I certify that this is a copy of the authorised version of this Statutory Rule as at 31 March 2020, 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 31 March 2020.

K Woodward Chief Parliamentary Counsel Dated 5 May 2020

# 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
- 13. 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. Sale or supply of restricted substances other than specified psychotropic substances without prescription

- 54. Supply of restricted substance in medical institution
- 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 pharmaceutical chemists
- 59. Administration of salbutamol (S3)
- 60. Administration of adrenaline (S3)
- 61. Obtaining potent substances through misrepresentation

## Division 4 – Use, &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 – 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 6 – Possession and supply of nitrous oxide and methoxyflurane at relevant workplaces

- 69. Interpretation of Division
- 70. Possession and supply of nitrous oxide at workplace
- 71. Possession and supply of methoxyflurane at workplace
- 72. Records of obtaining, supply and administration to be kept

# 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 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

SCHEDULE	<b>1 – REQUIREMENTS IN RELATION TO NARCOTIC SUBSTANCES REGISTER</b>
140.	Infringement offences
139.	Savings provision
138.	Possession of pseudoephedrine
137.	Administration of certain substances to animals
136.	Administration of certain substances to detainees
135.	Administration of certain substances by carers
134.	Administration of certain substances by aged-care workers in community care services
133.	Administration of certain substances by aged-care workers in residential care services
132.	Administration of certain substances by foster-parents
131.	Administration of certain substances by child carers, &c.
130.	Administration of certain substances by TasTAFE employees
129.	Administration of certain substances by school staff
128.	Disability service workers may assist with self-administration
127.	Administration of certain substances by disability service workers
126.	Administration of drugs by midwives under general orders
125.	Transport by drone prohibited
124.	Reporting of acquisition and disposal of relevant substances
123.	Emergency use of medicine chest
122.	Supply of medicine chests by RFDS
121.	Exemptions
120.	Prescribed authorities
119.	Application to extend suspension
118.	Surrender of licence or authority
117.	Duration of licence or authority
116.	Offence to act if right suspended or revoked
115.	Revocation of licence to be published

SCHEDULE 2 – REQUIREMENTS IN RELATION TO WARD NARCOTIC SUBSTANCES REGISTER

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 Pharmacy Board of Australia 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 pharmaceutical chemist employed as such in that

institution or, where more than one pharmaceutical chemist is employed, the chief pharmaceutical chemist; or

- (b) where no pharmaceutical chemist is employed in that institution, the medical practitioner in charge of that institution; or
- (c) where no pharmaceutical chemist 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 pharmaceutical chemist; 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 pharmaceutical chemist 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 pharmaceutical chemist; and

#### Part 1 – Preliminary

- (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 –

### Part 1 – Preliminary

- (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 dental nurse, 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 practitioner, nurse 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 pharmaceutical chemist;
- *podiatric surgeon* means a person registered under the Health Practitioner Regulation National Law (Tasmania) in the speciality of podiatric surgery;
- *podiatrist* means a person registered under the Health Practitioner Regulation National Law (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 created by section 56 of the *Training and Workforce Development Act 2013*;
- *TasTAFE chief executive officer* means the chief executive officer of TasTAFE appointed under section 66 of the *Training and Workforce Development Act 2013*.
- (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).
- (3) If a poison is present in a substance or preparation as a salt, active principle or derivative, any concentration, strength or quantity in respect of that substance or preparation is calculated to be as the 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. the the contrary intention preparation. unless 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, pharmaceutical chemist, 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
- where the carrying out of a (e) process involving a prohibited plant is only preparatory to the use of that plant the for manufacture of narcotic а 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

- 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

Part 2 – Administration

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

# 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
- to purchase that narcotic substance by an (e) order written in ink from а pharmaceutical chemist. licensed a manufacturing chemist, licensed a 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 a declared 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.

- (2) The holder of a licence granted under subregulation (1) 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) must keep the record for at least 2 years.

Penalty: Fine not exceeding 10 penalty units.

## **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 practitioner, dentist. authorised health professional or authorised nurse practitioner a narcotic substance by failing, before or at the material time, to notify the medical practitioner, authorised health professional dentist. or authorised nurse practitioner of the name and the place of practice of a medical practitioner, dentist. authorised health professional or 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 practitioner. dentist. authorised nurse practitioner, authorised health professional, licensed wholesale chemist, licensed manufacturing chemist pharmaceutical or

chemist, 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 in (2)Except as these regulations, a pharmaceutical chemist 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 pharmaceutical chemist, except on a prescription issued by a medical practitioner, veterinary surgeon, dentist, authorised health professional or authorised nurse practitioner.

Penalty: Fine not exceeding 10 penalty units

Except as otherwise provided in these (3) 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. veterinarv surgeon, dentist. authorised nurse practitioner, authorised health professional or pharmaceutical chemist.

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 r. 16

r. 16	Part 3 – Narcotic Substances and Prohibited Plants	
	substance to a person except for the purpose of its administration to a patient.	of
	Penalty: Fine not exceeding 10 penalty units.	
	(5) A veterinary surgeon must not supply a narcot 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 medical practitioner, veterinary surgeon, dentise authorised nurse practitioner, authorised health professional or authorised nurse from supplyin a narcotic substance to a medical practitioner veterinary surgeon, dentist, authorised nurse practitioner, authorised health professional licensed wholesale chemist, licensed manufacturing chemist or pharmaceutic chemist.	st, th ng er, se al, ed
	(7) Where a person supplies a narcotic substance of a written order, the person must –	n
	(a) write clearly in ink on the order the wor "Cancelled"; and	rd
	(b) retain that order in a file kept for the purpose for a period of 2 years from 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 pharmaceutical chemist, 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

## r. 17 Part 3 – Narcotic Substances and Prohibited Plants

- (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 pharmaceutical chemist, 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 pharmaceutical chemist;
  - (e) a licensed manufacturing chemist;
  - (f) a licensed wholesale chemist;
  - (g) an authorised health professional;
  - (h) an authorised officer;
  - (i) an authorised nurse practitioner;
  - (j) 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.

#### r. 18 Part 3 – Narcotic Substances and Prohibited Plants

- (3) A pharmaceutical chemist must keep a separate narcotic substances register in respect of each of the premises in which he or she carries on business as a pharmaceutical chemist.
- (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 in accordance with the rules contained in Schedule 1; 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.

Part 3 – Narcotic Substances and Prohibited Plants

(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,

Part 3 – Narcotic Substances and Prohibited Plants

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.

Penalty: Fine not exceeding 10 penalty units.

40

#### 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 an 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 the prescription and, except for а 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,

	Statutory Rules 2018, No. 79		
r. 20	Part 3 – Narcotic Substances and Prohibited Plants		
		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)	(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

Part 3 – Narcotic Substances and Prohibited Plants

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

## 22. Record of prescribing and supplying narcotic substances

- (1)As practicable after medical soon as a dentist. authorised practitioner, nurse 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

#### Part 3 – Narcotic Substances and Prohibited Plants

(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 pharmaceutical chemist 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 chemist.

50

Part 3 – Narcotic Substances and Prohibited Plants

- (2)A medical practitioner, veterinary surgeon, authorised professional dentist. health or authorised nurse practitioner who issues an instruction under subregulation (1) to a pharmaceutical chemist must send to that chemist, 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 chemist to supply the narcotic substance without a prescription.

Penalty: Fine not exceeding 10 penalty units.

## 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;
- (e) fentanyl, except in the case of a patient with cancer;
- (f) hydromorphone;

r. 25	Part 3 – Narcotic Substances and Prohibited Plants		
	(g)	ketamine;	
	(h)	lisdexamfetamine;	
	(i)	methadone;	
	(j)	methylamphetamine;	
	(k)	methylphenidate;	
	(1)	nabiximols;	
	(m)	pethidine;	
	(n)	phenmetrazine.	
	Penalty	y: Fine not exceeding 10 penalty units.	

# 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;
- (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 to attend and the nurse or midwife is acting

in accordance with the instructions of a medical 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 to attend after hours and the nurse or midwife is acting in accordance with the instructions of a medical 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;
- (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 to attend; and
  - (ii) acting in accordance with the instructions of a medical practitioner.

#### Division 6 – Dispensing of narcotic substances

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

 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 registered pharmaceutical chemist; or
  - (b) the person dispenses the prescription under the supervision of a medical practitioner or registered pharmaceutical chemist.

Penalty: Fine not exceeding 10 penalty units.

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

r. 27 Part 3 – Narcotic Substances and Prohibited Plants

Penalty: Fine not exceeding 10 penalty units.

- (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 pharmaceutical chemist 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.

Penalty: Fine not exceeding 10 penalty units.

- (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.

- (15) A pharmaceutical chemist 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

Part 3 – Narcotic Substances and Prohibited Plants

(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 registered pharmaceutical chemist 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 –

#### r. 27 Part 3 – Narcotic Substances and Prohibited Plants

- (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 registered pharmaceutical chemist who, in the course of the business of a pharmaceutical chemist carried on by the pharmaceutical chemist, 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).

Penalty: Fine not exceeding 10 penalty units.

(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.

Part 3 – Narcotic Substances and Prohibited Plants

(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.

Penalty: Fine not exceeding 10 penalty units.

(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

- 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.

- (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.

r. 31 Part 3 – Narcotic Substances and Prohibited Plants

Penalty: Fine not exceeding 10 penalty units.

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

- If the authorised officer in a medical institution is a pharmaceutical chemist, 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.

Penalty: Fine not exceeding 10 penalty units.

(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; and
- (b) to a patient in that ward.

Penalty: Fine not exceeding 10 penalty units.

## **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 –

#### r. 33 Part 3 – Narcotic Substances and Prohibited Plants

- (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.

Penalty: Fine not exceeding 10 penalty units.

(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.

- (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
  - giving verbal instructions for a narcotic (a) substance to be administered to a patient in a medical institution in an emergency if the medical practitioner, dentist, authorised professional health or 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.

Part 3 – Narcotic Substances and Prohibited Plants

- (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 professional or authorised health 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.

Part 3 – Narcotic Substances and Prohibited Plants

Penalty: Fine not exceeding 10 penalty units.

## 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 pharmaceutical chemist may supply the holder of the authority with such narcotic

#### r. 36 Part 3 – Narcotic Substances and Prohibited Plants

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.

r. 38 Part 3 – Narcotic Substances and Prohibited Plants

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.

Penalty: Fine not exceeding 10 penalty units.

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

#### 38. Destruction of narcotic substances prohibited

- 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.

Penalty: Fine not exceeding 10 penalty units.

(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.

Penalty: Fine not exceeding 10 penalty units.

# **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.

Penalty: Fine not exceeding 10 penalty units.

(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 –

<b>r. 42</b>	Part 3 – Narcotic Substances and Prohibited Plants		
	(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.	
	Penalt	y: Fine not exceeding 10 penalty units.	
(2	admini substat vessel service	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.

Penalty: Fine not exceeding 10 penalty units.

(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.

# 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.

- (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.

Part 4 - Poisons and Restricted Substances

- (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.

- (6) Notwithstanding subregulation (5)(a)(ii), 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, surgeon veterinary 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

- (1) Notwithstanding regulation 45(5), a pharmaceutical chemist may supply a restricted substance on the instruction of a medical practitioner, veterinary surgeon, dentist, endorsed midwife, authorised nurse practitioner or authorised health professional 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 chemist.
- (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 chemist, 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 chemist 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 pharmaceutical chemist may supply up to, and including, the PBS maximum quantity of an eligible 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 circumstances specified in the National Health (Continued Dispensing) Determination for that eligible restricted substance.
- (2) For the purposes of subregulation (1) –

eligible restricted substance means –

- (a) oral hormonal contraceptives for systemic use that are set out within the National Health (Continued Dispensing) Determination; and
- (b) HMG-CoA Reductase Inhibitors (Statins) that are set out within

the National Health (Continued Dispensing) Determination;

National Health (Continued Dispensing) Determination means the National Health (Continued Dispensing) Determination 2012 issued under section 89A(3) of the National Health Act 1953 of the Commonwealth, as amended from time to time;

National Health (Listing of Pharmaceutical<br/>Benefits) Instrument 2012 means the<br/>National Health (Listing of<br/>Pharmaceutical Benefits) Instrument<br/>2012 made under the National Health Act<br/>1953 of the Commonwealth, as amended<br/>from time to time;

**PBS maximum quantity**, in respect of an eligible restricted substance, means the maximum quantity specified for that substance in Schedule 1 to the National Health (Listing of Pharmaceutical Benefits) Instrument 2012.

# 49. Records of prescribing of declared restricted substances

(1) As soon as practicable after a medical practitioner, dentist, endorsed midwife, 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 the 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.

Penalty: Fine not exceeding 10 penalty units.

(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.

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

- Where (1)any medical practitioner, dentist. endorsed midwife, authorised nurse practitioner, authorised veterinary surgeon or health supplies professional sells or 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.
- Where (2)medical practitioner, dentist. any endorsed midwife, authorised nurse practitioner, authorised veterinary surgeon or health 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:

r. 51	Part 4 –	Poisons a	and Restricted Substances	
	(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)	substat office substat	cord of the supply of the restricted nce is to be kept at the surgery or of the person by whom that nce was supplied or sold, and is to duced on demand to an inspector.	
	Penalt	y: Fine	e not exceeding 10 penalty units.	
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# 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.

Part 4 – Poisons and Restricted Substances

r. 51

Penalty: Fine not exceeding 10 penalty units.

- (2)A person may dispense not more than once a prescription for a restricted substance that conforms in all other with respects regulation 45(5)but does specify not a 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) declared restricted substance is authorised. by the terms of the prescription, to be repeated but the prescription does not specify the minimum intervals which at the 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 pharmaceutical chemist or an assistant under the direct personal supervision of a pharmaceutical chemist, must not dispense a prescription for a restricted substance.

Penalty: Fine not exceeding 10 penalty units.

- (8) A pharmaceutical chemist or an assistant under supervision of the direct personal а subject pharmaceutical chemist, to this regulation, is authorised to dispense а 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 pharmaceutical chemist 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
  - whether the authority for the (ii) 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 dispensing repeated 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.

Penalty: Fine not exceeding 10 penalty units.

(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 pharmaceutical chemist 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 pharmaceutical chemist 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 pharmaceutical chemist must cancel it, or mark it, as required by whichever of those subregulations would so apply.

- (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.

- (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.

Penalty: Fine not exceeding 10 penalty units.

- (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 pharmaceutical chemist, 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 pharmaceutical chemist 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 pharmaceutical chemist in a form of packaging designed for supply intact to individual users; or
    - (B) a liquid supplied to the pharmaceutical chemist in a form of packaging designed for supply intact

to individual users, being metered-dose a pressurised spray pack, a dropper or applicator bottle form or a of packaging interference with the integrity of which would be detrimental to the proper administration to the 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 pharmaceutical chemist must make, in the approved recording system relating to the pharmacy which that supply at is effected. an entry signed by that pharmaceutical chemist that sets out -
  - (i) the date on which the restricted substance is supplied; and
  - a note to the effect that the supply (ii) 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 pharmaceutical chemist, the name of the 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. Sale or supply of restricted substances other than specified psychotropic substances without prescription

- Regulation 51 does not apply in respect of a restricted substance, other than a specified psychotropic substance, if the restricted substance is sold or supplied –
  - (a) by a pharmaceutical chemist in accordance with an order made by the Director of Public Health under section 53 of the *Public Health Act 1997* specifying the restricted substance and that it may be sold or supplied without a prescription; and
  - (b) while the order is in force under that Act.
- (2) Regulation 51 does not apply in respect of a restricted substance, other than a specified psychotropic substance
  - (a) if
    - (i) the exercise of emergency powers has been authorised under sections 40, 41A or 45 of the *Emergency Management Act* 2006 in respect of an emergency; or

- (ii) an emergency declaration has been made under section 14 of the *Public Health Act 1997*; and
- (b) the restricted substance is sold or supplied by a pharmaceutical chemist; and
- (c) the pharmaceutical chemist is satisfied on reasonable grounds that the person seeking the sale or supply of the restricted substance –
  - has a valid prescription for the (i) restricted substance to be sold or supplied but is unable to provide prescription to the the pharmaceutical chemist due to the emergency, to which the authorisation. or declaration, referred paragraph (a) to in relates; or
  - requires provision of (ii) the restricted substance and has previously had valid a prescription for the restricted substance to be sold or supplied but is unable to be issued with a new prescription for the restricted substance due to the emergency, to which the authorisation, or declaration. referred in to paragraph (a) relates.

- (3) If a restricted substance is sold or supplied in accordance with subregulation (1) or (2) -
  - (a) the maximum quantity of that substance that may be sold or supplied to a person under those subregulations is –
    - (i) if the substance is a PBS restricted substance, the PBS maximum quantity; and
    - (ii) if the substance is not a PBS restricted substance, the quantity contained in the smallest package in which the substance is generally available; and
  - (b) the restricted substance must be labelled in accordance with regulation 53(c); and
  - (c) the pharmaceutical chemist must make an entry into in the approved recording system relating to the pharmacy at which that supply is effected in accordance with regulation 53(d).
- (4) For the purposes of subregulation (3) –

National Health (Listing of Pharmaceutical<br/>Benefits) Instrument 2012 means the<br/>National Health (Listing of<br/>Pharmaceutical Benefits) Instrument<br/>2012 made under the National Health Act<br/>1953 of the Commonwealth, as amended<br/>from time to time;

- **PBS maximum quantity**, in respect of a PBS restricted substance, means the maximum quantity specified for that substance in Schedule 1 to the National Health (Listing of Pharmaceutical Benefits) Instrument 2012;
- **PBS restricted substance** means a restricted substance specified in Schedule 1 to the National Health (Listing of Pharmaceutical Benefits) Instrument 2012.

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

- (1) For the purposes of section 38(1)(b) of the Act, a pharmaceutical chemist 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 chemist has seen the chart or a copy of it; and
  - (c) the chemist is satisfied that the sale or supply of the substance is necessary for the continued treatment of the resident or patient; and

- (d) the chemist makes a record in an approved recording system of
  - name of the medical (i) the dentist, authorised practitioner. professional, health endorsed midwife or authorised 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 –
  - if the substance is included in the (i) 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 pharmaceutical chemist 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 chemist 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).

### 55. Information about drugs

(1) Subject to subregulation (2), a pharmaceutical chemist, 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 pharmaceutical chemist and the prescription according to which it is dispensed bears an endorsement that it is not necessary for the pharmaceutical chemist 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 pharmaceutical chemist, 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 pharmaceutical chemists

(1) In this regulation –

115

	Statutory Rules 2018, No. 79			
r. 58	Part 4 – Poisons and Restricted Substances			
	<i>school first aid kit</i> means a first aid kit used for the purposes of a school or TasTAFE.			
	(2) A pharmaceutical chemist must not supply a potent substance unless –			
	<ul> <li>(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</li> </ul>			
	(b) the pharmaceutical chemist, or a pharmaceutical chemist or pharmacy trainee employed by that pharmaceutical chemist –			
	(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 chief executive officer; or

Part 4 – Poisons and Restricted Substances

(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 pharmaceutical chemist 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 chief executive officer, unless its container is labelled in accordance with regulation 114(2).

Penalty: Fine not exceeding 10 penalty units.

(4) A pharmaceutical chemist 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 pharmaceutical chemist 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 pharmaceutical chemist or a pharmacy trainee 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 pharmaceutical chemist may supply the following substances to a person who may be

r. 58

required to administer those substances for the purposes specified:

- (a) adrenaline (S3) for the treatment of anaphylaxis;
- (b) naloxone (S3) for the treatment of opioid toxicity.
- (8) Notwithstanding this regulation, a pharmaceutical chemist may supply naloxone
   (S3) for the treatment of opioid toxicity to a certified person within the meaning of section 56A of the *Public Health Act 1997*.

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

- 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 chief executive officer 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 chief executive officer 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 chief executive officer 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 chief executive officer 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 pharmaceutical chemist to supply a potent substance.

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 –

r. 61

- (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, pharmaceutical chemist, 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 Α health professional, dentist. endorsed midwife or authorised nurse practitioner who orally authorises the emergency administration of a restricted substance to patient under 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 or 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

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

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

- (1) A registered nurse may administer a restricted 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.
- (2) For the purposes of subregulation (1), a registered nurse is acting under the instructions of a medical practitioner or a nurse practitioner if the registered nurse administers a restricted substance that is contained in a dose administration aid.
- (3) A registered nurse may administer a restricted substance to a person who is not in a medical institution or a residential care service if
  - (a) the registered nurse is acting under the 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;
- (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 to attend and the nurse or midwife is acting in accordance with the instructions of a medical 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 to attend after hours and the nurse or midwife is acting in accordance with the instructions of a medical 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 restricted substance in respect of a patient in the centre in accordance with the instructions of a medical practitioner;

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r. 69	Part 4 – Poisons and Restricted Substances				
	(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;			
	(g)	where the registered nurse or midwife is –			
		<ul> <li>(i) employed in a correctional health facility, or a children and youth services facility, at which it is impractical for a medical practitioner to attend; and</li> </ul>			
		(ii) acting in accordance with the			

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

instructions

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### 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 firstaiders

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 firstaiders

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

	Siu	iuiory Rules 2010, 110. 79	
r. 76	Part 4 – Poisons and Restricted Substances		
	(a)	possess methoxyflurane (S4); and	
	(b)	administer it, or supply it for self- administration, to a person, on the oral instruction of a medical practitioner; and	
	(c)	administer it, or supply it for self- administration, 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	

(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

	Statutory Rules 2018, No. 79					
r. 79			Part 4 –	Poisons and Restricted Substances		
			(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.	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.			
			Penalt	y: Fine not exceeding 10 penalty units.		
		(2)	medica	tten record is to include the name of the al practitioner or paramedic on whose ctions the substance was obtained or ed.		

### 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

professional,		authorised	nurse	
practitioner or midwife.		registered	nurse	or

#### 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 pharmaceutical chemist; 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 r. 82

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, midwife, pharmaceutical chemist or pharmaceutical chemist who holds provisional registration with AHRPA and who –

- (i) is undertaking an educational program approved by the Secretary relating to the administration of vaccines; or
- (ii) has been approved by the Director of Public Health to administer vaccines specified by the Director; and
- a person who is a pharmaceutical chemist (f) and who satisfies the requirements of paragraph (d)(iii) may supervise the administration of a vaccine, listed in Schedule 4 to the Poisons List, in accordance with immunisation an program approved by the Director of Public Health, by another person who is pharmaceutical chemist a or pharmaceutical chemist who holds provisional registration with AHPRA and who -

- (i) is undertaking an educational program approved by the Secretary relating to the administration of vaccines; or
- (ii) has been approved by the Director of Public Health to administer vaccines specified by the Director; 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) In this regulation
  - AHPRA means the Australian Health Practitioner Regulation Agency, established under section 23 of the Health Practitioner Regulation National Law (Tasmania).

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

- (1) A person must not
  - (a) buy or obtain or use –

r. 83

- (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

- 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.

Penalty: Fine not exceeding 10 penalty units.

- (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 the following substances:

r. 87	Part 4 –	Poisons and Restricted Substances
	(a)	acitretin for human use;
	(b)	alefacept for human use;
	(c)	ambrisentan for human use;
	(d)	bexarotene for human use;
	(e)	bosentan for human use;
	(f)	cannabidiol;
	(g)	clomiphene for human use;
	(h)	corifollitropin alfa (recombinant follicle stimulant) for human use;
	(i)	cyclofenil for human use;
	(j)	dinoprost for human use;
	(k)	dinoprostone;
	(1)	dronabinol (S8);
	(m)	etretinate for human use;
	(n)	follitropin alpha (recombinant human follicle-stimulating hormone) for human use;
	(0)	follitropin beta (recombinant human follicle-stimulating hormone) for human use;
	(oa)	hydroxychloroquine;
	(p)	isotretinoin for human oral use;

- (q) lenalidomide;
- (r) luteinising hormone (S4) for human use;
- (s) macitentan for human use;
- (t) riociguat for human use;
- (u) sitaxentan for human use;
- (v) teriparatide for human use;
- (w) thalidomide for human use;
- (x) tretinoin for human oral use;
- (y) urifollitropin (otherwise known as follicle-stimulating hormone) for human use.
- (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

#### Part 4 – Poisons and Restricted Substances

- (b) by a pharmaceutical chemist 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.

Penalty: Fine not exceeding 10 penalty units.

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

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

- 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

r. 88

subregulation (2), any child of that pregnancy is extremely likely to suffer severe birth defects.

Penalty: Fine not exceeding 10 penalty units.

- (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

- 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,Stributylphosphorothioate (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;
- *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 dangerous poison to which Condition 1 in Part 1 of Appendix J of the Uniform Standard applies;
- *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 –

156

r. 91

- (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.
- 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.

Penalty: Fine not exceeding 10 penalty units.

 (12) Subregulation (11) does not apply to a person who is a person conducting a business or undertaking at a workplace if –

#### Part 4 – Poisons and Restricted Substances

- (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

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 pharmaceutical chemist;
  - (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 pharmaceutical chemist;
  - (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;

r. 93	Part 4 -	Part 4 – Poisons and Restricted Substances	
	(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;	
	(1)	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.	
	specif	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 pharmaceutical chemist;
- (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;

r. 94		Part 4 –	Poisons and Restricted Substances	
		(k)	a person engaged in the occupation of jewellery manufacture;	
		(1)	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;	
		(0)	a person engaged in commercial pest control.	
	94. Retaining of records			
		restric whole	) 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.

Part 4 – Poisons and Restricted Substances

r. 95

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

165

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 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;
- *pharmaceutical chemist* does not include a pharmaceutical chemist trainee;
- 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

r. 96

(b) issued by a medical practitioner for the purposes of regulation 101, 102, 103 or 104.

#### 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 pharmaceutical chemist.
- (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

Narcotic Substances

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;

r. 98	Part 5 – Standing Order	rs for Administration of Restricted Substances and Narcotic Substances
	(g)	if applicable, the maximum duration for which the restricted substance or narcotic substance is to be administered;
	(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;
	(1)	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;
	(0)	any other information the Secretary considers necessary.

#### 99. Determination of application

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

r. 101	Part 5 – Standing Orders for Administration of Restricted Substances and
	Narcotic Substances

administration of a restricted substance, by a registered nurse or midwife, to persons affected by the public health emergency.

- (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

(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.

# 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 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 –

r. 105	Part 5 – Standing Order	s for Administration of Restricted Substances and Narcotic Substances
	(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 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

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

<ul> <li>(i) specify the clinical circumstances in which the restricted substance or narcotic substance may be administered; and</li> </ul>	(i)
(j) describe the people to whom the restricted substance or narcotic substance may be administered; and	(j)
<ul> <li>(k) if applicable, describe the people, if any, to whom the restricted substance or narcotic substance must not be administered; and</li> </ul>	(k)
<ol> <li>specify the Australian Approved Name of the restricted substance or narcotic substance and, if applicable, its brand name; and</li> </ol>	(1)
(m) if applicable, specify the form and strength of the restricted substance or narcotic substance; and	(m)
(n) specify the dose and route of administration of the restricted substance or narcotic substance; and	(n)
<ul><li>(o) if applicable, specify the frequency of the administration of the restricted substance or narcotic substance; and</li></ul>	(0)
<ul> <li>(p) if applicable, specify the maximum duration for which the restricted substance or narcotic substance is to be administered; and</li> </ul>	(p)

177

r. 105

r. 106	Part 5 – Standing Order	Part 5 – Standing Orders for Administration of Restricted Substances and Narcotic Substances	
	(q)	if applicable, specify the maximum quantity of the restricted substance or narcotic substance to be administered; and	
	(r)	if applicable, specify the educational and endorsement requirements necessary for a registered nurse or midwife to whom the standing order applies; and	
	(s)	be signed by the medical practitioner issuing the standing order.	
	(2) In this regulation –		
	Aus	<i>tralian Approved Name</i> means the name approved by the Therapeutic Goods	

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 –
  - (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

- 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.

Part 6 – Packaging and Labelling of Scheduled Substances

- (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.

r. 110

r. 111 Part 6 – Packaging and Labelling of Scheduled Substances

- (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 pharmaceutical chemist 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. 65, 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.

Part 6 – Packaging and Labelling of Scheduled Substances

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 –
  - 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

r. 114	Part 6 – Packaging and Labelling of Scheduled Substances
	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 –
	<ul> <li>(i) any expression required by the Uniform Standard as applied by regulation 109 to be written or embossed on that container; or</li> </ul>
	<ul><li>(ii) any ribs, grooves, points or stars required by the Uniform Standard as applied by regulation 109 to be embossed on that container; or</li></ul>
	<ul><li>(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.</li></ul>
	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 pharmaceutical chemist 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 pharmaceutical chemist 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 and subregulation (2).

- (2) Where a container contains medicine that
  - (a) is for internal use; and

r. 114 Part 6 – Packaging and Labelling of Scheduled Substances
 (b) contains a substance specified in

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.

Appendix K 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 pharmaceutical chemist;
- (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.

Part 7 – Miscellaneous

(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;

r. 125

- (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 –

r. 126		Part 7 – Miscellaneous	
	(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)		dical practitioner must not vary a general once it has been issued.	
(7)	order hours' Directe	dical practitioner may revoke a general at any time by giving not less than 24 written notice of the revocation to the or of Nursing of the hospital in respect of 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 –

## 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

#### Part 7 – Miscellaneous

- (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
- in the case of a potent substance, the (d)substance has been lawfully supplied and the administration is in accordance with the instructions of a medical practitioner. dentist. pharmaceutical chemist. endorsed midwife. authorised nurse practitioner authorised health or 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, pharmaceutical chemist, authorised nurse practitioner or authorised health professional; and

#### Part 7 – Miscellaneous

- (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* means a person appointed or employed for the purposes of TasTAFE, as specified in section 69 of the *Training and Workforce Development Act 2013*.
- (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 chief executive officer; and
      - (B) in accordance with guidelines approved by the TasTAFE chief executive officer; 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, pharmaceutical chemist, 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).

r. 131

Part 7 – Miscellaneous

- (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, pharmaceutical chemist, 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

r. 131		Part 7 – Miscellaneous
		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)	self-ac educat potent	son may administer, or make available for dministration, to a child attending an tion and care service a medicinal poison, a substance, restricted substance or narcotic nce 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, pharmaceutical chemist, 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

#### Part 7 – Miscellaneous

- (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, pharmaceutical chemist, authorised nurse practitioner or authorised health professional; and

r. 132

- (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, pharmaceutical chemist, 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, pharmaceutical chemist, 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 selfadministration, 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

#### Part 7 – Miscellaneous

- (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, pharmaceutical chemist, 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

r. 136	Part 7 – Miscellaneous		
(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.		
<b>136.</b> 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 pharmaceutical chemist, 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 –

r. 138

Part 7 – Miscellaneous

- *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, pharmaceutical chemist, 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

r. 139	Part 7 – Miscellaneous	
	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 pharmaceutical chemist, 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 pharmaceutical chemist on the written order of a medical practitioner, authorised nurse practitioner or veterinary surgeon.	
Penalt	y: 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.

Part 7 – Miscellaneous

(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.

# SCHEDULE 1 – REQUIREMENTS IN RELATION TO NARCOTIC SUBSTANCES REGISTER

Regulation 18

# PART 1 – RULES FOR KEEPING NARCOTIC SUBSTANCES REGISTER

# 1. Interpretation

- (1) In this Schedule
  - *authorised dispenser*, in relation to a medical institution, means a person authorised by the authorised officer to dispense narcotic substances within that institution;
  - *narcotic substance*, when used in relation to a register, means the narcotic substance to which that register relates;

register means a narcotic substances register.

- (2) In respect of a register, a reference in this Schedule to a space by a letter or to a column by a number is to be construed as a reference to the space so lettered or to the column so numbered, as the case may be, in the form of the register contained in this Part 1.
- (3) For the purpose of this Schedule, in respect of a register
  - (a) a narcotic substance is taken to be in the possession of a person if it is in the

possession of another person acting as the person's servant and under the person's orders; and

- (b) a narcotic substance that is delivered to an authorised dispenser, or to some person on the authorised dispenser's behalf, for use in the medical institution of which he or she is the authorised dispenser or to the dispensary of that medical institution is taken to be delivered into his or her possession and to remain in his or her possession until it is disposed of; and
- (c) a narcotic substance that is in a medical institution is taken, unless it is in the possession of the authorised dispenser of that institution, to be in the possession of the person in charge of that institution; and
- (d) a narcotic substance is taken to have been acquired where it is delivered, received or otherwise comes into the possession of a person required to keep the register or is manufactured by the person or by some person acting as that person's servant and under that person's orders; and
- (e) a narcotic substance is taken to have been disposed of if, being in the possession of the person required to keep the register –

- (i) it is supplied to some person other than a person acting as the person's servant and under the person's orders; or
- (ii) it is administered to any person; or
- (iii) it is destroyed or is converted or made up into another substance, whether or not that substance is a narcotic substance.
- (4) Without prejudice to the operation of subclause (3), where a narcotic substance that is in the possession of an authorised dispenser is supplied for the purpose of being kept or used elsewhere than in the dispensary at the medical institution of which he or she is the authorised dispenser, that narcotic substance is taken, for the purposes of the register required to be kept by that authorised dispenser, to have been disposed of.
- (5) Without prejudice to the operation of subclause (3), where a narcotic substance is transferred from premises in respect of which a register is kept by a person to other premises in respect of which a register is kept by the person, that narcotic substance is taken, for the purposes of the register, to have been acquired

#### 2. Particulars to be inserted in registers

- (1) Subject to this clause, where a register is required to be kept in respect of any narcotic substance, there is to be entered
  - (a) in space (a), the name and address of the premises to which the register relates; and
  - (b) in space (b), the name of the narcotic substance; and
  - (c) in space (c), the code number supplied by the Secretary that represents the narcotic substance; and
  - (d) in column (1), the date of the occurrence of the happening to which the entry relates; and
  - (e) in column (2), the quantity of the narcotic substance acquired; and
  - (f) in column (3), the quantity of the narcotic substance disposed of; and
  - (g) in column (4), the quantity of the narcotic substance left on hand after any acquisition or disposal has taken place; and
  - (h) in column (5), a code letter taken from Part 2 of this Schedule which represents the movements of the narcotic substance; and

- (i) in column (6), opposite every entry in the register, the initials of the person acquiring or disposing of the narcotic substance to which the entry relates; and
- (j) in column (7)
  - (i) particulars of every movement of the narcotic substance which was shown in column (5) by the code letter "F" or the code letter "X"; and
  - (ii) in the case of a register kept by a medical practitioner, dentist, authorised nurse practitioner or authorised nurse, the name of any person supplied with a narcotic substance by that medical practitioner, dentist, authorised nurse practitioner or authorised nurse; and
  - (iii) in the case of a register kept by a veterinary surgeon, a sufficient description of any animal for or in respect of which the veterinary surgeon has supplied a narcotic substance together with the name of the owner of the animal.
- (2) A licensed wholesale chemist or licensed manufacturing chemist is, instead of entering in a register the particulars required by subclause (1)(c), (h) and (j) in relation to a narcotic substance, to enter in the register –

- in space (c), the code name supplied by (a) the Secretary that represents the narcotic substance; and
- (b) in column (5), a code supplied by the Secretary that represents the movement of the narcotic substance: and
- in column (7), a code supplied by the (c) Secretary, that represents the recipient of the narcotic substance.

#### 3. **Provisions relating to sheets of register**

Where a register comprises 2 or more sheets, those sheets are to be kept securely attached together and numbered serially.

Code	NARCOTIC SUBSTANCES REGISTER Meaning	
D	Dispensed or supplied on written order from medical practitioner.	
R	Received.	
С	Returned to supplier.	
F	Formulated. (Indicate in remarks column of register what narcotic substance was obtained from the formulation and whether it was dispensed).	

# PART 2 - MOVEMENT CODES TO BE USED IN

Code	Meaning
X	Lost, stolen, destroyed under supervision, taken by inspector or sold to another pharmaceutical chemist. (Give details in remarks column of register).

## sch. 1

# SCHEDULE 2 – REQUIREMENTS IN RELATION TO WARD NARCOTIC SUBSTANCES REGISTER

Regulation 33

# 1. Interpretation

- (1) In this Schedule
  - *narcotic substance*, when used in relation to a register, means the narcotic substance to which that register relates;

*register* means a ward narcotic substances register.

- (2) In respect of a register, a reference in this Schedule to a space by a letter or to a column by a number is a reference to the space so lettered or to the column so numbered, as the case may be, in the form of the register contained in this Schedule.
- (3) For the purposes of this Schedule, in respect of a register
  - (a) a narcotic substance is taken to be in the possession of a person if it is in the possession of another person acting as the person's servant and under the person's orders; and
  - (b) a narcotic substance that is in a medical institution is taken, unless it is in the possession of the authorised dispenser of that institution, to be in the possession of

the person in charge of that institution; and

- (c) a narcotic substance is taken to have been acquired where it is delivered, received or otherwise comes into the possession of the person required to keep the register; and
- (d) a narcotic substance is taken to have been disposed of if, being in the possession of the person required to keep the register –
  - (i) it is supplied to some person other than a person acting as the person's servant and under the person's orders; or
  - (ii) it is administered to any person; or
  - (iii) it is destroyed or is converted or made up into another substance, whether or not that substance is a narcotic substance.
- Without (4) prejudice the operation to of subclause (3), where a narcotic substance that is in the possession of an authorised dispenser is supplied for the purpose of being kept or used elsewhere than in the dispensary at the medical institution of which he or she is the authorised dispenser, that narcotic substance is taken, for the purposes of the register required to be kept by the authorised dispenser, to have been disposed of.

(5) Without prejudice to the operation of subclause (3), where a narcotic substance is transferred from the ward in respect of which a register is kept to another ward in respect of which another register is kept, that narcotic substance is taken, for the purposes of the first-mentioned register, to be disposed of, and for the purposes of the second-mentioned register, to have been acquired.

# 2. Provisions relating to names and addresses

Where a register is required to be kept under regulation 33, there are to be inserted in space (a) the name of the medical institution to which the register relates, the address of the institution, and a sufficient description of the ward or other room containing the enclosure to which the register relates.

# 3. Name of narcotic substance

There is to be inserted in space (b) the name of the narcotic substance to which the register relates.

# 4. Particulars to be inserted when narcotic substance acquired

Where any narcotic substance is acquired, the following are to be inserted in the register:

(a) in column (1), the date on which it was acquired;

- (b) in column (2), a sufficient indication of the means by which it was acquired, whether by way of purchase, dispensing or otherwise;
- (c) in column (3), the name of the person, or a sufficient indication of the source, from whom or from which it was acquired;
- (d) in column (4), the amount acquired;
- (e) in column (5), the signature of the person making the entry or on whose instructions it is made.

# 5. Particulars to be inserted when narcotic substance disposed of, &c.

- (1) Where any narcotic substance is disposed of, the following are to be inserted in the register:
  - (a) in column (6), the date on which it was disposed of;
  - (b) in column (7), the amount disposed of;
  - (c) in column (8)
    - (i) if it was administered to a person,
       a sufficient indication of the
       means by which it was
       administered; or
    - (ii) if it was destroyed or lost, a sufficient indication that it was destroyed or lost;

- (d) where the drug is supplied for administration to a person, in column (9) the name of that person;
- (e) in column (11), the signature of the person by whom the drug was disposed of.
- (2) Where a narcotic substance is administered to a person and the nature or the amount of the narcotic substance so administered is checked by a person other than the person by whom it was administered, that other person is to insert his or her initials in column (10) against the entry relating to the administration of the narcotic substance.
- (3) Where a narcotic substance is disposed of -
  - (a) on the instructions of a medical practitioner (not being instructions contained in a prescription issued by that medical practitioner); or
  - (b) on the instructions of the person who has the possession of the narcotic substance or of a person acting on that person's behalf –

there is to be inserted in the entry relating to the disposal of the narcotic substance in column (12) the name in block capitals of the medical practitioner or the person and, in column (13), his or her signature.

(4) Where any narcotic substance is acquired or disposed of, there is to be inserted in column

(14) the amount of that narcotic substance held immediately after that acquisition or disposal.

# 6. Provisions relating to sheets of register

Where a register comprises 2 or more sheets, those sheets are to be kept securely attached together and numbered serially.

# 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

12. Carbroma
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- 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)
- **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 Schedule
35.	Ethchlorvynol

- **36.** Ethinamate
- **37.** Ethyloestrenol
- **38.** Fluoxymesterone
- **39.** Flurazepam

in this

- 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

52.	Mestanolone			
53.	Mesterolone methyldihydrotes	`	known	as
54.	Methandienone methandrostenolo	,	known	as
55.	Methandriol			
56.	Methenolone			
57.	Methylpentynol and other substituted alkynes for internal use			
58.	Methyltestosterone			
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)

78.	Stanolone (otherwise dihydrotestosterone)	known	as
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;

sch. 6

- (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.

### sch. 7

	SCHEDULE 7 – FEES	5
		Regulation 13 Fee units
1.	Licence under regulation 5 to manufacture and sell or supply –	
	(a) scheduled substances including narcotic substances	450
	(b) narcotic substances	350
	(c) scheduled substances other than narcotic substance	115
2.	Licence under regulation 5 to sell or supply by wholesale dealing –	
	(a) scheduled substances including narcotic substances	115
	(b) narcotic substances	60
	(c) scheduled substances other than narcotic substances	60
3.	Permit under regulation 6 to purchase a substance specified in Schedule 1, 2, 3 or 4 to the Poisons List for industrial, educational, advisory or research purposes	25
4.	Copy of certificate showing the result of an analysis or examination supplied under section 66 of the Act	12

# SCHEDIIE 7 FFFS

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

	(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

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	

### **PART 1 – OFFENCES UNDER THE ACT**

Column 1	Column 2	Column 3
Item No.	Section of Act	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
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
27.	Section 47D(3)	10
28.	Section 47D(4)	10
29.	Section 47D(5)	10
30.	Section 48(1)	10
		I

Column 1	Column 2	Column 3
Item No.	Section of Act	Penalty
		(penalty units)
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
44.	Section 80	2
45.	Section 81(1)	2
46.	Section 82(1)	10
47.	Section 82(2)	10

### sch. 8

Column 1	Column 2	Column 3	
Item No.	Section of Act	Penalty	
		(penalty units)	
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**

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
б.	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
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### sch. 8

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
40.	Regulation 28(1)	2
41.	Regulation 30	2
42.	Regulation 31(1)	2
	1	l

262

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
60.	Regulation 44	2
61.	Regulation 45(1)	2
62.	Regulation 45(5)	2
	I	

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
	I	l

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
99.	Regulation 87(2)	2
100.	Regulation 87(4)	2
101.	Regulation 88(1)	2
102.	Regulation 89(1)	2
	1	

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
119.	Regulation 118(2)	2
120.	Regulation 124(3)	2
121.	Regulation 124(4)	2
122.	Regulation 125	2
	I	l

123.	Regulation 138(2)	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 31 March 2020 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)	S.R. 2020, No. 22	31.3.2020
Regulations 2020		

<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
Regulation 20	Amended by S.R. 2020, No. 22
Regulation 45	Amended by S.R. 2020, No. 22
Regulation 48	Amended by S.R. 2020, No. 22
Regulation 53A	Inserted by S.R. 2020, No. 22
Regulation 58	Amended by S.R. 2019, No. 21 and S.R. 2020, No. 22
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

Provision affected	How affected
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
Regulation 87	Amended by S.R. 2020, No. 22
Regulation 127	Amended by S.R. 2020, No. 22
Part 1 of Schedule 8	Amended by S.R. 2020, No. 3 and S.R. 2020, No. 22