioner Regulation National Law (Tasmania).
- (2) For the purposes of section 25C of the Act
  - (a) the Optometry Board of Australia is prescribed as the authorised body for optometrists; and
  - (b) the Podiatry Board of Australia is prescribed as the authorised body for podiatric surgeons and podiatrists.
- (3) Subject to these regulations, an optometrist, podiatric surgeon or podiatrist, in the lawful practice of his or her profession may only possess, sell, supply or prescribe a scheduled substance if he or she is acting in accordance

with an endorsement on his or her registration under section 94 of the Health Practitioner Regulation National Law (Tasmania).

Penalty: Fine not exceeding 10 penalty units.

#### 8. Administration of listed substances by optometrists

(1) In this regulation –

optometry guidelines means the Guidelines for use of scheduled medicines published by the Optometry Board of Australia, as amended from time to time.

(2) Optometrists, in the lawful practice of the profession of optometry, may administer a substance listed in the optometry guidelines as being a scheduled medicine approved by the Optometry Board of Australia for administration by optometrists holding general registration.

#### 9. Administration of listed substances by podiatrists

A podiatrist in the lawful practice of the profession of podiatry, may administer –

- (a) local anaesthetics included in Schedule 4 of the Poisons List; and
- (b) adrenaline (S3).

### 10. Prescribed substances for certain first-aid services

For the purposes of the definition of *prescribed* substance in section 18A(1) of the Act, the following substances are prescribed:

- (a) adrenaline (S3);
- (b) methoxyflurane (S4);
- (c) naloxone (S3);
- (d) nitrous oxide (S4);
- (e) salbutamol (S3).

### PART 3 – NARCOTIC SUBSTANCES AND PROHIBITED PLANTS

# Division 1 – Licences in respect of narcotic substances and prohibited plants

# 11. Licences to manufacture, &c., narcotic substances for scientific purposes

- (1) The Minister may, on the application of a person
  - (a) who is in charge of a laboratory for the purpose of research or instruction; or
  - (b) who is an organisation; or
  - (c) who is an analyst appointed under section 19 of the Act –

grant a licence authorising that person –

- (d) to manufacture, use or possess any narcotic substance specified in the licence for such purpose as is specified in the licence; or
- (e) to purchase that narcotic substance by an order written in ink from a pharmacist, a licensed manufacturing chemist, a licensed wholesale chemist or such other person as may be specified in the licence.
- (2) The holder of a licence granted under subregulation (1) is to keep a record in the form and manner approved by the Secretary showing –

- (a) the amount of narcotic substance acquired for use under the licence; and
- (b) the date on which, and the source from which, the narcotic substance was acquired; and
- (c) the amount of the narcotic substance and the purpose for which, and the date on which, the narcotic substance was used.

# 12. Licences to manufacture, &c., prohibited substances for scientific purposes

- (1) The Minister may, on the application of a person
  - (a) who is in charge of a laboratory that is an exempted public institution for the purpose of research or instruction; or
  - (b) who is an analyst appointed under section 19 of the Act –

### grant a licence authorising that person –

- (c) to manufacture, use or possess any prohibited substance specified in the licence for such purpose as is specified in the licence; or
- (d) to purchase that prohibited substance by an order written in ink from a licensed manufacturing chemist, a licensed wholesale chemist or such other person as may be specified in the licence.

- (1A) The Minister may, on the application of a person who is in charge of a laboratory that is not an exempted public institution, grant a licence authorising that person
  - (a) to manufacture, use or possess any prohibited substance specified in the licence for such purpose as is specified in the licence; or
  - (b) to purchase that prohibited substance by an order written in ink from a licensed manufacturing chemist, a licensed wholesale chemist or such other person as may be specified in the licence.
  - (2) The holder of a licence granted under subregulation (1) or (1A) is to maintain a record in the form and manner approved by the Secretary showing
    - (a) the amount of prohibited substance acquired for use under the licence; and
    - (b) the date on which, and the source from which, the prohibited substance was acquired; and
    - (c) the amount of the prohibited substance and the purpose for which, and the date on which, the prohibited substance was used or destroyed.
  - (3) The holder of a licence granted under subregulation (1) or (1A) must keep the record for at least 2 years.

Penalty: Fine not exceeding 10 penalty units.

(4) In this regulation –

exempted public institution has the same meaning as in section 55 of the Act.

#### 13. Fees

The annual fees specified in Schedule 7 are prescribed as the annual fees that are payable in respect of the several matters to which they respectively relate.

#### Division 2 – Possession of narcotic substances

# 14. Possession of narcotic substances for purposes of profession, &c.

In addition to the persons authorised by section 48 of the Act to possess narcotic substances, a person who is –

- (a) an authorised officer of a medical institution; or
- (b) a registered nurse in charge of a ward in a medical institution; or
- (c) an authorised nurse; or
- (d) an ambulance officer, paramedic or interstate ambulance officer –

may possess and use any narcotic substances for the purposes of his or her profession or employment.

#### Division 3 – Supply of narcotic substances

# 15. Inquiries, &c., before supplying narcotic substance to patient

- (1) A medical practitioner, dentist, authorised nurse practitioner, authorised health professional or authorised nurse must not supply, or write or issue a prescription for the supply of, a narcotic substance to a person unless the medical practitioner, dentist, authorised nurse practitioner, authorised health professional or authorised nurse has taken such steps as are reasonably open to him or her to ascertain
  - (a) the nature and amount of any narcotic substances supplied to that person within the previous 2 months; and
  - (b) the circumstances in which those narcotic substances were so supplied.

Penalty: Fine not exceeding 10 penalty units.

(2) A person who obtains from, or as a result of a prescription written or issued by, a medical authorised practitioner, dentist. health professional or authorised nurse practitioner a narcotic substance by failing, before or at the material time, to notify the medical practitioner, professional dentist. authorised health authorised nurse practitioner of the name and the place of practice of a medical practitioner, authorised health professional dentist. authorised nurse practitioner by whom, within a period of 2 months before the material time, a narcotic substance was supplied to the person, or a prescription for a narcotic substance was written or issued in respect of the person, is guilty of an offence.

Penalty: Fine not exceeding 10 penalty units.

Subregulations (1) and (2) do not apply to the (3) supply of a narcotic substance to a medical authorised practitioner, dentist. nurse practitioner, authorised health professional, licensed wholesale chemist, licensed manufacturing chemist or pharmacist, otherwise than for the purpose of its administration to the person to whom it is supplied.

#### (4) In this regulation –

*material time*, when used in relation to the obtaining of –

- (a) a narcotic substance from a medical practitioner, veterinary surgeon, dentist, authorised nurse practitioner, authorised health professional or authorised nurse, means the time at which that substance was obtained; or
- (b) a narcotic substance as a result of a prescription written or issued by a medical practitioner, dentist, authorised health professional or authorised nurse practitioner, means the time at which that prescription was written or issued; or

(c) a prescription for a narcotic substance from medical a practitioner, veterinary surgeon, dentist. authorised health professional or authorised nurse practitioner, means the time at which the prescription was obtained.

#### 16. Supply of narcotic substances

(1) A person must not supply a narcotic substance to a person who is not authorised by the Act or these regulations to have possession of that narcotic substance.

Penalty: Fine not exceeding 10 penalty units.

otherwise provided (2) Except as in regulations, a pharmacist must not supply a narcotic substance to a person who is not a medical practitioner, veterinary surgeon, dentist, authorised nurse practitioner, authorised health professional, licensed manufacturing chemist, licensed wholesale chemist or pharmacist, except a prescription issued by a medical practitioner, veterinary surgeon, dentist. authorised health professional or authorised nurse practitioner.

Penalty: Fine not exceeding 10 penalty units

(3) Except as otherwise provided in these regulations, a licensed manufacturing chemist or licensed wholesale chemist must not supply, or cause or permit to be supplied, a narcotic

substance to a person who is not a medical practitioner, veterinary surgeon, dentist, authorised nurse practitioner, authorised health professional or pharmacist.

Penalty: Fine not exceeding 10 penalty units.

(4) A medical practitioner, dentist, authorised nurse practitioner, authorised health professional or authorised nurse must not supply a narcotic substance to a person except for the purpose of its administration to a patient.

Penalty: Fine not exceeding 10 penalty units.

(5) A veterinary surgeon must not supply a narcotic substance to a person except for the purpose of its administration to an animal.

Penalty: Fine not exceeding 10 penalty units.

- (6) Nothing in subregulation (4) or (5) prohibits a medical practitioner, veterinary surgeon, dentist, authorised nurse practitioner, authorised health professional or authorised nurse from supplying a narcotic substance to a medical practitioner, veterinary surgeon, dentist, authorised nurse practitioner, authorised health professional, licensed wholesale chemist, licensed manufacturing chemist or pharmacist.
- (7) Where a person supplies a narcotic substance on a written order, the person must
  - (a) write clearly in ink on the order the word "Cancelled"; and

(b) retain that order in a file kept for the purpose for a period of 2 years from the date on which the narcotic substance was supplied.

Penalty: Fine not exceeding 10 penalty units.

- (8) This regulation does not apply to a narcotic substance that is kept or used in a prescribed institution, within the meaning of section 48 of the Act, for the purposes of that institution or to a narcotic substance which is kept or used under a licence granted under regulation 11.
- (9) Nothing in this regulation prohibits the administration to a person, in the case of an emergency, of a narcotic substance kept in any aircraft, ambulance or vessel where
  - (a) the services of a medical practitioner are not readily available; or
  - (b) it is not practicable to obtain the narcotic substance from any other source.
- (10) Nothing in this regulation prohibits a pharmacist, licensed wholesale chemist or licensed manufacturing chemist from supplying any narcotic substance to
  - (a) an authorised officer in a medical institution for the use of the narcotic substance for the purpose of that institution; or
  - (b) a person holding a licence under regulation 11; or

- (c) an authorised nurse; or
- (d) a person holding the Secretary's written authority for use in respect of ambulance services; or
- (e) an authorised person; or
- (f) the master of a vessel for the purpose of providing medical treatment to passengers or crew of that vessel.
- (11) Nothing in this regulation prohibits a pharmacist, licensed wholesale chemist or licensed manufacturing chemist from supplying a midwifery narcotic substance to an endorsed midwife.

#### 17. Conveyance of narcotic substances

A person may possess a narcotic substance for the purpose of conveying it to any person or place if –

- (a) the narcotic substance is contained in a sealed package or container; and
- (b) the person is acting
  - (i) in the course of the person's business or employment to carry, convey or deliver articles or containers of a similar nature; or
  - (ii) under the directions of a person authorised by the Act to have

possession of that narcotic substance.

#### Division 4 – Records and returns as to narcotic substances

# 18. Narcotic substances register to be kept by certain persons

- (1) The following people must keep a narcotic substances register in accordance with this regulation:
  - (a) a medical practitioner;
  - (b) a veterinary surgeon;
  - (c) a dentist;
  - (d) a pharmacist;
  - (e) a licensed manufacturing chemist;
  - (f) a licensed wholesale chemist;
  - (g) an authorised health professional;
  - (h) an authorised officer:
  - (i) an authorised nurse practitioner;
  - (i) an authorised nurse;
  - (k) an endorsed midwife.

Penalty: Fine not exceeding 10 penalty units.

(2) A separate narcotic substances register is to be kept in respect of each type or kind of narcotic

- substance or any preparation of a narcotic substance.
- (3) A pharmacist must keep a separate narcotic substances register in respect of each of the premises in which he or she carries on business as a pharmacist.
- (4) Where a medical practitioner, veterinary surgeon, dentist, authorised health professional or authorised nurse practitioner carries on practice at 2 or more premises, he or she must keep a separate narcotic substances register in respect of each of those premises.
- (5) A narcotic substances register is to be
  - (a) in a form approved by the Secretary; and
  - (b) kept in such manner as the Secretary may direct.
- (6) Each entry, marking, number or note made in a narcotic substances register is to be made in ink.
- (7) No alteration, obliteration or cancellation may be made in any narcotic substances register, but any mistake in any entry in the register may be corrected by
  - (a) placing a line through the mistake; and
  - (b) including a substitution below the mistake and an explanatory note in the margin; and
  - (c) initialling and dating the correction.

(8) A person must not make any entry in a narcotic substances register if the person knows the entry to be false or misleading.

- (9) Each entry in a narcotic substances register is to be made as soon as practicable after the occurrence of the event to which it relates and, in any event, not later than 48 hours after the occurrence of that event.
- (10) Notwithstanding anything in this regulation, where a medical practitioner, other than a dispensing medical practitioner, who supplies a narcotic substance to a patient, keeps a day book, it is sufficient compliance with the provisions of this regulation if an entry containing all particulars in respect of the supply of that narcotic substance to the patient, which apart from this subregulation would be required to be made in the narcotic substances register, were made in the day book.
- (11) Where the Secretary requests by a notice in writing any person required by these regulations to keep a narcotic substances register to furnish to the Secretary any information relating to the keeping of the register, that person must as soon as practicable comply with the request.
- (12) Nothing in these regulations requires a person who is required to keep a narcotic substances register to make any entry in respect of a narcotic substance supplied to the person by a medical practitioner, veterinary surgeon, dentist,

authorised nurse practitioner, authorised health professional or authorised nurse if the narcotic substance is for the person's personal use.

#### 19. Retaining of records

(1) A person licensed or authorised under these regulations to manufacture, sell or supply any narcotic substance must keep every record, prescription, invoice and other document relating to any transaction involving any narcotic substance for not less than 2 years from the latest date on which such record, prescription, invoice, order or document was made or acted upon.

Penalty: Fine not exceeding 10 penalty units.

- (2) On demand by an inspector
  - (a) the holder of any licence to manufacture, sell or supply any narcotic substance; or
  - (b) any person authorised by regulation 14 to possess and use a narcotic substance –

must furnish particulars of the quantity of any narcotic substance obtained and the amount disposed of or on hand.

#### Division 5 – Prescriptions for narcotic substances

#### 20. Prescribing and supplying narcotic substances

(1) A person, other than a medical practitioner, veterinary surgeon, dentist, authorised health professional or authorised nurse practitioner, must not write or issue a prescription for a narcotic substance.

Penalty: Fine not exceeding 10 penalty units.

- (2) A medical practitioner, veterinary surgeon, authorised health professional or dentist, subject to this regulation, is authorised to write or issue a prescription for a narcotic substance.
- (3) An authorised nurse practitioner may write or issue a prescription for a narcotic substance in such circumstances, subject to such conditions and in relation to such substances or classes of substances as may be specified in an authorisation issued by the Secretary.
- (4) A person must not write or issue a prescription for the purpose of procuring a narcotic substance for administration to himself or herself.

Penalty: Fine not exceeding 10 penalty units.

(5) A person must not write or issue a prescription for a narcotic substance unless the prescription includes (otherwise than in handwriting) the name of the person writing or issuing the prescription and the address of the person's

place of residence or of the place at which the person carries on practice.

- (6) Subregulation (5) does not apply in the case of an emergency when the means of complying with that subregulation are not readily available to the person writing or issuing the prescription.
- (7) Subject to regulation 21, where a medical practitioner, veterinary surgeon, dentist, authorised health professional or authorised nurse practitioner writes or issues a prescription for a narcotic substance, he or she must comply with the following conditions:
  - (a) he or she is to include in the prescription
    - (i) the date on which it is written or issued; and
    - (ii) the name, including initials, date of birth and address, of the patient or, in the case of an animal, the name, date of birth and address of the owner; and
    - (iii) hand-written legibly in ink, the name of the narcotic substance, the dosage and quantity to be dispensed; and
    - (iv) subject to subregulation (10), the number of times that the dispensing of the prescription

may be repeated and the interval between each dispensing of the prescription; and

(v) adequate directions for use –

and sign the prescription with his or her usual signature;

- (b) he or she is not to include in that prescription more than one preparation which is or includes a narcotic substance;
- (c) he or she is not to include in that prescription a preparation other than the preparation which is or includes the narcotic substance;
- (d) if a medical practitioner, he or she is not to write or issue a prescription for the supply of a narcotic substance for any purpose other than in the course of medical treatment;
- (e) if a veterinary surgeon, he or she is not to write or issue a prescription for the supply of a narcotic substance for any purpose other than in the course of animal treatment and is to include in a prescription which he or she issues the words "For animal treatment only";
- (f) if a dentist, he or she is not to write or issue a prescription for the supply of a narcotic substance for any purpose other than in the course of dental treatment and is to include in a prescription which he or

- she issues the words "For dental treatment only";
- (g) if an authorised nurse practitioner, he or she is not to write or issue a prescription for the supply of a narcotic substance for any purpose other than in the course of nurse practitioner treatment;
- (h) if an authorised health professional, he or she is not to write or issue a prescription for the supply of a narcotic substance for any purpose other than in the lawful practice of his or her profession;
- (i) where the prescription contains unusual dose, the medical practitioner, veterinary surgeon, dentist, authorised health professional or authorised nurse practitioner by whom it is written or issued is to underline, or by some other means emphasise, that part of prescription and, except for a prescription issued in accordance with an approval under regulation 21, sign or initial that part in the margin.

- (8) A prescription is to be taken, for the purposes of these regulations, to have been issued in accordance with subregulation (7) if
  - (a) the patient is an admitted patient of a medical institution; and

- (b) the prescription is issued on a medication chart and the following fields have been completed legibly in ink by a medical practitioner, authorised nurse practitioner or authorised health professional:
  - (i) the name, form and strength of the narcotic substance;
  - (ii) the date of prescribing the narcotic substance;
  - (iii) the dose of the narcotic substance;
  - (iv) the frequency of administration of the narcotic substance;
  - (v) the route of administration of the narcotic substance:
  - (vi) the signature of the person prescribing the narcotic substance; and
- (c) the prescription does not include more than one preparation which is or includes a narcotic substance.
- (9) Notwithstanding subregulation (7)(a)(ii), a medical practitioner, veterinary surgeon, dentist, authorised health professional or authorised nurse practitioner may use a printed label in a prescription to identify the patient or owner of the animal, if that label is initialled by the medical practitioner, veterinary surgeon, dentist,

- authorised health professional or authorised nurse practitioner.
- (10) A dentist must not write or issue a prescription for a narcotic substance that may be dispensed on more than one occasion.
  - Penalty: Fine not exceeding 10 penalty units.
- (11) A person must not write or issue a prescription for a narcotic substance which, or any part of which, is in a code or cipher.
  - Penalty: Fine not exceeding 10 penalty units.
- (12) Subject to subregulation (13), a veterinary surgeon must not prescribe or supply any of the narcotic substances specified in regulation 24 otherwise than in accordance with an authorisation under subregulation (14).
  - Penalty: Fine not exceeding 10 penalty units.
- (13) A veterinary surgeon may administer fentanyl, ketamine or methadone to an animal in the course of animal treatment.
- (14) The Secretary may, either generally or in a particular case, authorise a veterinary surgeon to prescribe or supply methylphenidate for veterinary purposes.
- (15) An authorisation under subregulation (14)
  - (a) is to be in writing signed by the Secretary; and

- (b) in the case of a general authorisation, is to require that, within 24 hours of each occasion on which the veterinary surgeon prescribes or supplies methylphenidate, the veterinary surgeon send to the Secretary notice in writing specifying
  - (i) the name and address of the owner of the animal for the treatment of which the prescription was given or the methylphenidate was supplied; and
  - (ii) the amount of methylphenidate prescribed or supplied; and
  - (iii) the date of the prescription or supply; and
- (c) may specify such other conditions to which it is subject as the Secretary thinks fit; and
- (d) may, at any time, be revoked or amended by the Secretary by notice in writing given to the veterinary surgeon.
- (16) A dentist must not prescribe for, or supply to, a person any of the narcotic substances specified in regulation 24.

#### 21. Electronic prescriptions for narcotic substances

- (1) Where a medical practitioner, veterinary surgeon, dentist, authorised health professional or authorised nurse practitioner is authorised to issue a prescription for a narcotic substance, that prescription may be issued electronically if the Secretary so approves.
- (2) For the purpose of subregulation (1), issuing a prescription electronically includes issuing the prescription by transmitting data electronically without producing a printed copy of that data.
- (3) An approval under subregulation (1)
  - (a) is to be in writing signed by the Secretary; and
  - (b) may be of general or specific application; and
  - (c) may be made subject to such conditions as the Secretary thinks fit; and
  - (d) may be amended or revoked by the Secretary by notice in writing.
- (4) The conditions specified in regulation 20(7), with the exception of the condition that a prescription be handwritten in ink, apply to the issuing of a prescription electronically in accordance with an approval under subregulation (1).
- (5) For the purposes of regulation 20(7)(a) as it applies to the issuing of a prescription in

accordance with an approval under subregulation (1), a signature includes an electronic signature.

## 22. Record of prescribing and supplying narcotic substances

- (1) practicable after medical As soon as dentist, authorised nurse practitioner, practitioner, authorised health professional or veterinary surgeon issues a prescription for, or supplies, a narcotic substance, he or she must make a record, in a form approved by the Secretary, setting out –
  - (a) the name, date of birth and address of the person for the treatment of whom, or of the owner of the animal for the treatment of which, the narcotic substance was prescribed or supplied; and
  - (b) the date on which the prescription was issued or the narcotic substance was supplied, as the case requires; and
  - (c) particulars of the narcotic substance sufficient to identify it and to indicate in what quantity and strength it was prescribed or supplied; and
  - (d) particulars of the directions set out in the prescription, or provided with the narcotic substance, for the use of the narcotic substance; and

(e) where the record relates to the issue of a prescription, particulars of any provision made in the prescription in respect of the number of occasions on which, and the minimum intervals at which, the dispensing of the prescription was authorised to be repeated.

Penalty: Fine not exceeding 10 penalty units.

(2) A medical practitioner, dentist, authorised nurse practitioner, authorised health professional or veterinary surgeon must retain a record made under subregulation (1) for not less than 2 years.

Penalty: Fine not exceeding 10 penalty units.

### 23. Emergency prescribing and dispensing of narcotic substances

- (1) Notwithstanding regulation 16(2), a pharmacist may supply a narcotic substance on the instruction of a medical practitioner, veterinary surgeon, dentist, authorised health professional or authorised nurse practitioner if, because of the urgent circumstances in which the substance is required, it is impracticable, before the substance is required to be supplied, to
  - (a) issue a prescription for the substance; and
  - (b) cause the prescription to be delivered to the pharmacist.

- (2) A medical practitioner, veterinary surgeon, dentist, authorised health professional or authorised nurse practitioner who issues an instruction under subregulation (1) to a pharmacist must send to that pharmacist, within 5 days of issuing the instruction, a prescription that
  - (a) complies with regulation 20(7); and
  - (b) clearly states that it is in confirmation of the instruction to that pharmacist to supply the narcotic substance without a prescription.

# 24. Prescription for certain narcotic substances to be issued only on authority of Secretary

A medical practitioner must not, without the authority of the Secretary, issue a prescription for, or supply to a patient, the following narcotic substances, namely:

- (a) amphetamine;
- (b) cannabis;
- (c) dexamphetamine;
- (d) dextromoramide;
- (da) esketamine;
  - (e) fentanyl, except in the case of a patient with cancer;

- (f) hydromorphone;
- (g) ketamine;
- (h) lisdexamfetamine;
- (i) methadone;
- (j) methylamphetamine;
- (k) methylphenidate;
- (1) nabiximols;
- (m) pethidine;
- (n) phenmetrazine;
- (o) tetrahydrocannabinol.

# 25. Supply of certain narcotic substances without prior authority of Secretary

- (1) Notwithstanding the provisions of regulation 24, the Secretary may issue a general authorisation to a medical practitioner to supply to a patient a narcotic substance referred to in regulation 24 without seeking the prior approval of the Secretary.
- (2) A general authorisation under this regulation is to
  - (a) be in writing and be signed by the Secretary; and

- (b) state the purposes for which the narcotic substance may be used; and
- (c) require that, within 7 days of a narcotic substance referred to in regulation 24 being supplied to a patient, the medical practitioner advise the Secretary in writing of
  - (i) the name and address of the patient supplied; and
  - (ii) the name and amount of the narcotic substance supplied; and
  - (iii) the date of the supply.
- (3) The Secretary may at any time in writing revoke or amend a general authorisation issued under this regulation.

## 26. Minister's authorisation for possession and supply of narcotic substance

The Minister may make an authorisation under section 25A of the Act in respect of a narcotic substance, or a class of narcotic substances, in the following circumstances:

- (a) where the registered nurse in respect of whom the authorisation is made is employed in a palliative care service approved by the Secretary;
- (ab) where the registered nurse –

- (i) has, within the previous 5 years, completed approved voluntary assisted dying training within the meaning of the *End-of-Life Choices* (Voluntary Assisted Dying) Act 2021; and
- (ii) has at least 5 years' experience as a registered nurse;
- (b) where the registered nurse or midwife is employed in a community health centre approved by the Secretary at which it is impractical for a medical practitioner or an authorised nurse practitioner to attend and the nurse or midwife is acting in accordance with the instructions of a medical practitioner or an authorised nurse practitioner;
- (c) where the registered nurse or midwife is employed in a medical institution approved by the Secretary at which it is impractical for medical practitioners or authorised nurse practitioners to attend after hours and the nurse or midwife is acting in accordance with the instructions of a medical practitioner or an authorised nurse practitioner;
- (d) where the registered nurse or midwife is in charge of a day-treatment centre approved by the Secretary and is administering or supplying a narcotic substance in respect of a patient in the centre in accordance with the instructions

of a medical practitioner or an authorised nurse practitioner;

- (e) where the registered nurse or midwife is
  - (i) employed in a correctional health facility, or a children and youth services facility, at which it is impractical for a medical practitioner or an authorised nurse practitioner to attend; and
  - (ii) acting in accordance with the instructions of a medical practitioner or an authorised nurse practitioner.

#### Division 6 – Dispensing of narcotic substances

#### 27. Dispensing of narcotic substances (S8)

(1) A person must not dispense a narcotic substance except under regulation 23 or in accordance with a prescription written and issued in accordance with regulation 20.

- (2) If a prescription for a narcotic substance directs that the substance be dispensed more than once
  - (a) the person responsible for dispensing the substance is to retain the prescription at the place at which the substance is dispensed; and

- (b) any subsequent dispensing of the substance is to be from the same place as the original dispensing.
- (3) Subregulation (2) does not apply if the person responsible for dispensing the substance securely transfers the prescription to another pharmacy by mail or courier.
- (4) Where a prescription for a narcotic substance directs that substance to be dispensed more than once, but does not specify the minimum intervals at which that prescription may be dispensed
  - (a) a person may dispense that prescription if
    - (i) the prescription conforms in all other respects with regulation 20(7); and
    - (ii) that person ascertains, in accordance with subregulation (5), the earliest date on which the dispensing of the prescription may be repeated; and
    - (iii) on dispensing the prescription that person clearly and indelibly marks on it, over his or her signature and the date, a note specifying both the date so ascertained and how it was ascertained; and
  - (b) a person who is unable to ascertain, in accordance with subregulation (5), the

earliest date on which the dispensing of the prescription may be repeated may dispense that prescription not more than once if –

- (i) the prescription conforms in all other respects with regulation 20(7); and
- (ii) on dispensing the prescription that person clearly and indelibly marks the word "cancelled" on the prescription.
- (5) The date referred to in subregulation (4)(a)(ii) is to be ascertained by reference to either, or both, of the following:
  - (a) any specific directions incorporating a dosage rate that are included in the prescription for the use of that narcotic substance by the patient;
  - (b) information obtained directly from the prescriber as to the minimum intervals at which that narcotic substance should be dispensed to the patient.
- (6) If the date referred to in subregulation (4)(a)(ii) is ascertained by reference only to the information referred to in paragraph (a) of subregulation (5), that date is to be a date not earlier than 4 days before the day on which the quantity of the narcotic substance being dispensed would be exhausted if it is used strictly in accordance with the directions referred to in that paragraph.

- (7) A person must not dispense a prescription for a narcotic substance unless
  - (a) the person is a medical practitioner or pharmacist; or
  - (b) the person dispenses the prescription under the supervision of a medical practitioner or pharmacist.

(8) A person must not cause or permit a person to dispense a prescription contrary to subregulation (1) or (7).

- (9) In a proceeding for an offence committed or alleged to have been committed under subregulation (1), it is a defence to show that the defendant believed, on reasonable grounds, that the prescription was written and issued in accordance with regulation 20.
- (10) Nothing in subregulation (7) prevents the dispensing of a prescription for a narcotic substance by or under the supervision of a veterinary surgeon, if the narcotic substance is intended for administration to an animal.
- (11) A person must not dispense, or cause or allow to be dispensed, a prescription for a narcotic substance if the person knows, or has reason to believe, or if it appears from the markings made on the prescription, that the prescription has already been dispensed, unless the prescription

has been issued by a medical practitioner, authorised health professional or authorised nurse practitioner who has indicated on the prescription in accordance with regulation 20 that the prescription may be dispensed more times than once.

Penalty: Fine not exceeding 10 penalty units.

(12) Without prejudice to the foregoing provisions of this regulation, a person must not dispense, or cause or allow to be dispensed, a prescription for a narcotic substance on which it is indicated that that prescription may be dispensed more times than once, if the person knows, or has reason to believe, or if it appears from the markings on the prescription, that the prescription has already been dispensed the number of times indicated on the prescription.

- (13) The person by whom a narcotic substance is dispensed on a prescription and, if in so dispensing that narcotic substance that person is acting in the employment of some other person, that other person must ensure that, before the narcotic substance so dispensed is supplied to any person, there is clearly marked in ink on the prescription
  - (a) the date on which it is dispensed; and
  - (b) the signature of the medical practitioner, veterinary surgeon, dentist, authorised health professional or pharmacist by whom it is dispensed; and

- (c) the address of that person's residence or place of business, or the name and address of the residence or place of business of the person in whose employment that person was acting when that person dispensed the prescription; and
- (d) the word "cancelled", unless
  - (i) the medical practitioner, dentist, authorised nurse practitioner, authorised health professional or veterinary surgeon by whom the prescription was issued has indicated on the prescription in accordance with regulation 20(7)(a)(iv) that the prescription may be dispensed on more than one occasion; and
  - (ii) it appears from the prescription and the markings made on it that the prescription may be dispensed on a further occasion.

- (14) A person must not dispense a narcotic substance under a prescription which
  - (a) is illegible or defaced; or
  - (b) is marked "cancelled"; or
  - (c) appears to have been altered; or

(d) appears to be fraudulent in any respect or forged.

Penalty: Fine not exceeding 10 penalty units.

- (15) A pharmacist may write on a prescription for a narcotic substance the date of birth of the person for the treatment of whom the narcotic substance was prescribed.
- (16) A person to whom a prescription referred to in subregulation (14) is presented must
  - (a) retain the prescription notwithstanding that the prescription is not dispensed; and
  - (b) as soon as practicable, inform the Secretary or a police officer of the relevant circumstances and the person's reasons for not dispensing the prescription.

Penalty: Fine not exceeding 10 penalty units.

(17) A person must not dispense a narcotic substance under a prescription which is presented more than 6 months after the date on which the prescription was issued.

Penalty: Fine not exceeding 10 penalty units.

(18) A medical practitioner, veterinary surgeon, dentist, authorised health professional or pharmacist who, in the course of the practice or business carried on by him or her as such, dispenses, or causes or permits to be dispensed, a prescription that is required by this regulation to

be marked with the word "cancelled" must keep that prescription in a file kept for that purpose for 2 years from the date on which it is dispensed.

Penalty: Fine not exceeding 10 penalty units.

- (19) Where a prescription is dispensed by or under the supervision of a medical practitioner, veterinary surgeon, dentist or authorised health professional, he or she must mark, or cause to be marked, in ink on the package or container in which the narcotic substance is supplied
  - (a) a reference to the entry in the narcotic substances register, if an entry is made in the narcotic substances register; or
  - (b) a reference to the entry in the day book, if an entry is made in the day book –

in respect of the supply of that narcotic substance on that prescription.

Penalty: Fine not exceeding 10 penalty units.

(20) A pharmacist who, in the course of the business of a pharmacist carried on by the pharmacist, dispenses, or causes or permits to be dispensed, a prescription for a narcotic substance must mark, or cause to be marked, in ink on the label on the container of the narcotic substance the prescription reference number appearing in the approved recording system and such other particulars as are prescribed in regulation 114(2).

- (21) Where, under the requirements of any law of the Commonwealth or of any Department of the Commonwealth, a prescription for a narcotic substance is required to be issued in duplicate and one of the copies is delivered or sent to any authority or person in accordance with those requirements, this regulation applies only to the other of those copies, and that copy is taken to be a prescription for a narcotic substance for the purposes of this regulation.
- (22) A person must not dispense, or cause or permit to be dispensed, a repeat of a prescription for a narcotic substance at an interval of time less than that indicated on the prescription.

(23) For the purposes of subregulation (19) –

narcotic substances register means the narcotic substances register referred to in regulation 18.

(24) For the purposes of this regulation, 2 or more prescriptions issued to the same person in respect of the same narcotic substance are to be treated as a single prescription that directs that the substance may be dispensed more than once.

#### 28. Restriction on dispensing of narcotic substances

(1) A person who is unable to verify that a prescription for a narcotic substance is authentic must dispense no more of that substance than is sufficient for 2 days' treatment if it is used in

accordance with the instructions on the prescription.

Penalty: Fine not exceeding 10 penalty units.

- (2) For the purposes of subregulation (1), a person is to be taken to have authenticated a prescription if that person
  - (a) is familiar with the handwriting of the purported prescriber and is satisfied that the prescription is in that handwriting; or
  - (b) verifies with the purported prescriber that he or she wrote the prescription.

## Division 7 – Storage of narcotic substances and prohibited substances

# 29. Storage of narcotic substances and prohibited substances

- (1) A person who is authorised by the Act or these regulations to possess narcotic substances or prohibited substances for the purposes of the person's profession or employment
  - (a) must keep them stored apart from other goods in an enclosure that is constructed and secured in a manner approved by the Secretary; and
  - (b) when the narcotic substance or prohibited substance is not being used, must keep the enclosure securely locked and retain the key either on his or her person or in a

place not readily accessible to other persons.

(2) For the purposes of subregulation (1) –

goods does not include –

- (a) money or negotiable instruments; or
- (b) declared restricted substances stored in accordance with regulation 64; or
- (c) substances, or a package that contains substances, that are intended to be supplied under a VAD substance prescription, within the meaning of the *End-of-Life Choices* (Voluntary Assisted Dying) Act 2021.
- (3) Subregulation (1) does not apply to or in respect of an ambulance officer.
- (4) Notwithstanding subregulation (1), a medical practitioner, veterinary surgeon, dentist, endorsed midwife, authorised health professional or authorised nurse practitioner may, for emergency purposes, keep narcotic substances in a bag in a vehicle or room which is kept securely locked when the vehicle or room is not occupied by that medical practitioner, veterinary surgeon, dentist, endorsed midwife, authorised health professional or authorised nurse practitioner.

### Division 8 – Storage and supply of narcotic substances in medical institutions

### 30. Authorised officer to store, supply, &c., narcotic substances in medical institution

The authorised officer in a medical institution must –

- (a) receive all narcotic substances supplied to that institution for the purposes of that institution; and
- (b) store those narcotic substances in accordance with regulation 29; and
- (c) supply those narcotic substances in accordance with these regulations; and
- (d) keep a narcotic substances register in respect of those narcotic substances in accordance with regulation 18.

Penalty: Fine not exceeding 10 penalty units.

#### 31. Supply of narcotic substances in medical institution

- (1) If the authorised officer in a medical institution is a pharmacist, he or she must not supply a narcotic substance otherwise than for its administration
  - (a) on a prescription written in accordance with the provisions of regulation 20 or the written request of –

- (i) the registered nurse or midwife in charge of the ward in which the narcotic substance is to be used or stored; or
- (ii) an authorised nurse practitioner; or
- (iii) a medical practitioner; or
- (iv) an authorised health professional; or
- (v) a dentist; and
- (b) to a patient in that ward.

- (2) If the authorised officer in a medical institution is the medical officer in charge or registered nurse in charge of that institution, he or she must not supply a narcotic substance otherwise than for its administration
  - (a) on the written request of
    - (i) the registered nurse or midwife in charge of the ward in which the narcotic substance is to be used or stored; or
    - (ii) a dentist; or
    - (iii) an authorised nurse practitioner; or
    - (iv) a medical practitioner; or

- (v) an authorised health professional;
- (b) to a patient in that ward.

### 32. Receipt for supply of narcotic substance in medical institution

Where an authorised officer supplies a narcotic substance to any person in accordance with a written request under regulation 31, the authorised officer must obtain from that person a receipt for the substance at the time of supply.

Penalty: Fine not exceeding 10 penalty units.

### 33. Storage and control of narcotic substances in wards of medical institutions

- (1) The registered nurse or midwife in charge of a ward of a medical institution must
  - (a) keep the narcotic substances supplied to that ward stored apart from all other goods, other than declared restricted substances, in a separate cupboard or receptacle that is securely fixed to the premises; and
  - (b) keep that cupboard or receptacle securely locked at all times when the substances in it are not being used.

(2) The registered nurse or midwife in charge of a ward must keep, in accordance with this regulation, a narcotic substances register to be known as a "ward narcotic substances register" with pages numbered consecutively for each type or kind of preparation of narcotic substance supplied to the ward.

Penalty: Fine not exceeding 10 penalty units.

- (3) A ward narcotic substances register is to be
  - (a) kept in a form approved by the Secretary; and
  - (b) managed in accordance with procedures approved by the Secretary.
- (4) Every entry, marking, number or note made in or on a ward narcotic substances register is to be made in ink as soon as practicable after the occurrence of the event to which it relates but not later than 24 hours from the occurrence of that event.

# 34. Administration of narcotic substances (S8) in medical institutions

(1) Subject to subregulation (2) and regulation 126, a medical practitioner, dentist, authorised health professional or authorised nurse practitioner must not give instructions for a narcotic substance to be administered to a patient in a medical institution without completing and signing, in his or her own handwriting or in a

manner approved by the Secretary, an authorisation to do so.

- (2) Nothing in subregulation (1) prohibits a medical practitioner, dentist, authorised health professional or authorised nurse practitioner from
  - (a) giving verbal instructions for a narcotic substance to be administered to a patient in a medical institution in an emergency practitioner, the medical dentist, authorised health professional authorised practitioner nurse subsequently with complies subregulation (3); or
  - (b) including, in an authorisation under subregulation (1), a printed label identifying the patient if that label is initialled by the medical practitioner, dentist, authorised health professional or authorised nurse practitioner.
- (3) A medical practitioner, dentist, authorised health professional or authorised nurse practitioner who verbally authorises the emergency administration of a narcotic substance to a patient under subregulation (2)(a) must, within 24 hours after giving those instructions, sign an entry in the patient's medical history clearly indicating that the medical practitioner, dentist, authorised health professional or authorised nurse

practitioner authorised the administration of that substance.

- (4) If of the opinion that it is necessary for a patient's wellbeing, a registered nurse or midwife may continue to administer a narcotic substance to that patient in accordance with a verbal authorisation under subregulation (3) even though the medical practitioner, dentist, authorised health professional or authorised nurse practitioner has not signed an entry in accordance with that subregulation.
- (5) A person must not administer a narcotic substance to a patient in a medical institution except
  - (a) in a case to which subregulation (2)(a) or subregulation (4) applies; or
  - (b) as otherwise provided in the Act or these regulations; or
  - (c) on the written authorisation of a medical practitioner, dentist, authorised health professional or authorised nurse practitioner.

# Division 9 – Storage and use of narcotic substances in special cases

### 35. Minister may grant nurse's authority in certain circumstances

- (1) Where, on the application of a registered nurse, the Minister is satisfied that the nurse carries on his or her profession under such circumstances that the services of a medical practitioner are not readily available to give instructions for the administration of narcotic substances to the patients upon whom the nurse attends, the Minister may grant the nurse a nurse's authority.
- (2) A nurse's authority granted under subregulation (1)
  - (a) authorises its holder to have possession of such narcotic substances for the purpose for which the authority is issued and in such quantities as may be specified in the authority; and
  - (b) ceases to have effect when the person by whom it is held ceases to hold the appointment or employment specified in the authority.
- (3) On an order in writing signed by the holder of a nurse's authority granted under subregulation (1) and upon production by the holder of the authority, a pharmacist may supply the holder of the authority with such narcotic substances and in such quantities as may be specified in the authority.

(4) A person who has been granted a nurse's authority under this regulation must keep a narcotic substances register in accordance with regulation 18.

Penalty: Fine not exceeding 10 penalty units.

#### 36. Narcotic substances on vessels

- (1) The master of a vessel may have possession of such narcotic substances as may be necessary for the purpose of ensuring that the requirements of the law of the Commonwealth or of the *Marine* and Safety Authority Act 1997 are complied with in respect of the vessel, if those substances have been supplied to the master on an order in writing signed by the master.
- (2) Without prejudice to the operation of subregulation (1), a master of a vessel may keep on that vessel any narcotic substance that the Secretary may, in writing, allow to be kept on the vessel so long as
  - (a) the amount so kept does not exceed the amount of that substance that the Secretary has allowed to be so kept; and
  - (b) any requirements made by the Secretary in respect of the place or manner in which the substance is kept on that vessel, and in respect of the keeping of records of the acquisition, use or disposal of the substance, are complied with.

- (3) A chemist may supply a narcotic substance to the master of a vessel on an order in writing signed by the master, if the chemist is satisfied that the substance is required for the purpose referred to in subregulation (1) or that the keeping of that substance on the vessel is allowed under subregulation (2).
- (4) In this regulation –

*master* includes the person (not being a pilot or harbourmaster) for the time being in charge or having control of any vessel.

#### 37. Narcotic substances for first aid use

- (1) An authorised person must enter or cause to be entered in a register kept solely for that purpose a record of
  - (a) all supplies of any narcotic substances procured or which otherwise come into the possession of that person; and
  - (b) the quantity of the narcotic substance stored by that person together with the information as to the place in which the narcotic substance is so stored; and
  - (c) the date on which and the place in which the narcotic substance is used and the quantity of the narcotic substance that is used.

Penalty: Fine not exceeding 10 penalty units.

(2) Each entry made in the register is to –

- (a) indicate the amount of each narcotic substance to which the entry relates that is stored by an authorised person immediately after completion of the event to which the entry relates; and
- (b) be signed by the person by whom the entry is made.
- (3) An authorised person must, as soon as possible after a narcotic substance has been used, notify the Secretary of that use.

## Division 10 – Destruction, disposal and loss, &c., of narcotic substances

### 38. Destruction of narcotic substances prohibited

- (1) A person who is licensed or authorised to be in possession of a narcotic substance must not wilfully
  - (a) destroy that narcotic substance; or
  - (b) cause or permit that narcotic substance to be destroyed.

- (2) Subregulation (1) does not apply to the destruction of a narcotic substance
  - (a) by or under the personal supervision of an inspector under a direction of the Minister; or

- (b) in the possession of a person obtained pursuant to the prescription of a medical practitioner, veterinary surgeon, authorised health professional or dentist; or
- (c) by the person for the time being holding, or performing the duties of, the office of Chief Pharmacist in the Department in the course of the duties of that office; or
- (d) by the holder of an office of analyst under section 19 of the Act in the course of the duties of that office; or
- (e) by a person authorised in writing to do so by the Secretary; or
- (f) by any 2 health professionals working jointly to destroy the narcotic substance; or
- (g) by an enrolled nurse working jointly with a health professional to destroy the narcotic substance.
- (3) An authorisation given under subregulation (2)(e) is subject to any conditions specified in it.
- (4) A person who destroys, or works jointly with another person to destroy, a narcotic substance must complete a narcotic substances register in accordance with regulation 18 in respect of that substance.

## 39. Procedures in case of loss, &c., of narcotic substances

- (1) In this regulation
  - (a) a reference to the unintentional destruction of a narcotic substance includes a reference to the unintentional disposal of that substance; and
  - (b) a reference to a narcotic substance includes a reference to a narcotic substance in a parenteral solution.
- (2) If a narcotic substance is lost in a medical institution, clause 1 of Schedule 6 has effect.
- (3) If a narcotic substance is spilt, broken or unintentionally destroyed in a medical institution, clause 2 of Schedule 6 has effect.

#### Division 11 – General

#### 40. Miscellaneous duties of licence holder

- (1) The holder of a licence under this Part
  - (a) must not sell, keep or otherwise have possession of a narcotic substance except upon the premises specified in the licence; and
  - (b) must not transact any dealing in a narcotic substance except by himself or herself or by a competent or responsible person acting on his or her behalf; and

- (c) must not sell or supply a narcotic substance to any person who is not authorised under these regulations to purchase or receive the substance; and
- (d) must keep and store a narcotic substance in his or her possession in accordance with these regulations; and
- (e) must keep and maintain a narcotic substances register in accordance with these regulations.

(2) Notwithstanding subregulation (1)(a), the Minister may authorise, in writing, a holder of a licence to have possession of a narcotic substance for such purpose and for such period as may be specified in the authority.

# 41. Self-administration of narcotic substances prohibited

- (1) A person must not administer or cause to be administered to himself or herself by any means whatsoever a narcotic substance that is in the person's possession, unless the narcotic substance has been supplied to the person for that purpose
  - (a) by, or on a prescription issued by, a medical practitioner or authorised nurse practitioner; or
  - (b) by an authorised nurse; or

- (c) by a dentist; or
- (d) by an authorised health professional; or
- (e) by a person on the staff of a hospital in accordance with the instructions of a medical practitioner.

(2) Nothing in this regulation prohibits the administration to a person of a narcotic substance required to be kept in any aircraft or vessel in the case of an emergency where the services of a medical practitioner are not readily available.

## 42. Control of narcotic substances within Ambulance Service

- (1) Subject to subregulation (2), the Commissioner of Ambulance Services may issue directives to ambulance officers, paramedics or interstate ambulance officers in respect of the following matters:
  - (a) the procurement and distribution of narcotic substances for use by the Ambulance Service;
  - (b) the keeping of records and the furnishing of reports and returns in respect of narcotic substances;
  - (c) the procedures to be followed, and the precautions to be taken, in respect of –

- (i) the storage, handling and use of narcotic substances, whether in ambulance vehicles or elsewhere; and
- (ii) the loss, spillage, breakage or unintentional destruction of narcotic substances; and
- (iii) the disposal of unused or out-ofdate narcotic substances.
- (2) A directive issued under subregulation (1)
  - (a) is not to contain a provision that is inconsistent with, or contrary to, a provision of the Act or these regulations; and
  - (b) is of no effect until it has been approved by the Secretary.

#### PART 4 – POISONS AND RESTRICTED SUBSTANCES

Division 1 – Storage of poisons, &c.

### 43. Storage of poisons, &c.

(1) Where, at any premises, a person has possession, custody or control of, for sale or supply, a substance specified in Schedule 7 of the Poisons List, the person must keep the substance in a part of the premises that is partitioned off or otherwise separated from any part of the premises that is readily accessible to the public.

Penalty: Fine not exceeding 10 penalty units.

- (2) A chemist, medical practitioner, dentist, endorsed midwife, authorised nurse practitioner, veterinary surgeon, optometrist, podiatrist or authorised health professional who sells or supplies any substance specified in Schedule 3 or 4 to the Poisons List must keep it in either of the following so that the public does not have access to the substance:
  - (a) a storeroom;
  - (b) the dispensary.

- (3) If a person has possession, custody or control of, for sale or supply, a substance specified in Schedule 2 of the Poisons List
  - (a) at premises which are not a pharmacy, the person must keep the substance

- behind a serving counter or in such other manner as to ensure that it is not readily accessible to the public; or
- (b) at a pharmacy, the person must keep the substance as specified in paragraph (a) or on a horizontal shelf that is
  - (i) affixed to, or placed immediately against, an internal wall or partition separating the dispensary from the remainder of the premises; or
  - (ii) not more than 4 metres from, and in clear line of sight of, the dispensary; or
  - (iii) susceptible, in such other manner as may be approved by the Secretary, of close supervision from the dispensary.

(4) Where a person has possession, custody or control of, for sale or supply, a poison, the person must keep it separate and apart from other goods suitable for human or animal consumption in such a way that, if the container of the poison breaks or leaks, the poison will not intermix with or contaminate those goods.

Penalty: Fine not exceeding 10 penalty units.

(5) A person who has possession, custody or control, for sale or supply, of a substance

specified in Schedule 6 of the Poisons List must keep the substance in such a way as to prevent access by children.

Penalty: Fine not exceeding 10 penalty units.

# Division 2 – Advertising, prescribing, sale, supply and dispensing of restricted substances

### 44. Restriction on advertising of restricted substances

A person must not advertise a restricted substance except in publications that circulate generally only among persons lawfully engaged in medical, dental, nurse practitioner, veterinary, optometrical, podiatric, midwifery or pharmaceutical practice or in the manufacture or supply of restricted substances.

Penalty: Fine not exceeding 10 penalty units.

### 45. Prescriptions for restricted substances

(1) A person, other than a medical practitioner, dentist, endorsed midwife, authorised nurse practitioner, veterinary surgeon or authorised health professional must not issue a prescription for a restricted substance.

Penalty: Fine not exceeding 10 penalty units.

(2) A medical practitioner, dentist, authorised health professional or veterinary surgeon, subject to this regulation, is authorised to issue a prescription for any restricted substance.

- (3) An authorised health professional, subject to this regulation, is authorised to issue a prescription for a restricted substance if he or she is endorsed to prescribe that restricted substance by the relevant authorised body and is acting in accordance with that endorsement.
- (4) An authorised nurse practitioner may write or issue a prescription for a restricted substance in such circumstances, subject to such conditions and in relation to such substances or classes of substances as may be specified in an authorisation issued by the Secretary.
- (5) Subject to regulation 46, a medical practitioner, dentist, endorsed midwife, authorised nurse practitioner, veterinary surgeon or authorised health professional on issuing a prescription must comply with the following conditions:
  - (a) except in a case where the Secretary otherwise approves, he or she is to write the prescription legibly in ink and, in his or her own handwriting, is to include in the prescription
    - (i) the date on which it is written; and
    - (ii) the name and address of the patient or, in the case of an animal, the name and address of its owner; and
    - (iii) the date of birth of the patient; and

- (iv) the name and the quantity of the restricted substance to be dispensed; and
- (v) adequate directions for use; and
- (vi) the number of times (if any) the dispensing of the prescription may be repeated; and
- (vii) where the prescription is for a declared restricted substance and the dispensing of the prescription is authorised, by its terms, to be repeated, the minimum intervals at which it may be dispensed;
- (b) he or she must sign the prescription;
- (c) the prescription must include
  - (i) in print, the name and address of the medical practitioner, dentist, endorsed midwife, authorised nurse practitioner, veterinary surgeon or authorised health professional; or
  - (ii) where the patient is attending a public hospital, private hospital, correctional health facility, children and youth services facility or residential care facility, in print or block letters
    - (A) the name and address of the person writing or

issuing the prescription; and

- (B) the address of the hospital or facility;
- (d) the prescription must be issued
  - (i) by a medical practitioner for use in the course of medical treatment only; or
  - (ii) by a dentist for use in the course of dental treatment only and is to include the words "For dental treatment only"; or
  - (iii) by an endorsed midwife for use in the course of midwifery treatment only; or
  - (iv) by an authorised nurse practitioner for use in the course of nurse practitioner treatment only; or
  - (v) by a veterinary surgeon for use in the course of animal treatment only and is to include the words "For animal treatment only"; or
  - (vi) by an authorised health professional, for use in the course of the lawful practice of his or her profession;

(e) where the prescription contains an unusual dose, the medical practitioner, dentist, endorsed midwife, authorised nurse practitioner, veterinary surgeon or authorised health professional by whom it is issued must underline, or by some other means emphasise, that part of the prescription that refers to the unusual dose and, except for a prescription issued in accordance with an approval under regulation 46, initial that part in the margin.

- Notwithstanding subregulation (5)(a)(ii), (6) a medical practitioner, dentist, endorsed midwife, authorised nurse practitioner, veterinary surgeon or authorised health professional may use a printed label in a prescription to identify the patient or owner of the animal, if that label is initialled by the medical practitioner, dentist, endorsed midwife, authorised nurse practitioner, veterinary surgeon or authorised health professional.
- (7) A prescription is to be taken, for the purposes of these regulations, to have been issued in accordance with subregulation (5) if
  - (a) the prescription is issued in respect of a patient who is an admitted patient of a medical institution; and
  - (b) the prescription is issued on a medication chart and the following fields have been

completed legibly in ink by a medical practitioner, endorsed midwife, authorised nurse practitioner or authorised health professional:

- (i) the name, form and strength of the restricted substance;
- (ii) the date of prescribing the restricted substance;
- (iii) the dose of the restricted substance;
- (iv) the frequency of administration or a notation to the effect that the restricted substance is to be used as directed;
- (v) the route of administration of the restricted substance;
- (vi) the signature of the person prescribing the restricted substance.
- (8) A medical practitioner, endorsed midwife, authorised nurse practitioner or authorised health professional must not issue a prescription for a restricted substance in the form referred to in subregulation (7)(a) unless, at the time of issue of the prescription
  - (a) the patient to whom the prescription relates is a patient in the medical institution referred to in the prescription; and

(b) adequate directions, in writing, for the use of the restricted substance in relation to the patient have been, or are, given by the medical practitioner, endorsed midwife, authorised nurse practitioner or authorised health professional to a person having responsibility for the care of the patient in the medical institution.

Penalty: Fine not exceeding 10 penalty units.

### 46. Electronic prescriptions for restricted substances

- (1) Where a medical practitioner, dentist, endorsed midwife, authorised nurse practitioner, veterinary surgeon or authorised health professional is authorised to issue a prescription for a restricted substance, that prescription may be issued electronically if the Secretary so approves.
- (2) For the purpose of subregulation (1), issuing a prescription electronically includes issuing the prescription by transmitting data electronically without producing a printed copy of that data.
- (3) An approval under subregulation (1)
  - (a) is to be in writing signed by the Secretary; and
  - (b) may be of general or specific application; and
  - (c) may be made subject to such conditions as the Secretary thinks fit; and

- (d) may be amended or revoked by the Secretary by notice in writing.
- (4) The conditions specified in regulation 45(5) with the exception of the condition that a prescription be handwritten in ink, apply to the issuing of a prescription electronically in accordance with an approval under subregulation (1).
- (5) For the purposes of regulation 45(5)(b) as it applies to the issuing of a prescription in accordance with an approval under subregulation (1), sign includes sign electronically.

# 47. Emergency prescribing and dispensing of restricted substances

- Notwithstanding regulation 45(5), a pharmacist (1) may supply a restricted substance on the instruction of a medical practitioner, veterinary surgeon, dentist, endorsed midwife, authorised practitioner authorised nurse or professional if. because of the urgent circumstances in which the substance required, it is impracticable, before the substance is required to be supplied, to –
  - (a) issue a prescription for the substance; and
  - (b) cause the prescription to be delivered to the pharmacist.
- (2) A medical practitioner, veterinary surgeon, dentist, endorsed midwife, authorised nurse

practitioner or authorised health professional who issues an instruction under subregulation (1) must send to that pharmacist, within 5 days of issuing the instruction, a prescription that —

- (a) complies with regulation 45(5); and
- (b) clearly states that it is in confirmation of the instruction to that pharmacist to supply the restricted substance without a prescription.

Penalty: Fine not exceeding 10 penalty units.

# 48. Continued dispensing without prescription in specified circumstances

- (1) Notwithstanding regulation 45(5) and regulation 47, a pharmacist may supply up to, and including, the specified quantity of a restricted substance, other than a declared restricted substance, on the basis of a previous prescription if
  - (a) a valid prescription is unavailable; and
  - (b) the supply is in accordance with the conditions set out in subregulation (3).
- (2) Subregulation (1) does not apply where a prescriber, after considering the clinical safety of a person, specifies in writing on an individual prescription that continued dispensing on the basis of a previous prescription is not to occur.
- (3) For the purposes of subregulation (1), a pharmacist must not supply a restricted

substance to a person on the basis of a previous prescription unless –

- (a) the pharmacist is satisfied that
  - (i) the usual prescriber is unable to be contacted or is unable to provide an electronic prescription; and
  - (ii) the person has previously been supplied the restricted substance on the basis of a prescription from the usual prescriber; and
  - (iii) the person's therapy is stable; and
  - (iv) the person has been taking the restricted substance regularly for an uninterrupted period; and
  - (v) since the start of the period referred to in subparagraph (iv), the usual prescriber has assessed the person's condition and decided that there is a need for ongoing treatment with the restricted substance; and
  - (vi) the person had a valid prescription for the last supply of the restricted substance to the person before the requested supply; and
  - (vii) the person has not been supplied with the restricted substance via

continued dispensing without a prescription in the 12 months before the requested supply; and

- (b) the person, or an agent of the person (other than the pharmacist), signs a declaration acknowledging that the person is being supplied with the restricted substance without the presentation of a valid prescription.
- (4) A pharmacist who supplies a restricted substance to a person under subregulation (1) must
  - (a) record the information that the pharmacist used to support the pharmacist's decision to supply the restricted substance; and
  - (b) provide information to the usual prescriber about the supply to the person within 7 days of the supply occurring.

- (5) For the purposes of subregulation (4), the information must include a statement that
  - (a) the conditions specified in subregulation (3) have been satisfied; and
  - (b) the pharmacist is satisfied that the restricted substance was required to be supplied to the person to facilitate continuity of treatment.
- (6) For the purposes of this regulation –

- previous prescription, in respect of a restricted substance, means the most recent prescription for that substance that has been exhausted;
- specified quantity, in respect of a restricted substance, means the quantity of the substance that was supplied in accordance with the previous prescription;
- usual prescriber, in respect of a person being supplied with a restricted substance, means the prescriber who would ordinarily have prescribed the restricted substance for the person.

# 49. Records of prescribing of declared restricted substances

- (1) practicable after a medical As soon as dentist. endorsed midwife. practitioner, authorised nurse practitioner, authorised health professional or veterinary surgeon issues a prescription for a declared restricted substance, he or she must make a record of that prescription, in a form approved by Secretary, showing –
  - (a) the name and address of the person for the treatment of whom, or of the owner of the animal for the treatment of which, the substance was prescribed; and
  - (b) the date of issue of the prescription; and

- (c) particulars of the substance sufficient to identify it and to indicate in what quantity and strength it was prescribed; and
- (d) particulars of the directions set out in the prescription for the use of the substance; and
- (e) particulars of any provision made in the prescription in respect of the number of times, and the minimum intervals at which, the dispensing of the prescription was authorised to be repeated.

(2) A medical practitioner, dentist, endorsed midwife, authorised nurse practitioner, authorised health professional or veterinary surgeon must retain a record made under subregulation (1) for not less than 2 years.

Penalty: Fine not exceeding 10 penalty units.

## **50.** Sale or supply of restricted substances

- (1) Where any medical practitioner, dentist, endorsed midwife, authorised nurse practitioner, veterinary surgeon or authorised health professional sells or supplies a restricted substance otherwise than by way of wholesale dealing, the substance must be sold or supplied
  - (a) by the medical practitioner only for use in the course of medical treatment; or

- (b) by the dentist only for use in the course of dental treatment; or
- (c) by the endorsed midwife only for use in the course of midwifery treatment; or
- (d) by the authorised nurse practitioner only for use in the course of nurse practitioner treatment; or
- (e) by the veterinary surgeon only for use in the course of animal treatment; or
- (f) by the authorised health professional only for use in the course of the lawful practice of his or her profession.
- (2) Where any medical practitioner, dentist, endorsed midwife, authorised nurse practitioner, authorised veterinary surgeon or professional sells or supplies a restricted substance other than by way of wholesale dealing in a quantity exceeding that required for 3 days' treatment, he or she must comply with the following conditions:
  - (a) before the restricted substance is sold or supplied a record of the sale or supply of that substance is to be made showing
    - (i) the date on which it was supplied; and
    - (ii) the name and address of the person for whose treatment it was supplied or in the case of an

- animal the name and address of the owner; and
- (iii) the name and quantity of the restricted substance supplied;
- (b) the label on the container is to bear the particulars prescribed in regulation 114;
- (c) the record of the supply of the restricted substance is to be kept at the surgery or office of the person by whom that substance was supplied or sold, and is to be produced on demand to an inspector.

# 51. Dispensing prescriptions for restricted substances (S4)

(1) Subject to subregulations (2), (3) and (4) and to regulation 53, a person must not supply a restricted substance otherwise than on, and in accordance with, a prescription issued, or a direction given, in accordance with regulation 45.

Penalty: Fine not exceeding 10 penalty units.

A person may dispense not more than once a (2) prescription for a restricted substance that respects conforms in all other with regulation 45(5) but does not specify maximum number of times that the dispensing of the prescription may be repeated if, upon

dispensing the prescription, that person cancels it in accordance with subregulation (13).

(3) A person may only dispense a restricted substance that is not a declared restricted substance or a specified psychotropic substance in accordance with a medication chart, that is taken to be a prescription under regulation 45(7)(b) for the restricted substance, for up to 12 months from the date of the prescription.

#### (4) Where -

- the dispensing of a prescription for a (a) restricted substance declared is authorised, the terms of the by prescription, to be repeated but the prescription does not specify the intervals which minimum the at dispensing of the prescription may be repeated; and
- (b) the prescription conforms in all other respects with regulation 45(5) –

a person may dispense that prescription if –

- (c) the person
  - (i) ascertains, in accordance with subregulation (5), the earliest date on which the dispensing of the prescription may be repeated; and
  - (ii) upon dispensing the prescription, marks on it, over the person's

signature and the date, a note that specifies both the date so ascertained and how it was ascertained; or

- (d) upon dispensing the prescription, the person cancels it in accordance with subregulation (13).
- (5) The date referred to in subregulation (4)(c)(i) is to be ascertained by reference to either or both of the following:
  - (a) specific directions for the use by the patient of the declared restricted substance, being directions incorporating a dosage rate, that are included in the prescription;
  - (b) information obtained directly from the prescriber as to the minimum interval between occasions on which the declared restricted substance should be dispensed to the patient.
- (6) If the date referred to in subregulation (4)(c)(i) is ascertained by reference only to the information referred to in paragraph (a) of subregulation (5), that date is to be a date not earlier than 4 days before the day on which the quantity of the declared restricted substance being dispensed would be exhausted if used strictly in accordance with the directions referred to in that paragraph.
- (7) A person, other than a pharmacist or an assistant under the direct personal supervision of a

pharmacist, must not dispense a prescription for a restricted substance.

- (8) A pharmacist or an assistant under the direct personal supervision of a pharmacist, subject to this regulation, is authorised to dispense a prescription for a restricted substance.
- (9) A person must not dispense any prescription for a restricted substance or supply a restricted substance on or in accordance with any prescription unless the person complies with the following provisions:
  - (a) the dispensing of the prescription must not be repeated more than the maximum number of times indicated on it and, if an interval of times is specified, at a shorter interval than that specified, and on each occasion upon which it is dispensed there is to be stamped or marked in writing or clearly shown on the prescription
    - (i) the date upon which it is dispensed; and
    - (ii) the signature of the pharmacist by whom it is dispensed or by whom its dispensing is supervised; and
    - (iii) the address of the place at which it is dispensed;
  - (b) where the occasion of the dispensing of the prescription is, in accordance with the

terms of the prescription, the last occasion on which it may be dispensed, the person, upon dispensing it, must cancel it in accordance with subregulation (13);

- (c) before completion of the supply of the restricted substance, the person must make or cause to be made, in the approved recording system relating to the pharmacy at which that supply is effected, an entry that, subject to subregulation (10), sets out
  - (i) the date on which the restricted substance is dispensed; and
  - (ii) whether the authority for the dispensing by the person of the restricted substance is a prescription issued under regulation 45 or 46 or an instruction issued under regulation 47; and
  - (iii) the name of the person by whom that prescription or instruction was issued; and
  - (iv) the name and address of the person for the treatment of whom, or of the owner of the animal for the treatment of which, the restricted substance was dispensed; and

- (v) the material of the part prescription instruction, or including particulars of any specification in respect of the repeated dispensing the of prescription; and
- (vi) the text of any note marked, under subregulation (4)(c)(ii), on the prescription (if any) on the authority of which that person dispensed the restricted substance:
- (d) the label on the container of the restricted substance is to be marked with the prescription reference number appearing in the approved recording system and with such other particulars as are prescribed in regulation 114(2);
- (e) the approved recording system is to be kept at the place at which the restricted substance was dispensed and is produced on demand to an inspector.

- (10) Where the dispensing of a prescription is repeated at a pharmacy at which it was previously dispensed, the entry made under subregulation (9)(c) in relation to the repeat is to set out
  - (a) the date of the repeat; and

- (b) the name and address of the person for the treatment of whom, or of the owner of the animal for the treatment of which, the dispensing of the prescription was repeated; and
- (c) a note of the fact of the repeat by reference to the entry made under subregulation(8) (c) in relation to the first occasion of the dispensing of that prescription in that pharmacy.
- (11) As soon as possible after a prescription issued under regulation 47 is received at the pharmacy at which the restricted substance to which it relates was dispensed, a pharmacist engaged in the conduct of that pharmacy must
  - (a) clearly mark on the prescription a note setting out
    - (i) the date on which the restricted substance to which it relates was dispensed; and
    - (ii) the name of the pharmacist by whom, or under whose supervision, it was dispensed; and
    - (iii) the name and address of the pharmacy at which it was dispensed; and
    - (iv) the identifying mark relating to the approved recording system entry made in pursuance of subregulation (9)(c) in relation to

the dispensing of that restricted substance; and

(b) sign and date that note.

Penalty: Fine not exceeding 10 penalty units.

(12) Where the prescription is such that, if it were issued otherwise than under regulation 47, subregulation (2) or (4) of this regulation would apply in relation to it, the pharmacist must cancel it, or mark it, as required by whichever of those subregulations would so apply.

Penalty: Fine not exceeding 10 penalty units.

- (13) Subject to subregulations (14) and (15), where a person is required by any of the preceding provisions of this regulation to cancel a prescription
  - (a) the person must write, stamp or mark in ink in legible letters the word "Cancelled" across the prescription; and
  - (b) the person must retain the prescription, in a form that is retrievable within 48 hours, for a period of 2 years from the day on which the requirement to cancel the prescription arose.

Penalty: Fine not exceeding 10 penalty units.

(14) Where the original of a prescription that is prepared in duplicate is required, under a law of the Commonwealth, to be forwarded to a Department or authority of the Commonwealth –

- (a) it is sufficient compliance with the requirements of subregulation (4)(c)(ii), subregulation (9)(a), subregulation (11) or (13) if the duplicate of the prescription is dealt with in accordance with those requirements; and
- (b) a reference in the following provisions of this regulation to a prescription, unless the contrary intention appears, is to be taken to include a reference to such a duplicate.
- (15) Subregulation (13)(b) does not apply in relation to a prescription (other than a prescription that does not comply with regulation 20) that is written on the same piece of paper as another prescription that may lawfully subsequently be dispensed.
- (16) A person must not dispense a restricted substance on a prescription which
  - (a) is illegible or defaced; or
  - (b) is marked "cancelled"; or
  - (c) appears to have been altered; or
  - (d) appears to be fraudulent in any respect or forged.

(17) A person to whom a prescription of the kind referred to in subregulation (16) is presented must –

- (a) retain the prescription notwithstanding that it has not been dispensed; and
- (b) as soon as practicable inform the Secretary or a police officer of the relevant circumstances and the person's reasons for not dispensing the prescription.

- (18) A person must not dispense a prescription for a restricted substance or supply a restricted substance upon a prescription if the prescription is presented for dispensing
  - (a) in the case of a prescription for a restricted substance other than a declared restricted substance or a specified psychotropic substance, more than 12 months after the date on which the prescription was written; or
  - (b) in the case of a prescription for a declared restricted substance or a specified psychotropic substance, more than 6 months after the date on which the prescription was written.

Penalty: Fine not exceeding 10 penalty units.

(19) For the purposes of this regulation, 2 or more prescriptions issued to the same person in respect of the same declared restricted substance are to be treated as a single prescription that authorises the substance to be dispensed more than once.

### 52. Specified psychotropic substances

The restricted substances specified in Schedule 3 are specified psychotropic substances for the purposes of section 38(1)(b) of the Act.

# 53. Emergency supply of restricted substances other than specified psychotropic substances

The following conditions are prescribed, for the purposes of section 38(1)(b) of the Act, in relation to the sale or supply by a pharmacist, otherwise than on and in accordance with a prescription of a medical practitioner, dentist, endorsed midwife, authorised nurse practitioner, authorised health professional or veterinary surgeon, of a restricted substance other than a specified psychotropic substance:

- (a) the pharmacist must, before supplying the restricted substance, be satisfied, on reasonable grounds, that
  - (i) the person for the treatment of whom the supply of the restricted substance is sought ("the patient") is undergoing medical treatment which requires the use of that restricted substance; and
  - (ii) the continuation of that treatment is essential to the wellbeing of the patient; and
  - (iii) it is not practicable for the patient to obtain a prescription for that

restricted substance before the supply of it for his or her treatment will be necessary;

- (b) the quantity of the restricted substance supplied must not exceed
  - (i) the quantity necessary for 3 days' treatment of the patient; or
  - (ii) in the case of a restricted substance that is in the form of
    - (A) a cream or ointment supplied to the pharmacist in a form of packaging designed for supply intact to individual users; or
    - a liquid supplied to the (B) pharmacist in a form of packaging designed for supply intact to individual users, being a metereddose pressurised pack, a dropper applicator bottle or a form of packaging interference with the integrity which would be detrimental to the proper administration to patient of the restricted substance –

the minimum quantity that may be dispensed without interfering with the integrity of that packaging and is not less than the quantity referred to in subparagraph (i);

- (c) the container in which the restricted substance is supplied must be labelled in accordance with regulation 114(2) and, in addition, the principal label on that container must include
  - (i) the words "EMERGENCY SUPPLY"; and
  - (ii) the date of supply; and
  - (iii) the identifying mark relating to the entry made under paragraph (d) in relation to the supply of that restricted substance;
- (d) before completion of the supply of the restricted substance, the pharmacist must make, in the approved recording system relating to the pharmacy at which that supply is effected, an entry signed by that pharmacist that sets out
  - (i) the date on which the restricted substance is supplied; and
  - (ii) a note to the effect that the supply of the restricted substance was by way of emergency supply under this regulation, including the reasons for that emergency

supply and, to the best of the knowledge and belief of the of the pharmacist, the name medical practitioner, endorsed midwife. authorised health professional or authorised nurse practitioner by whom the restricted substance was last prescribed for the patient; and

- (iii) the name and address of the patient; and
- (iv) particulars of the restricted substance sufficient to identify it and to indicate in what quantity and strength it was supplied; and
- (v) the directions given for the use by the patient of the restricted substance.

53A. . . . . . . . .

#### 54. Supply of restricted substance in medical institution

(1) For the purposes of section 38(1)(b) of the Act, a pharmacist may sell or supply a restricted substance to a resident of, or a patient in, a medical institution, otherwise than in accordance with a prescription of a medical practitioner, dentist, authorised health professional, endorsed midwife or authorised nurse practitioner, if —

- (a) a valid prescription does not exist; and
- (b) the substance is included on the drug therapy chart of the resident or patient and the pharmacist has seen the chart or a copy of it; and
- (c) the pharmacist is satisfied that the sale or supply of the substance is necessary for the continued treatment of the resident or patient; and
- (d) the pharmacist makes a record in an approved recording system of
  - (i) of the medical the name practitioner, dentist, authorised professional, health endorsed authorised midwife or nurse practitioner responsible for preparing the drug therapy chart and the person to whom it is sold or supplied; and
  - (ii) the name and amount of the substance sold or supplied; and
  - (iii) the basis on which the substance is sold or supplied; and
- (e) the amount of the substance supplied does not exceed the smallest practicable amount and in any case does not exceed
  - (i) if the substance is included in the Schedule of Pharmaceutical

Benefits for Approved Pharmacists and Medical Practitioners published under Part VII of the *National Health Act* 1953 of the Commonwealth, the maximum quantity specified in that Schedule; or

- (ii) if the substance is not included in that Schedule, one month's supply.
- (2) Only one sale or supply of the substance may be made to the resident or patient under subregulation (1).
- (3) If a restricted substance is supplied under this regulation, the medical practitioner, authorised health professional, endorsed midwife or authorised nurse practitioner responsible for preparing the drug therapy chart must send to the pharmacist referred to in subregulation (1) supply, a prescription that
  - (a) complies with regulation 45(5); and
  - (b) clearly states that it is in authorisation of the supply, otherwise than in accordance with a prescription, by that pharmacist of the restricted substance.
- (4) This regulation does not apply in respect of a substance that has been dispensed in accordance with a medication chart that complies with regulation 45(7)(b).

#### 54A. Administration of certain vaccines

- (1) For the purposes of section 47A of the Act, a registered nurse, enrolled nurse, paramedic, midwife, pharmacist or provisionally registered pharmacist may administer, subject to the conditions specified in subregulation (2), a vaccine that is a restricted substance.
- (2) A person specified in subregulation (1) may only administer, under this regulation, a vaccine that is a restricted substance if
  - (a) the Director of Public Health has approved the administration of the vaccine under this regulation; and
  - (b) the person is
    - (i) a registered nurse, enrolled nurse, paramedic, midwife, pharmacist, or provisionally registered pharmacist, who has been approved by the Director of Public Health to administer the vaccine under this regulation; or
    - (ii) a member of a class of registered nurses, enrolled nurses, paramedics, midwives, pharmacists, or provisionally registered pharmacists, that has been approved by the Director of Public Health to administer the vaccine under this regulation; and

- (c) the vaccine is administered in accordance with a vaccination program approved by the Director of Public Health; and
- (d) the vaccine is administered under the supervision of
  - (i) if the person administering the vaccine is a registered nurse, enrolled nurse, paramedic, midwife, pharmacist or provisionally registered pharmacist, a person who
    - (A) is a registered nurse or midwife; and
    - (B) satisfies the requirements of regulation 82(1)(c); or
  - (ii) if the person administering the vaccine is a pharmacist or provisionally registered pharmacist, a pharmacist who satisfies the requirements of regulation 82(1)(d).

# 54B. Dental assistant may administer sodium fluoride varnish

(1) For the purposes of section 47A of the Act, a dental assistant may, subject to the conditions specified in subregulation (2), administer sodium fluoride varnish to a dental patient.

- (2) A dental assistant may only administer sodium fluoride varnish if the varnish is administered under the supervision of a dentist, dental therapist or oral health therapist.
- (3) In this regulation –

#### dental assistant means a person who –

- (a) has completed
  - (i) a Certificate IV in Dental Assisting (Oral Health Promotion); and
  - (ii) unit of learning HLTOHC011 (Apply Fluoride Varnish); or
- (b) has qualifications determined by the Secretary to be equivalent to such qualifications.

#### 55. Information about drugs

Subject to subregulation (2), a pharmacist, (1) medical practitioner, dentist, authorised health professional or authorised nurse practitioner must not supply to a person a substance listed in Schedule 4 unless, at the time that he or she supplies the substance, he or she also supplies to the person to whom the substance is supplied an information sheet, in the form required under regulation 9A of the Therapeutic Goods Regulations 1990 of the Commonwealth, concerning that substance.

- (2) An information sheet need not be supplied under subregulation (1) if
  - (a) the substance is supplied by a pharmacist and the prescription according to which it is dispensed bears an endorsement that it is not necessary for the pharmacist to supply the information sheet; or
  - (b) in a case where a medical practitioner, dentist, authorised health professional or authorised nurse practitioner supplies the substance without the intervention of a pharmacist, the medical practitioner, dentist, authorised health professional or authorised nurse practitioner is of the opinion that it is not in the patient's interests to supply the sheet.

# Division 3 – Advertising, sale, supply, dispensing and recording of potent substances

#### 56. Interpretation of Division

For the purposes of this Division –

child care service has the same meaning as in the Child Care Act 2001;

person-in-charge has the same meaning as in the Child Care Act 2001;

school means a school within the meaning of the Education Act 2016;

specified potent substance means a potent substance that is specified in Schedule 5.

#### 57. Advertising of potent substances

A person must not advertise a potent substance except –

- (a) in a publication circulating generally only among persons lawfully engaged in
  - (i) medical, dental, veterinary, nurse practitioner, optometrical, podiatric or pharmaceutical practice; or
  - (ii) the manufacture or supply of potent substances; or
- (b) in accordance with the Uniform Standard.

Penalty: Fine not exceeding 10 penalty units.

### 58. Supply of potent substances by pharmacists

(1) In this regulation –

school first aid kit means a first aid kit used for the purposes of a school or TasTAFE.

- (2) A pharmacist must not supply a potent substance unless
  - (a) the supply is made on the authority of a medical practitioner, veterinary surgeon, dentist, endorsed midwife, authorised health professional or authorised nurse

- practitioner, whether given in the form of a prescription or otherwise; or
- (b) the pharmacist, or a pharmacist or provisionally registered pharmacist employed by that pharmacist
  - (i) participates personally and directly in the supply of the substance; and
  - (ii) on consideration of the condition, disease or symptoms of the person for whom, or the animal for which, the substance is supplied (in this regulation referred to as "the patient") forms the opinion that the use of that substance in the treatment of the patient is justified; or
- (c) the supply is made for a school first aid kit in accordance with the written authority of the school principal or the TasTAFE CEO; or
- (d) the supply is made to a person or class of persons approved by the Secretary as having sufficient expertise to administer the substance.

Penalty: Fine not exceeding 10 penalty units.

(3) A pharmacist must not supply a substance listed in Schedule 3 to the Poisons List that is a specified potent substance, other than salbutamol (S3) supplied for a school first aid kit in

accordance with the written authority of the school principal or the TasTAFE CEO, unless its container is labelled in accordance with regulation 114(2).

Penalty: Fine not exceeding 10 penalty units.

(4) A pharmacist must not supply salbutamol (S3) for a school first aid kit otherwise than in accordance with subregulation (5)(b).

Penalty: Fine not exceeding 10 penalty units.

- (5) A pharmacist must not supply a substance listed in Schedule 3 to the Poisons List that is not a specified potent substance unless
  - (a) its container is labelled in accordance with regulation 114(2); or
  - (b) in addition to its container and any primary pack conforming to the requirements applicable under Part 6
    - (i) its container bears a label that identifies the pharmacy from which it was supplied; and
    - (ii) there are supplied with it directions for its use as specified in subregulation (6).

Penalty: Fine not exceeding 10 penalty units.

(6) The directions referred to in Subregulation (5)(b)(ii) for the use of a substance are to comprise either –

- (a) adequate written directions, on a label on its container, for its use specifically in the treatment of the patient; or
- (b) both of the following:
  - (i) written directions, on a label on its container, for its use generally;
  - (ii) an oral explanation of the specific application of those directions in relation to the treatment of the patient, being an explanation given by a pharmacist provisionally registered pharmacist to the patient or, where the potent substance is to be administered to the patient by another person, to that other person.
- (7) Notwithstanding this regulation, a pharmacist may supply the following substances to a person who may be required to administer those substances for the purposes specified:
  - (a) adrenaline (S3) for the treatment of anaphylaxis;
  - (ab) salbutamol (S3) for the treatment of acute bronchospasm;
    - (b) naloxone (S3) for the treatment of opioid toxicity.
- (8) Notwithstanding this regulation, a pharmacist may supply naloxone (S3) for the treatment of

#### Part 4 – Poisons and Restricted Substances

opioid toxicity to a certified person within the meaning of section 56A of the *Public Health Act* 1997.

#### 59. Administration of salbutamol (S3)

- (1) A person employed by or for the purposes of a child care service, school or TasTAFE may administer to a child salbutamol (S3) in accordance with its directions for use.
- (2) As soon as possible after a person administers salbutamol (S3) to a child, the person is to advise the person-in-charge, the school principal or the TasTAFE CEO of the following:
  - (a) the name of the person;
  - (b) the name of the child;
  - (c) the amount of salbutamol (S3) administered;
  - (d) the date on which the salbutamol (S3) was administered;
  - (e) any other relevant information.
- (3) The person-in-charge, the school principal and the TasTAFE CEO are responsible for the storage, and control of the use, of any salbutamol (S3) kept, respectively, by the child care service, the school or TasTAFE.
- (4) The following people may administer to another person salbutamol (S3) in accordance with its directions for use:

- (a) a St John Ambulance member;
- (b) the holder of a current relevant certificate issued on behalf of the Asthma Foundation of Victoria or St John Ambulance:
- (c) any other person whom the Secretary is satisfied has appropriate training or qualifications to administer salbutamol (S3).

#### 60. Administration of adrenaline (S3)

(1) In this regulation –

suitably qualified person means a person who has undertaken training in the administration of adrenaline as part of a course in first aid provided by a registered training organisation.

- (2) A suitably qualified person, employed by or for the purposes of a child care service, a school or TasTAFE may, in an emergency, administer to a child adrenaline in accordance with its directions for use.
- (3) As soon as possible after a person administers adrenaline to a child, the person is to advise the person-in-charge, the school principal or the TasTAFE CEO of the following:
  - (a) the name of the person who administered the adrenaline;

- (b) the name of the child to whom the adrenaline was administered;
- (c) the amount of adrenaline administered;
- (d) the date on which the adrenaline was administered;
- (e) any other relevant information.
- (4) The person-in-charge, the school principal and the TasTAFE CEO are responsible for the storage, and control of the use, of any adrenaline kept, respectively, by the child care service, school or TasTAFE.
- (5) A speech pathologist in the lawful practice of the profession of speech pathology may administer adrenaline (S3) if the speech pathologist can show, to the satisfaction of the Secretary, that the speech pathologist is competent in cardiopulmonary resuscitation, management of anaphylaxis and the use of an automated external defibrillator.

# 61. Obtaining potent substances through misrepresentation

A person must not make a representation, whether oral or in writing, which the person knows to be false or misleading, or engage in conduct which the person knows to be deceptive, for the purpose, whether achieved or not, of —

(a) obtaining the authority of a medical practitioner, dentist, endorsed midwife,

authorised nurse practitioner, authorised health professional or veterinary surgeon, whether in the form of a prescription or otherwise, for the supply of a potent substance; or

(b) inducing a medical practitioner, dentist, endorsed midwife, authorised nurse practitioner, authorised health professional, veterinary surgeon or pharmacist to supply a potent substance.

Penalty: Fine not exceeding 10 penalty units.

#### Division 3A – Advertising of narcotic substances

#### 61A. Restriction on advertising of narcotic substances

A person must not advertise a narcotic substance except in publications that circulate generally only among persons lawfully engaged in medical, dental, nurse practitioner, veterinary, optometrical, podiatric, midwifery or pharmaceutical practice or in the manufacture or supply of narcotic substances.

Penalty: Fine not exceeding 10 penalty units.

### Division 4 – Use, &c., of restricted substances in medical institutions

### 62. Authorised officer to store, &c., restricted substances

(1) In a medical institution the authorised officer must –

- (a) receive all restricted substances supplied to that institution for the purposes of that institution; and
- (b) store those restricted substances until their supply in accordance with subregulation (2); and
- (c) keep such records of those restricted substances as are required by these regulations.

Penalty: Fine not exceeding 10 penalty units.

- (2) A person other than the authorised officer must not supply restricted substances received and stored in accordance with subregulation (1), and the authorised officer must not supply a restricted substance, except
  - (a) on a prescription issued in accordance with regulation 45; or
  - (b) in the case of the supply of a restricted substance to a ward, on an order in writing of
    - (i) the registered nurse or midwife in charge of the ward in which the restricted substance is to be used or stored; or
    - (ii) a medical practitioner, dentist, authorised health practitioner or authorised nurse practitioner.

Penalty: Fine not exceeding 10 penalty units.

#### 63. Supply of restricted substances to patients

(1) Where any person authorised in accordance with the Act supplies a restricted substance to a patient in a medical institution, the person must do so in the original container in which the restricted substance was received from the manufacturer or distributor.

Penalty: Fine not exceeding 10 penalty units.

- (2) Subregulation (1) does not apply
  - (a) to the supply of an individual dose to a patient in that institution; or
  - (b) to the supply of a restricted substance packed and labelled under the direct personal supervision of a medical practitioner, pharmacist, dentist, endorsed midwife, authorised health professional or authorised nurse practitioner.

### 64. Storage of declared restricted substances in wards of medical institutions

The registered nurse or midwife in charge of a ward of a medical institution must –

(a) keep the declared restricted substances supplied to that ward stored apart from all other goods, other than narcotic substances, in a separate cupboard or receptacle that is securely fixed to the premises; and

(b) keep that cupboard or receptacle securely locked at all times when the substances in it are not being used.

Penalty: Fine not exceeding 10 penalty units.

### 65. Administration of restricted substances (S4) in medical institutions

(1) Subject to subregulation (2) and regulation 126, a medical practitioner, authorised health professional, dentist, endorsed midwife or authorised nurse practitioner must not give instructions for a restricted substance to be administered to a patient in a medical institution without completing and signing, in his or her own handwriting or in a manner approved by the Secretary, an authorisation to do so.

Penalty: Fine not exceeding 10 penalty units.

- (2) Nothing in subregulation (1) prohibits a medical practitioner, authorised health professional, dentist, endorsed midwife or authorised nurse practitioner from
  - (a) giving oral instructions for a restricted substance to be administered to a patient in a medical institution in an emergency if the medical practitioner, authorised health professional, dentist, endorsed midwife or authorised nurse practitioner subsequently complies with subregulation (3); or

- (b) including, in an authorisation under subregulation (1), a printed label identifying the patient if that label is initialled by the medical practitioner, authorised health professional, dentist, endorsed midwife or authorised nurse practitioner.
- (3) medical practitioner, authorised health professional, dentist, endorsed midwife or authorised nurse practitioner who orally authorises the emergency administration of a restricted substance patient to a subregulation (2)(a) must, within 24 hours after giving those instructions, sign an entry in the patient's medical history clearly indicating that the medical practitioner, authorised health professional, dentist, endorsed midwife authorised nurse practitioner authorised the administration of that substance.

Penalty: Fine not exceeding 10 penalty units.

- (4) If of the opinion that it is necessary for a patient's wellbeing, a registered nurse or midwife may continue to administer a restricted substance to that patient in accordance with a verbal authorisation under subregulation (3) even though the medical practitioner, authorised health professional, dentist, endorsed midwife or authorised nurse practitioner has not signed an entry in accordance with that subregulation.
- (5) A person must not administer a restricted substance to a patient in a medical institution except –

- (a) in a case to which subregulation (2)(a) or subregulation (4) applies; or
- (b) as otherwise provided in the Act or these regulations; or
- (c) on the written authorisation of a medical practitioner, authorised health professional, dentist, endorsed midwife or authorised nurse practitioner.

Penalty: Fine not exceeding 10 penalty units.

#### Division 5 – Administration of substances by nurses

#### 66. Enrolled nurse may administer certain substances

For the purposes of section 38(1)(i) and section 47(1)(e) of the Act, an enrolled nurse may administer a substance listed in Schedule 2, 3, 4 or 8 to the Poisons List if the enrolled nurse –

- (a) acts
  - (i) in accordance with the written authority of a medical practitioner, authorised health professional, dentist, endorsed midwife or authorised nurse practitioner; and
  - (ii) under the supervision of a medical practitioner, authorised health professional, dentist, authorised nurse practitioner or registered nurse or midwife; and

holds any qualifications that the Nursing (b) and Midwifery Board of Australia appropriate for determines are the administration of that substance.

#### **67.** Administration of restricted substances by registered nurses in certain circumstances

- A registered nurse may administer a restricted (1) substance to a person who is in a residential care service, within the meaning of regulation 133, if the registered nurse is acting under the instructions of a medical practitioner or a nurse practitioner.
- For the purposes of subregulation (1), a (2) registered nurse is acting under the instructions of a medical practitioner or a nurse practitioner if the registered nurse administers a restricted contained in substance that is a dose administration aid.
- A registered nurse may administer a restricted (3) substance to a person who is not in a medical institution or a residential care service if –
  - the registered nurse is acting under the (a) direct supervision, and in accordance with the instructions, of a medical practitioner or nurse practitioner; and
  - (b) the medical practitioner's or nurse practitioner's instructions are recorded on the person's medical record.

### 68. Minister's authorisation for possession and supply of restricted substance

The Minister may make an authorisation under section 25A of the Act in respect of a restricted substance, or a class of restricted substances, in the following circumstances:

- (a) where the registered nurse in respect of whom the authorisation is made is employed in a palliative care service approved by the Secretary;
- (ab) where the registered nurse
  - (iii) has, within the previous 5 years, completed approved voluntary assisted dying training within the meaning of the *End-of-Life Choices* (Voluntary Assisted Dying) Act 2021; and
  - (iv) has at least 5 years' experience as a registered nurse;
  - (b) where the registered nurse or midwife is employed in a community health centre approved by the Secretary at which it is impractical for a medical practitioner or an authorised nurse practitioner to attend and the nurse or midwife is acting in accordance with the instructions of a medical practitioner or an authorised nurse practitioner;
  - (c) where the registered nurse or midwife is employed in a medical institution

- approved by the Secretary at which it is impractical for medical practitioners or authorised nurse practitioners to attend after hours and the nurse or midwife is acting in accordance with the instructions of a medical practitioner or an authorised nurse practitioner;
- (d) where the registered nurse or midwife is in charge of a day-procedure centre, within the meaning of the *Health Service Establishments Act 2006*, approved by the Secretary and is administering or supplying a restricted substance in respect of a patient in the centre in accordance with the instructions of a medical practitioner or an authorised nurse practitioner;
- (da) where the registered nurse is employed in a community mental health service approved by the Secretary and the nurse is acting in accordance with the instructions of a medical practitioner or an authorised nurse practitioner;
  - (e) in the case of the possession or supply of lignocaine, where the registered nurse is employed by the Australian Red Cross Blood Service and is acting in the course of his or her professional practice;
  - (f) where the registered nurse or midwife is employed in an in-vitro fertilisation clinic approved by the Secretary and the nurse or midwife is acting in accordance

with the instructions of a medical practitioner or an authorised nurse practitioner;

- (g) where the registered nurse or midwife is
  - (i) employed in a correctional health facility, or a children and youth services facility, at which it is impractical for a medical practitioner or an authorised nurse practitioner to attend; and
  - (ii) acting in accordance with the instructions of a medical practitioner or an authorised nurse practitioner.

#### Division 5A – Non-application of section 59C

### 68A. Non-application of section 59C

In accordance with subsection (7) of section 59C of the Act, that section does not apply in respect of a prescriber or dispenser who is prescribing, dispensing, issuing or supplying a VAD substance in accordance with the *End-of-Life Choices (Voluntary Assisted Dying) Act 2021*.

# Division 6 – Possession and supply of nitrous oxide and methoxyflurane at relevant workplaces

#### 69. Interpretation of Division

In this Division –

first aid officer means a person who has a current certificate for the provision of first aid in a workplace granted by a registered training organisation;

#### mineral processing facility means –

- (a) a facility for the concentrating or processing of ores or minerals; or
- (b) operations for processing minerals at the site at which they are first obtained from the earth; or
- (c) leaching operations conducted on ores or minerals –

and includes any operations, for the management of residues and wastes, that are incidental to the operations of facilities, or the carrying out of operations, referred to in paragraph (a), (b) or (c);

#### relevant workplace means –

- (a) a mine within the meaning of section 5 of the Mines Work Health and Safety (Supplementary Requirements) Act 2012; or
- (b) a mineral processing facility.

#### 70. Possession and supply of nitrous oxide at workplace

A first aid officer who is engaged to provide first aid services at a relevant workplace and who has a current certificate in the use of nitrous oxide (S4) granted by a registered training organisation may –

- (a) possess nitrous oxide (S4); and
- (b) administer it, or supply it for selfadministration, to a person on the oral instruction of a medical practitioner; and
- (c) administer it, or supply it for selfadministration, to a person on the written instruction, other than on a standing order, of a medical practitioner; and
- (d) in an emergency, administer it, or supply it for self-administration, to a person without instruction from a medical practitioner.

# 71. Possession and supply of methoxyflurane at workplace

A first aid officer who is engaged to provide first aid services at a relevant workplace and who has a current certificate in the use of methoxyflurane granted by a registered training organisation may –

(a) possess methoxyflurane; and

- (b) administer it, or supply it for selfadministration, to a person on the oral instruction of a medical practitioner; and
- (c) administer it, or supply it for selfadministration, to a person on the written instruction, other than on a standing order, of a medical practitioner; and
- (d) in an emergency, administer it, or supply it for self-administration, to a person without instruction from a medical practitioner.

# 72. Records of obtaining, supply and administration to be kept

Where a substance is obtained, supplied or administered under this Division by a first aid officer, the first aid officer must make and keep a written record of that obtaining, supply or administration.

Penalty: Fine not exceeding 10 penalty units.

# Division 7 – Possession, &c., of nitrous oxide and methoxyflurane by relevant first-aiders

### 73. Interpretation of Division

In this Division –

*relevant first-aider* means a person who is –

(a) a St John Ambulance member, while he or she is acting in

- accordance with an agreement by St John Ambulance to provide its services at a particular event or location; or
- (b) a member of the Ben Lomond Ski Patrol, or the Mt Mawson Ski Patrol, while he or she is registered with, and acting as part of, that ski patrol; or
- (c) an employee of Medical Edge Australia (ABN 98 147 076 819), while he or she is acting in accordance with an agreement with Medical Edge Australia to provide its first aid services at a particular event or location; or
- (d) an employee of Acute Health Pty Ltd (ABN 68 151 470 049), while he or she is acting in accordance with an agreement with Acute Health Pty Ltd to provide its first aid services at a particular event or location; or
- (e) an employee of Ambulance Private Pty Ltd (ABN 78 083 065 605), while he or she is acting in accordance with an agreement with Ambulance Private Pty Ltd to provide its first aid services at a particular event or location; or

(f) an employee of Wilson Medic One (ABN 69 088 192 956), while he or she is acting in accordance with an agreement with Wilson Medic One to provide its first aid services at a particular event or location.

### 74. Possession, &c., of nitrous oxide by relevant first-aiders

A relevant first-aider who has a current certificate in the use of nitrous oxide (S4) granted by a registered training organisation may –

- (a) possess nitrous oxide (S4); and
- (b) administer it, or supply it for selfadministration, to a person, on the oral instruction of a medical practitioner; and
- (c) administer it, or supply it for selfadministration, to a person, on the written instruction, other than on a standing order, of a medical practitioner; and
- (d) in an emergency, administer it, or supply it for self-administration, to a person, without instruction from a medical practitioner.

### 75. Possession, &c., of methoxyflurane by relevant first-aiders

A relevant first-aider who has a current certificate in the use of methoxyflurane (S4) granted by a registered training organisation may –

- (a) possess methoxyflurane (S4); and
- (b) administer it, or supply it for selfadministration, to a person, on the oral instruction of a medical practitioner; and
- (c) administer it, or supply it for selfadministration, to a person, on the written instruction, other than on a standing order, of a medical practitioner; and
- (d) in an emergency, administer it, or supply it for self-administration, to a person, without instruction from a medical practitioner.

#### 76. Records of possession and supply to be kept

(1) If a substance comes into the possession of, or is supplied (including by being administered) under this Division by, a relevant first-aider, the relevant first-aider must make and keep a written record of that possession or supply.

Penalty: Fine not exceeding 10 penalty units.

(2) The written record made by a relevant first-aider is to include the name of the medical practitioner

or paramedic on whose instruction the substance came into the possession of, or was supplied (including by being administered) by, the relevant first-aider.

#### Division 8 – Possession and supply of salbutamol (S4)

#### 77. Interpretation of Division

In this Division –

#### relevant person means a person who is -

- (a) a St John Ambulance member, while he or she is acting in accordance with an agreement by St John Ambulance to provide its services at a particular event or location; or
- (b) an employee of Medical Edge Australia (ABN 98 147 076 819), while he or she is acting in accordance with an agreement by Medical Edge Australia to provide its services at a particular event or location.

# 78. Possession and supply of salbutamol (S4), for nebulisation, by relevant person

A relevant person who has a current certificate in the use of salbutamol (S4), for nebulisation, granted by a registered training organisation may –

- (a) obtain and possess salbutamol (S4) for nebulisation; and
- (b) supply it for self-administration on the oral instruction of a medical practitioner or paramedic; and
- (c) supply it for self-administration on the written instruction, other than on a standing order, of a medical practitioner or paramedic; and
- (d) in an emergency, supply it for self-administration without instruction from a medical practitioner or paramedic.

#### 79. Records of obtaining and supplying to be kept

(1) If salbutamol (S4) for nebulisation is obtained or supplied under this Division by a relevant person, the relevant person must make and keep a written record of that obtaining or supply.

Penalty: Fine not exceeding 10 penalty units.

(2) A written record is to include the name of the medical practitioner or paramedic on whose instructions the substance was obtained or supplied.

# Division 8A – Possession and supply of naloxone by needle and syringe services

#### 79A. Interpretation of Division

In this Division –

- certified person has the same meaning as in section 56A of the *Public Health Act* 1997:
- needle and syringe service has the same meaning as in section 56A of the *Public Health Act 1997*;
- permitted premises has the same meaning as in section 56A of the Public Health Act 1997.

# 79B. Possession, &c., of naloxone by certified person at permitted premises

- (1) Subject to subregulation (2), a certified person may, at permitted premises
  - (a) possess naloxone; and
  - (b) if the certified person believes that a person is at considerable risk of opioid toxicity, administer it, or supply it for administration, to the person with or without instruction from a prescriber.
- (2) If a certified person supplies naloxone to a person for administration in accordance with subregulation (1), the certified person is to also supply to the person an information sheet containing information regarding the use of naloxone for the treatment of opioid toxicity.

### 79C. Records of possession, supply and administration to be kept

- (1) If naloxone comes into the possession of, or is supplied or administered by, a certified person under this Division, the certified person must make and keep a written record of that possession, administration or supply.
- (2) A written record required under subregulation (1) is to include the name of the certified person and the address of the permitted premises and, if relevant, the name of a prescriber on whose instructions the substance was supplied.

#### Division 9 – Miscellaneous

### 80. Prescribed form of various certificates, applications and licences

- (1) For the purposes of section 25 of the Act
  - (a) a certificate of the result of an analysis under subsection (1) of that section is to be in a form approved by the Secretary; and
  - (b) a certificate of the result of an examination under subsection (1A) of that section is to be in a form approved by the Secretary; and
  - (c) a certificate of the results of an inspection under subsection (2) of that

section is to be in a form approved by the Secretary.

- (2) For the purposes of section 27 of the Act
  - (a) an application for a licence to sell or supply substances to which that section applies is to be in a form approved by the Secretary and contain particulars specified in the form; and
  - (b) a licence in that behalf is to be in a form approved by the Secretary.
- (3) For the purposes of section 28(3) of the Act, a securely bound book containing pages in a form approved by the Secretary and numbered consecutively is prescribed as the poisons book.

## 81. Aboriginal health worker may administer certain substances

For the purposes of section 38(1)(i) and section 47(1)(e) of the Act, an Aboriginal health worker may administer a substance listed in Schedule 2, 3, 4 or 8 to the Poisons List if the Aboriginal health worker acts –

- (a) in accordance with the written authority of a medical practitioner, dentist, authorised health professional, eligible midwife or authorised nurse practitioner; and
- (b) under the supervision of a medical practitioner, dentist, authorised health

#### Part 4 – Poisons and Restricted Substances

professional, authorised nurse practitioner or registered nurse or midwife.

#### 82. Prescribed persons for section 38(1)(i) of Act

- (1) For the purposes of section 38(1)(i) of the Act
  - (a) a person who is a dental therapist or an oral health therapist may, in the course of dental or oral health therapy, administer the following restricted substances to another person in the following specified circumstances:
    - (i) demeclocycline(demethylchlortetracycline),when used in dental preparations;
    - (ii) local anaesthetics, for use in dental treatment;
    - (iii) topical fluorides, when used in dental preparations;
    - (iv) triamcinolone acetonide, when used in dental preparations; and
  - (b) a person who is a registered nurse or midwife may, in the course of nursing practice or midwifery practice, administer to another person a substance listed in Schedule 2 or 3 to the Poisons List; and
  - (c) a person who is a registered nurse or midwife and who –

- (i) has completed an educational program approved by the Secretary relating to the administration of vaccines; and
- (ii) has been approved by the Secretary to administer vaccines independently –

may administer to another person a vaccine listed in Schedule 4 to the Poisons List in accordance with an immunisation program approved by the Director of Public Health; and

- (d) a person
  - (i) who is a pharmacist; and
  - (ii) who has been approved by the Secretary to administer vaccines independently; and
  - (iii) who has completed an educational program approved by the Secretary relating to the administration of vaccines –

may administer to another person, in accordance with an immunisation program approved by the Director of Public Health, a vaccine listed in Schedule 4 to the Poisons List; and

(e) a person who is a registered nurse or midwife and who satisfies the requirements of paragraph (c)(i) and (ii) may supervise the administration of a vaccine listed in Schedule 4 to the Poisons List in accordance with an immunisation program approved by the Director of Public Health, by another person who is a registered nurse, enrolled nurse, paramedic, midwife, pharmacist or provisionally registered pharmacist and who –

- (i) is undertaking an educational program approved by the Secretary relating to the administration of vaccines; or
- (ii) is authorised to administer the vaccine under regulation 54A; and
- (f) a person who is a pharmacist and who satisfies the requirements paragraph (d)(iii) may supervise the administration of a vaccine, listed in Schedule 4 to the Poisons List. accordance with an immunisation program approved by the Director of Public Health, by another person who is a pharmacist or provisionally registered pharmacist and who –
  - (i) is undertaking an educational program approved by the Secretary relating to the administration of vaccines; or

- (ii) is authorised to administer the vaccine under regulation 54A; and
- (g) a person who is a speech pathologist employed in the State Service and who has undertaken an educational program approved by the Secretary, in relation to the administration of local anaesthetics may administer, in the course of speech pathology practice, a topical local anaesthetic listed in Schedule 2, 3 or 4 to the Poisons List.
- $(2) \ldots \ldots \ldots$

# 83. Restrictions on purchase, &c., of certain pesticidal substances

- (1) A person must not
  - (a) buy or obtain or use
    - (i) fluoroacetic acid and substances structurally derived from fluoroacetic acid; or
    - (ii) thallium; or
    - (iii) thallium salts; or
  - (b) sell or supply any substance referred to in paragraph (a) to any person –

unless the person buying, obtaining, using or being supplied with the substance has the authority in writing of a competent officer to buy, obtain, use or be supplied with that substance.

Penalty: Fine not exceeding 10 penalty units.

(2) Every person who has a written authority referred to in subregulation (1) must comply with such conditions as are specified in the authority.

Penalty: Fine not exceeding 10 penalty units.

- (3) A competent officer may, in his or her absolute discretion, suspend or cancel any authority given under subregulation (1).
- (4) In this regulation –

#### competent officer means –

- (a) the Registrar of Chemical Products; or
- (b) the Secretary of the Department of Primary Industries; or
- (c) an employee in the Department of Primary Industries authorised, in writing, by the Secretary of that Department to perform the functions of a competent officer under this regulation;

Department of Primary Industries means the department that is responsible, in relation to the Vermin Control Act 2000 (or such other Act as from time to time has effect in substitution for that Act), to the

Minister to whom the administration of that Act is assigned.

#### 84. Veterinary use of chloramphenicol

- (1) A person must not
  - (a) put chloramphenicol to a prohibited use; or
  - (b) have possession of chloramphenicol for the purpose of its being put to a prohibited use; or
  - (c) in any advertisement, in any label, leaflet or other document included in, attached to or otherwise accompanying a container containing chloramphenicol, or in any other way in connection with the sale or supply of chloramphenicol, represent chloramphenicol as being suitable to be put to a prohibited use.

Penalty: Fine not exceeding 10 penalty units.

- (2) For the purposes of subregulation (1), the following uses are prohibited uses:
  - (a) systemic administration to a food-producing animal;
  - (b) topical administration (other than ocular topical administration) to an animal.

#### 85. Restriction on possession, &c., of diazepam

- (1) A person who is not the holder of a licence under section 16(1) of the Act to carry on business as a manufacturing chemist or as a wholesale chemist must not have possession of a quantity of diazepam in an undivided state that
  - (a) where the person is the holder of a permit granted by the Secretary for the purposes of this regulation, exceeds the quantity specified in the permit; or
  - (b) in any other case, exceeds 5 grams.

Penalty: Fine not exceeding 10 penalty units.

- (2) For the purposes of subregulation (1), diazepam is taken to be otherwise than in an undivided state only if it is in the form of tablets or capsules or it is packed in a selected container.
- (3) A permit granted for the purposes of this regulation is subject to any conditions specified in the permit.

#### 86. Restriction on sale, &c., of clozapine

- (1) Subject to subregulation (2), a person must not prescribe, sell or supply clozapine unless the person is
  - (a) authorised by the Secretary to do so; or
  - (b) included in a class of persons authorised by the Secretary to do so.

- (2) Subregulation (1) does not apply to the sale or supply of clozapine by a wholesale chemist in the ordinary course of wholesale dealing.
- (3) A person authorised by this regulation to prescribe, sell or supply clozapine must comply with such conditions as are specified in the authority.

Penalty: Fine not exceeding 10 penalty units.

(4) The Secretary may at any time revoke an authority given under this regulation.

# 87. Prescription, &c., of certain substances prohibited, unless authorised by Secretary

- (1) This regulation applies to each substance that is listed in Appendix D to the Uniform Standard, as amended from time to time, subject to such limitations, or in such circumstances, as may be determined by the Secretary.
- (2) Subject to subregulation (3), a person must not prescribe, sell or supply a substance to which this regulation applies for human use unless that person is
  - (a) authorised by the Secretary to do so; or
  - (b) included in a class of persons authorised by the Secretary to do so.

Penalty: Fine not exceeding 10 penalty units.

- (3) Subregulation (2) does not apply to the sale or supply of any substance specified in that subregulation
  - (a) by a wholesale chemist in the ordinary course of wholesale dealing; or
  - (b) by a pharmacist on the prescription of a person who has the authority of the Secretary to prescribe the substance.
- (4) A person authorised under this regulation to prescribe or supply any of the substances specified in this regulation must comply with such conditions as are specified in the authority.

(5) The Secretary may at any time revoke an authority given under this regulation.

# 88. Precautions in prescribing substances capable of producing birth defects

- (1) A medical practitioner must not prescribe or supply for use in the treatment of a female patient acitretin, bexarotene, bosentan, etretinate, sitaxentan, isotretinoin for oral use, tretinoin for oral use or thalidomide unless
  - (a) the medical practitioner is satisfied that, at that time, the patient is not pregnant; and
  - (b) the medical practitioner –

- (i) is satisfied that the patient is incapable, after that time, of becoming pregnant; or
- (ii) warns the patient that, if she is, or becomes, pregnant at any time during the period specified in subregulation (2), any child of that pregnancy is extremely likely to suffer severe birth defects.

- (2) The period referred to in subregulation (1)(b)(ii) is the period
  - (a) commencing at the commencement of the period of treatment of the patient with acitretin, bexarotene, bosentan, etretinate, sitaxentan, isotretinoin for oral use, tretinoin for oral use or thalidomide, as the case requires; and
  - (b) ending
    - (i) in the case of treatment with acitretin or etretinate, 2 years after the completion of that treatment; or
    - (ii) in the case of treatment with bosentan or sitaxentan, 3 months after the completion of that treatment; or
    - (iii) in the case of treatment with isotretinoin for oral use, tretinoin

for oral use, bexarotene or thalidomide, one month after the completion of that treatment.

## 89. Restrictions on use of certain poisons and restricted substances

- (1) A person must not, without the approval in writing of the Secretary or of the Secretary of the Commonwealth Department
  - (a) prescribe, or sell or supply, a substance specified in a succeeding subregulation of this regulation for a use that is not permitted in relation to that substance under that subregulation; or
  - (b) put such a substance to such a use; or
  - (c) in any advertisement or in any label, leaflet or other document included in, attached to or otherwise accompanying a container containing such a substance, or in any other way in connection with the sale or supply of such a substance, represent that substance to be suitable for such a use.

Penalty: Fine not exceeding 10 penalty units.

(2) A person must not put to human therapeutic use a substance listed in Schedule 10 of the Uniform Standard.

Penalty: Fine not exceeding 10 penalty units.

(3) A person must not use S,S,S-tributylphosphorothioate (S7) as a pesticide.

Penalty: Fine not exceeding 10 penalty units.

- (4) A person must not use nitrofuran
  - (a) in animal feed; or
  - (b) for the treatment of an animal used for the production of meat, edible offal, egg or milk.

Penalty: Fine not exceeding 10 penalty units.

#### 90. Restriction of possession of certain substances

A person must not have possession of a substance specified in Schedule 10 of the Uniform Standard otherwise than in accordance with the approval in writing of either the Secretary or the Secretary of the Commonwealth Department.

Penalty: Fine not exceeding 10 penalty units.

# 91. Authorisation to manufacture, &c., certain dangerous poisons

(1) In this regulation –

authorisation means authorisation by the Secretary under subregulation (9);

determined major hazard facility means a determined major hazard facility as defined in regulation 5 of the Work Health and Safety Regulations 2012;

# means a person conducting a business or undertaking means a person conducting a business or undertaking within the meaning of section 5 of the Work Health and Safety Act 2012;

- prescribed dangerous poison means a poison listed and marked with a "P" in Part 2 of Appendix J of the Uniform Standard;
- workplace means a workplace as defined in section 8 of the Work Health and Safety Act 2012.
- (2) A person may apply to the Secretary for authorisation.
- (3) The application is to be accompanied by the fee specified in item 8 of Schedule 7.
- (4) The application is to include information about
  - (a) the place or places at which the prescribed dangerous poison is to be kept; and
  - (b) any other matter the Secretary determines.
- (5) The Secretary may, in the Secretary's discretion
  - (a) grant the application, with or without conditions; or

- (b) refuse to grant the application.
- (6) Without limiting the Secretary's discretion, the conditions referred to in subregulation (5)(a) may include conditions relating to
  - (a) the quantity of the prescribed dangerous poison; and
  - (b) storage and security requirements for the prescribed dangerous poison; and
  - (c) record keeping in respect of the prescribed dangerous poison; and
  - (d) disposal of the prescribed dangerous poison.
- (7) Without limiting the Secretary's discretion, the Secretary may refuse to grant the application if the Secretary considers that
  - (a) the applicant has no legitimate need of authorisation; or
  - (b) in the case of an applicant who is a corporation, the officers of the corporation are not fit and proper persons to have the management of a corporation holding authorisation; or
  - (c) in the case of any other person, the applicant is not a fit and proper person to hold authorisation.
- (8) The Secretary, when considering whether a person is a fit and proper person for the purposes

- of subregulation (7)(b) or (c), may have regard to any matters the Secretary considers relevant.
- (9) If the application is granted, the Secretary is to authorise the person to manufacture, obtain, possess, sell or supply a prescribed dangerous poison.
- (10) If the application is refused, the Secretary is to give the applicant notice of the refusal.
- (11) Subject to subregulation (12), a person must not manufacture, obtain, possess, sell or supply a prescribed dangerous poison except
  - (a) if the person
    - (i) is authorised by the Secretary under subregulation (9); and
    - (ii) is acting in accordance with the authorisation and the conditions of the authorisation, if any; and
    - (iii) keeps the prescribed dangerous poison at the place or places specified in subregulation (4)(a), except as otherwise authorised by the Secretary under subregulation (5)(a); or
  - (b) for any purpose, or on any condition, set out in these regulations; or
  - (c) as authorised under any other relevant Act.

- (12) Subregulation (11) does not apply to a person who is a person conducting a business or undertaking at a workplace if
  - (a) the person has given written notice in accordance with rule 348(1) of the *Work Health and Safety Regulations 2012* and that notice has not be superseded by written notice given in accordance with rule 348(4) of those regulations; or
  - (b) the workplace is a determined major hazard facility.

#### 92. Restrictions applying to veterinary medicines

A person must not –

- (a) administer to himself or herself; or
- (b) administer to another person; or
- (c) sell or supply for human use; or
- (d) represent as being suitable for human use –

a medicine or other substance which contains a poison or restricted substance and which is prepared for the treatment of animals.

Penalty: Fine not exceeding 10 penalty units.

#### 93. Wholesale dealing

(1) The professions, businesses, trades or industries carried on by persons specified in

- subregulations (2), (3) and (4) are prescribed for the purposes of the definition of *wholesale dealing* in section 3(1) of the Act.
- (2) In respect of narcotic substances (S8) the following are specified:
  - (a) the holder of a licence to manufacture, use or possess narcotic substances in force under regulation 11;
  - (b) the holder of a licence to sell, distribute and supply narcotic substances in force under Division 2 of Part V of the Act;
  - (c) an authorised officer who is not a pharmacist;
  - (d) the master of a vessel, if the substances are intended to be used only for medical treatment on the vessel and are needed to complete the quantity of medicines and medical stores required to be carried on the vessel to comply with navigation requirements;
  - (e) a registered nurse or midwife authorised in respect of those substances under section 25A of the Act;
  - (f) an endorsed midwife, in respect of midwifery narcotic substances;
  - (g) an authorised person;
  - (h) a person directed under regulation 42 by the Commissioner of Ambulance

- Services to procure and distribute those substances for the Ambulance Service;
- (i) an authorised health professional;
- (j) in respect of the substances specified in a first-aid provider licence, a member or employee of the holder of that licence, acting in accordance with that licence.
- (3) In respect of restricted substances (S4) and potent substances (S3) the following are specified:
  - (a) a qualified person in charge of a laboratory or department engaged in medical or scientific research or instruction or in quality control or analysis;
  - (b) the holder of a licence to make or refine those substances in force under Division 3 of Part II of the Act;
  - (c) the holder of a licence to buy and sell those substances in force under Division 3 of Part II of the Act;
  - (d) an authorised officer who is not a pharmacist;
  - (e) the master of a vessel, if those substances are intended to be used only for medical treatment on the vessel and are needed to complete the quantity of medicines and medical stores required to be carried on

- the vessel to comply with navigation requirements;
- (f) a registered nurse or midwife authorised in respect of those substances under section 25A of the Act;
- (g) an endorsed midwife, in respect of midwifery restricted substances;
- (h) an authorised person;
- (i) a person directed under regulation 42 by the Commissioner of Ambulance Services to procure and distribute those substances for the Ambulance Service;
- (j) in respect of the substances specified in a first-aid provider licence, a member or employee of the holder of that licence, acting in accordance with that licence;
- (k) a podiatrist;
- (l) an optometrist;
- (m) in respect of the substances specified in regulation 82, a registered nurse or midwife referred to in paragraph (c) of that regulation or a dental therapist;
- (n) in respect of the substances specified in regulation 82(b), a registered nurse or midwife.
- (4) In respect of other scheduled substances not specified in regulation 83 the following are specified:

- (a) a qualified person in charge of a laboratory or department engaged in medical or scientific research or instruction or in quality control or analysis;
- (b) the holder of a licence to make or refine those substances in force under Division 3 of Part II of the Act;
- (c) the holder of a licence to buy and sell those substances in force under Division 3 of Part II of the Act;
- (d) an authorised officer who is not a pharmacist;
- (e) the master of a vessel, if those substances are intended to be used only for medical treatment on the vessel and are needed to complete the quantity of medicines and medical stores required to be carried on the vessel to comply with navigation requirements;
- (f) a person having control of an industrial first aid post;
- (g) a person directed under regulation 42 by the Commissioner of Ambulance Services to procure and distribute those substances for the Ambulance Service;
- (h) in respect of the substances specified in a first-aid provider licence, a member or employee of the holder of that licence, acting in accordance with that licence;

- (i) a podiatrist;
- (j) an optometrist;
- (k) a person engaged in the occupation of jewellery manufacture;
- (l) a person engaged in the occupation of electroplating;
- (m) a person engaged in the occupation of paint manufacture;
- (n) a person engaged in the occupation of ferrous hardening;
- (o) a person engaged in commercial pest control.

#### 94. Retaining of records

- (1) A person who sells or supplies a poison or restricted substance in the ordinary course of wholesale dealing must, on each occasion upon which the sale or supply is made
  - (a) issue an invoice to the purchaser of the substance or the person to whom the substance is supplied; and
  - (b) keep a record of the invoice showing
    - (i) the date of the sale or supply; and
    - (ii) the name and address of the purchaser or the person to whom the substance is supplied; and

(iii) the name and quantity of the substance sold or supplied.

Penalty: Fine not exceeding 10 penalty units.

(2) A person who sells or supplies any poison or restricted substance must keep any invoice and prescription record relating to that poison or restricted substance for not less than 2 years from the latest date on which the invoice or prescription record was made or acted upon.

Penalty: Fine not exceeding 10 penalty units.

(3) On demand by a person appointed or authorised under section 23 of the Act, any person authorised to supply, sell or be in possession of any poison or restricted substance must furnish particulars of the quantity of any poison or restricted substance on hand, the quantity obtained and the quantity disposed of.

Penalty: Fine not exceeding 10 penalty units.

#### 95. Supply of clinical samples

- (1) This regulation applies to
  - (a) a person engaged in the manufacture of, or wholesale dealing in, any substance specified in Schedule 1 or 4 to the Poisons List; and
  - (b) the agent of any such person –

who lawfully supplies any of those substances by way of free distribution as a clinical sample.

- (2) Any person to whom this regulation applies must, on each occasion upon which the person supplies any substance referred to in subregulation (1) by way of free distribution, make a record of the supply showing
  - (a) the date of the supply; and
  - (b) the name and address of the person to whom the substance was supplied; and
  - (c) the name and quantity of the substance so supplied.
- (3) Except in the case of the supply of the substance referred to in subregulation (1) by registered or certified mail, a person supplying the substance must obtain a receipt at the time of supply from the person to whom the supply was made.
- (4) The provisions of regulation 94(2) and (3) apply, with any necessary modification, to the records and receipts required to be made under this regulation.

#### PART 4A – MONITORED MEDICINES DATABASE

#### 95A. Interpretation

In this Part –

dispensing information includes the following information in relation to the dispensing of a monitored medicine:

- (a) the date on which the monitored medicine is dispensed;
- (b) the name, residential address and date of birth of the person to whom the monitored medicine is dispensed;
- (c) the healthcare identifier that is assigned to the person to whom the monitored medicine is dispensed;
- (d) the name, form, strength and quantity of the monitored medicine that is dispensed;
- (e) the directions in relation to the use of the monitored medicine that is dispensed;
- (f) the name, business address and telephone number of the dispenser of the monitored medicine;

- (g) the healthcare identifier that is assigned to the dispenser of the monitored medicine;
- (h) the healthcare identifier that is assigned to the healthcare provider organisation relevant to the dispenser of the monitored medicine;
- healthcare identifier means healthcare identifier within the meaning of the Healthcare Identifiers Act 2010 of the Commonwealth:
- prescription information includes the following information in relation to the issue of a prescription for the supply of a monitored medicine:
  - (a) the date on which the prescription is issued:
  - (b) the name, residential address and date of birth of the person to whom the prescription is issued;
  - (c) the healthcare identifier that is assigned to the person to whom the prescription is issued;
  - (d) the name, form, strength and quantity of the monitored medicine to be supplied;

- (e) the number of repeats for the supply of the monitored medicine;
- (f) the directions specified on the prescription in relation to the use of the monitored medicine;
- (g) the name, business address and telephone number of the prescriber;
- (i) the healthcare identifier that is assigned to the prescriber;
- (h) the healthcare identifier that is assigned to the healthcare provider organisation relevant to the prescriber;
- sale and supply information includes the following information in relation to the sale, or to the supply, of a monitored medicine otherwise than on and in accordance with a prescription:
  - (a) the date on which the monitored medicine is sold or supplied;
  - (b) the name, residential address and date of birth of the person to whom the monitored medicine is sold or supplied;
  - (c) the healthcare identifier that is assigned to the person to whom

- the monitored medicine is sold or supplied;
- (d) the name, form, strength and quantity of the monitored medicine that is sold or supplied;
- (e) the directions in relation to the use of the monitored medicine that is sold or supplied;
- (f) the name, business address and telephone number of the seller, or or supplier, of the monitored medicine;
- (g) the healthcare identifier that is assigned to the seller, or supplier, of the monitored medicine;
- (h) the healthcare identifier that is assigned to the healthcare provider organisation relevant to the sale, or supply, of the monitored medicine.

#### 95B. Prescribed monitored medicines

- (1) For the purposes of paragraph (b) of the definition of *monitored medicines* in section 3(1) of the Act, the following are prescribed to be monitored medicines:
  - (a) codeine (S4);
  - (b) dextropropoxyphene;

- (c) gabapentin;
- (d) olanzapine;
- (e) pregabalin;
- (f) quetiapine;
- (g) tramadol;
- (h) zolpidem;
- (i) zopiclone.
- (2) For the purposes of paragraph (c) of the definition of *monitored medicines* in section 3(1) of the Act, substances that are in the class of substances known as benzodiazepines are prescribed to be monitored medicines.

#### 95C. Prescribed dispenser

For the purposes of paragraph (b) of the definition of *dispenser* in section 38A of the Act, the following persons are prescribed as a dispenser:

- (a) a medical practitioner;
- (b) a dentist;
- (c) a nurse practitioner;
- (d) an endorsed midwife;
- (e) an authorised health professional;
- (f) a provisionally registered pharmacist.

#### 95D. Prescribed prescriber

For the purposes of paragraph (c) of the definition of *prescriber* in section 38A of the Act, the following persons are prescribed as a prescriber:

- (a) an authorised health professional;
- (b) a nurse practitioner;
- (c) an endorsed midwife.

# 95E. Prescribed manner and prescribed form of providing information to monitored medicines database

For the purposes of paragraph (c) of section 38C(1) of the Act, a data source entity is to provide information to the monitored medicines database in an electronic form and in an electronic manner.

# 95F. Prescribed information provided to, or collected and stored in, the monitored medicines database

For the purposes of section 38D(1) of the Act the following information must be provided to, or collected and stored in, the monitored medicines database:

(a) any personal information within the meaning of the *Right to Information Act* 2009;

- (b) any information obtained under a law of another jurisdiction for a purpose specified in section 38B(2) of the Act;
- (c) any prescription information that is obtained in relation to the issue of a prescription in Tasmania for the supply of a monitored medicine to
  - (i) a person who resides in Tasmania; or
  - (ii) a person who resides in another State or a Territory;
- (d) any prescription information that is obtained in relation to the issue of a prescription in another State or a Territory for the supply of a monitored medicine to a person who resides in Tasmania;
- (e) any dispensing information that is obtained in relation to the dispensing of a monitored medicine in Tasmania to
  - (i) a person who resides in Tasmania; or
  - (ii) a person who resides in another State or a Territory;
- (f) any dispensing information that is obtained in relation to the dispensing of a monitored medicine in another State or a Territory to a person who resides in Tasmania;

- (g) any sale and supply information that is obtained in relation to the sale and supply of a monitored medicine in Tasmania, otherwise than on and in accordance with a prescription, to
  - (i) a person who resides in Tasmania; or
  - (ii) a person who resides in another State or a Territory;
- (h) any sale and supply information that is obtained in relation to the sale and supply of a monitored medicine in another State or a Territory to a person who resides in Tasmania, otherwise than on and in accordance with a prescription.

# 95G. Prescriber or dispenser not required to check monitored medicines database

- (1) For the purposes of section 38G of the Act, a prescriber is not required to check the monitored medicines database when prescribing
  - (a) a VAD substance in accordance with the End-of-Life Choices (Voluntary Assisted Dying) Act 2021; or
  - (b) a substance to a person who is
    - (i) suffering an incurable, progressive, far-advanced disease or medical condition; and

- (ii) has limited life expectancy due to the disease or medical condition; and
- (iii) is receiving palliative treatment; or
- (c) a substance to a person who is an inpatient being treated in a medical institution; or
- (d) a substance to a person who is a patient being treated in an emergency department of a hospital and the monitored medicine is to be administered in the course of treatment given in that emergency department.
- (2) For the purposes of 38H of the Act, a dispenser is not required to check the monitored medicines database when dispensing, issuing or supplying
  - (a) a VAD substance in accordance with the End-of-Life Choices (Voluntary Assisted Dying) Act 2021; or
  - (b) a substance to a person who is
    - (i) suffering an incurable, progressive, far-advanced disease or medical condition; and
    - (ii) has limited life expectancy due to the disease or medical condition; and

r. 95G

- (iii) is receiving palliative treatment; or
- (c) a substance to a person who is an inpatient being treated in a medical institution; or
- (d) a substance to a person who is a patient being treated in an emergency department of a hospital and the monitored medicine is to be administered in the course of treatment given in that emergency department.

Part 5 – Standing Orders for Administration of Restricted Substances and Narcotic Substances

#### PART 5 – STANDING ORDERS FOR ADMINISTRATION OF RESTRICTED SUBSTANCES AND NARCOTIC SUBSTANCES

#### 96. Interpretation

In this Part –

- community health centre means a health centre approved in writing by the Secretary as a community health centre to which this Part applies;
- Drugs and Therapeutics Committee means a Drugs and Therapeutics Committee established under regulation 97(1) or (2);
- *medical intern* means a medical school graduate working in an intern position accredited by an authority approved by the Medical Board of Australia:
- *medical practitioner* does not include a medical intern;
- standing order means a standing order that complies with regulation 105 and that is
  - (a) issued by the Director of Public Health for the purposes of regulation 100; or
  - (b) issued by a medical practitioner for the purposes of regulation 101, 102, 103 or 104.

### Part 5 – Standing Orders for Administration of Restricted Substances and Narcotic Substances

#### 97. Drugs and Therapeutics Committee

- (1) The Secretary is to establish a Drugs and Therapeutics Committee for the purpose of considering applications from medical practitioners for authorisations to issue standing orders that are to apply in relation to public hospitals, day-treatment centres or community health centres.
- (2) The governing body of a private hospital or private day-treatment centre is to establish a Drugs and Therapeutics Committee for the purpose of considering applications from medical practitioners for authorisations to issue standing orders that are to apply in relation to the private hospital or private day-treatment centre.
- (3) A Drugs and Therapeutics Committee is to include at least one medical practitioner, one registered nurse and one pharmacist.
- (4) The Secretary, or the governing body of a private hospital or private day-treatment centre, may provide for, in writing, the regulation of the proceedings of a Drugs and Therapeutics Committee.
- (5) Except as provided otherwise by the Secretary, or the governing body of a private hospital or private day-treatment centre, a Drugs and Therapeutics Committee may regulate its own proceedings.

# 98. Application for authorisation of issue of standing order

- (1) A medical practitioner may apply to a Drugs and Therapeutics Committee for an authorisation to issue a standing order.
- (2) An application under subregulation (1) must include the following:
  - (a) a copy of the standing order that is the subject of the application;
  - (b) the name of the public hospital, daytreatment centre, community health centre, private hospital or private daytreatment centre in relation to which the standing order is to have effect;
  - (c) the name of the applicant;
  - (d) the name of the restricted substance or narcotic substance referred to in the standing order and its form and strength;
  - (e) the dose and route of administration of the restricted substance or narcotic substance;
  - (f) if applicable, the frequency of administration of the restricted substance or narcotic substance;
  - (g) if applicable, the maximum duration for which the restricted substance or narcotic substance is to be administered:

### Part 5 – Standing Orders for Administration of Restricted Substances and Narcotic Substances

- (h) if applicable, the maximum quantity of the restricted substance or narcotic substance that is to be administered;
- (i) the clinical circumstances in which the restricted substance or narcotic substance is to be administered;
- (j) if applicable, details of the persons to whom, and the clinical circumstances in which, the restricted substance or narcotic substance must not be administered;
- (k) if applicable, the clinical area in relation to which the standing order applies;
- (l) if applicable, the education and endorsement requirements required for a registered nurse or midwife to whom the standing order applies;
- (m) the date on which the standing order is to take effect;
- (n) the reasons for the standing order and how it will improve patient care;
- (o) any other information the Secretary considers necessary.

#### 99. Determination of application

(1) After considering an application made under regulation 98, a Drugs and Therapeutics Committee may –

#### Poisons Regulations 2018 Statutory Rules 2018, No. 79

### **r. 100** Part 5 – Standing Orders for Administration of Restricted Substances and Narcotic Substances

- (a) approve the application and authorise the issue of the standing order; or
- (b) refuse to approve the application.
- (2) If a Drugs and Therapeutics Committee approves an application under subregulation (1)(a), the Committee is to notify the applicant that the issue of the standing order is authorised.
- (3) If a Drugs and Therapeutics Committee refuses to approve an application under subregulation (1)(b), the Committee is to
  - (a) notify the applicant that the application has been refused and the issue of the standing order is not authorised; and
  - (b) advise the applicant of the reasons for the refusal.

# 100. Standing orders issued by Director of Public Health in public health emergencies or for treatment of notifiable diseases

(1) If the Director of Public Health makes a declaration under section 14(1) of the *Public Health Act 1997* that a public health emergency exists, the Director of Public Health may also issue a standing order in relation to the administration of a restricted substance, by a registered nurse or midwife, to persons affected by the public health emergency.

### Part 5 – Standing Orders for Administration of Restricted Substances and Narcotic Substances

- (2) If, in relation to a notifiable disease, the Director of Public Health issues
  - (a) a notice under section 42 of the *Public Health Act 1997*; or
  - (b) an order under section 53 of the *Public Health Act 1997*—

the Director of Public Health may also issue a standing order in relation to the administration of a restricted substance, by a registered nurse or midwife, to persons for the purpose of treating that notifiable disease.

# 101. Standing orders issued by medical practitioners for persons treated in public hospitals or day-treatment

- (1) A medical practitioner may issue a standing order in relation to the administration of a restricted substance or narcotic substance, by a registered nurse or midwife, or a registered nurse and midwife, to persons being treated in a public hospital or day-treatment centre.
- (2) Subregulation (1) only applies in relation to the issue of a standing order by a medical practitioner if
  - (a) the medical practitioner has made an application, under regulation 98, to the Drugs and Therapeutics Committee for authorisation to issue the standing order; and

#### Poisons Regulations 2018 Statutory Rules 2018, No. 79

### **r. 102** Part 5 – Standing Orders for Administration of Restricted Substances and Narcotic Substances

(b) the medical practitioner has received notification, under regulation 99(2), that the application has been approved and the issue of the standing order is authorised.

# 102. Standing orders issued by medical practitioner for patients of medical practitioner treated in private hospitals or private day-treatment centres

- (1) A medical practitioner may issue a standing order in relation to the administration of a restricted substance or narcotic substance, by a registered nurse or midwife, or a registered nurse and midwife, to a patient of the medical practitioner who is being treated in a private hospital or private day-treatment centre.
- (2) Subregulation (1) only applies in relation to the issue of a standing order by a medical practitioner if
  - (a) the medical practitioner has made an application, under regulation 98, to the Drugs and Therapeutics Committee at the private hospital or private day-treatment centre for authorisation to issue the standing order; and
  - (b) the medical practitioner has received notification, under regulation 99(2), that the application has been approved and the issue of the standing order is authorised.

Part 5 – Standing Orders for Administration of Restricted Substances and Narcotic Substances

# 103. Standing orders issued by medical practitioners for persons treated in community health centres

- (1) A medical practitioner may issue a standing order in relation to the administration of a restricted substance or narcotic substance, by a registered nurse employed at a community health centre, to persons being treated in the community health centre.
- (2) Subregulation (1) only applies in relation to the issue of a standing order by a medical practitioner if
  - (a) the medical practitioner has made an application, under regulation 98, to the Drugs and Therapeutics Committee for authorisation to issue the standing order; and
  - (b) the medical practitioner has received notification, under regulation 99(2), that the application has been approved and the issue of the standing order is authorised.

# 104. Standing orders issued by medical practitioners for persons treated in remote areas

(1) A medical practitioner may issue a standing order in relation to the administration of a restricted substance or narcotic substance, by a registered nurse or midwife who attends an emergency in a remote area, to persons who require urgent treatment, if it is not practicable

#### Poisons Regulations 2018 Statutory Rules 2018, No. 79

### Part 5 – Standing Orders for Administration of Restricted Substances and Narcotic Substances

for a medical practitioner to be present to administer the restricted substance or narcotic substance to the person requiring urgent treatment.

- (2) Subregulation (1) only applies in relation to the issue of a standing order by a medical practitioner if
  - (a) the medical practitioner has made an application, under regulation 98, to the Drugs and Therapeutics Committee for authorisation to issue the standing order; and
  - (b) the medical practitioner has received notification, under regulation 99(2), that the application has been approved and the issue of the standing order is authorised.

#### 105. Form of standing orders

- (1) A standing order must
  - (a) in the case of a standing order issued by a medical practitioner, specify the name of that medical practitioner; and
  - (b) contain a unique number for the standing order; and
  - (c) if applicable, specify that the Director of Public Health is issuing the standing order and describe the notifiable disease

r. 105

#### Poisons Regulations 2018 Statutory Rules 2018, No. 79

Part 5 – Standing Orders for Administration of Restricted Substances and Narcotic Substances

r. 105

- or public health emergency to which the standing order relates; and
- (d) if applicable, specify the public hospital, day-treatment centre, private hospital, private day-treatment centre or community health centre in relation to which the standing order applies; and
- (e) if applicable, specify the remote area in relation to which the standing order applies; and
- (f) specify the date on which the standing order is to take effect; and
- (g) specify the date, not more than 2 years after the specified date on which the standing order took effect, on which the standing order will cease to have effect; and
- (h) if applicable, specify the clinical area to which the standing order applies; and
- (i) specify the clinical circumstances in which the restricted substance or narcotic substance may be administered; and
- (j) describe the people to whom the restricted substance or narcotic substance may be administered; and
- (k) if applicable, describe the people, if any, to whom the restricted substance or

- narcotic substance must not be administered; and
- specify the Australian Approved Name (1)of the restricted substance or narcotic substance and, if applicable, its brand name; and
- if applicable, specify the form and (m) strength of the restricted substance or narcotic substance; and
- specify dose and of (n) the route administration of the restricted substance or narcotic substance; and
- if applicable, specify the frequency of the (0)administration of the restricted substance or narcotic substance; and
- if applicable, specify (p) the maximum for which duration the restricted substance or narcotic substance is to be administered; and
- if applicable, specify the maximum (q) quantity of the restricted substance or narcotic substance to be administered; and
- if applicable, specify the educational and (r) endorsement requirements necessary for a registered nurse or midwife to whom the standing order applies; and

### Part 5 – Standing Orders for Administration of Restricted Substances and Narcotic Substances

- (s) be signed by the medical practitioner issuing the standing order.
- (2) In this regulation –

Australian Approved Name means the name approved by the Therapeutic Goods Association.

#### 106. Authorisation by standing orders

A standing order authorises a registered nurse or midwife to whom the standing order applies to possess, and administer, in accordance with the standing order, a restricted substance or narcotic substance.

#### 107. Offences relating to standing orders

A person must not issue a standing order for a restricted substance or narcotic substance if the person is not authorised under these regulations to issue the standing order.

Penalty: Fine not exceeding 10 penalty units.

#### 108. Revocation of standing orders

(1) The Drugs and Therapeutics Committee, by notice in writing given to the medical practitioner who issued a standing order, may revoke the standing order –

#### Poisons Regulations 2018 Statutory Rules 2018, No. 79

**r. 108** Part 5 – Standing Orders for Administration of Restricted Substances and Narcotic Substances

- (a) if requested to do so by that medical practitioner; or
- (b) if the Committee considers it appropriate to do so.
- (2) The Drugs and Therapeutics Committee is to specify in the notice referred to in subregulation (1) the day on which a revocation takes effect.

### PART 6 – PACKAGING AND LABELLING OF SCHEDULED SUBSTANCES

#### Division 1 – Application of provisions of Uniform Standard

#### 109. Application of provisions of Uniform Standard

- (1) Subject to subregulation (3) and to any provision to the contrary in these regulations, sections 1 and 2 in Part 2, paragraph 6.2 of section 6 in Part 2 and Appendices E, F, J and L in Part 5 of the Uniform Standard (in this regulation referred to as "the applied provisions") have effect as if they were provisions of these regulations.
- (2) For the purposes of subregulation (1)–
  - (a) a reference in any of the applied provisions to a Schedule by number is to be read as a reference to the correspondingly numbered Schedule to the Poisons List; and
  - (b) an expression that is defined in Part 1 of the Uniform Standard has, unless the contrary intention appears, the corresponding meaning in the applied provisions; and
  - (c) a reference in any of the applied provisions to "authorised or licensed persons" is to be read as a reference to a person authorised, licensed, permitted or approved under any relevant Act.

- (3) The Minister may, by permit signed by the Minister, in such circumstances as the Minister thinks fit, authorise the sale or supply of a scheduled substance the labelling or packaging of which does not comply with a requirement of the applied provisions.
- (4) A permit under subregulation (3) has effect subject to any conditions specified in the permit.
- (5) A person must comply with paragraph 2 in Part 2 of the Uniform Standard.

Penalty: Fine not exceeding 10 penalty units.

#### Division 2 – Packaging of scheduled substances

## 110. Special provisions as to containers for narcotic substances

(1) A person must not sell or supply a narcotic substance unless its container is sealed in such a way that, when the seal is broken, the container can be readily distinguished from sealed containers.

Penalty: Fine not exceeding 10 penalty units.

(2) Where more than one container containing a narcotic substance is enclosed in a primary pack, a person must not sell or supply a narcotic substance in such a primary pack unless that primary pack is sealed in such a way that, when the seal is broken, the primary pack can be readily distinguished from sealed primary packs.

Penalty: Fine not exceeding 10 penalty units.

- (3) This regulation does not apply to the sale or supply of a narcotic substance
  - (a) by a medical practitioner, dentist, authorised nurse practitioner, authorised health professional or veterinary surgeon in the practice of his or her profession; or
  - (b) by a pharmacist on the prescription of a medical practitioner, dentist, authorised nurse practitioner, authorised health professional or veterinary surgeon; or
  - (c) by a registered nurse or midwife on the authorisation in writing of a medical practitioner, dentist, authorised health professional or authorised nurse practitioner.

#### 111. Child-resistant packaging of certain medicines

If goods to which the *Therapeutic Goods Order*No. 95 – Child-resistant Packaging
Requirements for Medicines 2017, made under
the Therapeutic Goods Act 1989 of the
Commonwealth, as amended from time to time,
applies consist of, or include, a scheduled
substance, the provisions of that order, or any
order made in substitution of that order, have
effect for the purposes of the Act in relation to
those goods as if those provisions were
provisions of these regulations.

#### Division 3 – Labelling of scheduled substances

#### 112. Labelling of poisons in poisons book

A person must not sell any poison, the sale of which requires an entry to be made in the poisons book, unless the person so selling has first affixed to the container in which the poison is sold a label on which is written the seller's name and address which may appear on a label separate from the principal label.

Penalty: Fine not exceeding 10 penalty units.

#### 113. Labelling prohibitions

A person must not sell or supply –

- (a) a substance included in a Schedule to the Poisons List in a container to which is affixed a label on which is written
  - (i) a reference to the Act or to these regulations, or any comment upon, or any reference to or any explanation of, any information required by the Act or by a regulation to be written on any label, which directly or by implication contradicts, qualifies or modifies such information; or
  - (ii) any device which is, or any words which are, false or misleading in any particular concerning the

substance or any one or more of the ingredients included in it; or

- (b) any poison, restricted substance or narcotic substance in a container on which is affixed a label which obscures
  - (i) any expression required by the Uniform Standard as applied by regulation 109 to be written or embossed on that container; or
  - (ii) any ribs, grooves, points or stars required by the Uniform Standard as applied by regulation 109 to be embossed on that container; or
  - (iii) any words required by the Act or these regulations to be written on such a container or on a label affixed to that container.

Penalty: Fine not exceeding 10 penalty units.

#### 114. Labelling of dispensed medicines

- (1) A scheduled substance when
  - (a) made up or compounded as a medicine by a pharmacist acting in the lawful practice of his or her profession as such, or by an assistant under his or her direct personal supervision, on and in accordance with the prescription of a medical practitioner, dentist or veterinary

surgeon or an authorised health professional; or

- (b) made up or compounded extemporaneously as a medicine by a pharmacist so acting for a specific and individual case, if the medicine does not contain any restricted substance or narcotic substance; or
- (c) made up or compounded as a medicine which is supplied
  - (i) by a medical practitioner so acting for the purposes of medical treatment; or
  - (ii) by a dentist so acting for the purposes of dental treatment; or
  - (iii) by a veterinary surgeon so acting for the purposes of animal treatment; or
  - (iv) by an authorised health professional acting in the course of his or her profession –

is exempt from all other provisions of these regulations relating to labels if the container of the substance is labelled in accordance with Appendix L to the Uniform Standard.

(1A) A container that contains a scheduled substance, other than one to which subregulation (1) applies, must be labelled in accordance with –

- (a) these regulations; and
- (b) Appendix L to the Uniform Standard; and
- (c) Appendix F to the Uniform Standard if the substance is listed in Part 3 of that Appendix.
- (2) Where a container contains medicine that
  - (a) is for internal use; and
  - (b) contains a substance specified in Appendix K to the Uniform Standard –

the labelling of the container is to include a warning statement in the form, or to the effect, of warning statement 39 or warning statement 40 in Part 1 of Appendix F to the Uniform Standard.

(3) The Secretary may approve a variation to the labelling requirements set out in this regulation subject to any condition that he or she considers appropriate.

#### PART 7 – MISCELLANEOUS

#### 115. Revocation of licence to be published

If, under section 92(1) of the Act, the Minister suspends or revokes a right conferred on a person by or under the Act, the Minister, if of the opinion that it is in the public interest to do so, may do any or all of the following:

- (a) give notice of the suspension or revocation to any professional registration authority;
- (b) cause notice of the suspension or revocation to be published in any professional publication;
- (c) cause notice of the suspension or revocation to be published in a newspaper;
- (d) cause notice of the suspension or revocation to be published in the *Gazette*;
- (e) give notice of the suspension or revocation to any employer or other relevant person or body.

#### 116. Offence to act if right suspended or revoked

A person must not –

(a) make, refine, prepare, prescribe, sell, supply or have in his or her possession a

scheduled substance, prohibited substance or raw narcotic; or

(b) grow, use or have in his or her possession a prohibited plant –

during any period in which a right conferred on the person to do so has been suspended or revoked by the Minister under section 92(1) of the Act.

Penalty: Fine not exceeding 10 penalty units.

#### 117. Duration of licence or authority

- (1) A licence or authority has effect until the date specified in it, unless it is renewed or cancelled.
- (2) Where an application for the renewal of a licence or authority is refused
  - (a) that licence or authority continues in force until the expiration of the period ordinarily limited for the bringing of an appeal against that refusal; and
  - (b) if such an appeal is brought, the licence or authority continues until the final determination or abandonment of that appeal.
- (3) A licence issued to a person to carry on business as a manufacturing chemist ceases to have effect upon that person ceasing to be a qualified person.

(4) A licence to grow a prohibited plant issued under section 52 of the Act in a certain year ceases to have effect on 31 December in the following year.

#### 118. Surrender of licence or authority

- (1) If a person holding a licence or authority surrenders it to the Secretary, the licence or authority ceases to have effect.
- (2) Where a licence or authority ceases to have effect otherwise than on its revocation, the person by whom the licence or authority is held must deliver that licence or authority to the Secretary.

Penalty: Fine not exceeding 10 penalty units.

#### 119. Application to extend suspension

- (1) For the purposes of section 92(3) of the Act, an application is to
  - (a) be in writing; and
  - (b) set out the grounds upon which the application is made; and
  - (c) be served on, or forwarded by certified mail to, the magistrate before the period of suspension expires.
- (2) A copy of the application is to be served on, or forwarded by certified mail to, the person in

respect of whom an application is being made under subregulation (1).

#### 120. Prescribed authorities

For the purposes of section 92A(2)(c) of the Act, the following are prescribed authorities:

- (a) the National Health and Medical Research Council, constituted under the *National Health and Medical Research Council Act 1992* of the Commonwealth;
- (b) the National Drugs and Poisons Schedule Committee, constituted under the *Therapeutic Goods Act 1989* of the Commonwealth.

#### 121. Exemptions

These regulations do not apply to –

- (a) a poison in a product listed in Appendix A to the Uniform Standard; or
- (b) a poison listed in column 1 of Appendix G to the Uniform Standard, at a concentration not exceeding the concentration specified in respect of the poison in column 2 of that Appendix; or
- (c) a poison listed in Schedules 1 to 6 to the Poisons List at a concentration not exceeding 10mg per litre or 10mg per kilogram unless that poison is also listed in Schedule 7 or 8 to the Poisons List; or

(d) a plant listed in any of Schedules 1 to 7, inclusive, to the Poisons List, or any part of that plant, except when packed or prepared for therapeutic use.

#### 122. Supply of medicine chests by RFDS

(1) In this regulation –

**RFDS** means the Royal Flying Doctor Service.

- (2) The RFDS may supply to a person a medicine chest containing any of the following:
  - (a) medicinal poisons;
  - (b) potent substances;
  - (c) restricted substances;
  - (d) narcotic substances.
- (3) If a medicine chest is supplied to a person under subregulation (2), the RFDS must enter into an arrangement with the person under which the person is given responsibility for the storage and security of the medicine chest.
- (4) If requested by the Secretary, the RFDS must provide the Secretary with the name and contact details of a person to whom a medicine chest is supplied under subregulation (2).
- (5) A person to whom a medicine chest is supplied under subregulation (2) must ensure that the

chest is kept in one of the following vehicles, places or localities:

- (a) on an RFDS aircraft;
- (b) on Maatsuyker Island;
- (c) on Swan Island;
- (d) on Maria Island;
- (e) on a Bass Strait oil rig or gas rig;
- (f) at Corinna;
- (g) at Ansons Bay;
- (h) at Musselroe Bay.

#### 123. Emergency use of medicine chest

In an emergency, any person, if so directed by a medical practitioner, may possess or administer any substance contained in a medicine chest supplied under regulation 122.

## 124. Reporting of acquisition and disposal of relevant substances

(1) In this regulation –

relevant substance means a substance in respect of which the Secretary determines records are to be kept in the relevant substances database;

- relevant substances database means the database established and maintained under subregulation (2)(a);
- required information means the particulars of each acquisition and disposal of a relevant substance required by the Secretary to be included in the relevant substances database;

#### *specified person* means the following persons:

- (a) a pharmacist;
- (b) a dispensing medical practitioner;
- (c) a dispensing authorised health professional;
- (d) a licensed manufacturing chemist;
- (e) a licensed wholesale chemist.
- (2) The Secretary
  - (a) is to establish and maintain a database containing records of the acquisition and disposal of relevant substances by specified persons; and
  - (b) may authorise a person, or class of persons, to access, use or disclose information contained in the relevant substances database if the Secretary is satisfied that such access would assist in achieving or implementing the purposes of the Act.

(3) A person, or class of persons, authorised by the Secretary under subregulation (2)(b), must not access, use or disclose information contained in the relevant substances database except in accordance with that authorisation.

Penalty: Fine not exceeding 10 penalty units.

(4) Except as otherwise approved by the Secretary, if a specified person acquires or disposes of a relevant substance, the specified person must, as close to immediately as practicable, enter the required information for that acquisition or disposal in the relevant substances database.

Penalty: Fine not exceeding 10 penalty units.

#### 125. Transport by drone prohibited

A person must not, without the Secretary's approval, use a drone for the transport of any scheduled substance.

Penalty: Fine not exceeding 10 penalty units.

### 126. Administration of drugs by midwives under general orders

(1) In this regulation –

drug means any of the following substances:

- (a) ergometrine;
- (b) metoclopramide;
- (c) morphine;

- (d) oxytocin;
- (e) pethidine;
- (f) promethazine;

general order means an order issued by a
 medical practitioner under
 subregulation (2);

*hospital* means a hospital that provides obstetric services.

- (2) Subject to this regulation, a medical practitioner may issue an order to the Director of Nursing of a hospital authorising a midwife who practises midwifery in that hospital to, in the midwife's discretion, do any one or more of the following things in that hospital in accordance with the order:
  - (a) administer any drug specified in the order to a patient of that medical practitioner;
  - (b) administer naloxone neonatally to a child born of a patient of that medical practitioner;
  - (c) administer hepatitis B vaccine neonatally to a child born of a patient of that medical practitioner.
- (3) A medical practitioner must not issue a general order that purports to authorise a midwife to –

- (a) administer a scheduled substance other than a drug, naloxone or hepatitis B vaccine; or
- (b) administer a drug otherwise than in accordance with subregulation (9); or
- (c) administer naloxone otherwise than in accordance with subregulation (10).
- (4) A general order is to
  - (a) be in writing; and
  - (b) specify which substances may be administered under the order; and
  - (c) state the name of the hospital in respect of which it is issued; and
  - (d) be signed and dated by the medical practitioner issuing the order.
- (5) A general order is taken to have been issued when it is received by the Director of Nursing of the hospital to which it applies.
- (6) A medical practitioner must not vary a general order once it has been issued.
- (7) A medical practitioner may revoke a general order at any time by giving not less than 24 hours' written notice of the revocation to the Director of Nursing of the hospital in respect of which the order was issued.
- (8) If a medical practitioner issues a general order in respect of a hospital, a midwife who practises

midwifery in that hospital may, in his or her discretion, do any one or more of the following things in that hospital in accordance with the order:

- (a) administer drugs to a patient of that medical practitioner;
- (b) administer naloxone neonatally to a child born of a patient of that medical practitioner;
- (c) administer hepatitis B vaccine neonatally to a child born of a patient of that medical practitioner.
- (9) For the purposes of this regulation, a general order may authorise the administration of drugs to a patient in the following doses and quantities and in the following manner of administration:
  - (a) in the case of ergometrine one dose not exceeding 0.5mg administered intramuscularly after delivery of the patient's child;
  - (b) in the case of metoclopramide one dose not exceeding 10mg administered intramuscularly;
  - (c) in the case of morphine one dose not exceeding 5mg administered intramuscularly;
  - (d) in the case of oxytocin one dose not exceeding 10 international units administered intravenously or

- intramuscularly after delivery of the patient's child;
- (e) in the case of pethidine one dose not exceeding 50mg administered intravenously or one dose not exceeding 100mg administered intramuscularly;
- (f) in the case of promethazine 2 doses, neither exceeding 25mg, administered intramuscularly.
- (10) A general order may authorise one dose of naloxone, not exceeding 0.02mg, to be administered neonatally.
- (11) A midwife who administers a drug, naloxone or hepatitis B vaccine to a person in accordance with a general order must enter details of the administration in that person's drug therapy record.

## 127. Administration of certain substances by disability service workers

(1) In this regulation –

**Department** means the department that is responsible to the Minister to whom the administration of the *Disability Services Act 2011* is assigned;

Secretary means the Secretary of the Department;

specified narcotic substance means –

- (a) dexamphetamine; or
- (b) methylphenidate; or
- (c) lisdexamphetamine.
- (2) A person may administer, or make available for self-administration, to another person a medicinal poison, potent substance, restricted substance or specified narcotic substance if
  - (a) the person administering or making available the poison or substance is
    - (i) employed by a disability services program approved by the Secretary or employed by a disability service provider who is funded by, and is the subject of a funding agreement with, the Department; and
    - (ii) acting in accordance with guidelines approved by the Secretary; and
  - (b) the person to whom the poison or substance is administered or made available
    - (i) is receiving services from a disability services program approved by the Secretary or from a disability service provider who is funded by, and is the subject of a funding agreement with, the Department; and

- (ii) is incapable of safely administering the poison or substance to himself or herself or needs assistance with selfadministration; and
- (c) in the case of a medicinal poison, the poison has been lawfully supplied and the administration is in accordance with the manufacturer's instructions; and
- (d) in the case of a potent substance, the substance has been lawfully supplied and the administration is in accordance with the instructions of a medical practitioner, dentist, pharmacist, endorsed midwife, authorised nurse practitioner or authorised health professional; and
- (e) in the case of a restricted substance, the substance has been lawfully prescribed and supplied for the person to whom it is being administered or made available and the administration is in accordance with the directions of a medical practitioner, dentist, authorised health professional endorsed midwife or authorised nurse practitioner; and
- (f) in the case of a specified narcotic substance, the substance has been lawfully prescribed and supplied for the person to whom it is being administered or made available and the administration is in accordance with the directions of a medical practitioner; and

(g) in the case of a specified narcotic substance, the storage and recording of the substance is in accordance with the guidelines referred to in paragraph (a)(ii).

#### 128. Disability service workers may assist with selfadministration

A person who is employed by a disability services program approved by the Secretary or employed by a disability service provider who is funded by, and is the subject of a funding agreement with, the Department may assist another person to self-administer a narcotic substance if —

- (a) the substance has been lawfully supplied to the other person; and
- (b) the other person has the mental capacity to manage the administration of his or her own medication; and
- (c) the other person does not have the physical capacity to self-administer the substance.

#### 129. Administration of certain substances by school staff

(1) In this section –

governing body has the same meaning as in the Education Act 2016;

parent has the same meaning as in the Education Act 2016;

- *principal* has the same meaning as in the *Education Act 2016*;
- registered school has the same meaning as in the Education Act 2016;
- school has the same meaning as in the Education Act 2016;
- school ancillary staff means any member of school staff who is not
  - (a) a teacher; or
  - (b) a guidance officer; or
  - (c) a social worker; or
  - (d) a speech pathologist;
- school staff includes teachers, guidance officers, social workers, speech pathologists and school ancillary staff;
- school student has the same meaning as in the *Education Act 2016*;
- State school has the same meaning as in the Education Act 2016.
- (2) A person may administer, or make available for self-administration, to a school student a medicinal poison, potent substance, restricted substance or narcotic substance if
  - (a) the person administering or making available the poison or substance –

- (i) is a member of the school staff; and
- (ii) is acting
  - (A) with the authority of the principal; and
  - (B) in the case of a State school, in accordance with guidelines approved by the Secretary of the department responsible for the administration of the Education Act 2016; and
  - (C) in the case of a registered school, in accordance with guidelines approved by the governing body of the registered school; and
- (b) the school student is incapable of safely administering the poison or substance to himself or herself or needs assistance with self-administration; and
- (c) in the case of a medicinal poison, the poison has been lawfully supplied and the administration is in accordance with the manufacturer's instructions; and
- (d) in the case of a potent substance, the substance has been lawfully supplied and the administration is in accordance with the instructions of a medical practitioner,

dentist, pharmacist, authorised nurse practitioner or authorised health professional; and

- (e) in the case of a restricted substance, the substance has been lawfully prescribed and supplied for the school student to whom it is being administered or made available and the administration is in accordance with the directions of a medical practitioner, dentist, authorised health professional or authorised nurse practitioner; and
- (f) in the case of a narcotic substance, the substance has been lawfully prescribed and supplied for the school student to whom it is being administered or made available and the administration is in accordance with the directions of a medical practitioner, dentist, authorised health professional or authorised nurse practitioner; and
- (g) in the case of a narcotic substance, the storage and recording of the substance is in accordance with the guidelines referred to in paragraph (a)(ii)(B) or (C).
- (3) The guidelines referred to in subregulation (2)(a)(ii)(B) or (C) must include the following:
  - (a) the form or method of authorisation that is to be given by a parent, medical practitioner, dentist, authorised health

- professional or authorised nurse practitioner;
- (b) storage and recording requirements for a medicinal poison, potent substance, restricted substance or narcotic substance;
- (c) protocols for the administration orally, subcutaneously or by any other means of a medicinal poison, potent substance, restricted substance or narcotic substance;
- (d) protocols for dealing with narcotics specified in Schedule 8 to the Poisons List;
- (e) information on the appropriate disposal of an unused medicinal poison, potent substance, restricted substance or narcotic substance.

# 130. Administration of certain substances by TasTAFE employees

- (1) In this section
  - parent includes a guardian or other person having the care or control of a Polytechnic student;
  - post-Year 10 education and training means education and training that is usually undertaken by persons following the completion of the year of secondary

education commonly known as Year 10, but does not include higher education, within the meaning of the *Tasmanian Qualifications Authority Act 2003*;

- TasTAFE employee has the same meaning as in the TasTAFE (Skills and Training Business) Act 2021.
- (2) A person may administer, or make available for self-administration, to a TasTAFE student a medicinal poison, potent substance, restricted substance or narcotic substance if
  - (a) the person administering making available the poison or substance
    - (i) is a TasTAFE employee; and
    - (ii) is acting -
      - (A) with the authority of the TasTAFE CEO; and
      - (B) in accordance with guidelines approved by the TasTAFE CEO; and
  - (b) the TasTAFE student is incapable of safely administering the poison or substance to himself or herself or needs assistance with self-administration; and
  - (c) in the case of a medicinal poison, the poison has been lawfully supplied and the administration is in accordance with the manufacturer's instructions; and

- (d) in the case of a potent substance, the substance has been lawfully supplied and the administration is in accordance with the instructions of a medical practitioner, dentist, pharmacist, authorised nurse practitioner or authorised health professional; and
- (e) in the case of a restricted substance, the substance has been lawfully prescribed and supplied for the TasTAFE student to whom it is being administered or made available and the administration is in accordance with the directions of a medical practitioner, dentist, authorised health professional or authorised nurse practitioner; and
- (f) in the case of a narcotic substance, the substance has been lawfully prescribed and supplied for the TasTAFE student to whom it is being administered or made available and the administration is in accordance with the directions of a medical practitioner, dentist, authorised health professional or authorised nurse practitioner; and
- (g) in the case of a narcotic substance, the storage and recording of the substance is in accordance with the guidelines referred to in paragraph (a)(ii)(B).
- (3) The guidelines referred to in subregulation (2)(a)(ii)(B) must include the following:

- (a) the form or method of authorisation that is to be given by a parent, medical practitioner, dentist, authorised health professional or authorised nurse practitioner;
- (b) storage and recording requirements for a medicinal poison, potent substance, restricted substance or narcotic substance;
- (c) protocols for the administration orally, subcutaneously or by any other means of a medicinal poison, potent substance, restricted substance or narcotic substance;
- (d) protocols for dealing with narcotics specified in Schedule 8 to the Poisons List;
- (e) information on the appropriate disposal of an unused medicinal poison, potent substance, restricted substance or narcotic substance.

# 131. Administration of certain substances by child carers, &c.

(1) In this regulation –

approved provider has the same meaning as in the Education and Care Services National Law (Tasmania);

- *child* means a child who has not attained the age of 13 years and who is being provided with child care;
- child care has the same meaning as in the Child Care Act 2001;
- child carer has the same meaning as in the Child Care Act 2001;
- child care service has the same meaning as in the Child Care Act 2001:
- education and care service has the same meaning as in the Education and Care Services National Law (Tasmania);
- **guidelines** means guidelines issued under subregulation (6);
- nominated supervisor has the same meaning as in the Education and Care Services National Law (Tasmania);
- parent includes a guardian or other person
   having the care or control of a child;
- person-in-charge has the same meaning as in the Child Care Act 2001;
- **Regulatory Authority** has the same meaning as in the Education and Care Services National Law (Tasmania).
- (2) A person may administer, or make available for self-administration, to a child attending child care a medicinal poison, potent substance, restricted substance or narcotic substance if –

- (a) the person administering or making available the poison or substance
  - (i) is a child carer; and
  - (ii) is acting with the authority of the person-in-charge given either specifically to the child carer or by the application of the general written policies of the child care service; and
  - (iii) is acting in accordance with Child Care Standards approved by the Secretary of the department responsible for the administration of the *Child Care Act 2001*; and
- (b) the child is incapable of safely administering the poison or substance to himself or herself or needs assistance with self-administration; and
- (c) in the case of a medicinal poison, the poison has been lawfully supplied and the administration is in accordance with the manufacturer's instructions; and
- (d) in the case of a potent substance, the substance has been lawfully supplied and the administration is in accordance with the instructions of a medical practitioner, dentist, pharmacist, authorised nurse practitioner or authorised health professional; and

- (e) in the case of a restricted substance, the substance has been lawfully prescribed and supplied for the child to whom it is being administered or made available and the administration is in accordance with the directions of a medical practitioner, dentist, authorised health professional or authorised nurse practitioner; and
- (f) in the case of a narcotic substance, the substance has been lawfully prescribed and supplied for the child to whom it is being administered or made available and the administration is in accordance with the directions of a medical practitioner, dentist, authorised health professional or authorised nurse practitioner; and
- (g) in the case of a narcotic substance, the storage and recording of the substance is in accordance with the Child Care Standards referred to in paragraph (a)(iii).
- (3) The Child Care Standards referred to in subregulation (2)(a)(iii) must include the following:
  - (a) the form or method of authorisation that is to be given by a parent, medical practitioner, dentist, authorised health professional or authorised nurse practitioner;
  - (b) storage and recording requirements for a medicinal poison, potent substance,

- restricted substance or narcotic substance;
- (c) protocols for the administration orally, subcutaneously or by any other means of a medicinal poison, potent substance, restricted substance or narcotic substance;
- (d) protocols for dealing with narcotics specified in Schedule 8 to the Poisons List;
- (e) information on the appropriate disposal of an unused medicinal poison, potent substance, restricted substance or narcotic substance.
- (4) A person may administer, or make available for self-administration, to a child attending an education and care service a medicinal poison, potent substance, restricted substance or narcotic substance if
  - (a) the person administering or making available the poison or substance
    - (i) is an approved provider; and
    - (ii) is acting with the authority of the nominated supervisor given either specifically to the approved provider or by the application of the general written policies of the education and care service; and

- (iii) is acting in accordance with the regulations made under the Education and Care Services National Law (Tasmania) and the guidelines; and
- (b) the child is incapable of safely administering the poison or substance to himself or herself or needs assistance with self-administration; and
- (c) in the case of a medicinal poison, the poison has been lawfully supplied and the administration is in accordance with the manufacturer's instructions; and
- (d) in the case of a potent substance, the substance has been lawfully supplied and the administration is in accordance with the instructions of a medical practitioner, dentist, pharmacist, authorised nurse practitioner or authorised health professional; and
- (e) in the case of a restricted substance, the substance has been lawfully prescribed and supplied for the child to whom it is being administered or made available and the administration is in accordance with the directions of a medical practitioner, dentist, authorised health professional or authorised nurse practitioner; and
- (f) in the case of a narcotic substance, the substance has been lawfully prescribed and supplied for the child to whom it is

being administered or made available and the administration is in accordance with the directions of a medical practitioner, dentist, authorised health professional or authorised nurse practitioner; and

- (g) in the case of a narcotic substance, the storage and recording of the substance is in accordance with the regulations made under the Education and Care Services National Law (Tasmania) and the guidelines.
- (5) The requirements of subregulation (4) apply in relation to a child attending an education and care service in addition to any requirements relating to the administration, or the making available for administration, of medication specified in the Education and Care Services National Law (Tasmania).
- (6) The Regulatory Authority may issue guidelines for the purposes of subregulation (4) that are not contrary to the regulations made under the Education and Care Services National Law (Tasmania).
- (7) The Regulatory Authority must include in the guidelines the following, unless to do so would cause the guidelines to be contrary to the regulations made under the Education and Care Services National Law (Tasmania):
  - (a) the form or method of authorisation that is to be given by a parent, medical practitioner, dentist, authorised health

- professional or authorised nurse practitioner;
- (b) storage and recording requirements for a medicinal poison, potent substance, restricted substance or narcotic substance;
- (c) protocols for the administration orally, subcutaneously or by any other means of a medicinal poison, potent substance, restricted substance or narcotic substance;
- (d) protocols for dealing with narcotic substances specified in Schedule 8 to the Poisons List;
- (e) information on the appropriate disposal of an unused medicinal poison, potent substance, restricted substance or narcotic substance.

### 132. Administration of certain substances by fosterparents

A person may administer, or make available for self-administration, to a child in his or her care a medicinal poison, potent substance, restricted substance or narcotic substance if –

- (a) the person administering or making available the poison or substance
  - (i) is a foster-parent; and

- (ii) is acting in accordance with guidelines approved by the Secretary; and
- (b) the child to whom the poison or substance is administered or made available
  - (i) is under the guardianship or in the custody of the Secretary of the department responsible for the administration of the Children, Young Persons and Their Families Act 1997; and
  - (ii) is incapable of safely administering the poison or substance to himself or herself or needs assistance with selfadministration; and
- (c) in the case of a medicinal poison, the poison has been lawfully supplied and the administration is in accordance with the manufacturer's instructions; and
- (d) in the case of a potent substance, the substance has been lawfully supplied and the administration is in accordance with the instructions of a medical practitioner, dentist, pharmacist, authorised nurse practitioner or authorised health professional; and
- (e) in the case of a restricted substance, the substance has been lawfully prescribed and supplied for the child to whom it is

being administered or made available and the administration is in accordance with the directions of a medical practitioner, dentist, authorised health professional or authorised nurse practitioner; and

- (f) in the case of a narcotic substance, the substance has been lawfully prescribed and supplied for the child to whom it is being administered or made available and the administration is in accordance with the directions of a medical practitioner, dentist, authorised health professional or authorised nurse practitioner; and
- (g) in the case of a narcotic substance, the storage and recording of the substance is in accordance with the guidelines referred to in paragraph (a)(ii).

## 133. Administration of certain substances by aged-care workers in residential care services

(1) In this regulation –

aged care service has the same meaning as in the Aged Care Act 1997 of the Commonwealth;

residential care has the same meaning as in the Aged Care Act 1997 of the Commonwealth;

residential care service has the same meaning as in the Aged Care Act 1997 of the Commonwealth;

- specified narcotic substance means buprenorphine in patches for transdermal delivery.
- (2) A person who is not a nurse may administer, or make available for self-administration, to another person who is being provided with residential care by a residential care service, a medicinal poison, potent substance, restricted substance or the specified narcotic substance if
  - (a) the person administering or making available the poison or substance
    - (i) is employed by an aged care service that provides a residential care service and is acting with the authority of the person in charge of that service; and
    - (ii) is acting under the general supervision or direction of a registered nurse; and
    - (iii) has met the requirements of relevant nationally accredited training modules relating to the administration and storage of medication and maintains any competency requirements of those modules; and
    - (iv) is acting in accordance with guidelines approved by the Secretary; and

- (b) the other person is incapable of safely administering the poison or substance to himself or herself or needs assistance with self-administration; and
- (c) in the case of a medicinal poison, the poison has been lawfully supplied and the administration is in accordance with the manufacturer's instructions; and
- (d) in the case of a potent substance, the substance has been lawfully supplied and the administration is in accordance with the instructions of a medical practitioner, dentist, pharmacist, authorised nurse practitioner or authorised health professional; and
- (e) in the case of a restricted substance, the substance has been lawfully prescribed and supplied for the person to whom it is being administered or made available and the administration is in accordance with the directions of a medical practitioner, dentist, authorised health professional or authorised nurse practitioner; and
- (f) in the case of the specified narcotic substance, the substance has been lawfully prescribed and supplied for the person to whom it is being administered or made available and the administration is in accordance with the directions of a medical practitioner, dentist, authorised health professional or authorised nurse practitioner.

# 134. Administration of certain substances by aged-care workers in community care services

- (1) In this regulation
  - aged care service has the same meaning as in the Aged Care Act 1997 of the Commonwealth;
  - community care has the same meaning as in the Aged Care Act 1997 of the Commonwealth;
  - community care service has the same meaning as in the Aged Care Act 1997 of the Commonwealth;
- (2) A person who is not a nurse may administer, or make available for self-administration, to another person, who is being provided with community care by a community care service, a medicinal poison, potent substance, restricted substance or narcotic substance if
  - (a) the person administering or making available the poison or substance
    - (i) is employed by an aged care service that provides a community care service and is acting with the authority of the person in charge of that service; and
    - (ii) is acting under the general supervision or direction of a registered nurse; and

- (iii) has met the requirements of relevant nationally accredited training modules relating to the administration and storage of medication and maintains any competency requirements of those modules; and
- (b) the other person is incapable of safely administering the poison or substance to himself or herself or needs assistance with self-administration; and
- (c) in the case of a medicinal poison, the poison has been lawfully supplied and the administration is in accordance with the manufacturer's instructions; and
- (d) in the case of a potent substance, the substance has been lawfully supplied and the administration is in accordance with the instructions of a medical practitioner, dentist, pharmacist, authorised nurse practitioner or authorised health professional; and
- (e) in the case of a restricted substance, the substance has been lawfully prescribed and supplied for the person to whom it is being administered or made available and the administration is in accordance with the directions of a medical practitioner, dentist, authorised health professional or authorised nurse practitioner; and

(f) in the case of a narcotic substance, the substance has been lawfully prescribed and supplied for the person to whom it is being administered or made available and the administration is in accordance with the directions of a medical practitioner, dentist, authorised health professional or authorised nurse practitioner.

#### 135. Administration of certain substances by carers

- (1) Subject to subregulation (2), a person may administer, or make available for self-administration, to another person a medicinal poison, potent substance, restricted substance or narcotic substance if
  - (a) the person administering the poison or substance, or making it available, has the care of, and responsibility for, the other person; and
  - (b) the other person is incapable of safely administering the poison or substance to himself or herself or needs assistance with self-administration; and
  - (c) in the case of a medicinal poison, the poison has been lawfully supplied and the administration is in accordance with the manufacturer's instructions; and
  - (d) in the case of a potent substance, the substance has been lawfully supplied and the administration is in accordance with the instructions of a medical practitioner,

- dentist, pharmacist, authorised nurse practitioner or authorised health professional; and
- (e) in the case of a restricted substance, the substance has been lawfully prescribed and supplied for the person to whom it is being administered or made available and the administration is in accordance with the directions of a medical practitioner, dentist, authorised health professional or authorised nurse practitioner; and
- (f) in the case of a narcotic substance, the substance has been lawfully prescribed and supplied for the person to whom it is being administered or made available and the administration is in accordance with the directions of a medical practitioner, dentist, authorised health professional or authorised nurse practitioner.
- (2) This regulation does not authorise the administration, or making available, of a poison or substance by
  - (a) a person employed by a disability services program approved by the Secretary or employed by a disability service provider who is funded by, and is the subject of a funding agreement with, the Department; or
  - (b) a member of school staff within the meaning of regulation 129; or

- (c) a TasTAFE employee within the meaning of regulation 130; or
- (d) a child carer within the meaning of regulation 131; or
- (e) a foster-parent within the meaning of regulation 132; or
- (f) a person employed by an aged care service that provides a residential care service within the meaning of regulation 133; or
- (g) a person employed by an aged care service that provides a community care service within the meaning of regulation 134; or
- (h) a person employed by a medical institution or day-treatment centre; or
- (i) a person employed at a detention centre.

#### 136. Administration of certain substances to detainees

A person may administer to a detainee a substance specified in Schedule 2, 3, 4 or 8 to the Poisons List if –

- (a) the person administering the substance
  - (i) is an employee employed at a detention centre; and
  - (ii) is acting –

- (A) in accordance with guidelines approved by the Secretary; or
- (B) in the case of a health professional, in the course of his or her professional practice; and
- (b) the detainee is incapable of safely administering the substance to himself or herself; and
- (c) in the case of a substance listed in Schedule 3 to the Poisons List, the substance has been supplied by a pharmacist, medical practitioner, dentist, authorised health professional or authorised nurse practitioner for the use of the detainee; and
- (d) in the case of a substance listed in Schedule 4 or 8 to the Poisons List, the substance has been prescribed or supplied by a medical practitioner, dentist, authorised health professional or authorised nurse practitioner for the use of the detainee.

#### 137. Administration of certain substances to animals

(1) A veterinary surgeon may issue a written order to a veterinary nurse, employed by the veterinary surgeon in the course of his or her practice or business –

- (a) authorising the veterinary nurse to administer a substance specified in Schedule 4 to the Poisons List, and also specified in the order, to an animal for the purpose of the treatment of that animal; and
- (b) setting out instructions for the administration by the veterinary nurse of that substance.
- (2) A veterinary nurse may administer a substance specified in Schedule 4 to the Poisons List to an animal for the purpose of treating that animal if
  - (a) the veterinary nurse is authorised by a veterinary surgeon, in accordance with subregulation (1), to administer the substance to the animal; and
  - (b) the substance has been lawfully prescribed and supplied for the animal to whom it is being administered; and
  - (c) the administration is in accordance with the instructions of that veterinary surgeon.

## 138. Possession of pseudoephedrine

(1) In this regulation –

registered goods has the same meaning as in the *Therapeutic Goods Act 1989* of the Commonwealth;

- therapeutic goods register means the Australian Register of Therapeutic Goods maintained under the *Therapeutic Goods Act 1989* of the Commonwealth.
- (2) A person must not possess more than 240 milligrams of pseudoephedrine which is not in a form included in that part of the therapeutic goods register relating to registered goods, or must not possess more than 6 grams of pseudoephedrine in a form which is included in that part of the register, unless
  - (a) the person is a medical practitioner, pharmacist, authorised nurse practitioner, registered nurse or veterinary surgeon who possesses the pseudoephedrine in the course of his or her professional practice; or
  - (b) the person is licensed or authorised under the Act or these regulations to possess pseudoephedrine and is acting in accordance with that licence or authorisation; or
  - (c) the person is the master of a vessel and the pseudoephedrine is intended to be used only for medical treatment on the vessel and is needed to complete the quantity of medicines and medical stores required or permitted to be carried on the vessel to comply with the law of the Commonwealth; or

- (d) the person is authorised in writing by the Secretary and is acting in accordance with that authorisation; or
- (e) the pseudoephedrine is prepared by a pharmacist, medical practitioner or veterinary surgeon in the course of his or her professional practice; or
- (f) the pseudoephedrine is supplied to the person by a medical practitioner, authorised nurse practitioner or a veterinary surgeon in the course of his or her professional practice; or
- (g) the pseudoephedrine is supplied to the person by a pharmacist on the written order of a medical practitioner, authorised nurse practitioner or veterinary surgeon.

Penalty: Fine not exceeding 10 penalty units.

#### 139. Savings provision

- (1) An approval, authorisation, authority, licence, permit or other similar instrument issued or granted under the *Poisons Regulations 2002* and in force immediately before the commencement of these regulations is taken to have been issued or granted under these regulations.
- (2) An authority issued or granted under the *Poisons* Regulations 1975 and in force immediately before the commencement of the *Poisons*

Regulations 2002 is taken to have been issued or granted under these regulations.

### 140. Infringement offences

- (1) For the purposes of section 92B of the Act
  - (a) an offence against a provision of the Act specified in column 2 of the table in Part 1 of Schedule 8 is prescribed to be an infringement offence for which an infringement notice may be issued; and
  - (b) an offence against a provision of the regulations specified in column 2 of the table in Part 2 of Schedule 8 is prescribed to be an infringement offence for which an infringement notice may be issued.
- (2) A penalty specified in column 3 of a table in Part 1 or 2 of Schedule 8 is prescribed as the penalty payable by a person for the relevant infringement offence specified in column 2 of the relevant table.

sch. 1

**SCHEDULE 1** – . . . . . . .

sch. 2

**SCHEDULE 2** – . . . . . . .

# SCHEDULE 3 – SPECIFIED PSYCHOTROPIC SUBSTANCES

Regulation 52

- 1. Anabolic and androgenic steroidal agents (S4)
- 2. Androisoxazole
- **3.** AOD-9604 (CAS No.221231-10-3)
- **4.** Benactyzine, and other substances structurally derived from diphenylmethane with ataractic properties
- **5.** Benzodiazepine derivatives not elsewhere specified in this Schedule (except clonazepam and midazolam)
- **6.** Boldenone (otherwise known as dehydrotestosterone)
- 7. Bromazepam
- **8.** Bromides (S4)
- **9.** Bromvaletone
- **10.** Butylchloral hydrate

11.	Captodiame
	Captomanic

- **12.** Carbromal
- 13. Cathine
- **14.** Chloral hydrate (S4)
- **15.** Chlorbutol (S4)
- **16.** Chlordiazepoxide
- 17. Chlormethiazole
- **18.** Chlormezanone
- **19.** CJC-1295 (CAS No.863288-34-0)
- **20.** Clobazam
- 21. Clonazepam
- 22. Clorazepate
- **23.** Clostebol (otherwise known as 4-chlorotestosterone)
- **24.** Codeine (S4)

sch. 3

- **25.** Darbepoetin alfa
- **26.** Dextropropoxyphene
- 27. Diazepam
- **28.** Diethylpropion
- **29.** Drostanolone
- **30.** Ephedrine
- **31.** Epoetin alfa
- **32.** Epoetin beta
- **33.** Erythropoietin
- **34.** Erythropoietins not elsewhere specified in this Schedule
- **35.** Ethchlorvynol
- **36.** Ethinamate
- **37.** Ethyloestrenol
- **38.** Fluoxymesterone

- **39.** Flurazepam
- **40.** Follistatin
- 41. Glutethimide
- **42.** Growth hormone-releasing hormones (GHRHs), including those separately specified in Schedule 4 to the Poisons List (S4)
- **43.** Growth hormone-releasing peptide-6 (GHRP-6)
- **44.** Growth hormone-releasing peptides (GHRPs), including those separately specified in Schedule 4 to the Poisons List (S4)
- **45.** Growth hormone-releasing secretagogues (GHSs), including those separately specified in Schedule 4 to the Poisons List (S4)
- **46.** Hexarelin
- **47.** Insulin-like growth factors
- 48. Ipamorelin
- **49.** Lorazepam
- **50.** Medazepam

**51.** Meprobamate

sch. 3

52.	Mestanolone			
53.	Mesterolone methyldihydrotes		known	as
54.	Methandienone methandrostenol		known	as
55.	Methandriol			
56.	Methenolone			
57.	Methylpentynol a internal use	and other substit	uted alkynes	for
58.	Methyltestostero	ne		
59.	Methyprylone			
60.	Mibolerone			
61.	Midazolam			
62.	Nalbuphine			
63.	Nandrolone nortestosterone)	(otherwise	known	as

64.	Nitrazepam
65.	Norethandrolone
66.	Oxandrolone
67.	Oxazepam
68.	Oxymesterone (otherwise known as hydroxymethyltestosterone)
69.	Oxymetholone
70.	Paraldehyde
71.	Phentermine
72.	Pralmorelin (growth hormone-releasing peptide- 2) (GHRP-2)
73.	Prasterone
74.	Prazepam
75.	Pseudoephedrine (S4)
76.	Selective androgen receptor modulators

**77.** Somatotropin (human growth hormone)

sch. 3

- **78.** Stanolone (otherwise known as dihydrotestosterone)
- 79. Stanozolol
- 80. Temazepam
- **81.** Testosterone (S4)
- **82.** Tramadol
- **83.** Trenbolone (S4)
- **84.** Triazolam
- **85.** Triclofos
- **86.** Zolpidem
- 87. Zopiclone

# SCHEDULE 4 – SUBSTANCES NOT TO BE SUPPLIED WITHOUT APPROVED INFORMATION SHEET

Regulation 55

- 1. Acitretin
- **2.** Bexarotene for human use
- 3. Bosentan for human use
- 4. Dextropropoxyphene
- **5.** Etretinate
- **6.** Isotretinoin
- 7. Sitaxentan
- **8.** Thalidomide

### **SCHEDULE 5 – SPECIFIED POTENT SUBSTANCES**

Regulation 56

- 1. Acepifylline (S3)
- **2.** Aminophylline (S3)
- **3.** Dihydrocodeine (S3) in undivided preparations
- **4.** Salbutamol (S3)
- **5.** Terbutaline (S3)
- **6.** Theophylline (S3)

### SCHEDULE 6 – PROCEDURES TO BE FOLLOWED IN A MEDICAL INSTITUTION IN CASE OF LOSS, SPILLAGE, BREAKAGE OR UNINTENTIONAL DESTRUCTION OF NARCOTIC SUBSTANCES

Regulation 39

#### 1. Procedure if narcotic substance lost

The procedure to be followed in a medical institution if a narcotic substance is lost is as follows:

- (a) the health professional who discovers the loss must, as soon as practicable, inform another health professional;
- (b) both of those health professionals must, as soon as practicable, enter details of the loss in the narcotic substances register and sign that entry;
- (c) the health professional who discovered the loss must, as soon as practicable, report the loss to the authorised officer.

## 2. Procedure if narcotic substance spilt, broken, &c.

The procedure to be followed in a medical institution if a narcotic substance is spilt, broken or unintentionally destroyed is as follows:

(a) the person handling the narcotic substance when the spillage, breakage or destruction occurs must, as soon as practicable, inform a health professional;

- (b) the health professional and that person must both, as soon as practicable, enter details of the spillage, breakage or destruction in the narcotic substances register and sign that entry;
- (c) the health professional must, as soon as practicable, arrange for and witness the disposal of any residue of the narcotic substance in the presence of another health professional;
- (d) the health professional must, as soon as practicable, report the spillage, breakage or destruction to the authorised officer.

#### **SCHEDULE 7 – FEES**

Regulation 13 **Fee units** 1. Licence under regulation to manufacture and sell or supply scheduled 450 (a) substances including narcotic substances narcotic substances 350 (b) (c) scheduled substances other 115 than narcotic substance 2. Licence under regulation 5 to sell or supply by wholesale dealing – scheduled (a) substances 115 including narcotic substances narcotic substances 60 (b) (c) scheduled substances other 60 than narcotic substances 3. Permit under regulation 6 to purchase 25 a substance specified in Schedule 1, 2, 3 or 4 to the Poisons List for industrial, educational, advisory or research purposes 4. Copy of certificate showing the result 12 analysis or examination of an supplied under section 66 of the Act

5.	Additional copy of certificate of analysis or certificate of inspection	6
6.	Analysis carried out under section 63 of the Act	
	(a) organic drugs –	
	(i) qualitative analysis	45
	(ii) quantitative analysis	60
	(b) inorganic drugs –	
	(i) qualitative analysis	45
	(ii) quantitative analysis	60
	(c) pesticides, herbicides, rodenticides, &c. –	
	(i) qualitative analysis	45
	(ii) quantitative analysis	60
	(d) poisons, not elsewhere included –	
	(i) organic – qualitative analysis	45
	(ii) organic – quantitative analysis	60
	(iii) inorganic – qualitative analysis	45
	I	

	(iv) inorganic – quantitative analysis	60
7.	Licence to sell or supply substances to which section 27 of the Act applies	25
8.	Application under regulation 91 for authorisation to manufacture, obtain, possess, sell or supply a prescribed dangerous poison	60

# SCHEDULE 8 – INFRINGEMENT NOTICE OFFENCES Regulation 140

#### PART 1 – OFFENCES UNDER THE ACT

Column 1	Column 2	Column 3	
Item No.	Section of Act	Penalty	
		(penalty units)	
1.	Section 12(4)	4	
2.	Section 13(2)	20	
3.	Section 13A	In the case of an individual, 20	
		In the case of a body corporate, 100	
4.	Section 18(1)	In the case of an individual, 20	
		In the case of a body corporate, 100	
5.	Section 18(2)	In the case of an individual, 20	
		In the case of a body corporate, 100	
6.	Section 18(2A)	In the case of an individual, 20	
		In the case of a body corporate, 100	
7.	Section 26(1)	2	
8.	Section 26(1B)	4	
9.	Section 27(6)	2	
10.	Section 28(1)	4	
11.	Section 28(2)	4	
		<u>I</u>	

sch. 8

Column 1 Item No.	Column 2 Section of Act	Column 3  Penalty  (penalty units)
12.	Section 29(1)	4
13.	Section 29(2)	2
14.	Section 31(4)	2
15.	Section 32(2)	2
16.	Section 33	2
17.	Section 34(1)	2
18.	Section 36(1)	10
19.	Section 37(2)	4
19A	Section 38G	2
19B	Section 38H	2
19C	Section 38I(1)	2
19D	Section 38I(2)	2
20.	Section 41(1)	2
21.	Section 43	2
22.	Section 45(1)	10
23.	Section 45(2)	10
24.	Section 46	10
25.	Section 47D(1)	10
26.	Section 47D(2)	10
	1	I

sch. 8

Column 1	Column 2	Column 3	
Item No.	Section of Act	Penalty	
		(penalty units)	
27.	Section 47D(3)	10	
28.	Section 47D(4)	10	
29.	Section 47D(5)	10	
30.	Section 48(1)	10	
31.	Section 49(1)	10	
32.	Section 52(1)	10	
33.	Section 55(1)	10	
34.	Section 56(1)	4	
35.	Section 58(1)	10	
36.	Section 59B(1B)	10	
37.	Section 59C(1)	10	
38.	Section 59C(2)	10	
39.	Section 59C(3)	10	
40.	Section 59C(4)	10	
41.	Section 59C(5)	10	
42.	Section 69	1	
43.	Section 69AC	In the case of an individual, 20	
		In the case of a body corporate, 100	

#### sch. 8

Column 1	Column 2	Column 3	
Item No.	Section of Act	Penalty	
		(penalty units)	
44.	Section 80	2	
45.	Section 81(1)	2	
46.	Section 82(1)	10	
47.	Section 82(2)	10	
48.	Section 83(1)	2	
49.	Section 83A(1)	In the case of an individual, 10	
		In the case of a body corporate, 20	
50.	Section 83B	10	
51.	Section 83C	20	
52.	Section 84B(2)	In the case of an individual, 2	
		In the case of a body corporate, 10	
52A.	Section 86E	In the case of an individual, 10	
		In the case of a body corporate, 20	
52B.	Section 86G(4)	10	
53.	Section 90D(2)	2	

#### PART 2 – OFFENCES UNDER THE REGULATIONS

		ER THE RECEPTION
Column 1	Column 2	Column 3
Item No.	Regulation	Penalty

		(penalty units)
1.	Regulation 7(3)	2
2.	Regulation 12(3)	2
3.	Regulation 15(1)	2
4.	Regulation 15(2)	2
5.	Regulation 16(1)	2
6.	Regulation 16(2)	2
7.	Regulation 16(3)	2
8.	Regulation 16(4)	2
9.	Regulation 16(5)	2
10.	Regulation 16(7)	2
11.	Regulation 18(1)	2
12.	Regulation 18(8)	2
13.	Regulation 19(1)	2
14.	Regulation 19(2)	2
15.	Regulation 20(1)	2
16.	Regulation 20(4)	2
17.	Regulation 20(5)	2
18.	Regulation 20(7)	2
19.	Regulation 20(10)	2

20.	Regulation 20(11)	2
21.	Regulation 20(12)	2
22.	Regulation 20(16)	2
23.	Regulation 22(1)	2
24.	Regulation 22(2)	2
25.	Regulation 23(2)	2
26.	Regulation 24	2
27.	Regulation 27(1)	2
28.	Regulation 27(7)	2
29.	Regulation 27(8)	2
30.	Regulation 27(11)	2
31.	Regulation 27(12)	2
32.	Regulation 27(13)	2
33.	Regulation 27(14)	2
34.	Regulation 27(16)	2
35.	Regulation 27(17)	2
36.	Regulation 27(18)	2
37.	Regulation 27(19)	2
38.	Regulation 27(20)	2
39.	Regulation 27(22)	2
	1	

40.	Regulation 28(1)	2
41.	Regulation 30	2
42.	Regulation 31(1)	2
43.	Regulation 31(2)	2
44.	Regulation 32	2
45.	Regulation 33(1)	2
46.	Regulation 33(2)	2
47.	Regulation 34(1)	2
48.	Regulation 34(5)	2
49.	Regulation 35(4)	2
50.	Regulation 37(1)	2
51.	Regulation 37(3)	2
52.	Regulation 38(1)	2
53.	Regulation 38(4)	2
54.	Regulation 40(1)	2
55.	Regulation 41(1)	2
56.	Regulation 43(1)	2
57.	Regulation 43(2)	2
58.	Regulation 43(3)	2
59.	Regulation 43(4)	2

59A.	Regulation 43(5)	2
60.	Regulation 44	2
61.	Regulation 45(1)	2
62.	Regulation 45(5)	2
63.	Regulation 45(8)	2
64.	Regulation 47(2)	2
65.	Regulation 49(1)	2
66.	Regulation 49(2)	2
67.	Regulation 50(2)	2
68.	Regulation 51(1)	2
69.	Regulation 51(7)	2
70.	Regulation 51(9)	2
71.	Regulation 51(11)	2
72.	Regulation 51(12)	2
73.	Regulation 51(13)	2
74.	Regulation 51(16)	2
75.	Regulation 51(17)	2
76.	Regulation 51(18)	2
77.	Regulation 57	2
78.	Regulation 58(2)	2

79.	Regulation 58(3)	2
80.	Regulation 58(4)	2
81.	Regulation 58(5)	2
82.	Regulation 61	2
83.	Regulation 62(1)	2
84.	Regulation 62(2)	2
85.	Regulation 63(1)	2
86.	Regulation 64	2
87.	Regulation 65(1)	2
88.	Regulation 65(3)	2
89.	Regulation 65(5)	2
90.	Regulation 72	2
91.	Regulation 76(1)	2
92.	Regulation 79(1)	2
93.	Regulation 83(1)	2
94.	Regulation 83(2)	2
95.	Regulation 84(1)	2
96.	Regulation 85(1)	2
97.	Regulation 86(1)	2
98.	Regulation 86(3)	2
	ı	ı

99.	Regulation 87(2)	2
100.	Regulation 87(4)	2
101.	Regulation 88(1)	2
102.	Regulation 89(1)	2
103.	Regulation 89(2)	2
104.	Regulation 89(3)	2
105.	Regulation 89(4)	2
106.	Regulation 90	2
107.	Regulation 91(11)	2
108.	Regulation 92	2
109.	Regulation 94(1)	2
110.	Regulation 94(2)	2
111.	Regulation 94(3)	2
112.	Regulation 107	2
113.	Regulation 109(5)	2
114.	Regulation 110(1)	2
115.	Regulation 110(2)	2
116.	Regulation 112	2
117.	Regulation 113	2
118.	Regulation 116	2

sch.	8
------	---

119.	Regulation 118(2)	2	
120.	Regulation 124(3)	2	
121.	Regulation 124(4)	2	
122.	Regulation 125	2	
123.	Regulation 138(2)	2	

Printed and numbered in accordance with the *Rules Publication Act* 1953.

Notified in the *Gazette* on 17 December 2018.

These regulations are administered in the Department of Health.

#### **NOTES**

The foregoing text of the *Poisons Regulations 2018* comprises those instruments as indicated in the following table. Any reprint changes made under any Act, in force before the commencement of the *Legislation Publication Act 1996*, authorising the reprint of Acts and statutory rules or permitted under the *Legislation Publication Act 1996* and made before 14 March 2023 are not specifically referred to in the following table of amendments.

Citation	Serial Number	Date of
		commencement
<sup>1</sup> Poisons Regulations 2018	S.R. 2018, No. 79	17.12.2018
Poisons Amendment Regulations 2019	S.R. 2019, No. 21	17.4.2019
Poisons Amendment Regulations 2020	S.R. 2020, No. 3	31.1.2020
Poisons Amendment (Miscellaneous) Regulations 2020	S.R. 2020, No. 22	31.3.2020
Poisons Amendment Regulations 2021	S.R. 2021, No. 32	28.5.2021
Poisons Amendment Regulations (No. 2) 2021	S.R. 2021, No. 45	1.7.2021
Poisons Amendment Regulations (No. 4) 2021	S.R. 2021, No. 111	14.12.2021
Poisons Amendment Regulations (No. 3) 2021	S.R. 2021, No. 110	17.12.2021
TasTAFE (Skills and Training Business) Act 2021	No. 32 of 2021	1.7.2022
Poisons Amendment (Monitored Medicines) Regulations 2022	S.R. 2022, No. 28	1.7.2022
Poisons Amendment (Miscellaneous) Regulations 2022	S.R. 2022, No. 45	13.7.2022
Poisons Amendment Regulations 2022	S.R. 2022, No. 54	27.7.2022 Part 2 23.10.2022 Part 3
Poisons Amendment Regulations (No. 2) 2022	S.R. 2022, No. 78	24.10.2022

Citation	Serial Number	Date of
		commencement
Health Legislation (Miscellaneous Amendments) Act 2022	No. 23 of 2022	24.10.2022
Poisons Amendment Regulations 2023	S.R. 2023, No. 5	6.3.2023
Legislation Publication Act 1996	No. 17 of 1996	14.3.2023
		minor corrections

<sup>1</sup>Expires 17 December 2028 - Subordinate Legislation Act 1992

#### TABLE OF AMENDMENTS

Provision affected	How affected
Regulation 3	Amended by S.R. 2020, No. 22, No. 32 of 2021, Sched. 4,
Negulation 3	No. 23 of 2022, s. 46, S.R. 2022, No. 45 and S.R. 2022,
	No. 78
Regulation 5	Amended by No. 23 of 2022, s. 47
Regulation 11	Amended by No. 23 of 2022, s. 47 Amended by No. 23 of 2022, s. 48
Regulation 12	Amended by No. 20 of 2022, 8. 40 Amended by S.R. 2022, No. 45
Regulation 15	Amended by No. 23 of 2022, s. 49
Regulation 16	Amended by No. 23 of 2022, s. 50
Regulation 18	Amended by No. 23 of 2022, s. 51 and S.R. 2022, No. 45
Regulation 20	Amended by S.R. 2020, No. 22
Regulation 23	Amended by No. 23 of 2022, s. 52
Regulation 24	Amended by S.R. 2022, No. 45
Regulation 26	Amended by S.R. 2022, No. 78 and S.R. 2023, No. 5
Regulation 27	Amended by No. 23 of 2022, s. 53
Regulation 29	Amended by S.R. 2022, No. 54
Regulation 31	Amended by No. 23 of 2022, s. 54
Regulation 35	Amended by No. 23 of 2022, s. 55
Regulation 43	Amended by S.R. 2023, No. 5
Regulation 45	Amended by S.R. 2020, No. 22
Regulation 47	Amended by No. 23 of 2022, s. 56
Regulation 48	Amended by S.R. 2020, No. 22, No. 23 of 2022, s. 57, S.R. 2022, No. 54
	Subregulation (1A) inserted by S.R. 2022, No. 54
	Amended by S.R. 2022, No. 54, S.R. 2022, No. 78
	Substituted by S.R. 2023, No. 5
Regulation 51	Amended by No. 23 of 2022, s. 58
Regulation 53	Amended by No. 23 of 2022, s. 59
Regulation 53A	Inserted by S.R. 2020, No. 22
	Rescinded by S.R. 2021, No. 110
Regulation 54	Amended by No. 23 of 2022, s. 60
Regulation 54A	Amended by No. 17 of 1996
	Inserted by S.R. 2021, No. 32
	Amended by No. 23 of 2022, s. 61
Regulation 54B	Inserted by S.R. 2022, No. 45
Regulation 55	Amended by No. 23 of 2022, s. 62

	** **
Provision affected	How affected
Regulation 58	Amended by S.R. 2019, No. 21, S.R. 2020, No. 22, No. 32 of 2021, Sched. 4, No. 23 of 2022, s. 63 and S.R. 2022, No. 45
Regulation 59	Amended by No. 32 of 2021, Sched. 4
Regulation 60	Amended by No. 32 of 2021, Sched. 4
Regulation 61	Amended by No. 23 of 2022, s. 64
Regulation 61A of Part 4	Inserted by S.R. 2022, No. 45
Regulation 63	Amended by No. 23 of 2022, s. 65
Regulation 68	Amended by S.R. 2022, No. 45, S.R. 2022, No. 78 and S.R. 2023, No. 5
Regulation 68A of Part 4	Inserted by S.R. 2022, No. 78
Regulation 70	Amended by S.R. 2020, No. 22
Regulation 71	Amended by S.R. 2020, No. 22
Regulation 74	Amended by S.R. 2020, No. 22
Regulation 75	Amended by S.R. 2020, No. 22
Regulation 79A of Part 4	Inserted by S.R. 2020, No. 22
Regulation 79B of Part 4	Inserted by S.R. 2020, No. 22
Regulation 79C of Part 4	Inserted by S.R. 2020, No. 22
Regulation 82	Amended by S.R. 2020, No. 22, S.R. 2021, No. 32 and No. 23 of 2022, s. 66
Regulation 87	Amended by S.R. 2020, No. 22, S.R. 2021, No. 45, S.R. 2021, No. 111, No. 23 of 2022, s. 67 and S.R. 2022, No. 45
Regulation 91	Amended by S.R. 2022, No. 45
Regulation 93	Amended by No. 23 of 2022, s. 68
Regulation 95A	Inserted by S.R. 2021, No. 110
Regulation 95B	Inserted by S.R. 2021, No. 110 Substituted by S.R. 2022, No. 28
Regulation 95C	Inserted by S.R. 2021, No. 110
	Amended by No. 23 of 2022, s. 69
Regulation 95D	Inserted by S.R. 2021, No. 110
Regulation 95E	Inserted by S.R. 2021, No. 110
Regulation 95F	Inserted by S.R. 2021, No. 110
Regulation 95G	Substituted by No. 17 of 1996
	Inserted by S.R. 2022, No. 78
Population 06	Substituted by S.R. 2023, No. 5
Regulation 96	Amended by No. 23 of 2022, s. 70
Regulation 97	Amended by No. 23 of 2022, s. 71
Regulation 110	Amended by No. 23 of 2022, s. 72
Regulation 111	Amended by S.R. 2022, No. 45
Regulation 114	Amended by No. 23 of 2022, s. 73 and S.R. 2022, No. 45
Regulation 124	Amended by No. 23 of 2022, s. 74
Regulation 127	Amended by S.R. 2020, No. 22, No. 23 of 2022, s. 75 and S.R. 2022, No. 45
Regulation 129	Amended by No. 23 of 2022, s. 76

Provision affected	How affected
Regulation 130	Amended by No. 32 of 2021, Sched. 4 and No. 23 of 2022,
rtogulation 100	s. 77
Regulation 131	Amended by No. 23 of 2022, s. 78
Regulation 132	Amended by No. 23 of 2022, s. 79
Regulation 133	Amended by No. 23 of 2022, s. 80
Regulation 134	Amended by No. 23 of 2022, s. 81
Regulation 135	Amended by No. 23 of 2022, s. 82
Regulation 136	Amended by No. 23 of 2022, s. 83
Regulation 138	Amended by No. 23 of 2022, s. 84
Schedule 1	Rescinded by S.R. 2022, No. 45
Part 1 of	Amended by S.R. 2022, No. 45
Schedule 1	•
Part 2 of	Amended by S.R. 2022, No. 45
Schedule 1	•
Schedule 2	Rescinded by S.R. 2022, No. 45
Part 1 of	Amended by S.R. 2020, No. 3, S.R. 2020, No. 22 and S.R.
Schedule 8	2021, No. 110
Part 2 of	Amended by S.R. 2023, No. 5
Schedule 8	•