

### Queensland

## **Medicines and Poisons (Medicines) Regulation 2019**

### Subordinate Legislation 2019 No. ...

made under the

Medicines and Poisons Act 2019

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## **Chapter 1** Introduction

### Part 1 Preliminary

### 1 Short title

This regulation may be cited as the *Medicines and Poisons* (*Medicines*) Regulation 2019.

### 2 Commencement

This regulation commences on [date].

### Part 2 Key concepts

### Division 1 Interpretation

### 3 Definitions

The dictionary in schedule 20 defines particular words used in this regulation.

### 4 Meaning of registration under Health Practitioner Regulation National Law

A provision of this regulation referring to a person registered under the Health Practitioner Regulation National Law to practise in a profession—

- (a) includes a person with provisional registration or limited registration; but
- (b) does not include a person registered to practise in the profession as a student or only for training.

Note-

See section 12 in relation to trainees.

## 5 References to extended practice authorities and departmental standards

- (1) A reference in this regulation to an extended practice authority by its number and name is a reference to the extended practice authority mentioned in schedule 1, part 1 with that number and name.
- (2) A reference in this regulation to a departmental standard by its number and name is a reference to the standard mentioned in schedule 1, part 2 with that number and name.

### Division 2 Categories of medicines

### 6 Restricted medicines

A medicine mentioned in schedule 2, part 1 is a *restricted medicine*.

### 7 High-risk medicines—Act, s 40

A medicine mentioned in schedule 2, part 2 is prescribed for section 40(4) of the Act, definition *high-risk medicine*.

### 8 Diversion-risk medicines—Act, sch 1

A medicine mentioned in schedule 2, part 3 is prescribed for schedule 1 of the Act, definition *diversion-risk medicine*.

### 9 Monitored medicines—Act, sch 1

A medicine mentioned in schedule 2, part 4 is prescribed for schedule 1 of the Act, definition *monitored medicine*.

## **Chapter 2** Approved persons

### Part 1

Prescribed classes of persons and regulated activities—Act, section 54

### **Division 1**

### Particular professions and services

### 10 Classes of persons and regulated activities

- (1) For section 54(1) of the Act, a class of persons mentioned in any of schedules 3 to 15 (each a *relevant schedule*) is prescribed for the regulated activity with the regulated substance mentioned in the relevant schedule.
- (2) Subsection (1) applies subject to division 3.

### Division 2 Additional authorisations

## 11 Possession incidental to other regulated activities with medicines

- (1) This section applies in relation to a class of persons mentioned in section 10 for whom the regulated activity stated in a relevant schedule is supplying or administering a medicine.
- (2) For section 54(1) of the Act, the class of persons is also prescribed for the regulated activity of possessing the medicine to the extent immediately necessary to prepare for, carry out or complete the supply or administration of the medicine.

### Examples—

- 1 A dentist removes a medicine from storage to give a treatment dose of the medicine.
- 2 A registered nurse prepares a medicine for administration.

(3) The regulated activity prescribed under subsection (2) is *incidental possession*.

### 12 Trainees

- (1) For section 54(1) of the Act, trainees are prescribed for the regulated activity of dealing with a medicine to the extent necessary for undertaking their training.
- (2) However, the regulated activity for trainees does not include giving a direction to supply or administer the medicine to a patient.
- (3) In this section—

*trainee* means a person who is undertaking training to obtain a qualification required to be a member of a class of persons mentioned in section 10.

## Division 3 General limitations on regulated activities

### 13 Membership of profession or carrying out functions

- (1) This section applies in relation to a class of persons mentioned in section 10 for whom the regulated activity stated in a relevant schedule is dealing with a medicine.
- (2) For section 54(1) of the Act, the regulated activity for the class of persons is dealing with the medicine only to the extent—
  - (a) the dealing is necessary for—
    - (i) practising the profession required for a person to be a member of the class of persons; or
    - (ii) carrying out the functions required for a person to be a member of the class of persons; and
  - (b) the dealing is carried out at a place—

- (i) stated in the relevant schedule for the class of persons for the regulated activity; or
- (ii) where a person who is a member of the class of persons lawfully practises the profession, or carries out the functions, mentioned in paragraph (a).

### 14 Health practitioners—therapeutic need

- (1) This section applies in relation to a class of persons mentioned in section 10 who are health practitioners for whom the regulated activity stated in a relevant schedule is prescribing, making a standing order, dispensing, giving a treatment dose of, or administering, a medicine.
- (2) For section 54(1) of the Act, the regulated activity for the class of persons is prescribing, making a standing order, dispensing, giving a treatment dose of, or administering, the medicine only for a purpose, and to the extent, that is consistent with recognised therapeutic practices for appropriate treatment of patients in the circumstances of the regulated activity.

Part 2 Requirements for dealings—

Act, section 91

Division 1 Preliminary

Subdivision 1 Purpose

### 15 Purpose of part

(1) This part prescribes requirements under section 91(1) of the Act for classes of persons mentioned in a relevant schedule or section 12.

(2) However, the requirements stated in division 2 to division 8 apply only to the extent provided for under the relevant schedule or section.

### Subdivision 2 General requirements

## 16 Storage of S8 medicines in relation to incidental possession

- (1) This section applies to a class of persons carrying out a regulated activity with a medicine for which they are prescribed under section 11.
- (2) For section 91(1) of the Act, if the medicine is an S8 medicine, a person who is a member of the class of persons must comply with any rules of a compliant stock system applying to stock of the medicine.

### 17 Trainee requirements

- (1) This section applies to a trainee carrying out a regulated activity that is incidental possession.
- (2) For section 91(1) of the Act, the requirements for the trainee are—
  - (a) the trainee must carry out the regulated activity—
    - (i) under the direct supervision of a person who is authorised to carry out the regulated activity in the same circumstances; and
    - (ii) in accordance with the requirements that apply to the class of person mentioned in section 10 for which the trainee is undertaking training; and
  - (b) if the trainee is undertaking training to become an enrolled nurse—the person supervising the trainee for paragraph (a)(i) must not be an enrolled nurse.

### 18 Health practitioners—therapeutic need requirements

- (1) This section applies in relation to a class of persons carrying out a regulated activity with a medicine for which they are prescribed under section 13.
- (2) For section 91(1) of the Act, the requirements for the health practitioner carrying out the regulated activity include the requirement that the regulated activity is carried out only if the health practitioner is reasonably satisfied the patient or patients to whom the activity relates has a therapeutic need for the medicine.

### Division 2 Buying stock

### 19 Purchase order must be given

A buyer of stock of a medicine must give a purchase order to a supplier of the stock before or at the time of supply.

### 20 Purchase order requirements

- (1) The purchase order must be in writing and state the following—
  - (a) a unique identifier;
  - (b) the date of the purchase order;
  - (c) the contact details of the buyer;
  - (d) the details of the buyer's authority to purchase the stock;
  - (e) the name of the medicine, and the form, strength and amount of stock of the medicine, to be supplied;
  - (f) if the stock is to be delivered to the buyer—the delivery address.
- (2) The purchase order must—

- (a) be prepared in a way that allows the supplier to verify the buyer is authorised under the Act or another law to buy the stock; and
- (b) be prepared and sent to the supplier in a way that is reasonably likely to—
  - (i) minimise fraud or tampering; and
  - (ii) if sent electronically—be transmitted securely or on a secure electronic ordering system; and
- (c) be signed or otherwise marked in a way that uniquely identifies the buyer; and

Example of otherwise marked—

the buyer has a unique user name and account number that is marked on the purchase order after the buyer accesses a secure ordering website

- (d) if amended—only be amended by the buyer marking or otherwise identifying any changes from the original purchase order.
- (3) Each of the following orders is taken to comply with the requirements of this section—
  - (a) an eligible order under the National Health (Remote Area Aboriginal Health Services Program) Special Arrangement 2017 (Cwlth);
  - (b) an order complying with the *National Health* (*Pharmaceutical Benefits*) Regulations 2017 (Cwlth), section 33.

Note—

The National Health (Pharmaceutical Benefits) Regulations 2017 (PB 107 of 2017) (Cwlth), section 33 allows particular pharmaceutical benefits to be supplied by an approved pharmacist to a medical practitioner, authorised midwife or authorised nurse practitioner if an order complying with that section is lodged with an approved pharmacist under that regulation.

### 21 Buyer to notify for receipt of stock of S8 medicines

A buyer of stock of an S8 medicine must ensure a notice acknowledging receipt of the stock is given to the supplier of the stock on the day the buyer receives the stock.

Division 3 Prescribing

Subdivision 1 Preliminary

### 22 Definitions for division 3

In this division—

### electronic communication—

- (a) means a facsimile, email or photograph sent digitally; but
- (b) does not include a communication made in an electronic medication management system.

### medication chart prescription means—

- (a) a prescription contained in a medication chart entry for a patient being treated in a hospital; or
- (b) a national medication chart prescription.

national medication chart prescription has the same meaning as a medication chart prescription under the *National Health* (*Pharmaceutical Benefits*) Regulations 2017, section 41(1).

*non-compliant electronic communication* means a form of electronic communication that is not—

- (a) an electronic medication management system; or
- (b) a paper prescription sent using electronic communication under section 26.

Examples—

text messages on a mobile phone, communications on an app

*repeats*, for a medicine, means the number of times the medicine may be supplied after the first time the medicine is supplied.

supply means dispense or give a treatment dose.

## Subdivision 2 Requirements for supply and administration

### 23 Application of subdivision

This subdivision applies in relation to a prescriber who prescribes a medicine for supply or administration for a patient or an animal, unless a provision states it does not to apply for an animal.

### 24 Form of prescriptions

A written prescription for a medicine must—

- (a) be signed by the prescriber; and
- (b) be legible; and
- (c) use terms or symbols used in the ordinary practice of the prescriber's profession; and
- (d) if the prescription is amended by the prescriber—have the amendment signed and dated by the prescriber; and
- (e) if the prescription is amended by the dispenser under this regulation—have the amendment signed and dated by the dispenser.

### 25 Paper prescriptions

- (1) If a prescriber handwrites a prescription on paper, the prescriber must use durable ink to write the prescription.
- (2) If a sticker is used to record information on a paper prescription, the sticker must—

- (a) be legible; and
- (b) attach to the prescription in a way that can not be easily removed; and
- (c) be placed in a way that clearly connects the information to a patient.
- (3) To remove any doubt, it is declared that the prescriber may send a paper prescription using electronic communication to a person authorised to supply or administer the medicine.

### 26 Paper prescriptions sent electronically to pharmacist

- (1) This section applies if a prescriber sends a paper prescription to a pharmacist using electronic communication.
- (2) The prescriber must—
  - (a) telephone the pharmacist as soon as practicable, but no later than the next business day, to confirm the prescription; and
  - (b) give the paper prescription to the pharmacist as soon as practicable, but no later than—
    - (i) if the prescription is for an S8 medicine—the next business day after the electronic communication was sent; or
    - (ii) otherwise—7 days after the electronic communication was sent.

### 27 Electronic prescriptions

- (1) This section applies if a prescriber uses an electronic medication management system to make a prescription.
- (2) The prescriber must comply with the rules of the electronic medication management system.

### 28 Amending a prescription

A prescriber must not amend a prescription unless the prescriber prepared the prescription in the first instance.

### 29 Preventing loss of prescription stationery

A prescriber must take all reasonable steps to ensure another person does not access or use stationery kept by the prescriber for handwriting prescriptions.

### Subdivision 3 Requirements for supply only

### 30 Application of subdivision

This subdivision applies in relation to a prescriber who prescribes a medicine only for supply for a patient or an animal, unless a provision states it does not to apply for an animal.

### 31 Compliance with monitored medicines standard

- (1) If the medicine proposed to be stated in the prescription is a monitored medicine, the prescriber must prescribe the medicine in accordance with 'Departmental standard 4: Monitored medicines'.
- (2) This section does not apply to a prescription for an animal.

### 32 Generation of paper prescriptions using computer

- (1) A prescriber may generate a paper prescription using a computer only if the way of generating the paper prescription complies with this section.
- (2) The prescriber may use the computer to generate the prescription only if—

- (a) the computer allows only the prescriber to generate the prescription; and
- (b) the computer does not generate a paper prescription that is signed.
- (3) When a paper prescription is generated by the computer, the following must appear on the paper prescription—
  - (a) a mark or line between each item on the prescription;
  - (b) the total number of items included on the prescription;
  - (c) a unique number that allows the prescription and the prescription record for the patient or animal for whom it is written to be matched;
  - (d) a space for the prescriber's handwritten signature.
- (4) The area below the space for the prescriber's handwritten signature must be scored, hatched or marked in another way to prevent another item being written below the signature.
- (5) This section does not affect another requirement for information to be included on the paper prescription under this regulation.

## 33 Content of prescriptions other than medication chart prescriptions

- (1) This section does not apply if the prescription is a medication chart prescription.
- (2) The following information must be included on the prescription for the supply of a medicine—
  - (a) the prescriber's name;
  - (b) the place where the prescriber usually practices;
  - (c) the prescriber's phone number or pager number;
  - (d) the prescriber's qualifications;
  - (e) the date of the prescription;
  - (f) the date for supplying the medicine, if applicable;

- (g) the name of the medicine including, for example, the approved name or brand name of the medicine, or a description of the medicine if it is compounded for supply, including the name and strength of any medicines compounded;
- (h) the form, strength and amount of the medicine to be supplied;
- (i) instructions about using the medicine;
- (j) the number of repeats for the medicine, if any;
- (k) if the medicine is for a patient—the contact details of the patient;
- (1) if the medicine is for an animal—
  - (i) the name or species of the animal; and
  - (ii) the address of the owner of the animal; and
  - (iii) a statement that the medicine is for animal treatment only;
- (m) if the prescriber is authorised to prescribe the medicine only because of the specialist qualifications of the prescriber—the specialist qualifications of the prescriber.
- (3) If the medicine is an S8 medicine, the following information must be included on the prescription—
  - (a) the amount of the medicine described in both words and numbers;
  - (b) for a repeat prescription—the minimum number of days, of at least 1 day, in which a repeat for the medicine can be supplied;
  - (c) if the S8 medicine is amfetamine, dexamfetamine, lisdexamfetamine or methylphenidate and the prescriber may prescribe the medicine under this regulation—the words 'specified condition' or words to indicate the condition being treated;

- (d) if the medicine is a monitored medicine for a patient—the patient's date of birth;
- (e) if the medicine is for a particular animal—sufficient information to identify the animal.
- (4) The prescription must not authorise the dispensing of more than 1 S8 medicine but may authorise the dispensing of an S8 medicine in more than 1 form.

### 34 Content of medication chart prescriptions

- (1) This section applies only if the prescription is a medication chart prescription.
- (2) The following information must be included on the prescription for the supply of a medicine—
  - (a) the prescriber's name;
  - (b) the prescriber's phone number or pager number;
  - (c) the date of the prescription;
  - (d) the date for supplying the medicine, if applicable;
  - (e) the name of the medicine including, for example, the approved name or brand name of the medicine, or a description of the medicine if it is compounded for supply, including the name and strength of any medicines compounded;
  - (f) an indication of the amount of the medicine to be supplied;
  - (g) instructions about using the medicine;
  - (h) the number of repeats for the medicine, if any;
  - (i) if the medicine is for a patient—the contact details of the patient for whom the medicine is prescribed;
  - (j) if the medicine is for an animal—
    - (i) the name or species of the animal; and
    - (ii) the address of the owner of the animal; and

- (iii) a statement that the medicine is for animal treatment only;
- (k) if the medicine is a restricted medicine—the specialist qualifications or prescribing approval number of the prescriber.

### 35 Oral or informal prescribing

- (1) This section applies to a prescriber prescribing an S4 or S8 medicine for supply to a patient orally or by using non-compliant electronic communication (an *informal prescription*).
- (2) If the prescriber gives an informal prescription, it may be given only to a person who is authorised to supply the medicine.
- (3) If the prescriber supplies the medicine for a patient or animal on the informal prescription, the prescriber must—
  - (a) give the person a written prescription, including a medication chart prescription, that confirms the informal prescription; or
  - (b) sign another record made about the supply from the informal prescription.
- (4) The written prescription must be given, or the signature made, within the following periods—
  - (a) for the supply of an S4 medicine—7 days after the informal prescription was given;
  - (b) for the supply of an S8 medicine—as soon as practicable but no later than the next business day after the informal prescription was given.
- (5) This section does not apply to a prescriber prescribing a medicine from a medicine chest used by the Royal Flying Doctor Service of Australia.

## Subdivision 4 Requirements for administration only

### 36 Application of subdivision

This subdivision applies in relation to a prescriber who prescribes a medicine only for administration for a patient or an animal, unless a provision states it does not to apply for an animal.

### 37 Content of prescriptions for administration

The following information must be included on a prescription for the administration of a medicine—

- (a) the prescriber's name;
- (b) the date of the prescription;
- (c) the name, form, strength and amount of the medicine to be administered:
- (d) instructions about using the medicine;
- (e) if the medicine is for a patient—the name and address of the patient;
- (f) if the medicine is for an animal—
  - (i) the name or species of the animal; and
  - (ii) the name and address of the owner of the animal.

### 38 Oral or informal prescribing

- (1) This section applies to a prescriber prescribing an S8 medicine for administration to a patient orally or by using non-compliant electronic communication (an *informal prescription*).
- (2) If the prescriber gives an informal prescription, it may be given only to a person who is authorised to administer the medicine.

- (3) If the person administers the medicine to the patient on the informal prescription, the prescriber must—
  - (a) give the person a written prescription, including a medication chart prescription, that confirms the informal prescription; or
  - (b) sign another record made about the administration from the informal prescription.
- (4) The written prescription must be given, or the signature made, as soon as practicable but no later than the next business day after the medicine was administered.
- (5) This section does not apply to a prescriber prescribing a medicine from a medicine chest used by the Royal Flying Doctor Service of Australia.

### Division 4 Making standing orders

## Subdivision 1 Standing orders other than clinical protocols

### 39 Application of subdivision

This subdivision in relation to a prescriber making a standing order other than a clinical protocol.

### 40 Making standing orders at relevant institutions

- (1) The prescriber may make a standing order for a relevant institution only if—
  - (a) a medicines and therapeutics committee of the institution has approved the order; and
  - (b) the order is signed by a member of the committee who is a prescriber authorised to make standing orders.
- (2) In this section—

*medicines and therapeutics committee*, of a relevant institution, means a committee that—

- (a) is established by the institution to approve standing orders for the administration and giving of treatment doses of medicines to patients at the institution; and
- (b) has at least 1 medical practitioner, 1 registered nurse, and 1 pharmacist as members.

### 41 Making standing orders at other places

The prescriber may make a standing order for a place other than a relevant institution if the chief executive has approved the use of standing orders at the place.

### 42 Circumstances for making order

The prescriber may make the standing order for the place only if the prescriber is reasonably satisfied that—

- (a) the proposed order would not, if made, allow a person to administer or give a treatment dose of a medicine in a way that exceeds the person's authorisation under the Act or the person's training; and
- (b) if the circumstances stated in the proposed order applied, action taken under the order would be likely to improve the timeliness of treatment and access to care by patients at the place.

### 43 Contents of standing order

A standing order must—

- (a) be made in writing: and
- (b) state the name of the prescriber making the order; and
- (c) be signed and dated by the prescriber making the order; and

- (d) identify the class of persons who may administer or give a treatment dose of a medicine under the order; and
  - Example for paragraph (d)
    - the standing order applies to a registered nurse working in a hospital emergency department
- (e) state the medical conditions to which the order applies; and
- (f) state a medicine that may be administered under the order and the way the medicine may be administered; and
- (g) state a medicine that may be given as a treatment dose under the order; and
- (h) state the maximum duration for which treatment of a patient under the order is authorised; and
- (i) state in what circumstances the medicine may be administered, and the recommended dose or dose range for the circumstances; and
- (j) state the circumstances in which the medicine should not be administered; and
- (k) include the reference charts for dose calculation, if required, the monitoring requirements, if required, and the type of equipment and management procedures required for management of an emergency associated with the use of the medicine; and
- (l) state the date, no later than 2 years after the order was made, by which the order must be reviewed.

### 44 Inspection and review

When making a standing order for a place, the prescriber must ensure—

(a) the order is reviewed at least once every 2 years after the order is made; and

- (b) the order is readily available for inspection at the place by—
  - (i) the persons who may administer or give a treatment dose of a medicine under the order; and
  - (ii) the prescriber's employer; and
  - (iii) the chief executive; and
  - (iv) an inspector; and
  - (v) a health ombudsman official.

### Subdivision 2 Clinical protocols

### 45 Application of subdivision

This subdivision applies in relation to a prescriber making a standing order that is a clinical protocol.

### 46 Contents of clinical protocol

A clinical protocol must—

- (a) be made in writing: and
- (b) state the name of the medical practitioner making the protocol; and
- (c) identify the class of persons who may administer, or give a treatment dose of, a medicine under the protocol; and
- (d) state the circumstances in which the protocol applies;
- (e) state a medicine that may be administered under the protocol and the way the medicine may be administered; and

- (f) state any procedures that apply to the administration, or giving of a treatment dose, of a medicine under the protocol; and
- (g) state the date by which the protocol must be reviewed.

#### 47 Inspection and review

When making a clinical protocol for a place, the medical practitioner must ensure the protocol is readily available for inspection at the place by—

- (a) the persons who may administer or give a treatment dose of a medicine under the protocol; and
- (b) the chief executive; and
- (c) an inspector; and
- (d) a health ombudsman official.

## Division 5 Dispensing

#### 48 Application of division

This division applies in relation to a dispenser dispensing a medicine for a patient or an animal, unless a provision states it does not to apply for an animal.

#### 49 Compliance with monitored medicines standard

- (1) If the medicine proposed to be dispensed is a monitored medicine, the dispenser must dispense the medicine in accordance with 'Departmental standard 4: Monitored medicines'.
- (2) This section does not apply to a monitored medicine proposed to be dispensed for an animal.

#### 50 Dispensing diversion-risk medicines

If the dispenser is dispensing a diversion-risk medicine on a prescription, the dispenser must take reasonable steps to ensure the prescription has been given by a prescriber.

Example of reasonable steps—

attempting to contact the person who gave the prescription

#### 51 Dispensing generic medicines

- (1) This section applies if a medicine (the *prescribed medicine*) is prescribed to a patient by an approved name or brand name but the medicine (the *generic medicine*) is also available under another brand name or without a brand name.
- (2) The dispenser may dispense the generic medicine to the patient instead of the prescribed medicine if—
  - (a) the generic medicine is, in the reasonable opinion of the dispenser, physiologically equivalent to the prescribed medicine in its clinical effect and has the same active ingredients; and

Examples—

- a medicine is approved by the Therapeutic Goods Administration for sale as a generic medicine to substitute for a brand name medicine
- a medicine is flagged in the 'Schedule of pharmaceutical benefits' as biosimilar or equivalent to another medicine
- (b) the prescriber did not specifically state that only the prescribed medicine is to be dispensed; and
- (c) the patient asks for, or agrees to, the dispensing of the generic medicine instead of the prescribed medicine.
- (3) This section does not apply to a medicine dispensed to a patient at a public sector hospital under the *Hospital and Health Boards Act 2011*.

#### When dispensing not permitted or restricted

- (1) This section applies if the dispenser reasonably suspects any of the following in relation to the prescription of a medicine for a patient—
  - (a) the prescription has been fraudulently prepared;
  - (b) the prescription has been given by a person who is not authorised to prescribe the medicine;
  - (c) the prescription has been fulfilled or cancelled;
  - (d) the prescription does not otherwise comply with the requirements of this regulation.
- (2) The dispenser must not dispense the medicine on the prescription to the patient unless subsection (3) applies.
- (3) If the dispenser reasonably believes the patient has a therapeutic need for the medicine, the dispenser may dispense an amount of the medicine up to a maximum period of 2 days supply of the medicine.
- (4) If a paper prescription was sent to the dispenser using electronic communication, the dispenser may dispense the medicine only if the dispenser makes a reasonable effort to confirm the authenticity of the prescription.

#### 53 Notifying police

- (1) If the dispenser is given a prescription for a medicine that the dispenser reasonably believes has been fraudulently prepared, the dispenser must—
  - (a) retain the prescription or a copy of the prescription; and
  - (b) if practicable, record the contact details of the person who gave the dispenser the prescription; and
  - (c) notify the police service as soon as practicable.
- (2) The dispenser is required to comply with subsection (1)(a) and (b) only to the extent it is safe for the dispenser to comply.

#### 54 Marking dispensed prescriptions

After dispensing a medicine on a prescription, the dispenser must mark the prescription with the following information—

- (a) the date the medicine is dispensed;
- (b) the dispenser's contact details and signature;
- (c) for a repeat prescription—the number of the repeat dispensed;
- (d) if the last repeat was dispensed—that the prescription is cancelled:
- (e) if a generic medicine is dispensed under section 51—
  - (i) the brand name of the generic medicine; or
  - (ii) if the generic medicine does not have a brand name—the name of the manufacturer of the medicine.

#### 55 Marking non-dispensed prescriptions

- (1) This section applies if the dispenser does not dispense a medicine on a prescription under section 52 or 53.
- (2) The dispenser must cancel the prescription by marking it with the following information—
  - (a) a statement that the prescription is not to be dispensed;
  - (b) the date of cancellation;
  - (c) the dispenser's name and signature;
  - (d) the contact details for the place where the prescription is cancelled.
- (3) The dispenser is required to comply with subsection (2) only to the extent it is safe for the dispenser to comply.

#### 56 Amending a prescription

- (1) The dispenser must not amend a prescription other than under this section.
- (2) A dispenser may amend a prescription by adding additional information to clarify instructions on the prescription but only if the information is not inconsistent with the instructions on the prescription.
- (3) Also, a dispenser may amend a prescription for a patient if—
  - (a) the patient consents to the amendment; and
  - (b) the dispenser contacts the prescriber who prepared the prescription and the prescriber agrees to the amendment; and
  - (c) the dispenser amends the prescription in the way agreed; and
  - (d) the dispenser immediately makes a record of the details of the amendment and agreement in a record kept under section 58 for the patient.

#### 57 Paper prescriptions sent electronically

- (1) This section applies if a dispenser (the *sender*) sends a paper prescription using electronic communication to another dispenser (the *receiver*).
- (2) Before dispensing a medicine on the prescription, the receiver must take reasonable steps to check with the sender whether the medicine has already been dispensed.
- (3) The sender must give the paper prescription to the receiver as soon as practicable, but no later than 7 days after the day the electronic communication was sent.
- (4) In this section—

#### electronic communication—

(a) means a facsimile, email or photograph sent digitally; but

(b) does not include a communication made in an electronic medication management system.

#### 58 Records of dispensed medicines

- (1) The dispenser must make and keep a record of the following information as soon as practicable after dispensing a medicine to a patient—
  - (a) the name of the dispenser;
  - (b) the name and address of the patient;
  - (c) if the medicine is a monitored medicine—the date of birth of the patient;
  - (d) the date the medicine is dispensed;
  - (e) the approved name or brand name of the medicine;
  - (f) the form, strength and amount of the medicine dispensed;
  - (g) the name of the prescriber of the medicine;
  - (h) the date of the prescription;
  - (i) a unique identifier given to the prescription for the medicine by the dispenser;
  - (j) for a repeat prescription—the number of the repeat dispensed.
- (2) If the last repeat of a medicine is dispensed on a paper prescription, the dispenser must keep the paper prescription after dispensing the medicine.
- (3) A record of information mentioned in subsection (1)(e) or (f) must be sufficient to accurately identify the medicine dispensed.

#### 59 Expired prescription

The dispenser must not dispense a medicine to the patient if—

- (a) for an S2, S3 or S4 medicine—the prescription for the medicine was given more than 1 year before the day the medicine is to be dispensed; or
- (b) for an S8 medicine—the prescription for the medicine was given more than 6 months before the day the medicine is to be dispensed.

#### 60 Expired medicines

The dispenser must not dispense a medicine to a patient or for an animal after the expiry date stated on the container or label of the medicine.

### Division 6 Giving a treatment dose

#### 61 Application of division

This division applies in relation to an approved person giving a treatment dose of a medicine for a patient or an animal, unless a provision states it does not to apply for an animal.

#### 62 Compliance with standard

- (1) The approved person must give a treatment dose of a medicine in accordance with 'Departmental standard 3: Safe supply of medicines'.
- (2) This section does not apply to a treatment dose given for an animal.

#### 63 Diversion-risk medicines

When the approved person is giving a treatment dose on a prescription for a diversion-risk medicine, the person must take reasonable steps to determine that the prescription has been given by someone who is authorised to give the prescription.

#### When giving is not permitted or restricted

- (1) The approved person must not give a treatment dose of the medicine if the person reasonably suspects—
  - (a) the prescription has been fraudulently prepared; or
  - (b) the prescription has been given by someone who is not authorised to prescribe the medicine; or
  - (c) the prescription has been fulfilled or cancelled; or
  - (d) the prescription does not otherwise comply with the requirements of this regulation.
- (2) If a paper prescription was sent to an approved person who is a pharmacist using electronic communication under section 26, the person may give a treatment dose of the medicine only if the person makes a reasonable effort to confirm the authenticity of the prescription.

#### 65 Notifying police

- (1) If the approved person is given a prescription for a medicine that the person reasonably believes has been fraudulently prepared, the person must—
  - (a) retain the prescription or a copy of the prescription; and
  - (b) if practicable, record the contact details of the person who gave the prescription; and
  - (c) notify the police service as soon as practicable.
- (2) The approved person is required to comply with subsection (1)(a) and (b) only to the extent it is safe for the person to comply.

#### 66 Marking prescriptions

- (1) The approved person must mark the prescription with the following information when the treatment dose is given—
  - (a) the date;

- (b) the person's name and signature;
- (c) that the prescription is cancelled.
- (2) However, if the approved person does not give a treatment dose of the medicine on a prescription under section 64 or 65, the person must cancel the prescription by marking it with the following information—
  - (a) a statement that the prescription is not to be supplied;
  - (b) the date of cancellation;
  - (c) the person's name and signature;
  - (d) the contact details of the place where the prescription is marked.

#### 67 Records for giving a treatment dose

- (1) This section applies if the approved person gives a treatment dose of an S3 medicine that contains pseudoephedrine or an S4 or S8 medicine.
- (2) The approved person must record the following information as soon as practicable after giving the treatment dose—
  - (a) the person's name;
  - (b) the name of the prescriber who gave the prescription;
  - (c) the name and address of the patient or person who owns the animal;
  - (d) the date the medicine is given;
  - (e) the approved name or brand name of the medicine;
  - (f) the form, strength and amount of the medicine.
- (3) A record of information mentioned in subsection (1)(e) or (f) must be sufficient to accurately identify the medicine given.
- (4) Subsection (1) does not apply to a person who gives a treatment dose from a medicine chest used by the Royal Flying Doctor Service of Australia.

#### 68 Expired prescription

The approved person must not give a treatment dose of a medicine for a patient or an animal if—

- (a) for an S2, S3 or S4 medicine—the prescription for the medicine was given more than 1 year before the day the medicine is to be given; or
- (b) for an S8 medicine—the prescription for the medicine was given more than 6 months before the day the medicine is to be given.

#### 69 Expired medicines

The approved person must not give a treatment dose of a medicine for a patient or an animal after the expiry date stated on the container or label of the medicine.

## Division 7 Administering

#### 70 Application of division

This division applies in relation to an approved person administering a medicine on a prescription for a patient or an animal, unless a provision states it does not to apply for an animal.

#### 71 Expired prescription

The approved person must not administer a medicine on a prescription for a patient if—

- (a) for an S2, S3 or S4 medicine—the prescription for the medicine was given more than 1 year before the day the medicine is to be administered; or
- (b) for an S8 medicine—the prescription for the medicine was given more than 6 months before the day the medicine is to be administered.

#### 72 Records for administering on a standing order

- (1) This section applies if the approved person administers a medicine on a standing order.
- (2) The approved person must record the following information as soon as practicable after administering the medicine—
  - (a) the person's name;
  - (b) the name of the prescriber who made the standing order;
  - (c) the name and address of the patient;
  - (d) the date the medicine is given;
  - (e) the approved name or brand name of the medicine;
  - (f) the form, strength and amount of the medicine.
- (3) A record of information mentioned in subsection (1)(e) or (f) must be sufficient to accurately identify the medicine administered.
- (4) This section does not apply in relation to an animal.

## Division 8 Disposal

### 73 Application of division

This division applies in relation to an approved person disposing of waste from an S8 medicine.

#### 74 Disposal of S8 medicine waste

- (1) The approved person must ensure the waste from the S8 medicine is destroyed in a way that does not endanger the life or safety of a person or animal.
- (2) The destruction must be witnessed by—
  - (a) another person who is authorised under the Act or another law to dispose of waste from an S8 medicine; and

- (b) an inspector or police officer.
- (3) However, subsection (2) does not apply to either of the following circumstances—
  - (a) the waste is a portion of a tablet, a used transdermal patch, or the partial contents of a previously sterile ampoule or container;
  - (b) the approved person is also authorised to administer the S8 medicine.

## **Chapter 3** Substance authorities

## Part 1 Preliminary

#### 75 Purpose of chapter

This chapter prescribes standard conditions for substance authorities for section 70(1)(a) of the Act.

## Part 2 Manufacturing licences

#### 76 Application of part

This part applies in relation to a manufacturing licence for a medicine.

#### 77 Manufacturing supervisor

The holder of the manufacturing licence must ensure the medicine—

(a) is manufactured under the direct supervision of the manufacturing supervisor for the licence; and

(b) is not handled by a person other than the holder, manufacturing supervisor or a competent adult person employed by the holder.

#### 78 Quality control

- (1) The holder of the manufacturing licence must take reasonable steps to ensure the medicine manufactured is fit for its intended use and free from contamination.
- (2) The holder complies with subsection (1) if the holder complies with an industry recognised code, guideline, protocol or standard about best practice manufacturing.

Example of a recognised guideline—

the Pharmaceutical Inspection Co-operation Scheme's 'Guide to good practices for the preparation of medicinal products in healthcare establishments'

#### 79 Notification of loss or theft

- (1) The holder of the manufacturing licence must report the loss or theft of a diversion-risk medicine that was in the possession of the holder immediately before the loss or theft.
- (2) The report must be made to the police service and chief executive as soon as practicable and no later than the next business day after the loss or theft.
- (3) The holder must—
  - (a) ask for a record from the police service of the report made under subsection (2); and
  - (b) keep the record, if it is provided to the holder.

## 80 Supply to authorised buyer on a compliant purchase order

The holder of the manufacturing licence must supply the medicine only if—

- (a) the buyer of the medicine is authorised under the Act or another law to buy the medicine; and
- (b) the buyer gives the holder a compliant purchase order for the medicine.

#### 81 Open for inspection

The holder of the manufacturing licence must keep the place where the holder is authorised to manufacture the medicine open for inspection.

#### Part 3 Wholesale licences

#### 82 Application of part

This part applies in relation to a wholesale licence for a medicine.

#### 83 Responsibilities generally

The holder of the wholesale licence must—

- (a) ensure the medicine is not handled by a person other than the holder or a competent adult person employed by the holder; and
- (b) keep records of any medicines given to a wholesale representative of the holder; and
- (c) take reasonable steps to ensure each wholesale representative of the holder complies with this regulation and the wholesale licence; and
- (d) ensure a carrier engaged by the holder is capable of complying with the requirements in schedule 15, part 1.

#### 84 Compliance with codes

The holder of the wholesale licence must comply with, and take reasonable steps to ensure the holder's employees, agents and representatives comply with—

- (a) the 'Australian code of good wholesaling practice for medicines in schedules 2, 3, 4 and 8' dated 1 April 2011 and published by the Therapeutic Goods Administration; and
- (b) the document called the 'Code of conduct' dated 11 June 2015 and published by Medicines Australia ABN 23 126 990 001.

## 85 Supply to authorised buyer on a compliant purchase order

The holder of the wholesale licence must supply the medicine only if—

- (a) the buyer of the medicine is authorised under the Act or another law to buy the medicine; and
- (b) the buyer gives the holder a compliant purchase order for the medicine.

#### 86 Open for inspection

The holder of the wholesale licence must keep a place where the holder is authorised to sell the medicine by wholesale open for inspection.

#### 87 Notification of loss or theft

- (1) The holder of the wholesale licence must report the loss or theft of a diversion-risk medicine that was in the possession of the holder immediately before the loss or theft.
- (2) The report must be made to the police service and chief executive as soon as practicable and no later than the next business day after the loss or theft.

#### (3) The holder must—

- (a) ask the police service for a record of the report made under subsection (2); and
- (b) keep the record, if it is given to the holder.

## Part 4 Retail licences

#### 88 Application of part

This part applies in relation to an S2 retail licence for an S2 medicine.

#### 89 Prevention of public access

The holder of the S2 retail licence must ensure the S2 medicines are stored in a place where the public does not have access to the medicines.

#### 90 Manufacturer's packs only

The holder of the S2 retail licence may sell the S2 medicines only in manufacturer's packs.

## Part 5 Prescribing approvals

## Division 1 Prescribing generally

#### 91 Application of division

This division applies in relation to a prescribing approval that authorises prescribing a medicine.

#### 92 Prescribing requirements in part 2 apply as conditions

For prescribing the medicine, the holder of the prescribing approval must comply with the requirements stated in chapter 2, part 2, division 3 as if a reference in the division to the prescriber were a reference to the prescriber under the approval.

## Division 2 Approved opioids

#### 93 Application of division

This division applies in relation to a prescribing approval to supply an approved opioid for an opioid treatment program.

#### 94 Notification about starting treatment

- (1) The holder of the prescribing approval must give notice to the chief executive if the holder has started treatment of a patient under the opioid treatment program.
- (2) The notice must be given to the chief executive as soon as practicable, but no later than the next business day, after the patient has started treatment.

#### 95 Additional content for prescriptions

- (1) The holder of the prescribing approval must ensure the following information is included on a prescription for the approved opioid—
  - (a) the identifying number of the prescribing approval, if any;
  - (b) the name of the place where the approved opioid is to be supplied;
  - (c) if the prescription authorises the supply of more than 1 dose of the approved opioid—instructions for how the doses are to be supplied and administered;

- (d) if the prescription authorises a dispenser to administer a dose of the approved opioid—a statement that the dispenser may administer the dose and instructions for the administration.
- (2) This section applies in addition to the prescribing requirements under chapter 2, part 2, division 3.

## Part 6 Dealings under substance authorities

#### Division 1 Supplying stock

### 96 Application of division

This division applies in relation to a substance authority that authorises supply of stock of a medicine or medicated animal feed.

#### 97 Packaging for supplying S8 medicines

If the stock is an S8 medicine other than medicated animal feed, the holder of the substance authority must not arrange to deliver the S8 medicine to a buyer unless—

- (a) the medicine is sealed in a securely closed package that will show if the package breaks or anyone tampers with it; and
- (b) the medicine is not mixed with anything other than S8 medicines; and
- (c) the package is clearly labelled with—
  - (i) the contact details of the buyer; or
  - (ii) if the buyer is not an individual—the position and address of an individual employed by the buyer who may confirm receipt of the package; and

(d) the package has no writing on it that shows it contains an S8 medicine.

#### 98 Engaging carrier

If the holder of the substance authority engages a carrier to deliver the stock, the holder must engage a carrier who is capable of complying with the requirements in schedule 15, part 1.

#### 99 Supplier to give invoice

- (1) If the holder of the substance authority supplies the stock to a buyer, the holder must give the buyer an invoice stating the following information—
  - (a) a unique identifier;
  - (b) the date of the supply;
  - (c) the contact details of the buyer;
  - (d) for a medicine—
    - (i) the approved name and brand name of the medicine supplied, if applicable; and
    - (ii) the form, strength and amount of the medicine supplied;
  - (e) for medicated animal feed—details about the feed supplied.
- (2) The holder must keep a copy of the invoice or a record of the details contained in the invoice.

#### 100 Completing and keeping purchase orders

After the holder of the substance authority supplies the stock on a purchase order, the holder must—

(a) mark the purchase order in a way that shows the order has been supplied; and

(b) keep a copy of the marked purchase order.

#### 101 Supplier to notify chief executive if no receipt provided

If the holder of the substance authority has supplied stock of an S8 medicine to a buyer, and has not received a notice of receipt within 7 days after the date of supply, the holder must give a notice to the chief executive about the buyer's failure to confirm receipt.

#### 102 Notice of delivery

If the holder of the substance authority delivers medicated animal feed directly to a person on a medicated animal feed order, the holder must give the veterinary surgeon who signed the order notice that the feed has been delivered within 30 days after the delivery.

#### 103 Record-keeping

After the holder of the substance authority has supplied medicated animal feed on the medicated animal feed order, the holder must—

- (a) mark the order in a way that shows the order has been supplied; and
- (b) give a copy of the marked order to the veterinary surgeon who authorised the supply; and
- (c) keep a copy of the marked order.

## Division 2 Other dealings

#### 104 Application of division

This division applies in relation to a substance authority that authorises—

- (a) buying stock of a medicine; or
- (b) dispensing a medicine; or
- (c) giving a treatment dose of a medicine; or
- (d) administering a medicine; or
- (e) disposing of waste from a medicine.

#### 105 Requirements in chapter 2, part 2 apply as conditions

- (1) For buying stock of a medicine, the holder of the substance authority must comply with the requirements stated in chapter 2, part 2, division 2.
- (2) For dispensing a medicine, the holder of the substance authority must comply with the requirements stated in chapter 2, part 2, division 5.
- (3) For giving a treatment dose of a medicine, the holder of the substance authority must comply with the requirements stated in chapter 2, part 2, division 6.
- (4) For administering a medicine, the holder of the substance authority must comply with the requirements stated in chapter 2, part 2, division 7.
- (5) For disposing of waste from an S8 medicine, the holder of the substance authority must comply with the requirements stated in chapter 2, part 2, division 8.

#### 106 Keeping records

If there is more than 1 authorised place for the substance authority, the holder of the authority must ensure any records required to be kept in relation to the authority are accessible from each authorised place.

#### 107 Notification of changes affecting authority

- (1) The holder of the substance authority must give notice to the chief executive in the approved form if the holder's circumstances change in a way that substantially affects—
  - (a) the dealing the holder is authorised to carry out under the substance authority; or
  - (b) the ability of the holder to comply with the conditions of the substance authority.

Examples for subsection (1)—

- the holder of a manufacturing licence intends to go on a holiday for an extended period of time
- the person supervising manufacturing under a manufacturing licence will change
- the holder intends to change the place for carrying out a regulated activity with a regulated substance
- (2) The notice must be given as soon as practicable, and no later than 7 days, after a change of circumstances mentioned in subsection (1) happens.

# Chapter 4 Substance management plans

## 108 Regulated places and responsible persons prescribed—Act, s 92

- (1) For section 92 of the Act, definition *regulated place*, paragraph (b), the places stated in schedule 16, section 2, column 1 are prescribed.
- (2) For section 92 of the Act, definition *responsible person*, the person stated in schedule 16, section 2, column 2 is prescribed for the regulated place stated opposite in column 1.

#### 109 Prescribed matters—Act, s 93

For section 93(2)(b) of the Act, the matters to be addressed for a substance management plan mentioned in 'Departmental standard 6: Substance management plans' are prescribed.

#### 110 Review—Act, s 93

- (1) For section 93(3)(b) of the Act, a substance management plan for a regulated place must be reviewed—
  - (a) as soon as practicable after a review incident happens in relation to the place;
  - (b) at least every 5 years after the day the substance management plan starts or the plan is reviewed under paragraph (a), whichever day is later.

#### (2) In this section—

**review incident** means an incident identified in 'Departmental standard 6: Substance management plans' as an incident in which a substance management plan must be reviewed.

# Chapter 5 Requirements for establishing systems

# Part 1 Electronic medication management systems

#### 111 Application of part

This part states requirements that apply to an entity establishing or using a system (an *electronic medication management system*) to electronically make, transmit and record prescriptions.

#### 112 Managing system

(1) The entity must ensure a person (a *system manager*) is appointed to be responsible for setting up and maintaining the electronic medication management system for the entity.

Maximum penalty—80 penalty units.

- (2) The system manager must ensure—
  - (a) the electronic medication management system complies with the system requirements stated in section 113 and 'Departmental standard 7: Technical requirements for an electronic medication management system'; and
  - (b) policies and procedures are prepared, stating how the entity will comply with the requirements of this regulation and the departmental standard; and
  - (c) the policies and procedures mentioned in paragraph (b) are given to users of the electronic medication management system; and
  - (d) compliance with the policies and procedures mentioned in paragraph (b) is monitored; and
  - (e) appropriately qualified persons (each a *system administrator*) are appointed to be responsible for the administration and technical maintenance of the system.

Maximum penalty—80 penalty units.

(3) The system manager must keep a record of the information mentioned in subsection (2)(b) and (c).

#### 113 Requirements for system

- (1) The system manager of an entity's electronic medication management system must ensure the system has the following properties—
  - (a) access and use of the system is controlled using security measures to prevent a person who is not an authorised user of the system from accessing or using the system;

- (b) each authorised user or system administrator for the system has a secure system identifier;
- (c) the secure system identifier is recorded with each entry made in the system by the user or administrator;
- (d) the system only allows an authorised user of the system to create or view an entry if the user is permitted to create or view the entry;

#### Examples—

- a prescriber creates a prescription in the system
- a registered nurse views a prescription for a patient in the system to administer the prescribed medicine to the patient
- a pharmacist views a prescription for a patient in the system to dispense the prescribed medicine to the patient
- (e) a prescription made in the system records the information required for the prescription under this regulation and the time and day the prescription is made;
- (f) if the system allows the transmission of entries electronically—the transmission is conducted securely;
- (g) an entry in the system is kept for at least 2 years after the entry is created;
- (h) all entries in the system are copied and saved for the period in which the entries must be kept.
- (2) The electronic medication management system must also comply with the document called 'National requirements for electronic prescriptions version 1.0' dated 29 September 2017 and published by the Australian Digital Health Agency.

Maximum penalty—80 penalty units.

(3) In this section—

Australian Digital Health Agency means the Australian Digital Health Agency established by the Public Governance, Performance and Accountability (Establishing the Australian Digital Health Agency) Rule 2016 (Cwlth) under the Public Governance, Performance and Accountability Act 2013 (Cwlth).

authorised user, of an electronic medication management system, means a person who is permitted to access and use the system.

#### 114 Administration of system

 A system administrator for an entity may give a person access to the entity's electronic medication management system only if the administrator reasonably believes the access is necessary for the person to perform the person's role or function for the entity.

Maximum penalty—80 penalty units.

Examples of giving access to perform a role or function—

- 1 A prescriber is given access to the electronic medication management system to view information about patients and record prescriptions.
- 2 An information technology technician is given access to perform administrative or technical tasks to maintain the system.
- (2) A system administrator must, at any given time, be able to prepare a report showing the following information about a person's access to the electronic medication management system—
  - (a) the name of the person and the person's secure system identifier;
  - (b) the date on which the person was given access;
  - (c) the date on which the person's access was cancelled, if applicable;
  - (d) the times and dates when the person accessed, or attempted to access, the system.

- (3) The information mentioned in subsection (2) must be kept in a way that can not be amended or deleted.
  - Maximum penalty—40 penalty units.

#### 115 Using system

A person (an *authorised user*) permitted to access and use an electronic medication management system must take reasonable steps to ensure—

- (a) the authorised user's secure system identifier is not lost or stolen; or
- (b) another person does not use the authorised user's secure system identifier to access the system.

Maximum penalty—20 penalty units.

Examples of reasonable steps—

using a strong password for an authorised user's secure system identifier or locking a device that can be used to access an electronic medication management system

#### 116 Maintaining system

The system manager for an entity's electronic medication management system must take reasonable steps to maintain the security of the system.

Maximum penalty—80 penalty units.

Examples of reasonable steps—

regularly checking and updating the security of the system, running virus protection programs for the system and installing software updates

#### 117 Reporting system breaches

(1) The system manager, or a system administrator, of an entity's electronic medication management system must notify the chief executive if the manager or administrator becomes aware that the system may have been fraudulently accessed or used to obtain a monitored medicine.

Example of fraudulent use—

virus software is introduced into an electronic medication management system to create false prescriptions for S8 medicines

Maximum penalty—80 penalty units.

(2) For subsection (1), an authorised user of an entity's electronic medication management system must advise the system manager or system administrator if the user suspects the system may have been fraudulently accessed or used to obtain a monitored medicine.

## Part 2 Storage systems

### Division 1 Preliminary

#### 118 Application of part

This part applies to a person (the *storage system controller*) who is responsible for setting up a system for storing stock of a medicine at a specified place.

## Division 2 Storing medicines

#### 119 Compliance with storage standard

(1) The storage system controller must set up a system for storing stock of medicines that complies with 'Departmental standard 2: Storage of medicines'.

Maximum penalty—40 penalty units.

(2) The system set up under subsection (1) is a *compliant storage system*.

## Division 3 Register for S8 medicines

#### 120 Definition for division

In this division—

*type*, of S8 medicine, means each form and strength of a type of S8 medicine.

#### 121 Keeping a register

(1) The storage system controller must keep a register (an *S8 medicine register*) for the stock of an *S8* medicine stored in the compliant storage system.

Maximum penalty—40 penalty units.

- (2) The purpose of keeping the register is to—
  - (a) record each dealing with a type of S8 medicine; and
  - (b) track the use of the type until it is completely used or destroyed.

#### 122 Register to be kept with stock

(1) The storage system controller must keep the S8 medicine register at the place where the stock of an S8 medicine is stored.

Maximum penalty—40 penalty units.

(2) If the compliant storage system provides for stock of an S8 medicine to be carried in a bag or vehicle to practise a profession, the S8 medicine register may be kept in a way that is accessible with the bag or vehicle.

Maximum penalty—40 penalty units.

#### 123 Information for register

(1) The storage system controller must establish a system for recording the information mentioned in subsection (2) in the S8 medicine register for each dealing with a type of S8 medicine no later than 24 hours after the dealing happens.

Maximum penalty—40 penalty units.

(2) The information is—

- (a) the date of the dealing; and
- (b) the amount of the medicine; and
- (c) the nature of the dealing; and
- (d) the name and signature of the person recording the dealing; and
- (e) if the dealing is distribution—the name of the person to whom the medicine was given or the place where the medicine was moved; and
- (f) if the dealing is supply of the medicine into the stock recorded on the register—the contact details of the supplier and the unique identifier (if any) of the lawful direction for the supply; and
- (g) if the dealing is supply of the medicine out of the stock recorded on the register—the name of the person to whom the medicine was supplied and the unique identifier (if any) of the lawful direction for the supply; and
- (h) if the dealing is administration—
  - (i) the name of the person to whom the medicine was administered or who owns the animal to which the medicine was administered, or identifying information about the person or animal if the name is unknown; and
  - (ii) the name of the person who was supplied the medicine for administration and the name of the person who administered the medicine if it is not the same person; and
- (i) if the medicine was supplied on a prescription—the contact details of the prescriber; and
- (j) if the supply or administration happened at a relevant institution—the name of the person who authorised the supply or administration; and

- (k) if the dealing is disposal—the name and position of the person who witnessed the destruction of the medicine.
- (3) In this section—

*dealing* includes possessing for the purpose of moving or distributing stock within a place.

#### 124 Layout of S8 medicine register

The storage system controller must organise the S8 medicine register in a way that shows—

- (a) the stock of S8 medicines stored at a location at any given time; and
- (b) the dealings in a consecutive order based on the time the dealings occurred, to the extent practicable; and
- (c) a separate record for each type of medicine, other than a record of a medicine destroyed that may be shown in a combined record with other medicines destroyed.

Maximum penalty—40 penalty units.

#### 125 Corrections to register

(1) The storage system controller must establish a system for making corrections to the S8 medicine register in the way mentioned in subsection (2).

- (2) The following information must be recorded when making a correction to the S8 medicine register—
  - (a) the date the correction was made;
  - (b) the name and position of the person who made the correction;
  - (c) the name and position of another person who witnessed the person making the correction;
  - (d) the reason for the correction;

- (e) if the correction relates to the destruction of an S8 medicine—the name and position of the person who witnessed the destruction of the medicine.
- (3) The correction must not cancel, delete or obliterate the original entry.

#### 126 Electronic register

- (1) This section applies if the S8 medicine register is kept in an electronic form.
- (2) The storage system controller must ensure the S8 medicine register has the following properties—
  - (a) a person cannot make entries in the register unless the person has a secure system identifier provided by the controller;
  - (b) a person's secure system identifier is automatically recorded with the person's entry in the register;
  - (c) it is easy to identify changes made to entries in the register;
  - (d) it is not possible to delete entries in the register;
  - (e) entries in the register are able to be easily reproduced on paper.

Maximum penalty—40 penalty units.

(3) The storage system controller must not give a secure system identifier to a person unless the person is permitted to possess the stock of S8 medicines to which the S8 medicine register applies.

Maximum penalty—40 penalty units.

(4) The storage system controller must keep a record of each person's secure system identifier in a form that cannot be altered.

(5) The storage system controller must ensure the electronic form of the S8 medicine register is regularly copied and saved during the period in which it must be kept.

#### 127 Paper register

- (1) This section applies if the S8 medicine register is kept on paper.
- (2) The storage system controller must ensure the S8 medicine register has the following properties—
  - (a) a page cannot be removed from the register without detection;

Example—

a bound book with consecutively numbered pages

- (b) a separate page is used for each type of S8 medicine.
- Maximum penalty—40 penalty units.
- (3) The storage system controller must take reasonable steps to ensure a person making an entry in the S8 medicine register—
  - (a) is permitted by the controller to make the entry; and
  - (b) signs the entry, including any corrections to the entry; and
  - (c) does not remove or tamper with pages in the register.

#### 128 Reconciling register with stock

(1) The storage system controller must reconcile the S8 medicine register with the amount of stock of S8 medicines physically held at the storage facility to which the register applies.

- (2) The reconciliation must be done—
  - (a) in accordance with any requirements stated in a substance management plan applying to the storage facility; or

- (b) otherwise—at least monthly.
- (3) The date the reconciliation is done must be recorded in the register.
- (4) Subsection (5) applies if the S8 medicine register is kept on paper (the *original register*) and another register (the *new register*) is required because the original register has no pages remaining to record information.
- (5) The storage system controller must, in the new register, record the amount of stock stated in the last entry of the original register and reconcile the record with the amount of stock physically held at the storage facility to which the new register applies.

Maximum penalty—40 penalty units.

(6) In this section—

storage facility means the specified place, vehicle or bag in which stock of S8 medicines is stored.

#### 129 Reporting lost, stolen or destroyed register

(1) If an S8 medicine register is lost, stolen or destroyed (each an *incident*), the storage system controller must give notice about the incident to the chief executive.

Maximum penalty—40 penalty units.

(2) The notice must be given to the chief executive as soon as practicable, and no later than the next business day, after the incident.

## Chapter 6 Miscellaneous

#### Part 1 Miscellaneous offences

#### 130 Compliance with Poisons Standard, part 2

- (1) A person doing a thing mentioned in a part 2 requirement must comply with the requirement for doing the thing.
  - Maximum penalty—40 penalty units.
- (2) A person does not commit an offence against subsection (1) if the part 2 requirement relates to possessing a regulated substance and—
  - (a) the schedule of the Poisons Standard in which the substance is listed has changed since the substance was originally labelled and packaged; and
  - (b) the substance is labelled and packaged in compliance with the schedule of the Poisons Standard in which the substance was listed before the change happened.
- (3) The chief executive may approve another way (an *alternative requirement*) of satisfying a part 2 requirement if—
  - (a) the chief executive is satisfied the alternative requirement is as safe as the part 2 requirement; and
  - (b) the alternative requirement is published on the department's website and states the date it takes effect.
- (4) A person who complies with the alternative requirement does not commit an offence against subsection (1).
- (5) In this section
  - *part 2 requirement*, for a medicine, means a requirement in relation to labels or containers for the medicine in the Poisons Standard, part 2, section 1 or 2.

Note-

Other laws may regulate labelling, including, for example, the *Biosecurity Regulation 2016* which regulates the labelling of medicated animal feed for food producing animals.

#### 131 Recording and keeping information

- (1) This section applies to a person marking, recording or keeping information to comply with a requirement under this regulation, including marking information on a prescription.
- (2) The person marking or recording the information must ensure the information—
  - (a) is written in English or uses terms or symbols, including Latin terms, used in the ordinary practice of the person's profession; and
  - (b) if written on paper—is legibly and durably marked on the paper; and
  - (c) if written on an electronic document—is written on, or linked or attached to, the electronic document.
- (3) The person responsible for keeping the information must ensure the information—
  - (a) is kept for a period of 2 years after the date the information is recorded; and
  - (b) during the period—
    - (i) is readily retrievable; and
    - (ii) is kept in a way that cannot be altered, obliterated, deleted or removed without detection.
- (4) If a record is kept electronically, the person required to keep the electronic system on which the record is recorded ensures the record is kept is regularly copied and saved during the period in which the record must be kept.

#### 132 Restriction on supplying medicines in used containers

A person preparing a medicine for supply must not use an immediate container to package the medicine if the person knows the container has previously been used.

Maximum penalty—20 penalty units.

Note—

See the Poisons Standard, part 1 for the definition *immediate container*.

## 133 Selling in original packaging

- (1) A person selling a medicine, other than medicated animal feed, must sell the medicine unopened and in the same packaging that the seller received from the manufacturer or wholesaler of the medicine.
- (2) This section does not apply to a dispenser or person who is authorised to give a treatment dose of a medicine on a prescription.

Maximum penalty—20 penalty units.

#### 134 Offence to install medicine vending machines

(1) A person who is the owner or occupier of premises must not install a medicine vending machine on the premises.

Maximum penalty—30 penalty units.

(2) In this section—

*medicine vending machine* means a machine or device that supplies a medicine to a person on the payment of money.

#### 135 Advertising medicines

(1) A person must not advertise, or cause someone else to advertise, a medicine, whether or not the medicine is named in the advertisement.

Maximum penalty—80 penalty units.

- (2) However, subsection (1) does not apply to—
  - (a) an S2 medicine or S3 medicine to which the Poisons Standard, Appendix H applies; or
  - (b) an advertisement in a professional or trade journal; or
  - a price list, advertisement or promotional material intended for circulation only to wholesalers or the dental, medical, pharmaceutical or veterinary professions; or
  - (d) a price list complying with the document called 'Price information code of practice', published by the Therapeutic Goods Administration.
- (3) In this section—

*advertise*, in relation to a medicine, has the same meaning as it has in the *Therapeutic Goods Act 1989* (Cwlth), section 3 in relation to therapeutic goods.

#### 136 Reporting lost or stolen medicines

- (1) This section applies to each of the following approved persons in the following circumstances (each an *incident*)—
  - (a) an approved person, in the course of practising the person's profession or carrying out the person's functions, reasonably suspects an S8 medicine has been lost or stolen;
  - (b) an approved person, in the course of practising the person's profession, reasonably suspects pentobarbitone has been lost or stolen;
  - (c) a pharmacist, in the course of practising the pharmacist's profession, reasonably suspects pseudoephedrine has been lost or stolen.
- (2) The person must give notice about the incident to the chief executive and the police service as soon as practicable, and no later than the next business day, after the incident.

Maximum penalty—40 penalty units.

(3) However, if the medicine is lost or stolen from a medicine chest used by the Royal Flying Doctor Service of Australia, the report about the incident must be given to the senior medical officer of the Royal Flying Doctor Service of Australia.

## 137 Reporting failure to give written prescriptions

(1) This section applies if a prescriber fails to comply with section 38 when prescribing a medicine.

Note—

Section 38 requires a prescriber to give a written prescription after orally prescribing or prescribing by using non-compliant electronic communication.

- (2) A person (an *authorised person*) who supplies or administers the medicine must give notice to the following person within the following period about the prescriber's failure to comply—
  - (a) if the authorised person is employed by the same entity as the prescriber—the relevant manager of the prescriber as soon as practicable;
  - (b) otherwise—the chief executive within 48 hours after the end of the period for compliance mentioned in subsection (1).

Maximum penalty—20 penalty units.

(3) If an authorised person notifies the relevant manager of a prescriber's failure to comply, and the prescriber does not rectify the failure within 48 hours after the notification, the relevant manager must give notice to the chief executive about the failure to comply as soon as practicable.

Maximum penalty—20 penalty units.

(4) In this section—

**relevant manager**, of an prescriber, means a person who is responsible for managing the prescriber's compliance with section 38.

# Part 2 Administration by chief executive

## 138 Matters to be considered for extended practice authority—Act, s 232

- (1) This section prescribes, for section 232(3) of the Act, the matters to be considered in relation to a document mentioned in section 232(2) of the Act.
- (2) The matters are—
  - (a) the nature of the dealings and the medicines proposed to be dealt with under the document;
  - (b) whether there is a community need for the service to be facilitated by the proposed dealings under the document;
  - (c) the way in which any health risks associated with the dealings with the medicines are proposed to be managed under the document;
  - (d) the need and timing for a review of the document;
  - (e) if an entity intends to manage the persons proposed to deal with medicines under the document—the governance capability of the entity.

## 139 Chief executive may set up electronic system for information

- (1) This section applies in relation to a requirement (a *notification requirement*) under this regulation for a person to notify, or give information to, the chief executive about a matter.
- (2) The chief executive may establish or approve an electronic system to receive and record information for the notification requirement.
- (3) If subsection (2) applies, the chief executive must take reasonable steps to ensure that any person the chief executive

- intends should use the electronic system is made aware of the establishment or approval of the system.
- (4) A person complying with a notification requirement must use the electronic system established or approved for the notification requirement, unless the chief executive has not complied with subsection (3) in relation to the person.

Maximum penalty—40 penalty units.

## Part 3 Fees

## 140 Fees payable

- (1) The fees payable under the Act are stated in schedule 19.
- (2) However, if an application mentioned in schedule 19 is made for a term that is not 1 year or a number of whole years, the fee for the application is to be adjusted in proportion to the term
- (3) Also, no fee is payable in relation to a site if—
  - (a) a fee has been paid under the *Medicines and Poisons* (*Pest Management, Poisons and Other Regulated Substances*) Regulation 2019 for an application for a substance authority; and
  - (b) the application has been made to authorise dealing with a medicine, in addition to a poison, at the site.
- (4) A reference in this section and schedule 19 to a site is a reference to a place—
  - (a) where an entity has applied to deal with a medicine; and
  - (b) that is proposed to be stated in the substance authority as a place where the dealing may be carried out with the medicine.

#### 141 Refunds

- (1) This section applies if—
  - (a) an entity has paid a fee for an application for a substance authority or renewal of a substance authority; and
  - (b) the substance authority or renewal is not granted to the entity or is not granted for the period sought by the entity.
- (2) The chief executive may refund the fee, or a proportion of the fee, if the chief executive is satisfied it is appropriate and reasonable to do so in the circumstances.
- (3) In considering a refund under subsection (2), the chief executive may retain a proportion of the fee that represents the cost of considering the application or renewal.

# Schedule 1 Extended practice authorities and departmental standards

section 5

## Part 1 Extended practice authorities

Number	Name	Date
1	Isolated practice area paramedics	[to be made]
2	Midwives	[to be made]
3	Registered nurses	[to be made]
4	Orthoptists	[to be made]
5	Vaccinations by pharmacists	[to be made]
6	Aboriginal and Torres Strait Islander health practitioners	[to be made]
7	Indigenous health workers	[to be made]
8	Queensland Ambulance Service	[to be made]

## Part 2 Departmental standards

Number	Name	Date
1	Compounding	[to be made]
2	Storage of medicines	[to be made]
3	Safe supply of medicines	[to be made]
4	Monitored medicines	[to be made]

### Schedule 1

Number	Name	Date
5	Pseudoephedrine recording standard	[to be made]
6	Substance management plans	[to be made]
7	Technical requirements for an electronic medication management system	[to be made]

## Schedule 2 Categories of medicines

sections 6 to 9

## Part 1 Restricted medicines

acitretin

ambrisentan

amfetamines

bexarotene

bosentan

buprenorphine when used for treating opioid dependency

cannabis for human therapeutic use

clomifene

clozapine

corifollitropin alfa

cyclofenil or any other substance specifically prepared to

stimulate ovulation

dinoprost

dinoprostone

dronabinol (delta-9-tetrahydrocannabinol)

enzalutamide

etretinate

follitropin alpha

follitropin beta

isotretinoin for human oral use

lenalidomide

luteinising hormone

macitentan

methadone when used for treating opioid dependency

methylphenidate

nabilone

nabiximols

pomalidomide

riociguat

sodium oxybate

teriparatide

tetrahydrocannabinols for human therapeutic use

thalidomide

tretinoin for human oral use

urofollitropin (human follicle stimulating hormone)

## Part 2 High-risk medicines

an S8 medicine

the following S4 medicines—

- all benzodiazepines
- codeine
- gabapentin
- pregabalin
- quetiapine
- tramadol
- zolpidem
- zopiclone

## Part 3 Diversion-risk medicines

an S8 medicine

the following S4 medicines—

- acetyldihyrocodeine
- adiphenine
- amyl nitrite
- androgenic steroidal agents
- anabolic steroidal agents
- AOD-9604 (CAS No. 221231-10-3)
- barbiturates
- benzhexol
- benzodiazepine derivatives
- chloral hydrate
- chlordiazepoxide
- CJC-1295 (CAS No. 863288-34-0)
- clorazepate
- codeine
- darbepoetin
- dexfenfluramine
- dextromethorphan
- dextropropoxyphene
- dextrorphan
- diethylproprion
- dihydrocodeine
- ephedrine
- epoetins
- all erythropoietins

#### Schedule 2

- ethylmorphine
- fenfluramine
- fibroblast growth factors
- follistatin
- gabapentin
- gluthimide
- growth hormone releasing hormones
- all growth hormone releasing peptides
- growth hormone releasing secretagogues
- hexarelin
- ibutamoren insulin-like growth factors
- ipamorelin
- mazindol
- meprobamate
- perampanel for human use
- phentermine
- pralmorelin (growth hormone releasing peptide-2)
- pregabalin
- propofol
- propylhexedrine
- pseudoephedrine
- selective androgen receptor modulators
- somatropin (human growth hormone)
- stenabolic (SR9009) and other synthetic REV-ERB agonists
- TB-500
- thymosin beta 4
- tianeptine
- tramadol

- quetiapine
- zolpidem
- zopiclone

## Part 4 Monitored medicines

an S8 medicine

the following S4 medicines—

- all benzodiazepines
- codeine
- gabapentin
- pregabalin
- quetiapine
- tramadol
- zolpidem
- zopiclone

# Schedule 3 Aboriginal and Torres Strait Islander health services

section 10

## Part 1 Preliminary

#### 1 Definitions for schedule

In this schedule—

Aboriginal and Torres Strait Islander health practitioner means a person registered under the Health Practitioner Regulation National Law to practise in the Aboriginal and Torres Strait Islander health practice profession.

Indigenous health worker means a person who—

- (a) holds a Diploma of Health Science ATSI Primary Health Care (Generalist) ASF 5 from a college of technical and further education or a certified equivalent qualification; and
- (b) has successfully completed the North Queensland Rural Health Training Unit Isolated Practice Course or a certified equivalent course of training for the accreditation of registered nurses for practice in an isolated practice area.

*practice plan*, for an Aboriginal and Torres Strait Islander health practitioner, means a document in a form approved by the chief executive—

- (a) developed and signed by the health practitioner and the primary clinical supervisor for the practitioner; and
- (b) stating the circumstances and conditions for the practitioner to administer or give a treatment dose of a medicine.

*primary clinical supervisor*, for an Aboriginal and Torres Strait Islander health practitioner, means the person who has

primary responsibility for supervising the clinical work performed by the health practitioner for the practitioner's employment in a relevant Health Service.

#### relevant Health Service means—

- (a) a Hospital and Health Service; or
- (b) a service for maintaining, improving, restoring or managing the health of Aboriginal people or Torres Strait Islanders provided by—
  - (i) a corporation registered under the *Corporations* (Aboriginal and Torres Strait Islander) Act 2006 (Cwlth); or
  - (ii) a registered entity under the Australian Charities and Not-for-profits Commission Act 2012 (Cwlth).

## Part 2 Aboriginal health services

## 2 Buying and possessing stock for Aboriginal health services

- (1) A person may buy and possess stock of a medicine for a health service if—
  - (a) the service is an approved Aboriginal health service under the *National Health (Remote Area Aboriginal Health Services Program) Special Arrangement 2017* (Cwlth); and
  - (b) the order is an eligible order under that arrangement; and
  - (c) the person is permitted by the service to order the stock for the service.
- (2) The person must ensure the stock is stored in a compliant storage system.

# Part 3 Aboriginal and Torres Strait Islander health practitioners

## 3 Application of part

This part applies to an Aboriginal and Torres Strait Islander health practitioner employed by a relevant Health Service and practising in an isolated practice area.

## 4 Buying and possessing stock

- (1) An Aboriginal and Torres Strait Islander health practitioner may buy stock of a medicine mentioned in 'Extended practice authority 6: Aboriginal and Torres Strait Islander health practitioners' for practising under the authority in the isolated practice area or at the relevant Health Service.
- (2) The Aboriginal and Torres Strait Islander health practitioner must comply with chapter 2, part 2, division 2 when buying the stock.
- (3) The Aboriginal and Torres Strait Islander health practitioner must ensure the stock is stored in a compliant storage system.

#### 5 Giving a treatment dose generally

- (1) The Aboriginal and Torres Strait Islander health practitioner may give a treatment dose of an S4 medicine on a prescription from a medical practitioner, nurse practitioner or dentist.
- (2) However, if the medicine is any of the following S4 medicines, the Aboriginal and Torres Strait Islander health practitioner may give a treatment dose of the medicine without a prescription—
  - (a) an S4 fluoride applied directly to a tooth's surface;
  - (b) box jellyfish antivenom;
  - (c) S4 ipratropium;
  - (d) S4 salbutamol.

(3) The Aboriginal and Torres Strait Islander health practitioner must comply with chapter 2, part 2, division 6 when giving the treatment dose.

## 6 Giving a treatment dose under extended practice authority

- (1) The Aboriginal and Torres Strait Islander health practitioner may give a treatment dose of a medicine to a patient—
  - (a) under 'Extended practice authority 6: Aboriginal and Torres Strait Islander health practitioners'; and
  - (b) in accordance with the practice plan for the Aboriginal and Torres Strait Islander health practitioner.
- (2) The Aboriginal and Torres Strait Islander health practitioner must comply with chapter 2, part 2, division 6 when giving the treatment dose.

## 7 Administering generally

- (1) The Aboriginal and Torres Strait Islander health practitioner may administer an S8 medicine on a prescription from a medical practitioner or nurse practitioner.
- (2) The Aboriginal and Torres Strait Islander health practitioner may administer an S4 medicine on a prescription from a medical practitioner, nurse practitioner or dentist.
- (3) However, if the medicine is any of the following S4 medicines, the Aboriginal and Torres Strait Islander health practitioner may administer the medicine without a prescription—
  - (a) an S4 fluoride applied directly to a tooth's surface;
  - (b) box jellyfish antivenom;
  - (c) S4 ipratropium;
  - (d) S4 salbutamol.
- (4) The Aboriginal and Torres Strait Islander health practitioner must comply with chapter 2, part 2, division 7 when administering the medicine.

## 8 Administering under extended practice authority

- (1) The Aboriginal and Torres Strait Islander health practitioner may administer a medicine to a patient—
  - (a) under 'Extended practice authority 6: Aboriginal and Torres Strait Islander health practitioners'; and
  - (b) in accordance with the practice plan for the Aboriginal and Torres Strait Islander health practitioner.
- (2) The Aboriginal and Torres Strait Islander health practitioner must comply with chapter 2, part 2, division 7 when administering the medicine.

## 9 Packaging and repackaging

For giving a treatment dose, the Aboriginal and Torres Strait Islander health practitioner may package or repackage a medicine under 'Departmental standard 3: Safe supply of medicines'.

## Part 4 Indigenous health workers

## 10 Application of part

This part applies to an Indigenous health worker—

- (a) practising in an isolated practice area; and
- (b) employed by any of the following Hospital and Health Services—
  - (i) Cairns and Hinterland Hospital and Health Service;
  - (ii) North West Hospital and Health Service;
  - (iii) Torres and Cape Hospital and Health Service.

#### 11 Giving a treatment dose generally

- (1) The Indigenous health worker may give a treatment dose of an S4 medicine on a prescription from a medical practitioner, nurse practitioner or physician assistant.
- (2) However, if the medicine is any of the following S4 medicines, the Indigenous health worker may give a treatment dose of the medicine without a prescription—
  - (a) box jellyfish antivenom;
  - (b) S4 ipratropium;
  - (c) S4 salbutamol.
- (3) The Indigenous health worker must comply with chapter 2, part 2, division 6 when giving the treatment dose.

## 12 Giving a treatment dose under extended practice authority

- (1) The Indigenous health worker may give a treatment dose of a medicine to a patient under 'Extended practice authority 7: Indigenous health workers'.
- (2) The Indigenous health worker must comply with chapter 2, part 2, division 6 when giving the treatment dose.

#### 13 Administering generally

- (1) The Indigenous health worker may administer an S8 medicine on a prescription from a medical practitioner, nurse practitioner or physician assistant.
- (2) The Indigenous health worker may administer an S4 medicine on a prescription from a medical practitioner, nurse practitioner or physician assistant.
- (3) However, if the medicine is any of the following S4 medicines, the Indigenous health worker may administer the medicine without a prescription—
  - (a) box jellyfish antivenom;
  - (b) S4 ipratropium;

- (c) S4 salbutamol.
- (4) The Indigenous health worker must comply with chapter 2, part 2, division 7 when administering the medicine.

## 14 Administering under extended practice authority

- (1) The Indigenous health worker may administer a medicine to a patient under 'Extended practice authority 7: Indigenous health workers'.
- (2) The Indigenous health worker must comply with chapter 2, part 2, division 7 when administering the medicine.

## 15 Packaging and repackaging

For giving a treatment dose, the Indigenous health worker may package or repackage a medicine under 'Departmental standard 3: Safe supply of medicines'.

## Schedule 4 Dentistry

section 10

## Part 1 Preliminary

#### 1 Definitions for schedule

In this schedule—

dental hygienist means a person who is—

- (a) registered under the Health Practitioner Regulation National Law—
  - (i) to practise in the dental profession; and
  - (ii) in the dental hygienists division of that profession; and
- (b) in a structured professional relationship with a dentist.

#### dental therapist means a person who is—

- (a) registered under the Health Practitioner Regulation National Law—
  - (i) to practise in the dental profession; and
  - (ii) in the dental therapists division of that profession; and
- (b) in a structured professional relationship with a dentist.

*dentist* means a person registered under the Health Practitioner Regulation National Law—

- (a) to practise in the dental profession; and
- (b) in the dentists division of that profession.

*immediate release formulation*, of a medicine, means a formulation in which the rate of release and absorption of the medicine is not appreciably or intentionally modified by the way in which it is formulated.

#### oral health therapist means a person who—

- (a) is registered under the Health Practitioner Regulation National Law—
  - (i) to practise in the dental profession; and
  - (ii) in the oral health therapists division of that profession; and
- (b) is in a structured professional relationship with a dentist.

## Part 2 Dentists

## 2 Buying and possessing stock

- (1) A dentist may buy stock of a medicine mentioned in this part for practising independently or at a clinic, other than a clinic in a specified place.
- (2) The dentist must comply with chapter 2, part 2, division 2 when buying the stock.
- (3) The dentist must ensure the stock is stored in a compliant storage system.

#### 3 Prescribing

- (1) A dentist may prescribe an S2, S3 or S4 medicine, other than a restricted medicine, to a patient.
- (2) A dentist may prescribe any of the following S8 medicines in an immediate release formulation to a patient—
  - (a) codeine:
  - (b) hydromorphone;
  - (c) morphine;
  - (d) oxycodone.
- (3) However, a dentist prescribing an S8 medicine must not—
  - (a) give a repeat prescription for the medicine; or
  - (b) prescribe more than 3 days supply of the medicine.

(4) The dentist must comply with chapter 2, part 2, division 3 when prescribing the medicine.

### 4 Giving a treatment dose

- (1) A dentist may give a treatment dose of an S2, S3 or S4 medicine, other than a restricted medicine, to a patient.
- (2) The dentist must comply with chapter 2, part 2, division 6 when giving the treatment dose.

## 5 Administering

- (1) A dentist may administer an S2, S3 or S4 medicine, other than a restricted medicine, to a patient.
- (2) A dentist may administer any of the following S8 medicines in an immediate release formulation to a patient—
  - (a) codeine;
  - (b) hydromorphone;
  - (c) morphine;
  - (d) oxycodone.
- (3) A dentist who is an endorsed conscious sedation practitioner may also administer fentanyl or pethidine to a patient.
- (4) The dentist must comply with chapter 2, part 2, division 7 when administering the medicine.

#### 6 Disposing of S8 medicine waste

- (1) A dentist may dispose of waste from an S8 medicine.
- (2) The dentist must comply with chapter 2, part 2, division 8 when disposing of the waste.

## Part 3 Dental hygienists

## 7 Administering

- (1) A dental hygienist may administer any of the following S2 and S3 medicines to a patient—
  - (a) an adrenaline (epinephrine) autoinjector;
  - (b) anaesthetics in preparations for topical human therapeutic use;
  - (c) fluorides in preparations for topical human therapeutic use;
  - (d) silver salts.
- (2) A dental hygienist may administer a local anaesthetic, whether alone or in combination with adrenaline (epinephrine) or felypressin, to a patient.
- (3) The dental hygienist must comply with chapter 2, part 2, division 7 when administering the medicine.

## Part 4 Oral health therapists

## 8 Administering

- (1) An oral health therapist may administer any of the following S2 and S3 medicines to a patient—
  - (a) an adrenaline (epinephrine) autoinjector;
  - (b) anaesthetics in preparations for topical human therapeutic use;
  - (c) ether;
  - (d) ferric sulphate;
  - (e) fluorides in preparations for topical human therapeutic use;
  - (f) phenol;
  - (g) silver salts.

- (2) An oral health therapist may administer any of the following S4 medicines to a patient—
  - (a) local anaesthetics, whether alone or in combination with adrenaline (epinephrine) or felypressin;
  - (b) antibiotics and corticosteroids in combination for topical endodontic use;
  - (c) mercury for human therapeutic use.
- (3) The oral health therapist must comply with chapter 2, part 2, division 7 when administering the medicine.

## Part 5 Dental therapists

## 9 Administering

- (1) A dental therapist may administer any of the following S2 and S3 medicines to a patient—
  - (a) an adrenaline (epinephrine) autoinjector;
  - (b) ether;
  - (c) ferric sulphate;
  - (d) fluorides in preparations for topical human therapeutic use;
  - (e) phenol;
  - (f) silver salts.
- (2) A dental therapist may administer any of the following S4 medicines to a patient—
  - (a) local anaesthetics, whether alone or in combination with adrenaline (epinephrine) or felypressin;
  - (b) antibiotics and corticosteroids in combination for topical endodontic use;
  - (c) mercury for human therapeutic use.
- (3) The dental therapist must comply with chapter 2, part 2, division 7 when administering the medicine.

# Schedule 5 Emergency and remote service providers

section 10

## Part 1 Preliminary

#### 1 Definitions for schedule

In this schedule—

first aid provider means a person who—

- (a) has a current certificate granted by a registered training organisation for the provision of first aid; and
- (b) is employed to perform first aid at a place or is a volunteer at a place.

*isolated practice area paramedic* means an ambulance officer who has successfully completed—

- (a) the Isolated Practice Area Paramedic course developed by the Northern Area Health Service Workforce Directorate that leads to the issue of a Graduate Certificate of Rural and Remote Paramedic Practice from James Cook University; or
- (b) an equivalent course approved by the chief executive.

**Queensland** Ambulance Service means the Queensland Ambulance Service under the Ambulance Service Act 1991.

## Part 2 Ambulance services

#### 2 Buying and possessing stock for Queensland Ambulance Service

(1) The commissioner of the Queensland Ambulance Service, or the commissioner's delegate, may buy and possess stock of a

- medicine for a place or equipment used by the Queensland Ambulance Service.
- (2) The commissioner or the commissioner's delegate must comply with chapter 2, part 2, division 2 when buying the stock.
- (3) The commissioner or the commissioner's delegate must ensure the stock is stored in a compliant storage system.

#### 3 Administering under extended practice authority

- (1) An ambulance officer may administer a medicine to a patient under 'Extended practice authority 8: Queensland Ambulance Service'.
- (2) The ambulance officer must comply with chapter 2, part 2, division 7 when administering the medicine.

## 4 Disposing of S8 medicine waste

- (1) An ambulance officer may dispose of waste from an S8 medicine.
- (2) The ambulance officer must comply with chapter 2, part 2, division 8 when disposing of the waste.

## Part 3 First aid providers

### 5 Buying and possessing stock

- (1) A first aid provider may buy stock of a medicine mentioned in this part, other than methoxyflurane, for practising independently.
- (2) The first aid provider must comply with chapter 2, part 2, division 2 when buying the stock.
- (3) The first aid provider must ensure the stock is stored in a compliant storage system.

#### 6 Administering

- (1) A first aid provider may administer methoxyflurane to a patient on a prescription for the patient if the first aid provider has completed methoxyflurane training.
- (2) A first aid provider may administer an adrenaline (epinephrine) autoinjector to a patient if the first aid provider has completed anaphylaxis training.
- (3) A first aid provider may administer naloxone to a patient if the first aid provider has completed naloxone training.
- (4) A first aid provider may administer an inhaled asthma reliever, other than an S4 medicine, to a patient if the first aid provider has completed asthma training.
- (5) The first aid provider must comply with chapter 2, part 2, division 7 when administering the medicine.

# Part 4 Isolated practice area paramedics

## 7 Buying and possessing stock

- (1) An isolated practice area paramedic may buy stock of a medicine mentioned in this part for practising independently.
- (2) The isolated practice area paramedic must comply with chapter 2, part 2, division 2 when buying the stock.
- (3) The isolated practice area paramedic must ensure the stock is stored in a compliant storage system.

## 8 Giving a treatment dose generally

- (1) An isolated practice area paramedic may give a treatment dose of a medicine to a patient on a prescription for the patient from a prescriber.
- (2) The isolated practice area paramedic must comply with chapter 2, part 2, division 6 when giving the treatment dose.

## 9 Giving a treatment dose under extended practice authority

- (1) An isolated practice area paramedic may give a treatment dose of a medicine to a patient under 'Extended practice authority 1: Isolated practice area paramedics'.
- (2) The isolated practice area paramedic must comply with chapter 2, part 2, division 6 when giving the treatment dose.

## 10 Administering generally

- (1) An isolated practice area paramedic may administer a medicine to a patient on a prescription for the patient from a prescriber.
- (2) The isolated practice area paramedic must comply with chapter 2, part 2, division 7 when administering the medicine.

## 11 Administering under extended practice authority

- (1) An isolated practice area paramedic may administer a medicine to a patient under 'Extended practice authority 1: Isolated practice area paramedics'.
- (2) The isolated practice area paramedic must comply with chapter 2, part 2, division 7 when administering the medicine.

## Part 5 Royal Flying Doctor Service

## 12 Definitions for part

In this part—

authorised medical practitioner means a medical
practitioner—

- (a) employed by the RFDS; and
- (b) authorised in writing by the RFDS to approve the keeping of a medicine chest at a place.

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

## 13 Application of part

This part applies in relation to a medicine chest of the RFDS kept at a place approved by an authorised medical practitioner.

## 14 Giving a treatment dose

A person in charge of the medicine chest, or the person's delegate, may give a treatment dose of a medicine from the chest to a patient on a prescription for the patient from any medical practitioner.

## 15 Administering

A person in charge of the medicine chest, or the person's delegate, may administer a medicine from the chest to a patient on a prescription for the patient from any medical practitioner.

# Schedule 6 Medical practitioners and assistants

section 10

## Part 1 Preliminary

#### 1 Definitions for schedule

In this schedule—

*physician assistant* means a person appointed and employed as a physician assistant by a Hospital and Health Service or the chief executive.

## Part 2 Medical practitioners generally

## Division 1 Buying and possessing stock

### 2 Buying and possessing stock

- (1) A medical practitioner may buy stock of a medicine mentioned in this part for practising independently or at a clinic, other than a clinic in a specified place.
- (2) The medical practitioner must comply with chapter 2, part 2, division 2 when buying the stock.
- (3) The medical practitioner must ensure the stock is stored in a compliant storage system.

## Division 2 Medicines other than restricted medicines

## 3 Prescribing

- (1) A medical practitioner may prescribe a medicine, other than a restricted medicine, for a patient.
- (2) The medical practitioner must comply with chapter 2, part 2, division 3 when prescribing the medicine.

## 4 Making standing order

- (1) A medical practitioner may make a standing order, other than a clinical protocol, for a place.
- (2) The standing order may be made in relation to an S2, S3 or S4 medicine, other than an S4 diversion-risk medicine.
- (3) A medical practitioner may make a clinical protocol in relation to a place.
- (4) The medical practitioner must comply with chapter 2, part 2, division 4 when making the standing order.

## 5 Dispensing

- (1) A medical practitioner may dispense a medicine, other than a restricted medicine, to a patient.
- (2) The medical practitioner must comply with chapter 2, part 2, division 5 when dispensing the medicine.

### 6 Giving a treatment dose

- (1) A medical practitioner may give a treatment dose of a medicine, other than a restricted medicine, to a patient.
- (2) The medical practitioner must comply with chapter 2, part 2, division 6 when giving the treatment dose.

## 7 Administering

A medical practitioner may administer a medicine, other than a restricted medicine, to a patient.

## 8 Disposing of S8 medicine waste

- (1) A medical practitioner may dispose of waste from an S8 medicine.
- (2) The medical practitioner must comply with chapter 2, part 2, division 8 when disposing of the waste.

# Division 3 Continuing treatment with restricted medicines

## 9 Application of division

This division applies if—

- (a) a medical practitioner is treating a patient in a hospital or watch-house; and
- (b) the patient was being treated with the medicine prior to admission to the hospital or watch-house.

## 10 Continuing treatment

- (1) The medical practitioner may prescribe or administer the medicine, or give a treatment dose of the medicine, to the patient under the supervision of a registrar or specialist medical practitioner authorised to deal with the medicine.
- (2) The medical practitioner must comply with requirements that normally apply to the medical practitioner when prescribing, administering or giving treatment doses of other medicines, other than section 34.

### Division 4 Particular restricted medicines

#### 11 Definition for division

In this division—

deal, with a medicine, means—

- (a) prescribe the medicine to a patient; or
- (b) administer the medicine to a patient; or
- (c) give a treatment dose of the medicine to a patient; or
- (d) dispense a medicine to the patient.

## 12 Amfetamines or methylphenidates

- (1) A medical practitioner may deal with an amfetamine or methylphenidate if the practitioner is treating—
  - (a) narcolepsy of a patient; or
  - (b) brain damage or attention deficit disorder in a child patient who is at least 4 years.
- (2) Also, a medical practitioner may deal with an amfetamine or methylphenidate if the practitioner—
  - (a) is a specialist paediatrician or specialist psychiatrist and the amfetamine or methylphenidate is for the treatment of brain damage or attention deficit disorder in a child patient; or
  - (b) is a psychiatrist treating an adult patient and prescribes the amfetamine or methylphenidate to the adult within the following dosage limits—
    - (i) for dexamfetamine—not exceeding a dose of 40mg a day;
    - (ii) for lisdexamfetamine—not exceeding a dose of 70mg a day;
    - (iii) for methylphenidate—not exceeding a dose of 80mg a day.

#### 13 Medicinal cannabis

A medical practitioner may deal with any of the following restricted medicines—

- (a) cannabis for human therapeutic use;
- (b) dronabinol (delta-9-tetrahydrocannabinol);
- (c) nabilone;
- (d) nabiximols;
- (e) tetrahydrocannabinols for human therapeutic use.

## Division 5 Packaging or repackaging

## 14 Packaging or repackaging

A medical practitioner may package or repackage a medicine for supply to a patient in accordance with 'Departmental standard 3: Safe supply of medicines'.

## Part 3 Specialist medical practitioners

## Division 1 Preliminary

## 15 Definition for part

In this part—

*deal*, with a medicine, means—

- (a) prescribe the medicine to a patient; or
- (b) administer the medicine to a patient; or
- (c) give a treatment dose of the medicine to a patient; or
- (d) dispense a medicine to the patient.

## Division 2 Buying and possessing stock

### 16 Buying and possessing stock

- (1) A medical practitioner may buy stock of a medicine mentioned in this part for practising independently or at a clinic, other than a clinic in a specified place.
- (2) The medical practitioner must comply with chapter 2, part 2, division 2 when buying the stock.
- (3) The medical practitioner must ensure the stock is stored in a compliant storage system.

## Division 3 Registrars

## 17 Registrars in hospitals

- (1) A medical practitioner employed as a registrar in a hospital may deal with a restricted medicine relating to the specialty area of practice in which the registrar is working.
- (2) The medical practitioner must comply with chapter 2, part 2, other than division 7, when dealing with the medicine.

## Division 4 Specialists

#### 18 Specialist medical practitioners

A medical practitioner registered under the Health Practitioner Regulation National Law to practise as a specialist registrant in the specialty area of practice stated in column 1 of the table below may deal with the restricted medicine stated opposite in column 2 of the table.

Column 1	Column 2
Specialty area of practice	Restricted medicines
cardiology	ambrisentan
	bosentan
	macitentan
	riociguat
dermatology	acitretin
	bexarotene
	etretinate
	isotretinoin for human oral use
	thalidomide
	tretinoin for human oral use
geriatrics	teriparatide
gynaecology, obstetrics or	clomifene
endocrinology	corifollitropin alfa
	cyclofenil
	dinoprost
	dinoprostone
	follitropin alpha
	follitropin beta
	luteinising hormone
	urofollitropin (human follicle stimulating hormone)
haematology	bexarotene
	lenalidomide
	pomalidomide
	thalidomide

#### Schedule 6

Column 1	Column 2
Specialty area of practice	Restricted medicines
infectious diseases	thalidomide
medical oncology	bexarotene
	enzalutamide
	lenalidomide
	pomalidomide
	thalidomide
neurology, respiratory and sleep medicine, or paediatrics	sodium oxybate
psychiatry	clozapine
rheumatology	ambrisentan
	bosentan
	macitentan
	riociguat
	teriparatide
specialist general practitioner or rural	dinoprost
generalist with advanced skills in gynaecology employed by a rural health service	dinoprostone

Column 1	Column 2
Specialty area of practice	Restricted medicines
specialist physician	acitretin
	ambrisentan
	bexarotene
	bosentan
	dronabinol (delta-9-tetrahydrocannabinol)
	enzalutamide
	etretinate
	isotretinoin for human oral use
	lenalidomide
	macitentan
	pomalidimide
	riociguat
	teriparatide
	thalidomide
	tretinoin for human oral use
urology	enzalutamide

# Part 4 Physician assistants

# 19 Definition for part

In this part—

*practice plan*, for a physician assistant, means a document in the approved form—

(a) developed and signed by the physician assistant and the medical practitioner supervising the assistant; and

(b) stating the circumstances and conditions for the physician assistant to prescribe, administer, or give a treatment dose, of a medicine.

#### 20 Prescribing

- (1) A physician assistant may prescribe a medicine, other than a restricted medicine, to a patient under—
  - (a) the supervision of a medical practitioner; and
  - (b) the practice plan for the physician assistant.
- (2) The physician assistant must comply with chapter 2, part 2, division 3 when prescribing the medicine.

## 21 Giving a treatment dose

- A physician assistant may give a treatment dose of a medicine, other than a restricted medicine, to a patient under—
  - (a) the supervision of a medical practitioner; and
  - (b) the practice plan for the physician assistant.
- (2) The physician assistant must comply with chapter 2, part 2, division 6 when giving the treatment dose.

#### 22 Administering

- (1) A physician assistant may administer a medicine, other than a restricted medicine, to a patient under—
  - (a) the supervision of a medical practitioner; and
  - (b) the practice plan for the physician assistant.
- (2) The physician assistant must comply with chapter 2, part 2, division 7 when administering the medicine.

# Schedule 7 Nursing and midwifery

section 10

# Part 1 Preliminary

#### 1 Definitions for schedule

In this schedule—

enrolled nurse means a person registered under the Health Practitioner Regulation National Law—

- (a) to practise in the nursing profession; and
- (b) in the enrolled nurses division of that profession.

*midwife* means a person registered under the Health Practitioner Regulation National Law to practise in the midwifery profession as a midwife.

nurse practitioner means a person who is a registered nurse and endorsed under the Health Practitioner Regulation National Law as being qualified to practise as a nurse practitioner.

*registered nurse* means a person registered under the Health Practitioner Regulation National Law—

- (a) to practise in the nursing profession; and
- (b) in the registered nurses division of that profession.

# Part 2 Nurse practitioners

# 2 Buying and possessing stock

(1) A nurse practitioner may buy stock of a medicine mentioned in this part for practising independently or at a clinic, other than a clinic in a specified place.

- (2) The nurse practitioner must comply with chapter 2, part 2, division 2 when buying the stock.
- (3) The nurse practitioner must ensure the stock is stored in a compliant storage system.

## 3 Prescribing

- (1) A nurse practitioner may prescribe a registered medicine, other than a restricted medicine, to a patient.
- (2) A nurse practitioner may prescribe a restricted medicine to a patient if—
  - (a) the practitioner is treating the patient in a hospital or watch-house; and
  - (b) the patient was being treated with the medicine prior to admission to the hospital or watch-house; and
  - (c) the dealing is under the supervision of a registrar or specialist medical practitioner authorised to deal with the medicine.
- (3) The nurse practitioner must comply with chapter 2, part 2, division 3 when prescribing the medicine.
- (4) However, if the medicine is prescribed in the circumstances mentioned in subsection (2), the nurse practitioner does not need to comply with section 34.

## 4 Making standing order

- (1) A nurse practitioner may make a standing order, other than a clinical protocol, for a place.
- (2) The standing order may be made in relation to an S2, S3 or S4 medicine, other than an S4 diversion-risk medicine.
- (3) The nurse practitioner must comply with chapter 2, part 2, division 4 when making the standing order.

## 5 Giving a treatment dose

- (1) A nurse practitioner may give a treatment dose of a registered medicine, other than a restricted medicine, to a patient.
- (2) A nurse practitioner may give a treatment dose of a medicine, including a restricted medicine, on a prescription for a patient from a prescriber.
- (3) A nurse practitioner may give a treatment dose of a restricted medicine to a patient if—
  - (a) the practitioner is treating the patient in a hospital or watch-house; and
  - (b) the patient was being treated with the medicine prior to admission to the hospital or watch-house; and
  - (c) the dealing is under the supervision of a registrar or specialist medical practitioner authorised to deal with the medicine.
- (4) The nurse practitioner must comply with chapter 2, part 2, division 6 when giving the treatment dose.

#### 6 Administering

- (1) A nurse practitioner may administer a registered medicine, other than a restricted medicine, to a patient.
- (2) A nurse practitioner may administer a medicine, including a restricted medicine, on a prescription for a patient from a prescriber.
- (3) A nurse practitioner may administer a restricted medicine to a patient if—
  - (a) the practitioner is treating the patient in a hospital or watch-house; and
  - (b) the patient was being treated with the medicine prior to admission to the hospital or watch-house; and
  - (c) the dealing is under the supervision of a registrar or specialist medical practitioner authorised to deal with the medicine.

(4) The nurse practitioner must comply with chapter 2, part 2, division 7 when administering the medicine.

## 7 Disposing of S8 medicine waste

- (1) A nurse practitioner may dispose of waste from an S8 medicine.
- (2) The nurse practitioner must comply with chapter 2, part 2, division 8 when disposing of the waste.

# Part 3 Midwives

#### Division 1 Midwives

# 8 Buying and possessing stock

- (1) A midwife may buy stock of a medicine mentioned in 'Extended practice authority 2: Midwives', for practising under the authority.
- (2) The midwife must comply with chapter 2, part 2, division 2 when buying the stock.
- (3) The midwife must ensure the stock is stored in a compliant storage system.

# 9 Giving a treatment dose generally

- (1) A midwife may give a treatment dose of an S2 or S3 medicine to a patient being treated at a rural hospital or in an isolated practice area.
- (2) A midwife may give a treatment dose of a medicine on a standing order applying to the midwife.
- (3) A midwife may give a treatment dose of an S4 or S8 medicine to a patient on prescription for the patient from a prescriber.
- (4) The midwife must comply with chapter 2, part 2, division 6 when giving the treatment dose.

# 10 Giving a treatment dose under extended practice authority

- (1) A midwife may give a treatment dose of an S4 or S8 medicine to a patient under 'Extended practice authority 2: Midwives'.
- (2) The midwife must comply with chapter 2, part 2, division 6 when giving the treatment dose.

## 11 Administering generally

- (1) A midwife may administer any of the following medicines to a patient—
  - (a) an S2 or S3 medicine;
  - (b) if the patient is a woman—a nitrous oxide mixture as an analgesic during childbirth.
- (2) A midwife may administer a medicine on a standing order applying to the midwife.
- (3) A midwife may administer an S4 or S8 medicine to a patient on a prescription for the patient from a prescriber.
- (4) A midwife may administer an S4 or S8 medicine to a patient in accordance with the medicine's approved label.
- (5) The midwife must comply with chapter 2, part 2, division 7 when administering the medicine.
- (6) In this section—

*childbirth* means the process of labour and delivery beginning with uterine contractions and ending with the expulsion of the placenta and membranes from the woman giving birth.

## 12 Administering under extended practice authority

- (1) A midwife may administer an S4 or S8 medicine to a patient under 'Extended practice authority 2: Midwives'.
- (2) The midwife must comply with chapter 2, part 2, division 7 when administering the medicine.

#### 13 Disposing of S8 medicine waste

- (1) A midwife may dispose of waste from an S8 medicine.
- (2) The midwife must comply with chapter 2, part 2, division 8 when disposing of the waste.

## Division 2 Endorsed midwives

## 14 Buying and possessing stock

- (1) An endorsed midwife may buy stock of a medicine mentioned in this division for practising independently or at a clinic, other than a clinic in a specified place.
- (2) The endorsed midwife must comply with chapter 2, part 2, division 2 when buying the stock.
- (3) The endorsed midwife must ensure the stock is stored in a compliant storage system.

#### 15 Prescribing

- (1) An endorsed midwife may prescribe a registered medicine, other than a restricted medicine, to a patient.
- (2) The endorsed midwife must comply with chapter 2, part 2, division 3 when prescribing the medicine.

#### 16 Making standing order

- (1) An endorsed midwife may make a standing order, other than a clinical protocol, in relation to a place.
- (2) The standing order may be made in relation to an S2, S3 or S4 medicine, other than an S4 diversion-risk medicine.
- (3) The endorsed midwife must comply with chapter 2, part 2, division 4 when making the standing order.

#### 17 Giving a treatment dose

- (1) An endorsed midwife may give a treatment dose of a registered medicine, other than a restricted medicine, to a patient.
- (2) The endorsed midwife must comply with chapter 2, part 2, division 6 when giving the treatment dose of the medicine.

# 18 Administering

- (1) An endorsed midwife may administer a registered medicine, other than a restricted medicine, to a patient.
- (2) The endorsed midwife must comply with chapter 2, part 2, division 7 when administering the medicine.

# Part 4 Registered nurses

#### 19 Buying and possessing stock

- (1) A registered nurse may buy stock of a medicine mentioned in 'Extended practice authority 3: Registered nurses', for practising under the authority.
- (2) The registered nurse must comply with chapter 2, part 2, division 2 when buying the stock.
- (3) The registered nurse must ensure the stock is stored in a compliant storage system.

# 20 Giving a treatment dose under extended practice authority

- (1) This section applies to a registered nurse practising in an area or program stated in 'Extended practice authority 3: Registered nurses'.
- (2) The registered nurse may give a treatment dose of a medicine under 'Extended practice authority 3: Registered nurses'.

#### Example—

A registered nurse practising in a rural area or isolated practice area may give a treatment dose of a stated medicine under the relevant conditions of the extended practice authority.

(3) The registered nurse must comply with chapter 2, part 2, division 6 when giving the treatment dose.

## 21 Giving a treatment dose at rural or isolated hospitals

- (1) A registered nurse employed at a rural hospital or at a hospital in an isolated practice area may give a treatment dose of a medicine to a patient on a prescription for the patient from a prescriber if—
  - (a) the patient is being discharged from, or is an outpatient of, the hospital; and
  - (b) the hospital does not employ a pharmacist or the pharmacist is absent from the hospital when it is necessary to give the treatment dose of the medicine; and
  - (c) the registered nurse is the hospital's nurse manager or a delegate of the hospital's nurse manager.
- (2) The registered nurse must comply with chapter 2, part 2, division 6 when giving the treatment dose.

# 22 Giving a treatment dose at prisons

- (1) This section applies to a registered nurse employed at a prison if a pharmacist is not available to dispense a medicine at the prison.
- (2) The registered nurse may give a treatment dose of an S2, S3 or S4 medicine, of not more than 7 days supply, to the following patients on a prescription for the patient from a prescriber employed to provide health services at the prison—
  - (a) a patient released from the prison into the custody of the court;
  - (b) a patient transferred from 1 prison to another prison;

- (c) a patient released from the prison into the community.
- (3) The registered nurse must comply with chapter 2, part 2, division 6 when giving the treatment dose.

# 23 Administering generally

- (1) A registered nurse may administer an S2 or S3 medicine to a patient.
- (2) A registered nurse working at a relevant institution may administer a medicine on a standing order applying to the registered nurse.
- (3) A registered nurse may administer an S4 or S8 medicine to a patient—
  - (a) on a prescription for the patient from a prescriber; or
  - (b) in accordance with the medicine's approved label.
- (4) The registered nurse must comply with chapter 2, part 2, division 7 when administering the medicine.

#### 24 Administering under extended practice authority

- (1) This section applies to a registered nurse practising in an area or program stated in 'Extended practice authority 3: Registered nurses'.
- (2) The registered nurse may administer a medicine under 'Extended practice authority 3: Registered nurses'.

#### Examples—

- 1 A registered nurse practising in a rural area or isolated practice area may administer a stated medicine under the relevant conditions of the extended practice authority.
- 2 A registered nurse practising in a sexual or reproductive health program may administer a stated medicine under the relevant conditions of the extended practice authority.
- 3 A registered nurse practising in an immunisation program may administer a stated vaccine under the relevant conditions of the extended practice authority.
- (3) The registered nurse must comply with chapter 2, part 2, division 7 when administering the medicine.

#### 25 Disposing of S8 medicine waste

- (1) A registered nurse may dispose of waste from an S8 medicine.
- (2) The registered nurse must comply with chapter 2, part 2, division 8 when disposing of the waste.

# Part 5 Enrolled nurses

# 26 Possessing

An enrolled nurse may possess an S4 or S8 medicine for a patient on a written prescription for the patient from a medical practitioner administering anaesthesia at a hospital when preparing for, and during, anaesthetic procedures for the patient.

## 27 Administering

- (1) An enrolled nurse may administer a medicine to a patient under the direct supervision of a medical practitioner administering anaesthesia if it is reasonably necessary to ensure the safety of the patient before, or during, the patient's anaesthetic procedure.
- (2) An enrolled nurse may administer an S4 or S8 medicine to a patient—
  - (a) on a prescription for the patient from a prescriber; or
  - (b) if the medicine has been dispensed to the patient—under the supervision of a dentist, medical practitioner, midwife or registered nurse and in accordance with the medicine's approved label.
- (3) An enrolled nurse may administer another S2 or S3 medicine to a patient in accordance with the medicine's approved label.
- (4) The enrolled nurse must comply with chapter 2, part 2, division 7 when administering the medicine.

# 28 Disposing of S8 medicine waste

- (1) An enrolled nurse may dispose of waste from an S8 medicine.
- (2) The enrolled nurse must comply with chapter 2, part 2, division 8 when disposing of the waste.

# Schedule 8 Ocular treatment

section 10

# Part 1 Preliminary

#### 1 Definitions for schedule

In this schedule—

*ophthalmologist* means a person registered under the Health Practitioner Regulation National Law to practise in the specialty of ophthalmology.

*optometrist* means a person registered under the Health Practitioner Regulation National Law to practise in the optometry profession.

*Optometry Board* means the Optometry Board of Australia established under the Health Practitioner Regulation National Law.

*orthoptist* means a person whose name is recorded in the register of orthoptists kept by the Australian Orthoptists Registration Body Pty Ltd ACN 095 117 678.

# Part 2 Optometrists

#### 2 Buying and possessing stock

- (1) An optometrist may buy stock of a medicine mentioned in this part for practising independently or at a clinic, other than a clinic in a specified place.
- (2) The optometrist must comply with chapter 2, part 2, division 2 when buying the stock.
- (3) The optometrist must ensure the stock is stored in a compliant storage system.

# 3 Administering

An optometrist may administer a topical S2, S3 or S4 medicine to a patient if—

- (a) the medicine is stated in appendix A of the document called 'Guidelines for use of scheduled medicines' made by the Optometry Board on 10 September 2018; and
- (b) the optometrist administers the medicine under the guidelines.

# Part 3 Endorsed optometrists

# 4 Buying and possessing stock

- (1) An endorsed optometrist may buy stock of a medicine mentioned in this part for practising independently or at a clinic, other than a clinic in a specified place.
- (2) The endorsed optometrist must comply with chapter 2, part 2, division 2 when buying the stock.
- (3) The endorsed optometrist must ensure the stock is stored in a compliant storage system.

#### 5 Prescribing

- (1) An endorsed optometrist may prescribe an S2, S3, or S4 medicine to a patient if—
  - (a) the medicine is stated in appendix B or appendix C of the document called 'Guidelines for use of scheduled medicines' made by the Optometry Board on 10 September 2018; and
  - (b) the optometrist prescribes the medicine under the guidelines.
- (2) The endorsed optometrist must comply with chapter 2, part 2, division 3 when prescribing the medicine.

#### 6 Giving a treatment dose

- (1) An endorsed optometrist may give a treatment dose of an S2, S3 or S4 medicine to a patient if—
  - (a) the medicine is stated in appendix B or appendix C of the document called 'Guidelines for use of scheduled medicines' made by the Optometry Board on 10 September 2018; and
  - (b) the optometrist gives a treatment dose of the medicine under the guidelines.
- (2) The endorsed optometrist must comply with chapter 2, part 2, division 6 when giving the treatment dose.

## 7 Adminstering

An endorsed optometrist may administer an S2, S3 or S4 medicine to a patient if—

- (a) the medicine is stated in appendix B or appendix C of the document called 'Guidelines for use of scheduled medicines' made by the Optometry Board on 10 September 2018; and
- (b) the optometrist administers the medicine under the guidelines.

# Part 4 Orthoptists

# 8 Administering generally

- (1) An orthoptist may administer a topical opthalmic preparation on a prescription for the patient from an ophthalmologist.
- (2) The orthoptist must comply with chapter 2, part 2, division 7 when administering the medicine.

# 9 Administering under extended practice authority

(1) An orthoptist may administer an S2, S3 or S4 medicine to a patient under 'Extended practice authority 4: Orthoptists'.

(2) The orthoptist must comply with chapter 2, part 2, division 7 when administering the medicine.

# Schedule 9 Pharmaceutical services

section 10

# Part 1 Preliminary

#### 1 Definitions for schedule

In this schedule—

hospital pharmaceutical technician means a person who—

- (a) has a qualification, or statement of attainment, recognising the person has the skills and knowledge required to carry out pharmaceutical imprest duties in a hospital; and
- (b) carries out pharmaceutical imprest duties in a hospital.

*pharmaceutical imprest duties* means duties related to keeping an inventory of medicines possessed at a hospital or supplied for treatment of the hospital's patients.

# Part 2 Pharmacists

# Division 1 Supply

#### 2 Dispensing

- (1) A pharmacist may dispense a medicine to a patient on a prescription for the patient from a prescriber.
- (2) The pharmacist must comply with chapter 2, part 2, division 5 when dispensing the medicine.

## 3 Selling S2 and S3 medicines

- (1) A pharmacist may sell an S2 medicine to a patient without a prescription at a pharmacy.
- (2) A pharmacist may sell an S3 medicine to a patient without a prescription at a pharmacy only if—
  - (a) the pharmacist reasonably believes the patient has a therapeutic need for the medicine; or
  - (b) the S3 medicine is sold in a manufacturer's pack.

## 4 Labelling S3 medicines

- (1) This section applies in relation to the sale of an S3 medicine for a patient without a prescription.
- (2) The pharmacist must—
  - (a) ensure a label is attached to the medicine with the contact details of the pharmacist; and
  - (b) ensure the label does not obscure the instructions for the use of the medicine.
- (3) The pharmacist must—
  - (a) give instructions about the appropriate way to use the S3 medicine to the person buying the medicine; and
  - (b) if the S3 medicine is naloxone—ask whether the person who will be administering the naloxone has received naloxone training.

## 5 Continued supply

- (1) A pharmacist may supply a medicine to a patient without a prescription for the patient from a prescriber if—
  - (a) in the Continued Dispensing Determination, the medicine is stated to be a medicine to which the pharmaceutical benefits schedule applies; and
  - (b) the pharmacist supplies the medicine to the patient in compliance with the requirements of the Continued Dispensing Determination.

#### (2) In this section—

Continued Dispensing Determination means the National Health (Continued Dispensing) Determination 2012 (Cwlth) made by the Commonwealth Minister responsible for the National Health Act 1953 (Cwlth), section 89A.

*pharmaceutical benefits schedule* means the schedule of pharmaceutical benefits issued by the department of the Commonwealth in which the *National Health Act 1953* (Cwlth) is administered.

## 6 Supply of S4 medicines in urgent circumstances

- (1) A pharmacist may supply an S4 medicine to a patient without a prescription for the patient from a prescriber if the pharmacist reasonably believes—
  - (a) the patient seeking the medicine is under medical treatment requiring the use of the medicine; and
  - (b) it is urgent and essential to continue the treatment for the patient's wellbeing.
- (2) However, if the medicine is an S4 diversion-risk medicine, the pharmacist may supply the medicine only if the pharmacist also reasonably believes a failure to supply the medicine could be life-threatening for the patient.
- (3) The pharmacist may—
  - (a) only supply an amount of the S4 medicine that is reasonably necessary to continue the treatment of the patient until the patient can obtain a prescription for the medicine from a prescriber; and
  - (b) supply the S4 medicine in a container with a label, securely attached, that complies with the requirements of the Poisons Standard, part 2 for a dispensing label.
- (4) However, the pharmacist must not supply more than—
  - (a) for an S4 medicine that is a prepacked liquid, cream, ointment or aerosol—the minimum standard pack; or

- (b) for another S4 medicine—3 days supply of the medicine.
- (5) The pharmacist must make a record of the following as soon as practicable after selling the medicine—
  - (a) the pharmacist's name;
  - (b) the name and address of the patient;
  - (c) the date the medicine is sold;
  - (d) the approved name and brand name of the medicine;
  - (e) the form, strength and amount of the medicine supplied;
  - (f) the instructions given for the use of the medicine;
  - (g) the name of the prescriber who last prescribed the medicine to the person, if known.
- (6) A record of information mentioned in subsection (5)(d) or (e) must be sufficient to accurately identify the medicine sold.

#### 7 Selling stock

- (1) A pharmacist may sell stock of a medicine to a person who is authorised under the Act or another law to buy the stock if—
  - (a) the medicines sold to the person in a month do not exceed 10 whole packs for the medicine; and
  - (b) the medicines are sold to the person on the basis the medicines are not for re-sale.
- (2) Also, a pharmacist may sell stock of a medicine to a person if the *National Health (Pharmaceutical Benefits) Regulations* 2017 (Cwlth), section 33 applies to selling the medicine to the person.

Note-

The National Health (Pharmaceutical Benefits) Regulations 2017 (Cwlth), section 33 (Prescriber bag supplies—obtaining benefits by practitioners) allows particular pharmaceutical benefits to be supplied by a pharmacist to a medical practitioner, midwife or nurse practitioner.

(3) The pharmacist must not sell the stock to the person unless the person gives the pharmacist a compliant purchase order for the medicine.

#### 8 Supply of wholesale stock

- (1) A pharmacist may supply stock of a medicine by wholesale to another pharmacist (the *receiver*) if—
  - (a) the receiver gives a signed, written request for the stock to the pharmacist; and
  - (b) the pharmacist is reasonably satisfied the request is for satisfying an order made by a customer of the pharmacy in which the receiver practices; and
  - (c) the pharmacist supplies the minimum amount of stock necessary to satisfy the customer's order.
- (2) The pharmacist must keep a record of the following details of the medicine supplied under subsection (1)—
  - (a) the date on which the medicine was supplied;
  - (b) the type of medicine supplied;
  - (c) the amount of medicine supplied.
- (3) The pharmacist may continue to supply stock of a medicine by wholesale to the receiver if the receiver is supplying a similar amount of the medicine as a replacement for the supply under subsection (1).

#### 9 Buying from another pharmacist

- (1) This section applies to a pharmacist (the *buyer*) buying stock of a medicine from another pharmacist (the *seller*).
- (2) The buyer may buy the stock of medicines from the seller—
  - (a) to urgently fill a shortage of stock held by the buyer; or
  - (b) as part of an arrangement between the buyer and seller to prevent the stock from expiring.
- (3) However, if the buying is to fill a shortage of stock, the seller must—

- (a) be reasonably satisfied the request from the buyer is to satisfy an order made by a customer of the buyer; and
- (b) supply the minimum amount of stock necessary to satisfy the customer's order.
- (4) The seller must keep a copy of the purchase order or the details of the purchase order.

# 10 Record keeping for pseudoephedrine

- (1) This section applies if a pharmacist sells an S3 medicine containing pseudoephedrine.
- (2) The pharmacist must record the following matters in relation to the sale—
  - (a) the date of the sale;
  - (b) the name of the medicine;
  - (c) the amount of the medicine;
  - (d) the patient's contact details;
  - (e) the type of document used to identify the patient and an identifier for the document, if applicable.

Examples for paragraph (e)—

driver licence number, passport number

(3) The record must be kept electronically in a way that complies with 'Departmental standard 5: Pseudoephedrine recording standard'.

# Division 2 Dealings other than supply

#### 11 Buying and possessing stock

- (1) A pharmacist may buy stock of a medicine mentioned in this division for practising at a pharmacy, other than a pharmacy in a specified place.
- (2) The pharmacist must comply with chapter 2, part 2, division 2 when buying the stock.

(3) The pharmacist must ensure the stock is stored in a compliant storage system.

#### 12 Administering under extended practice authority

A pharmacist may administer a medicine to a patient under 'Extended practice authority 5: Vaccinations by pharmacists'.

## 13 Administering approved opioids

- (1) A pharmacist may administer an approved opioid to a patient if—
  - (a) the administration is on a prescription for the patient from a prescriber; and
  - (b) the prescriber has a prescribing approval authorising the supply or administration of the approved opioid.
- (2) The pharmacist must comply with chapter 2, part 2, division 7 when administering the medicine.

# 14 Packaging

A pharmacist may package or repackage a medicine for dispensing, or giving a treatment dose, to a patient under 'Departmental standard 3: Safe supply of medicines'.

#### 15 Compounding

- (1) A pharmacist may compound an S4 or S8 medicine for supply to, and the treatment of, a patient on a prescription from a prescriber for the patient.
- (2) A pharmacist may compound an S2 or S3 medicine for supply to, and the treatment of, a patient in accordance with 'Departmental standard 2: Compounding'.
- (3) The pharmacist must ensure the medicine is fit for its intended use and free from contamination.

#### 16 Disposing of waste

A pharmacist may dispose of waste from a medicine by giving it to another person—

- (a) who is authorised to dispose of the waste under the Act or another law; or
- (b) who takes the waste under the national program called the 'Return Unwanted Medicines Project'.

# Division 3 Reporting

# 17 Giving chief executive information about diversion-risk medicines

A pharmacist must give notice to the chief executive in the approved form if a person seeks the supply of a diversion-risk medicine from the pharmacist that exceeds the amount or frequency of doses that the person could reasonably be seeking for the person's therapeutic treatment.

# Part 3 Hospital pharmaceutical technicians

#### 18 Possessing

A hospital pharmaceutical technician may possess an S4 or S8 medicine at a hospital under the supervision of a pharmacist.

# Part 4 Pharmacy employees

#### 19 Application of part

This part applies to a person (a *pharmacy employee*) who is 16 years or more and employed at a pharmacy.

#### 20 Possessing

A pharmacy employee may possess a medicine to assist a pharmacist at the pharmacy to dispense the medicine only if the employee is acting under the direct supervision of the pharmacist.

# 21 Selling

A pharmacy employee may sell an S2 medicine to a patient at the pharmacy under the direct supervision of a pharmacist.

# Part 5 Delivery

# 22 Delivery of pharmacy medicines

A pharmacist may engage a carrier to deliver dispensed medicines to a patient if the pharmacist believes the carrier is capable of complying with schedule 15, part 1.

# Schedule 10 Podiatry

section 10

# Part 1 Preliminary

#### 1 Definitions for schedule

In this schedule—

**podiatric surgeon** means a person registered under the Health Practitioner Regulation National Law to practise in the podiatry profession as a specialist registrant in the specialty of podiatric surgery.

*podiatrist* means a person registered under the Health Practitioner Regulation National Law to practise in the podiatry profession.

**Podiatry Board** means the Podiatry Board of Australia established under the Health Practitioner Regulation National Law.

# Part 2 Podiatrists

#### 2 Buying and possessing stock

- (1) A podiatrist may buy stock of a medicine mentioned in this part for practising independently or at a clinic, other than a clinic in a specified place.
- (2) The podiatrist must comply with chapter 2, part 2, division 2 when buying the stock.
- (3) The podiatrist must ensure the stock is stored in a compliant storage system.

## 3 Administering

- (1) A podiatrist may administer any of the following medicines to a patient—
  - (a) an S2 medicine;
  - (b) an adrenaline (epinephrine) autoinjector;
  - (c) each of the following medicines, other than when combined with adrenaline (epinephrine) or another vasoconstrictor medicine—
    - (i) bupivacaine of a strength of 0.5% or less;
    - (ii) levobupivacaine of a strength of 0.5% or less;
    - (iii) lidocaine (lignocaine) of a strength of 2% or less;
    - (iv) prilocaine of a strength of 2% or less.
- (2) The podiatrist must comply with chapter 2, part 2, division 7 when administering the medicine.

# Part 3 Endorsed podiatrists

# 4 Application of part

This part applies to an endorsed podiatrist, whether or not the podiatrist is also a podiatric surgeon.

## 5 Buying and possessing stock

- (1) The endorsed podiatrist may buy stock of a medicine to deal with a medicine mentioned in this part for practising independently or at a clinic, other than a clinic in a specified place.
- (2) The endorsed podiatrist must comply with chapter 2, part 2, division 2 when buying the stock.
- (3) The endorsed podiatrist must ensure the stock is stored in a compliant storage system.

# 6 Prescribing

- (1) The endorsed podiatrist may prescribe a medicine if—
  - (a) the medicine is stated in attachment A of the document called 'Registration standard: endorsement for scheduled medicines' made by the Podiatry Board on 1 August 2018; and
  - (b) the podiatrist prescribes the medicine under the standard.
- (2) The endorsed podiatrist must comply with chapter 2, part 2, division 3 when prescribing the medicine.

# 7 Giving a treatment dose

- (1) The endorsed podiatrist may give a treatment dose of a medicine if—
  - (a) the medicine is stated in attachment A of the document called 'Registration standard: endorsement for scheduled medicines' made by the Podiatry Board on 1 August 2018; and
  - (b) the podiatrist gives a treatment dose of the medicine under the standard.
- (2) The endorsed podiatrist must comply with chapter 2, part 2, division 6 when giving the treatment dose.

#### 8 Administering

- (1) The endorsed podiatrist may administer a medicine if—
  - (a) the medicine is stated in attachment A of the document called 'Registration standard: endorsement for scheduled medicines' made by the Podiatry Board on 1 August 2018; and
  - (b) the podiatrist administers the medicine under the standard.
- (2) The endorsed podiatrist must comply with chapter 2, part 2, division 7 when administering the medicine.

#### 9 Disposing of S8 medicine waste

- (1) An endorsed podiatrist may dispose of waste from an S8 medicine.
- (2) The endorsed podiatrist must comply with chapter 2, part 2, division 8 when disposing of the waste.

# Part 4 Podiatric surgeons

## 10 Application of part

This part applies to a podiatric surgeon who is not endorsed.

## 11 Buying and possessing stock

- (1) The podiatric surgeon may buy stock of a medicine mentioned in this part for practising independently or at a clinic, other than a clinic in a specified place.
- (2) The podiatric surgeon must comply with chapter 2, part 2, division 2 when buying the stock.
- (3) The podiatric surgeon must ensure the stock is stored in a compliant storage system.

## 12 Prescribing

(1) The podiatric surgeon may prescribe an S2 or S3 medicine stated in column 1 of the table below to a patient to the extent stated opposite in column 2.

Column 1	Column 2
diclofenac	an oral preparation for a 10 day course of treatment for the patient's condition
fexofenadine	an oral preparation for a 10 day course of treatment for the patient's condition

Column 1	Column 2
hydrocortisone	a topical preparation for a 10 day course of treatment for the patient's condition with each dose being of a strength of 1% or less
ibuprofen	an oral preparation for a 10 day course of treatment for the patient's condition
loratadine	an oral preparation for a 10 day course of treatment for the patient's condition
naproxen	an oral preparation for a 10 day course of treatment for the patient's condition
promethazine	an oral preparation for a 10 day course of treatment for the patient's condition

(2) The podiatric surgeon may prescribe an S4 medicine stated in column 1 of the table below to a patient to the extent stated opposite in column 2.

Column 1	Column 2
amoxycillin or amoxycillin with clavulanic acid	an oral preparation for a 10 day course of treatment for the patient's condition
cephalexin	an oral preparation for a 10 day course of treatment for the patient's condition
codeine	an oral preparation of 20 doses for the patient's condition with each dose being not more than 30mg in combination with each 500mg of paracetamol
diazepam	an oral preparation of 10 doses of 5mg each for the patient's condition
dicloxacillin	an oral preparation for a 10 day course of treatment for the patient's condition
doxycycline	an oral preparation for a 10 day course of treatment for the patient's condition

Column 1	Column 2
erythromycin	an oral preparation for a 10 day course of treatment for the patient's condition
metronidazole	an oral preparation for a 10 day course of treatment for the patient's condition
mupirocin	a topical preparation for a 10 day course of treatment for the patient's condition
roxithromycin	an oral preparation for a 10 day course of treatment for the patient's condition
temazepam	an oral preparation of 2 doses of 10mg each for the patient's condition

- (3) The podiatric surgeon may prescribe an S8 medicine that is oxycodone as an oral preparation in a short acting form of no more than 10 doses of 5mg each for a patient's condition.
- (4) The podiatric surgeon must comply with chapter 2, part 2, division 3 when prescribing the medicine.

#### 13 Administering

- (1) A podiatric surgeon may administer any of the following S4 medicines—
  - (a) dexamethasone as a local injection;
  - (b) ropivacaine of a strength of 1% or less;
  - (c) epinephrine (adrenaline) when combined with lidocaine (lignocaine), bupivacaine or prilocaine.
- (2) The podiatric surgeon must comply with chapter 2, part 2, division 7 when administering the medicine.

# 14 Disposing of S8 medicine waste

(1) A podiatric surgeon may dispose of waste from an S8 medicine.

(2) The podiatric surgeon must comply with chapter 2, part 2, division 8 when disposing of the waste.

# Schedule 11 Veterinary services

section 10

# Part 1 Preliminary

#### 1 Definitions for schedule

In this schedule—

**recognised veterinary practice** means practice recognised as appropriate for the treatment or euthanasia of animals by the Veterinary Surgeons Board of Queensland established under the *Veterinary Surgeons Act 1936*, section 4.

# Part 2 Veterinary surgeons

#### 2 Buying and possessing stock

- (1) A veterinary surgeon may buy stock of a medicine mentioned in this part for practising independently or at a clinic, other than a clinic in a specified place.
- (2) The veterinary surgeon must comply with chapter 2, part 2, division 2 when buying the stock.
- (3) The veterinary surgeon must ensure the stock is stored in a compliant storage system.

#### 3 Prescribing

- (1) A veterinary surgeon may prescribe a medicine, other than a diversion-risk medicine, for the treatment of an animal to the extent of recognised veterinary practice.
- (2) A veterinary surgeon may prescribe a diversion-risk medicine for the treatment of an animal if the amount of medicine prescribed is no more than the amount necessary for treating

- the animal for 6 months in accordance with recognised veterinary practice.
- (3) The veterinary surgeon must comply with chapter 2, part 2, division 3 when prescribing the medicine.

#### 4 Dispensing

- (1) A veterinary surgeon may dispense a medicine, other than a diversion-risk medicine, for the treatment of an animal to the extent of recognised veterinary practice.
- (2) A veterinary surgeon may dispense a diversion-risk medicine for the treatment of an animal if the amount of medicine dispensed is no more than the amount necessary for treating the animal for 6 months in accordance with recognised veterinary practice.
- (3) The veterinary surgeon must comply with section 60 when dispensing the medicine.

#### 5 Giving a treatment dose

- (1) A veterinary surgeon may give a treatment dose of a medicine, other than a diversion-risk medicine, for the treatment of an animal to the extent of recognised veterinary practice.
- (2) A veterinary surgeon may give a treatment dose of a diversion-risk medicine for the treatment of an animal if the amount of medicine supplied is no more than the amount necessary for treating the animal for 6 months in accordance with recognised veterinary practice.
- (3) The veterinary surgeon must comply with chapter 2, part 2, division 6, other than section 62, when giving the treatment dose.

#### 6 Administering

A veterinary surgeon may administer a medicine to an animal to the extent of recognised veterinary practice.

#### 7 Compounding

A veterinary surgeon may compound a medicine for supply to, and the treatment of, an animal.

#### 8 Packaging and repackaging

A veterinary surgeon may package or repackage a medicine for dispensing the medicine for an animal.

#### 9 Disposing of S8 medicine waste

- (1) A veterinary surgeon may dispose of waste from an S8 medicine.
- (2) The veterinary surgeon must comply with chapter 2, part 2, division 8 when disposing of the waste.

# Part 3 Trained veterinary assistants

#### 10 Application of part

This part applies to a person (a *trained veterinary assistant*) who—

- (a) practises veterinary nursing; and
- (b) holds a qualification that makes the person eligible for full membership of the Veterinary Nurses Council of Australia Inc.

#### 11 Administering S8 medicines at veterinary premises

- (1) This section applies if—
  - (a) a veterinary surgeon is not able to be physically present at the veterinary premises; but
  - (b) is available to be contacted using technology to communicate with a veterinary assistant in real time.

- (2) A trained veterinary assistant employed to practise veterinary nursing at the veterinary premises may administer the S8 medicine to an animal if—
  - (a) the medicine has been pre-prepared into a treatment dose by a veterinary surgeon or a pharmacist; and
  - (b) the medicine is administered in accordance with a written direction for the animal and the medicine's approved label.

#### 12 Administering other medicines at veterinary premises

A trained veterinary assistant employed to practise veterinary nursing at veterinary premises may administer an S2, S3 or S4 medicine to an animal—

- (a) under the supervision of a veterinary surgeon; and
- (b) in accordance with the medicine's approved label or a direction to administer the medicine to the animal.

#### 13 Administering at other places

A trained veterinary assistant practising veterinary nursing at a place other than veterinary premises may administer an S2, S3 or S4 medicine to an animal—

- (a) under the direct supervision of a veterinary surgeon; and
- (b) in accordance with a direction to administer the medicine to the animal.

#### 14 Record keeping

A trained veterinary assistant administering a medicine under a direction under this part must make a record of the direction and the name of the veterinary surgeon giving the direction.

#### Part 4 Medicated animal feed

### Division 1 Preliminary

#### 15 What is a medicated animal feed order

- (1) For this part, a *medicated animal feed order* is an order that—
  - (a) is given before or at the time of the supply of medicated animal feed; and
  - (b) is authorised by a veterinary surgeon; and
  - (c) states, in writing, the matters mentioned in subsection (2).
- (2) The matters are—
  - (a) a unique identifier; and
  - (b) the date of the order; and
  - (c) the contact details of the veterinary surgeon and the buyer; and
  - (d) the qualifications of the veterinary surgeon; and
  - (e) the date the supply of the feed is to start; and
  - (f) the species of animal that the feed is for; and
  - (g) that the feed is for animal treatment only; and
  - (h) the name of the medicines contained in the feed, and the form, strength and amount of the medicines, to be supplied; and
  - (i) if the feed is to be delivered to the buyer—the delivery address; and
  - (j) instructions for how to store and administer the feed.

#### Notes-

Other laws may require other information to be given in relation to the supply of medicated animal feed, including, for example, the *Chemical Usage (Agricultural and Veterinary) Control Act 1988*, section 12S.

#### 16 Requirements for preparing medicated animal feed order

- (1) A medicated animal feed order must—
  - (a) be prepared in a way that allows the supplier to verify the veterinary surgeon is authorised to supply the medicated animal feed; and
  - (b) be prepared and sent to the supplier in a way that is reasonably likely to—
    - (i) minimise fraud or tampering; and
    - (ii) allow the order to be amended only by the veterinary surgeon; and
    - (iii) if sent electronically—be transmitted securely or on a secure electronic ordering system; and
  - (c) be signed by the veterinary surgeon authorising the order.

## Division 2 Veterinary surgeons

## 17 Buying

A veterinary surgeon may buy stock of medicated animal feed on a medicated animal feed order.

#### 18 Supplying

A veterinary surgeon may give a medicated animal feed order to a client of the veterinary surgeon for the client's animals only if the veterinary surgeon is reasonably satisfied the client, or a person employed by the client, is able to competently administer the medicated animal feed stated in the order.

#### 19 Record keeping

(1) A veterinary surgeon who prepares a medicated animal feed order must keep a copy of the order.

(2) If a supplier gives a veterinary surgeon a medicated animal feed order that has been marked to indicate the supply of the feed to the veterinary surgeon's client, the veterinary surgeon must give a copy of the order to the client.

## Division 3 Clients of veterinary surgeons

#### 20 Buying

A person may buy stock of medicated animal feed on a medicated animal feed order.

#### 21 Administering

A client of a veterinary surgeon given a medicated animal feed order may administer medicated animal feed stated in the order in accordance with the order and any other written procedures agreed with the veterinary surgeon for the client to follow to administer the medicated animal feed.

# Schedule 12 Other health practitioners

section 10

# Part 1 Preliminary

#### 1 Definitions for schedule

In this schedule—

anaesthetic technician means a person who holds a qualification acceptable to the Australian and New Zealand College of Anaesthetists to be an anaesthetic technician.

anaesthetist means a person who holds a qualification acceptable to the Australian and New Zealand College of Anaesthetists to be an anaesthetist.

clinical perfusionist means a person who is—

- (a) employed as a clinical perfusionist at a Hospital and Health Service, private health facility or approved health facility; or
- (b) accredited or certified to work as a clinical perfusionist by a professional body approved by the chief executive.

*nuclear medicine technologist* means a person registered under the Health Practitioner Regulation National Law—

- (a) to practise in the medical radiation practice profession; and
- (b) in the nuclear medicine technology division of that profession.

*physiotherapist* means a person registered with the Physiotherapy Board of Australia, established under the Health Practitioner Regulation National Law, to practise in the physiotherapy profession.

respiratory scientist means a person who—

- (a) is employed as a respiratory scientist at a Hospital and Health Service, private health facility or approved health facility; or
- (b) is accredited or certified to work as a respiratory scientist by a professional body approved by the chief executive.

#### speech pathologist means a person who is—

- (a) employed as a speech pathologist at a Hospital and Health Service, private health facility or in another government entity under the *Public Service Act 2008*, section 24; or
- (b) accredited or certified to work as a speech pathologist by a professional body approved by the chief executive.

#### Part 2 Anaesthetic technicians

#### 2 Possessing

An anaesthetic technician may possess an S4 or S8 medicine on a direction from a medical practitioner administering anaesthesia at a hospital in relation to anaesthetic procedures for the patient.

#### 3 Administering

An anaesthetic technician may administer a medicine to a patient under the direct supervision of a medical practitioner administering anaesthesia at a hospital only if the administration is reasonably necessary to ensure the safety of the patient in relation to an anaesthetic procedure.

# Part 3 Clinical perfusionists

#### 4 Administering

- (1) A clinical perfusionist may administer a medicine to a patient—
  - (a) under the supervision of an anaesthetist or cardiothoracic surgeon; or
  - (b) on a clinical protocol applying to the clinical perfusionist.
- (2) The medicine may be administered only—
  - (a) into extracorporeal circulation equipment; or
  - (b) if the administration is necessary to prepare for an anaesthetic, intensive care or surgical procedure for the patient.
- (3) The clinical perfusionist must comply with chapter 2, part 2, division 7 when administering the medicine.

# Part 4 Nuclear medicine technologists

- (1) A nuclear medicine technologist may administer any of the following medicines to a patient on a clinical protocol applying to the nuclear medicine technologist or on a written prescription for the patient from a prescriber—
  - (a) an S2 medicine;
  - (b) an S3 medicine;
  - (c) an S4 medicine that is—
    - (i) an angiotensin-converting enzyme antagonist or angiotensin II receptor inhibitor, whether alone or in combination with a diuretic; or
    - (ii) a diuretic; or

- (iii) a histamine H<sub>2</sub> receptor antagonist.
- (2) If the S3 medicine is an adrenaline (epinephrine) autoinjector, the nuclear medicine technologist may administer the medicine to a patient only—
  - (a) to treat anaphylaxis; and
  - (b) if the technologist has completed anaphylaxis training.
- (3) The nuclear medicine technologist must comply with chapter 2, part 2, division 7 when administering the medicine.

# Part 5 Physiotherapists

- (1) A physiotherapist may administer any of the following medicines to a patient—
  - (a) an S2 medicine;
  - (b) a nitrous oxide mixture in a hospital on a written prescription for the patient from a prescriber;
  - (c) an S3 medicine for pain relief—
    - (i) on a written prescription for the patient from a prescriber; or
    - (ii) that has been lawfully supplied to the patient;
  - (d) an S3 or S4 medicine for the physiotherapy treatment of a respiratory condition—
    - (i) on a written prescription for the patient from a prescriber; or
    - (ii) that has been lawfully supplied to the patient.
- (2) The physiotherapist must comply with chapter 2, part 2, division 7 when administering the medicine.

# Part 6 Respiratory scientists

#### 7 Administering

- (1) A respiratory scientist may administer any of the following medicines on a clinical protocol applying to the respiratory scientist or on a written prescription for the patient from a prescriber—
  - (a) an S2 or S3 medicine;
  - (b) an S4 medicine that is an anti-histamine for systemic use or a broncho-constrictor agent or bronchodilator agent.
- (2) If the S3 medicine is an adrenaline (epinephrine) autoinjector, the respiratory scientist may administer the medicine to a patient only—
  - (a) to treat anaphylaxis; and
  - (b) if the respiratory scientist has completed anaphylaxis training.
- (3) The respiratory scientist must comply with chapter 2, part 2, division 7 when administering the medicine.

# Part 7 Speech pathologists

- (1) A speech pathologist may administer any of the following medicines to a patient on a clinical protocol applying to the speech pathologist or on a written prescription for the patient from a prescriber if the speech pathologist has completed a safe medicine administration course—
  - (a) an S2 or S3 medicine;
  - (b) an S4 medicine that is a topical antibiotic or a topical corticosteroid.

- (2) If the S3 medicine is an adrenaline (epinephrine) autoinjector, the speech pathologist may administer the medicine to a patient only—
  - (a) to treat anaphlaxis; and
  - (b) if the speech pathologist has completed anaphylaxis training.
- (3) The speech pathologist must comply with chapter 2, part 2, division 7 when administering the medicine.
- (4) In this section—

*safe medicine administration course* means a training course about the safe administration of medicines approved by the chief executive.

#### Schedule 13 Institutions and facilities

section 10

# Part 1 Aged care facilities

Note—

Policy changes to this part will be discussed with relevant stakeholders while the Medicines and Poisons Bill 2019 is considered by the Parliamentary Committee.

#### 1 Definition for part

In this part—

*resident*, of an aged care facility, means a person living at the facility.

#### 2 Buying and possessing stock

- (1) The following persons may buy and possess stock of a medicine at an aged care facility for the therapeutic treatment of a resident of the facility—
  - (a) a nurse manager for the facility;
  - (b) the medical practitioner in charge of clinical services at the facility;
  - (c) the registered nurse in charge of the facility;
  - (d) the pharmacist in charge of a dispensary at the facility.
- (2) The person must comply with chapter 2, part 2, division 2 when buying the stock.
- (3) The person must ensure the stock is stored in a compliant storage system.

#### Part 2 Detention institutions

#### Division 1 Detention centres

#### 3 Buying and possessing stock

- (1) The following persons may buy and possess stock of a medicine for the therapeutic treatment of a child detained at a detention centre—
  - (a) the general manager of the detention centre;
  - (b) the detention centre's nurse manager;
  - (c) the detention centre's medical practitioner in charge of clinical services;
  - (d) the pharmacist in charge of the detention centre's dispensary.
- (2) The person must comply with chapter 2, part 2, division 2 when buying the stock.
- (3) The person must ensure the stock is stored in a compliant storage system.

#### Division 2 Prisons

#### 4 Buying and possessing stock

- (1) The following persons may buy and possess stock of a medicine for the therapeutic treatment of a person detained at a prison or a child accommodated with the person detained—
  - (a) the general manager of the prison;
  - (b) the prison's nurse manager;
  - (c) the prison's medical practitioner in charge of clinical services:
  - (d) the pharmacist in charge of the prison's dispensary.

- (2) The person must comply with chapter 2, part 2, division 2 when buying the stock.
- (3) The person must ensure the stock is stored in a compliant storage system.

#### Division 3 Watch-houses

#### 5 Administering

- (1) A watch-house manager of a police establishment or watch-house may administer a medicine to a person if—
  - (a) the person is detained at the police establishment or watch-house; and
  - (b) the medicine was lawfully supplied to the person; and
  - (c) the medicine is administered to the person in accordance with the medicine's approved label.
- (2) The watch-house manager must comply with chapter 2, part 2, division 7 when administering the medicine.
- (3) In this section—

*police establishment* see the *Police Powers and Responsibilities Act 2000*, schedule 6.

#### Part 3 Schools

#### 6 Buying and possessing

- (1) The principal of a school, or the principal's delegate, may buy and possess stock of the following medicines for ensuring the health and wellbeing of a child at the school—
  - (a) an adrenaline (epinephrine) autoinjector;
  - (b) an inhaled asthma reliever, other than an S4 medicine.
- (2) The principal, or the principal's delegate, must comply with chapter 2, part 2, division 2 when buying the stock.

(3) The principal, or the principal's delegate, must ensure the stock is stored in a compliant storage system.

#### 7 Administering

- (1) The following persons employed at a school may administer the following medicines to a child at the school, whether or not the medicine has been dispensed for the child—
  - (a) a person who has completed anaphylaxis training may administer an adrenaline (epinephrine) autoinjector;
  - (b) a person who has completed asthma training may administer an inhaled asthma reliever, other than an S4 medicine.
- (2) The principal of a school or the principal's delegate may administer a medicine to a child at the school only if—
  - (a) the medicine was dispensed for the child or supplied for the child by the child's parent or guardian; and
  - (b) the administration is carried out in accordance with the medicine's approval label.

# Part 4 Child care facilities

#### 8 Definition for part

In this part—

**head**, of a child care facility, means—

- (a) if the facility provides an education and care service under the Education and Care Services National Law (Queensland)—an approved provider or nominated supervisor for the service within the meaning of the Education and Care Services National Law (Queensland), section 5(1); or
- (b) if the facility provides a Queensland education and care service under the *Education and Care Services Act* 2013—an approved provider or supervisor within the

meaning of the *Education and Care Services Act 2013*, schedule 1.

#### 9 Buying and possessing

- (1) The head of a child care facility, or the head's delegate, may buy and possess stock of the following medicines for ensuring the health and wellbeing of a child at the facility—
  - (a) an adrenaline (epinephrine) autoinjector;
  - (b) an inhaled asthma reliever, other than an S4 medicine.
- (2) The head or the head's delegate must comply with chapter 2, part 2, division 2 when buying the stock.
- (3) The head or the head's delegate must ensure the stock is stored in a compliant storage system.

- (1) The following persons employed at a child care facility may administer the following medicines to a child at the facility, whether or not the medicine has been dispensed for the child—
  - (a) a person who has completed anaphylaxis training may administer an adrenaline (epinephrine) autoinjector;
  - (b) a person who has completed asthma training may administer an inhaled asthma reliever, other than an S4 medicine.
- (2) The head of a child care facility, or the head's delegate, may administer a medicine to a child at the facility only if——
  - (a) the medicine was dispensed for the child or supplied for the child by the child's parent or guardian; and
  - (b) the administration is carried out in accordance with the medicine's approval label.

# Part 5 Local governments

#### 11 Buying and possessing stock

- (1) This section applies to a person employed as an environmental health officer in a local government.
- (2) The person may buy and possess stock of a medicine that is a vaccine for human therapeutic use for an immunisation program carried out by the department, the local government or a Hospital and Health Service.
- (3) The person must comply with chapter 2, part 2, division 2 when buying the stock.
- (4) The person must ensure the stock is stored in a compliant storage system.

# Part 6 Hospitals

#### 12 Buying and possessing for hospitals

- (1) The following persons (each a *supervisor*) may buy and possess stock of a medicine for a hospital—
  - (a) the medical practitioner (the *superintendent*) responsible for medical services provided at the hospital;
  - (b) a medical practitioner nominated in writing by the superintendent;
  - (c) if there is a pharmacist in charge of the hospital's dispensary—
    - (i) the pharmacist in charge; and
    - (ii) a pharmacist nominated in writing by the pharmacist in charge.
- (2) If a supervisor is not present at the hospital, the nurse manager of the hospital may buy the stock for the hospital.

- (3) If neither a supervisor nor the nurse manager is present at the hospital, the registered nurse in charge of the hospital may buy the stock for the hospital.
- (4) The supervisor or person mentioned in subsection (2) or (3) must comply with chapter 2, part 2, division 2 when buying the stock.
- (5) The supervisor or person mentioned in subsection (2) or (3) must ensure the stock is stored in a compliant storage system.

# Part 7 Ships

#### 13 Definitions for part

In this part—

*master*, of a ship, means the person having command or charge of the ship.

ship see the Transport Operations (Marine Safety) Act 1994, section 10.

#### 14 Buying and possessing stock

- (1) The master of a ship may buy and possess stock of a medicine for ensuring the health or safety of persons on the ship.
- (2) The master must comply with subsection (3) and chapter 2, part 2, division 2 when buying the stock.
- (3) The purchase order under that division must be signed by a medical practitioner unless the medicine is required to be kept on the ship under another law.
- (4) The master must ensure the stock is stored in a compliant storage system.

#### 15 Administering by master

The master of a ship may administer a medicine to a person on the direction from a prescriber if it is reasonably necessary to treat the person on the ship.

#### 16 Administering by other persons

- (1) A person employed on a ship may administer an S2 or S3 medicine to someone on the ship if the medicine is kept under any of the following laws and is administered in accordance with the medicine's approved label—
  - (a) the Transport Operations (Marine Safety) Act 1994;
  - (b) the Marine Safety (Domestic Commercial Vessel) National Law Act 2012 (Cwlth);
  - (c) the Navigation Act 2012 (Cwlth).
- (2) The person must comply with chapter 2, part 2, division 7 when administering the medicine.

#### Part 8 Mines

#### 17 Definition for part

In this part—

**S4** inhaled analgesic means an S4 medicine analgesic that is administered by inhalation.

#### 18 Buying and possessing stock

- (1) A person in charge of a mine may buy and possess stock of an S4 inhaled analgesic for the first aid treatment of a person at the mine.
- (2) The person must comply with chapter 2, part 2, division 2 when buying the stock.
- (3) The person must ensure the stock is stored in a compliant storage system.

#### 19 Administering by first aid provider

(1) A first aid provider employed at a mine may administer an S4 inhaled analgesic for the first aid treatment of a person at the mine only if the provider has completed training from a

- registered training organisation on using the S4 inhaled analgesic.
- (2) If the S4 inhaled analgesic is methoxyflurane, the first aid provider must only administer 1 dose of no greater than 3 millilitres unless directed otherwise by a prescriber.

#### Schedule 14 Wholesalers

section 10

# Part 1 Commonwealth law manufacturers

#### 1 Application of part

This part applies to an entity permitted to manufacture a medicine under a Commonwealth law.

#### 2 Possessing

The entity may possess the medicine if the entity—

- (a) complies with any conditions of the entity's permission under the Commonwealth law; and
- (b) possesses, including distributes, the medicine only from a place where the entity is permitted to manufacture the medicine under the Commonwealth law.

#### 3 Wholesale supply

- (1) The entity may supply the medicine by wholesale provided the entity—
  - (a) complies with any conditions of the entity's permission under the Commonwealth law; and
  - (b) supplies the medicine only from a place where the entity is permitted to manufacture the medicine.
- (2) The supply under subsection (1) may be only—
  - (a) to someone in Queensland who is authorised to buy the medicine; or
  - (b) to someone in another jurisdiction who is authorised to obtain the medicine under a corresponding law.

# Part 2 Corresponding law wholesalers

#### 4 Application of part

This part applies to a person permitted to supply a medicine by wholesale under a corresponding law.

#### 5 Possessing

The person may possess the medicine if the person—

- (a) complies with any conditions of the person's permission under the corresponding law; and
- (b) only arranges the delivery of the medicine to a person within Queensland who is authorised to possess the medicine; and
- (c) does not—
  - (i) store the medicine at a place in Queensland; or
  - (ii) arrange for the medicine to be collected from a storage facility located in Queensland.

#### 6 Wholesale supply

The person may supply the medicine by wholesale if the person—

- (a) complies with any conditions of the person's permission under the corresponding law; and
- (b) only arranges the delivery of the medicine to a person within Queensland who is authorised to possess the medicine; and
- (c) does not—
  - (i) store the medicine at a place in Queensland; or
  - (ii) arrange for the medicine to be collected from a storage facility located in Queensland.

# Part 3 Requirements for wholesaling

#### 7 Application of part

This part applies to an entity mentioned in part 1 or 2 that supplies a medicine by wholesale.

#### 8 Responsibilities generally

The entity must—

- (a) ensure the medicine is not handled by a person other than the entity or a competent adult person employed by the entity; and
- (b) keep records of any medicines given to a representative of the entity; and
- (c) take reasonable steps to ensure each representative of the entity complies with this regulation and the law under which the entity operates; and
- (d) ensure a carrier engaged by the entity is capable of complying with schedule 15, part 1.

#### 9 Compliance with codes

The entity must comply with, and take reasonable steps to ensure the entity's employees, agents and representatives comply with—

- (a) the 'Australian code of good wholesaling practice for medicines in schedules 2, 3, 4 and 8' dated 1 April 2011 and published by the Therapeutic Goods Administration; and
- (b) the document called the 'Code of Conduct', edition 18, dated 16 May 2015 and published by Medicines Australia ABN 23 126 990 001.

#### 10 Packaging for supplying S8 medicines

The entity must not arrange to deliver an S8 medicine to a buyer unless—

- (a) the medicine is sealed in a securely closed package that will show if the package breaks or anyone tampers with it; and
- (b) the medicine is not mixed with anything other than S8 medicines; and
- (c) the package is clearly labelled with—
  - (i) the contact details of the buyer; or
  - (ii) if the buyer is not an individual—the position and address of an individual employed by the buyer who may confirm receipt of the package; and
- (d) the package has no writing on it that shows it contains an S8 medicine.

# 11 Supply to authorised buyer on a compliant purchase order

The entity must supply the medicine only if—

- (a) the buyer of the medicine is authorised under the Act or another law to buy the medicine; and
- (b) the buyer gives the entity a compliant purchase order for the medicine.

#### 12 Open for inspection

If the entity is a Commonwealth law manufacturer, the manufacturer must keep the place where the entity is permitted to manufacture the medicine open for inspection.

#### 13 Notification of loss or theft

(1) The entity must report the loss or theft of a diversion-risk medicine that was in the possession of the entity immediately before the loss or theft.

- (2) The report must be made to the police service and chief executive as soon as practicable and no later than the next business day after the loss or theft.
- (3) The entity must—
  - (a) ask for a record from the police service of the report made under subsection (2); and
  - (b) keep the record, if it is provided to the entity.

# Part 4 Wholesale representatives

#### 14 Definition for part

In this part—

authorised practitioner, for a medicine, means a health practitioner or veterinary surgeon who is authorised to prescribe or supply the medicine.

*employer*, of a wholesale representative, means the wholesaler that the representative acts as an agent or representative for.

*starter pack*, for a medicine, means a small pack of the medicine supplied as a sample or at no cost.

wholesale representative means a person who acts as an agent or representative of—

- (a) a wholesaler; or
- (b) a person permitted to supply a medicine by wholesale under a corresponding law.

#### 15 Possessing stock

The wholesale representative may possess stock of an S2, S3 or S4 medicine in a starter pack.

#### 16 Supply of starter packs

The wholesale representative may give an S2, S3 or S4 medicine in a starter pack to an authorised practitioner for the

medicine in accordance with the document called the 'Code of Conduct', edition 18, dated 16 May 2015 and published by Medicines Australia ABN 23 126 990 001.

#### 17 Notification of loss or theft

- (1) A wholesale representative must report the loss or theft of an S4 diversion-risk medicine that was in the possession of the representative immediately before the loss or theft.
- (2) The report must be made to the police service, the chief executive and the representative's employer as soon as practicable and no later than the next business day after the loss or theft.
- (3) The wholesale representative must—
  - (a) ask for a record from the police service of the report made under subsection (2); and
  - (b) keep the record, if it is provided to the representative.

#### 18 Storage and record-keeping responsibilities

A wholesale representative must ensure that medicines in the possession of the representative are stored, and records are kept about the medicines, in accordance with the requirements stated in the document called the 'Code of Conduct', edition 18, dated 16 May 2015 and published by Medicines Australia ABN 23 126 990 001.

#### 19 Return of transactions

- (1) A wholesale representative must, periodically but at least every 3 months, give the representative's employer a return complying with subsection (2) about the transactions carried out by the representative for the period.
- (2) The return must state the following information—
  - (a) the period of the return;

- (b) the total amount of each type of S4 medicine in the representative's possession at the start and end of the period;
- (c) the amount of each type of monitored medicine received by the representative;
- (d) the amount of each type of monitored medicine given as a sample, or returned by, the representative;
- (e) the invoice number for each monitored medicine given as a sample or return.
- (3) The wholesale representative and the representative's employer must each keep a copy of the return.

#### Schedule 15 Miscellaneous

section 10

#### Part 1 Carriers

#### 1 Possessing S4 and S8 medicines during transport

A carrier who transports stock of S4 and S8 medicines from 1 place to another must not leave the medicines unattended, other than in a secure area.

#### 2 Receipt for delivery on purchase order

- (1) A carrier delivering stock of medicines on a purchase order must deliver the stock only to the delivery address stated on the purchase order.
- (2) The carrier must not leave the stock at the delivery address unless it is left with the buyer stated on the purchase order or someone who has written authority from the buyer to receive the stock.

# Part 2 Corresponding law retailers

#### 3 Application of part

This part applies to a person permitted to supply a medicine by retail under a corresponding law.

#### 4 Possessing

The person may possess the medicine if the person—

(a) complies with any conditions of the person's permission under the corresponding law; and

- (b) only arranges the delivery of the medicine to a person within Queensland who is authorised to possess the medicine; and
- (c) does not—
  - (i) store the medicine at a place in Queensland; or
  - (ii) arrange for the medicine to be collected from a storage facility located in Queensland.

#### 5 Retail supply

The person may supply the medicine by retail if the person—

- (a) complies with any conditions of the person's permission under the corresponding law; and
- (b) only arranges the delivery of the medicine to a person within Queensland who is authorised to possess the medicine; and
- (c) does not—
  - (i) store the medicine at a place in Queensland; or
  - (ii) arrange for the medicine to be collected from a storage facility located in Queensland.

# Schedule 16 Regulated places and responsible persons

section 108

#### 1 Definitions for schedule

In this schedule—

appropriately qualified means a person who holds an office at a regulated place that is sufficiently senior to ensure compliance with a substance management plan made for the place.

*manager*, of a place, means the person who has responsibility for the day-to-day management of the place.

#### specified pharmacy means—

- (a) a community pharmacy operated by a friendly society or the Mater Misericordiae Health Services Brisbane Limited; or
- (b) a pharmacy supplying medicines to inpatients of a hospital.

#### 2 Regulated places and responsible persons

Regulated place	Responsible person
a place where a medicine is manufactured under a manufacturing licence	if the holder of the licence is an individual—the individual
	if the holder of the licence is a body corporate—each executive officer of the body corporate
	if the holder of the licence is another entity—the manager of the place where the medicine is manufactured

Regulated place	Responsible person
a place where a medicine is supplied by wholesale, other than a community pharmacy or specified pharmacy	if the wholesaler of the medicine is an individual—the individual
	if the wholesaler of the medicine is a body corporate—each executive officer of the body corporate
	if the wholesaler of the medicine is another entity—the manager of the place where the medicine is supplied
a place required to have a substance management plan under a condition	if the holder of the authority is an individual—the individual
of a substance authority	if the holder of the authority is a body corporate—each executive officer of the body corporate
	if the holder of the authority is another entity—the manager of the place required to have the substance management plan
an aged care facility	the nurse manager for the aged care facility
an ambulance station	the ambulance officer in charge of the ambulance station
a child care facility	the appropriately qualified person appointed to be the responsible person by the approved provider of the child care facility
a community pharmacy other than a specified pharmacy	each pharmacist who owns the community pharmacy
a specified pharmacy	the manager of the pharmacy
a detention centre	the manager of the detention centre

# Tabled draft May 2019

Regulated place	Responsible person
a non-State school	the principal of the non-State school or, if a person has not been appointed to be the principal, the manager of the non-State school
a prison	the manager of the prison
a private health facility	the appropriately qualified person appointed to be the responsible person by the holder of the licence for the private health facility
a public sector hospital under the Hospital and Health Boards Act 2011	the appropriately qualified person appointed to be the responsible person by the board of a Hospital and Health Service for the hospital
a State school	the principal of the State school
veterinary premises in which a veterinary surgeon compounds a medicine for supply	the manager of the veterinary premises

# Schedule 17 Areas of local government for isolated practice areas

schedule 5, definition isolated practice area

Aurukun, Balonne, Banana, Barcaldine, Barcoo, Blackall-Tambo, Boulia, Bulloo, Burke, Carpentaria, Central Highlands, Charters Towers, Cloncurry, Cook, Croydon, Diamantina, Doomadgee, Douglas, Etheridge, Flinders, Hope Vale, Isaac, Kowanyama, Lockhart River, Longreach, Maranoa, Mareeba, McKinlay, Mornington, Mount Isa, Murweh, Napranum, North Burnett, Northern Peninsula Area, Palm Island, Paroo, Pormpuraaw, Quilpie, Richmond, Tablelands, Torres, Torres Strait Island, Western Downs, Winton, Woorabinda, Wujal Wujal, Yarrabah

# Schedule 18 Rural hospitals

schedule 5, definition rural hospital

Atherton, Ayr, Babinda, Baralaba, Barcaldine, Beaudesert, Biggenden, Biloela, Blackall, Blackwater, Boonah, Bowen, Caboolture, Capella, Charleville, Charters Towers, Cherbourg, Childers, Chinchilla, Clermont, Collinsville, Cooktown, Cracow, Cunnamulla, Dalby, Dingo, Dunwich, Dysart, Eidsvold, Emerald, Emu Park, Esk, Gatton, Gayndah, Gin Gin, Gladstone, Goondiwindi, Gordonvale, Gympie, Hervey Bay, Home Hill, Hughenden, Ingham, Inglewood, Injune, Innisfail, Jandowae, Kilcoy, Kingaroy, Laidley, Longreach, Magnetic Island, Malanda, Many Peaks, Mareeba, Maryborough, Miles, Millaa Millaa, Millmerran, Mitchell, Monto, Moranbah, Mossman, Mount Perry, Moura, Mt Morgan, Mundubbera, Murgon, Nanango, Oakey, Proserpine, Proston, Quilpie, Ravenshoe, Richmond, Roma, Sapphire, Sarina, Springsure, Stanthorpe, St George, Tara, Taroom, Texas, Theodore, Thursday Island, Tully, Wandoan, Warwick, Weipa, Winton, Wondai, Yeppoon

# Schedule 19 Fees

section 140

		\$
1	Application for the grant of an initial manufacturing licence or wholesale licence to deal with an S8 medicine (Act, s 75(c))—	
	(a) for 1 site for each year	733.40
	(b) for each additional site for each year	733.40
2	Application for the grant of an initial manufacturing licence or wholesale licence to deal with an S2, S3 or S4 medicine (Act, s 75(c))—	
	(a) for 1 site for each year	733.40
	(b) for each additional site for each year	733.40
3	Application for the grant of an initial S2 retail licence (Act, s 75(c))—	
	(a) for 1 site for each year	345.95
	(b) for each additional site for each year	345.95
4	Application for the renewal of a manufacturing licence or wholesale licence to deal with an S8 medicine (Act, s 82(2)(c))—	
	(a) for 1 site for each year	595.00
	(b) for each additional site for each year	595.00
5	Application for the renewal of a manufacturing licence or wholesale licence to deal with an S2, S3 or S4 medicine (Act, s 82(2)(c))—	
	(a) for 1 site for each year	595.00

		\$
	(b) for each additional site for each year	595.00
6	Application for the renewal of an S2 retail licence (Act, s 82(2)(c))—	
	(a) for 1 site for each year	207.60
	(b) for each additional site for each year	207.60

# Schedule 20 Dictionary

section 3

Note-

See the Poisons Standard, part 1 for the definition approved name.

*adrenaline* (*epinephrine*) *autoinjector* means an autoinjector—

- (a) preloaded with adrenaline (epinephrine) of a strength of 0.1% or less for managing anaphylaxis or allergic reactions; and
- (b) approved by the Therapeutic Goods Administration under the *Therapeutic Goods Act 1989* (Cwlth).

aged care facility means a place where nursing and personal care services are provided to persons living at the place by an approved provider under the *Aged Care Act 1997* (Cwlth).

ambulance officer see the Ambulance Service Act 1991.

*amount*, of a medicine, includes a volume or quantity of the medicine.

anaphylaxis training means training in the following matters—

- (a) recognition of the symptoms and signs of anaphylaxis;
- (b) knowledge of the appropriate use of adrenaline (epinephrine), including competency in using an adrenaline (epinephrine) autoinjector;
- (c) implementing an anaphylaxis first aid plan.

approved opioid means a medicine approved for administration to patients under an opioid treatment program.

approved health facility means a laboratory or facility, other than a private health facility, at which clinical procedures are carried out, that is approved by—

(a) the chief executive; or

(b) another entity responsible for accrediting the compliance of the laboratory or facility with regulatory or professional standards under another Act or a law of the Commonwealth.

asthma training means training in the following matters—

- (a) recognition of the symptoms and signs of asthma;
- (b) knowledge of the appropriate use of asthma reliever medication, including competency in using a spacer device;
- (c) implementing an asthma first aid plan.

authorised place means a place stated in this regulation or a substance authority to be a place at which a dealing is authorised with a medicine.

**buyer** means a person who is authorised to buy stock of a medicine.

carrier means a person engaged to transport a medicine or medicated animal feed.

*child care facility* means a place at which either of the following services is provided—

- (a) an education and care service under the Education and Care Services National Law (Queensland);
- (b) a Queensland education and care service under the *Education and Care Services Act 2013*.

*clinical protocol* means a standing order applying in relation to an approved person performing a procedure or diagnostic test for practising any of the following professions—

- (a) clinical perfusion;
- (b) nuclear medicine technology;
- (c) respiratory science;
- (d) speech pathology.

community pharmacy means a pharmacy business under the *Pharmacy Business Ownership Act 2001*.

*compliant purchase order* means a purchase order complying with chapter 2, part 2, division 2.

compliant storage system see section 119(2).

*compound*, a medicine for supply, means manufacture a medicine for a particular patient or animal by mixing, compounding or formulating a regulated substance with any other substance.

computer includes an application or program used on the computer.

contact details, in relation to a person dealing with a medicine, means—

- (a) the name of the person; and
- (b) information sufficient to contact the person at the place where the dealing was carried out.

detention centre means a detention centre established under the *Youth Justice Act 1992*, section 262.

*direct supervision*, by a supervisor, of another person, means the supervisor supervises the other person by—

- (a) being in physical proximity to the other person; or
- (b) using technology that allows the supervisor to communicate with the person in real time.

*dispensary* means the area within a pharmacy or other place used to store and dispense regulated substances.

dispensed medicine means a medicine that is—

- (a) supplied to someone, other than someone who is a patient in a hospital, by a person authorised to supply the medicine; or
- (b) supplied for animal treatment by a veterinary surgeon; or
- (c) dispensed or supplied by a pharmacist for the treatment of a particular person or animal.

electronic medication management system see section 111.

endorsed, in relation to a health practitioner, means the practitioner is endorsed under the Health Practitioner Regulation National Law, section 94 as being qualified to administer, obtain, possess, prescribe, sell, supply or use a medicine.

*food producing animal* means a food producing animal under the *Biosecurity Regulation 2016*, schedule 3, part 2.

function includes a power.

#### hospital means—

- (a) a public sector hospital under the *Hospital and Health Boards Act 2011*; or
- (b) a private health facility.

Hospital and Health Service see the Hospital and Health Boards Act 2011, section 17.

*incidental possession* see section 7(3).

*inhaled asthma reliever* means an S3 or S4 medicine that is a bronchodilator in a metered dose inhaler.

#### isolated practice area means—

- (a) a place that is at Cow Bay, Mapoon or Weipa; or
- (b) a place that is—
  - (i) within the area of a local government mentioned in schedule 3; and
  - (ii) remote from pharmaceutical services; or
- (c) a clinic conducted by the Royal Flying Doctor Service of Australia (Qld section) in an area isolated from medical, pharmaceutical and hospital services; or
- (d) a plane operated by the Royal Flying Doctor Service of Australia (Qld section).

*manufacturer* means the holder of a manufacturing licence or a person permitted under a Commonwealth law to manufacture a medicine.

*manufacturer's pack*, of a medicine, means a primary pack of the medicine supplied by the manufacturer of the medicine.

Note-

See the Poisons Standard, part 1 for the definition *primary pack*.

*manufacturing supervisor*, for a manufacturing licence, means the person responsible for supervising manufacture under the licence.

*medicated animal feed* means a product containing an S4 medicine that is used to feed, or is mixed with food to feed, a food producing animal.

*methoxyflurane training* means training in the use and administration of methoxyflurane provided by a registered training organisation.

mine means a place where activities are permitted under—

- (a) a mining tenement within the meaning of the *Mineral Resources Act 1989*, other than a prospecting permit or water monitoring authority within the meaning of that Act; or
- (b) a GHG authority within the meaning of the *Greenhouse Gas Storage Act 2009*; or
- (c) a geothermal tenure within the meaning of the *Geothermal Energy Act 2010*; or
- (d) an authority under the *Petroleum and Gas (Production and Safety) Act 2004*, other than an authority to prospect or water monitoring authority within the meaning of that Act.

*naloxone training* means training in the following matters—

- (a) recognition of the symptoms and signs of suspected opioid overdose;
- (b) knowledge of the appropriate use of naloxone, including competency in administering naloxone;
- (c) implementing an opioid first aid plan.

**nitrous** oxide mixture means a substance containing a mixture of nitrous oxide and oxygen in which the concentration of nitrous oxide is not more than 70%.

non-State school means an accredited school under the Education (Accreditation of Non-State Schools) Act 2017.

**nurse manager**, in relation to a place, means the registered nurse responsible for the provision of nursing services at the place.

**on**, in relation to a prescription or standing order, means for the purposes of, and in accordance with, the prescription or standing order.

*opioid treatment program* means a program, for the treatment of persons dependent on opioids, administered under the *National Health Act 1953* (Cwlth), section 100.

*paper prescription* means a prescription in paper form, whether or not the prescription is generated by a computer.

#### patient—

- (a) means a person seeking or receiving therapeutic treatment or the supply or administration of a medicine; and
- (b) in relation to the supply of the medicine—includes someone else seeking the supply for the person.

*pharmacist* means a person registered under the Health Practitioner Regulation National Law to practise in the pharmacy profession.

**pharmacy** means a community pharmacy or a place in a relevant institution where medicines are supplied by a pharmacist to the public.

*prescriber*, in relation to a medicine, means a person who is authorised to prescribe the medicine.

*prison* means a place declared to be a prison under the *Corrective Services Act 2006*, section 149.

private health facility see the Private Health Facilities Act 1999, section 8.

registered medicine means a medicine included in a product on the Australian Register of Therapeutic Goods maintained under the *Therapeutic Goods Act 1989* (Cwlth). registered training organisation see the National Vocational Education and Training Regulator Act 2011 (Cwlth), section 3.

relevant schedule see section 10.

*relevant institution* means an aged care facility, hospital, prison or detention centre.

**repeat prescription** means a prescription that directs the repeat of the dispensing of a stated amount of a medicine a stated number of times.

restricted medicine see section 6.

#### rural hospital means—

- (a) a public sector hospital at a place mentioned in schedule 4; or
- (b) Maleny Soldiers Memorial Hospital.

**S4** diversion-risk medicine means an S4 medicine that is a diversion-risk medicine.

**S8** *medicine register*, for chapter 3, part 2, division 3, see section 121(1).

**school** means a State school or a non-State school.

**secure area** means an area, or receptacle in an area, that is locked or otherwise secured in a way that is designed to prevent access to the area or receptacle by a person who is not authorised to access the area or receptacle.

#### Examples—

- a padlocked cupboard or chest
- a room that can only be accessed with an electronic code
- a locked cage in a vehicle

secure system identifier, for a person, means a unique number or word to identify the person that can only be used in combination with a password.

**sign** includes using initials or signing in an electronic form or using a unique identifying mark encoded in a digital form.

*specified place* means—

- (a) a health service that is an approved Aboriginal health service under the *National Health (Remote Area Aboriginal Health Services Program) Special Arrangement 2017* (Cwlth); or
- (b) an aged care facility; or
- (c) a hospital; or
- (d) a school or child care facility; or
- (e) a prison, detention centre or watch-house; or
- (f) a mine; or
- (g) a place stated in a substance authority to be a place where a dealing is authorised.

*State school* means a school established under the *Education* (*General Provisions*) *Act 2006*, section 13.

storage system controller, for chapter 5, part 2, see section 118.

*supervision*, by a supervisor of another person, means the oversight by the supervisor of the dealings of the other person for—

- (a) directing, demonstrating and monitoring the dealings; and
- (b) checking the other person's level of competency for the dealings.

*supplier* means a person who is authorised to supply stock of a medicine to a buyer.

system administrator see section 112(2)(c).

system manager see section 112(1).

*type*, of S8 medicine, for chapter 5, part 2, division 3, see section 120.

*trainee* see section 12.

veterinary premises see the Veterinary Surgeons Act 1936, schedule.

watch-house manager means—

- (a) a watch-house manager under the *Police Powers and Responsibilities Act 2000*, schedule 6; or
- (b) a person performing the functions of a watch-house manager.

wholesaler means a person authorised under the Act or another law to supply medicines by wholesale in Queensland.

#### **ENDNOTES**

- 1 Made by the Governor in Council on [Made by Governor Date].
- 2 Notified on the Queensland legislation website on [Notification Date].
- 3 The administering agency is Queensland Health.