EXPOSURE DRAFT

(Prepared by Parliamentary Counsel's Office)

Medicines and Poisons Regulation 2007

Subordinate Law SL2007-

The Australian Capital Territory Executive makes the following regulation under the *Medicines and Poisons Act 2006*.

Dated 2007.

Minister

Minister

J2005-805

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Chapter 1 Preliminary

1 Name of regulation

This regulation is the *Medicines and Poisons Regulation 2007*.

2 Commencement

This regulation commences on the commencement of the *Medicines and Poisons Act 2006*.

3 Dictionary

The dictionary at the end of this regulation is part of this regulation.

Note 1 The dictionary at the end of this Act defines certain terms used in this Act, and includes references (***signpost definitions***) to other terms defined elsewhere.

For example, the signpost definition '***health profession***—see the *Health Professionals Act 2004*, dictionary.' means that the term 'health professional' is defined in that dictionary and the definition applies to this Act.

Note 2 A definition in the dictionary (including a signpost definition) applies to the entire Act unless the definition, or another provision of the Act, provides otherwise or the contrary intention otherwise appears (see Legislation Act, s 155 and s 156 (1)).

4 Notes

A note included in this regulation is explanatory and is not part of this regulation.

Note See the Legislation Act, s 127 (1), (4) and (5) for the legal status of notes.

5 Offences against regulation—application of Criminal Code etc

Other legislation applies in relation to offences against this regulation.

Note 1 *Criminal Code*

The Criminal Code, ch 2 applies to all offences against this regulation (see Code, pt 2.1).

The chapter sets out the general principles of criminal responsibility (including burdens of proof and general defences), and defines terms used for offences to which the Code applies (eg ***conduct***, ***intention***, ***recklessness*** and ***strict liability***).

Note 2 *Penalty units*

The Legislation Act, s 133 deals with the meaning of offence penalties that are expressed in penalty units.

Chapter 2 Medicines authorisations generally

Part 2.1 Overview of medicines authorisations

10 General overview of authorisations for medicines

(1) Several provisions of the Act require that a person must not deal with a medicine in a particular way unless the person is authorised to deal with the medicine.

Example

the Act, section 32 is about obtaining certain substances (which include medicines)

Note 1 An example is part of the regulation, is not exhaustive and may extend, but does not limit, the meaning of the provision in which it appears (see Legislation Act, s 126 and s 132).

Note 2 Under the Act, s 16, a person ***deals*** with a medicine if—

(a) the person manufactures, obtains, possesses, supplies, administers or disposes of the medicine; or

(b) the person issues a prescription, requisition, purchase order or standing order for the medicine; or

(c) the medicine otherwise comes into, or goes out of, the person's possession.

(2) The Act, section 17 (Meaning of *authorised*) sets out when a person is authorised to deal with a medicine.

(3) This regulation—

(a) authorises certain dealings with medicines; and

(b) prescribes dealings with medicines that need not be authorised; and

(c) exempts certain regulated substances from the Act (see s 780).

Examples—par (b)

1 self-administration of a medicine obtained by a person from someone who is authorised to supply the medicine to the person (see s 21)

2 an employee at a community pharmacy for the delivery or sale of a dispensed medicine if the delivery or sale is to the person for whom the medicine is prescribed or the person's agent (see s 24 (1) (c))

(4) An authorisation may be subject to limitations under this regulation.

Examples

1 a health professional's authorisation is subject to any condition or restriction to which the health professional is subject to under the *Health Professionals Act 2004* (see s 15)

2 the authorisation of a person to prescribe a medicine is subject to any condition or restriction included in schedule 1 in relation to the person (see s 30 (1) (b))

Note For the power to impose other limitations, see the Act, ch 6 (Restrictions on dealing with regulated substances).

11 Overview of provisions authorising dealings with medicines

(1) Most medicines authorisations under this regulation are given by the following provisions (and are set out in schedule 1):

(a) section 30 (Authorisation to prescribe medicines—sch 1);

(b) section 60 (Authorisation to supply medicines—sch 1);

Note ***Supply*** includes dispense on prescription (see Act, s 18).

(c) section 140 (which gives authorisations to manufacture, obtain, possess and administer medicines and to issue requisitions and purchase orders for medicines).

(2) For other medicines authorisations, see the following provisions:

(a) section 111 (Authorisation of certain prescribers to supply manufacturers packages of medicines);

(b) section 121 (Authorisation to supply designated prescription only medicines without prescription in emergencies);

(c) section 130 (Authorisation of CHO to issue standing orders for supply of medicines);

(d) section 131 (Authorisation of CHO to issue standing orders for administration of medicines);

(e) section 132 (Authorisation of doctors to issue standing orders for administration of medicines at institutions);

(f) chapter 12 (Medicines licences).

Part 2.2 Important concepts

15 Medicines authorisations subject to Health Professionals Act

A health professional's authorisation under the Act to deal with a medicine is subject to any condition or restriction to which the health professional is subject under the *Health Professionals Act 2004*.

Example

Section 30 authorises various health professionals to prescribe medicines. If a particular health professional's registration under the *Health Professionals Act 2004* is subject to the condition or restriction that the person may prescribe medicines only under the direct supervision of another health professional, the health professional's authorisation under the *Medicines and Poisons Act 2006* to prescribe medicines is subject to that condition or restriction.

Note 1 A reference to an Act includes a reference to the statutory instruments made or in force under the Act, including any regulation (see Legislation Act, s 104).

Note 2 An example is part of the regulation, is not exhaustive and may extend, but does not limit, the meaning of the provision in which it appears (see Legislation Act, s 126 and s 132).

16 Quality use of medicines principles

A health professional prescribes or supplies a medicine to a patient in accordance with the quality use of medicines principles if the health professional—

(a) selects management options for the patient wisely by—

(i) considering the place of medicines in treating illness and maintaining health; and

(ii) recognising that there may be better ways than medicines to manage many disorders; and

(b) chooses suitable medicines, if a medicine is considered necessary, so that the best available option is selected by taking into account the following:

(i) the patient;

(ii) the patient's clinical condition;

(iii) any risks, and the benefits, of each option to the patient;

(iv) the dosage and length of treatment of the patient under each option;

(v) any co-existing condition of the patient;

(vi) any other therapy available;

(vii) any monitoring considerations;

(viii) costs for the patient, the community and the health system; and

(c) uses medicines safely and effectively to get the best possible results by—

(i) monitoring outcomes; and

(ii) minimising misuse, overuse and under-use; and

(iii) improving the patient's ability to solve problems relating to the use of medicines, for example, negative effects or managing multiple medicines.

Note An example is part of the regulation, is not exhaustive and may extend, but does not limit, the meaning of the provision in which it appears (see Legislation Act, s 126 and s 132).

Part 2.3 Medicines authorisations—when not required

20 Exemptions for certain personal use-related dealings with medicines—Act, s 175 (1) (a)

(1) A person is exempt from the Act, section 32 (Obtaining certain part 3.2 substances) in relation to obtaining a medicine if the person obtains the medicine from someone who is authorised to supply the medicine to the person.

(2) A person is exempt from the Act, section 33 (Possession of certain part 3.2 substances) in relation to possessing a medicine if the person obtains the medicine from someone who is authorised to supply the medicine to the person.

(3) Subsection (1) and subsection (2) apply in relation to a person whether the medicine is obtained by the person for the person's own use or as agent for someone else.

21 Exemptions for self-administration etc of medicines—Act, s 175 (1) (a)

(1) This section applies in relation to a medicine obtained by a person from someone who is authorised to supply the medicine to the person.

(2) The following dealings by the person with the medicine are exempt from the Act, section 34 (Administration of part 3.2 substances):

(a) self-administering the medicine;

(b) if the person is an animal owner—administering the medicine to the animal.

(3) In this section:

animal owner, in relation to an animal, means—

(a) an adult who has lawful custody of the animal; or

(b) if the animal is owned by a child or person with a guardian—a parent or guardian of the child or person.

22 Exemption for administration of medicines by assistants—Act, s 175 (1) (a)

(1) A person (the ***assistant***) is exempt from the Act, section 34 (Administration of part 3.2 substances) in relation to the administration of a medicine to someone else (the ***assisted person***) if—

(a) the medicine is obtained by or for the assisted person from someone who is authorised to supply the medicine to the assisted person; and

(b) the assistant helps the assisted person to take the medicine in accordance with the directions on the medicine's packaging; and

(c) if the assisted person is not a person under a legal disability—the assisted person asks for the assistant's help to take the medicine; and

(d) if the assisted person is a person under a legal disability—the assistant is authorised by the assisted person's parent or guardian to administer the medicine.

(2) In this section:

impaired decision-making ability—a person has ***impaired decision-making ability*** if the person's decision-making ability is impaired because of a physical, mental, psychological or intellectual condition or state, whether or not the condition or state is a diagnosable illness.

person under a legal disability means—

(a) a child; or

(b) a person with impaired decision-making ability in relation to a matter relating to the person's health.

23 Exemption for disposal of residue of administered medicines—Act, s 175 (1) (a)

(1) This section applies in relation to a medicine obtained by a person from someone who is authorised to supply the medicine to the person.

(2) The person is exempt from the Act, section 35 (Disposal of part 3.2 substances) in relation to the disposal of the medicine left after administration.

24 Exemptions for delivery and sale of medicines by certain health-related employees—Act, s 175 (1) (a)

(1) An employee at a community pharmacy, and a health professional employed at an institution, are exempt from the Act, section 23 (Supply of part 3.2 substances) to the extent necessary to deliver or sell—

(a) a pharmacy medicine; or

(b) a pharmacist only medicine personally supplied by a pharmacist or student pharmacist at the pharmacy or institution; or

(c) a medicine dispensed at the pharmacy or institution if the delivery or sale is to the person for whom the medicine is prescribed or the person's agent.

(2) An employee at a veterinary surgery is exempt from the Act, section 23 (Supply of part 3.2 substances) to the extent necessary for the employee to deliver or sell the following medicines if labelled with the words 'For animal use only':

(a) a pharmacy medicine;

(b) a medicine personally supplied by a veterinary surgeon at the surgery.

25 Exemption for transport and delivery of medicines—Act, s 175 (1) (a)

(1) This section applies to an adult (a ***delivery person***) who is—

(a) engaged to transport or deliver a medicine supplied on a supply authority; or

(b) acting for a person mentioned in paragraph (a).

(2) A delivery person is exempt from the following provisions of the Act to the extent necessary to transport and deliver the medicine as engaged:

(a) section 23 (Supply of part 3.2 substances);

(b) section 32 (Obtaining certain part 3.2 substances);

(c) section 33 (Possession of certain part 3.2 substances).

26 Exemption for supply of medicines to pharmacists and student pharmacists for disposal—Act, s 175 (1) (a)

A person is exempt from the Act, section 23 (Supply of part 3.2 substances) in relation to the supply of a medicine to a pharmacist or student pharmacist for disposal.

Chapter 3 Authorisation to prescribe medicines

Part 3.1 Prescribing medicines

30 Authorisation to prescribe medicines—sch 1

(1) A person mentioned in schedule 1, column 2 is authorised to prescribe a medicine if—

(a) prescribing the medicine is included in the schedule, column 3 in relation to the person; and

(b) the prescribing is consistent with any condition or restriction for the prescribing mentioned in the schedule, column 3; and

(c) if the medicine is prescribed for human use—the medicine is prescribed in accordance with the quality use of medicines principles under section 16; and

(d) if the prescription is a self-prescription of the medicine—

(i) the person is not a student dentist or student doctor; or

(ii) the medicine is not a restricted medicine; and

Note ***Restricted medicine***—see s (2).

(e) if the prescription is a written prescription—

(i) the prescription is in accordance with section 40 (General requirements for written prescriptions—Act, s 54 (2) (c)); and

(ii) the prescription includes the particulars mentioned in section 42 (Particulars for prescriptions—Act, s 54 (2) (c)) on the front of the prescription; and

(f) if the prescription is an oral prescription—

(i) the person believes, on reasonable grounds, that prescribing the medicine is reasonably necessary for emergency treatment; and

(ii) the prescription is in accordance with section 41 (General requirements for oral prescriptions—Act, s 54 (2) (c)); and

(iii) the prescription includes the particulars mentioned in section 42; and

(g) if the medicine is a controlled medicine—the person complies with the additional requirements under section 31 in relation to the prescription; and

(h) if the medicine is an appendix D medicine—the person complies with the additional requirements under section 32 in relation to the prescription.

(2) In this section:

restricted medicine means—

(a) an anabolic steroid; or

(b) an appendix D medicine; or

(c) a benzodiazepine; or

(d) a controlled medicine.

31 Additional authorisation requirements for controlled medicines prescriptions

For section 30 (1) (g), the following are the additional requirements for a prescription for a controlled medicine:

(a) the prescriber has a controlled medicines approval to prescribe the medicine; and

Note For controlled medicines approvals, see pt 11.1.

(b) if the approval is for a particular form of the medicine—the prescription is for the form of the medicine approved or a bioequivalent form; and

(c) if the approval is for a particular strength of the medicine—the prescription is for the strength approved or a weaker strength; and

(d) if the approval is for a particular quantity of the medicine—the prescription is for no more than the quantity approved; and

(e) the prescriber complies with each condition (if any) of the approval.

Example—par (b)

if a slow release form of a medicine is approved, the prescriber is not authorised to prescribe an immediate release form of the medicine

Example—par (c) and (d)

If a doctor is given an approval to prescribe 25 morphine 20mg capsules, the doctor may prescribe 5 20mg capsules and 10 15mg capsules. Later, if the approval is still is force, the doctor may prescribe no more than 10 morphine capsules of any strength up to and including 20mg.

Note An example is part of the regulation, is not exhaustive and may extend, but does not limit, the meaning of the provision in which it appears (see Legislation Act, s 126 and s 132).

32 Additional authorisation requirements for appendix D medicines prescriptions

For section 30 (1) (h) (Authorisation to prescribe medicines—sch 1), the following are the additional requirements for a prescription for an appendix D medicine:

(a) the prescriber prescribing the medicine has an Appendix D medicines approval to prescribe the medicine;

(b) the prescriber complies with each condition (if any) of the approval.

Note An appendix D medicines approval may only be given to a doctor (see pt 11.2).

Part 3.2 Prescriptions

Note A prescription may provide for a medicine to be dispensed or administered (see Act, dict, def ***prescription***).

40 General requirements for written prescriptions—Act, s 54 (2) (c)

A written prescription for a medicine must—

(a) be signed by the prescriber; and

Note The prescription must be signed with the prescriber's usual signature (see Act, dict, def ***signs***).

(b) if the prescriber amends the prescription—be initialed and dated beside the amendment by the prescriber; and

(c) be written in terms and symbols used in ordinary professional practice; and

(d) if the prescription is for an unusual or dangerous dose—include the prescriber's initials beside an underlined reference to the dose.

Note ***Written*** includes in electronic form (see dict).

41 General requirements for oral prescriptions—Act, s 54 (2) (c)

An oral prescription for a medicine must—

(a) be for no more than the amount of the medicine that is reasonably necessary for the emergency for which the medicine is prescribed; and

(b) if the prescription is for an unusual or dangerous dose—include a statement telling the person who is to dispense or administer the medicine that the prescription is for an unusual or dangerous dose.

Note An oral prescription may only be issued for emergency treatment (see s 30 (1) (f)).

42 Particulars for prescriptions—Act, s 54 (2) (c)

(1) A prescription must include the following particulars:

(a) the prescriber's name, professional qualifications and business address and telephone number;

(b) the date the prescription is written;

(c) the medicine, and the form, strength and quantity of the medicine, to be dispensed or administered under the prescription;

(d) the name and address of the person for whom the medicine is prescribed;

(e) directions about the use of the medicine, including the dose of the medicine, that are adequate to allow the medicine to be taken safely;

(f) the number of times the medicine may be dispensed or administered under the prescription;

(g) if the prescription is for a controlled medicine—

(i) the relevant approval particulars; and

Note ***Relevant approval particulars***—see s (3).

(ii) if the prescription is a repeat prescription—the period that must elapse between each dispensing or administration of the medicine;

(h) if the prescription is for an appendix D medicine—the relevant approval particulars;

Note ***Relevant approval particulars***—see s (3).

(i) if the prescriber is a dentist—the words 'for dental treatment only';

(j) if the prescriber is an optometrist—the words 'for optometry use only';

(k) if the prescriber is a veterinary surgeon—

(i) the words 'for animal treatment only'; and

(ii) the species of the animal for which the medicine is to be dispensed; and

(iii) if possible, a way of identifying the animal.

(2) However, if the prescription is written for an in-patient at a hospital, the prescription need not include—

(a) the prescriber's professional qualifications and business address and telephone number; and

(b) if the medicine prescribed is a controlled medicine or appendix D medicine—the relevant approval particulars.

Note 1 ***Hospital*** means a public hospital, private hospital or day hospital (see Act, dictionary).

Note 2 A hospice is a hospital (see *The Macquarie Dictionary*, 3rd ed, def ***hospice***).

(3) In this section:

relevant approval particulars means—

(a) for a controlled medicine—

(i) for an approval under section 251 (Standing approvals to prescribe controlled medicines for short-term treatment)—the words 'standing short-term approval'; or

(ii) for an approval under section 252 (Standing approval to prescribe buprenorphine and methadone for opioid dependency treatment centres)—the words 'standing opioid dependency treatment centre approval'; or

(iii) for an approval under division 11.1.3 (Chief health officer controlled medicines approvals)—the words 'CHO approval number' followed by the identifying number for the approval; or

(b) for an appendix D medicine—

(i) for an approval under section 291 (Standing approvals to prescribe appendix D medicines)—the words 'standing approval' and the specialist area in which the prescriber practices; or

Note An appendix D medicines approval may only be given to a doctor (see pt 11.2).

(ii) for an approval under section 293 (CHO decisions on applications to prescribe appendix D medicines)—the words 'CHO approval number' followed by the identifying number for the approval.

43 Additional requirement for prescriptions faxed to pharmacists

(1) In this section:

pharmacist includes a student pharmacist.

(2) A prescriber commits an offence if—

(a) the prescriber faxes a copy of a prescription to a pharmacist; and

(b) the prescriber fails to send the pharmacist the prescription not later than 24 hours after the prescriber faxes the copy to the pharmacist.

Maximum penalty: 30 penalty units.

Note A pharmacist is authorised to dispense on a faxed copy of a prescription in certain circumstances (see s 51, def ***prescription*** and s 60 (1) (d)).

(3) An offence against this section is a strict liability offence.

Chapter 4 Authorisations to supply medicines

Part 4.1 Preliminary

50 Overview of supply authorisations for medicines

The following provisions of this chapter authorise a person to supply a medicine:

(a) section 60 (which is about supply authorisations set out in schedule 1, including dispensing on prescription and supply on requisition, purchase order and standing order);

(b) section 111 (which is about authorisation of certain prescribers to supply manufacturers packages of medicines during consultations);

(c) section 121 (which is about authorisation of pharmacists to supply certain perscription only medicines without a prescription in emergencies).

Note A person may also be authorised to supply a medicine in a way mentioned in section 10 (2) (General overview of authorisations scheme for medicines) (including under a licence, see ch 12).

51 Meaning of *prescription*—ch 4

In this chapter:

prescription means—

(a) see the Act, dictionary; or

(b) a faxed copy of a prescription.

Part 4.2 Supply authorisations—sch 1

Division 4.2.1 Authorisations to supply medicines—sch 1

60 Authorisation to supply medicines—sch 1

(1) A person mentioned in schedule 1, column 2 is authorised to supply a medicine if—

(a) supplying the medicine is included in the schedule, column 3 in relation to the person; and

(b) the supply is consistent with any condition or restriction for the supply mentioned in the schedule, column 3; and

(c) if the supply is on a prescription—the medicine is dispensed in accordance with section 70 (How medicines are dispensed); and

Note Only a pharmacist or student pharmacist may dispense a medicine (see sch 1).

(d) if the prescription is a faxed copy of a prescription—the copy has been faxed to the pharmacist or student pharmacist by an authorised prescriber; and

(e) if the supply is on a requisition—the supply complies with section 80 (Supplying medicines on requisition); and

(f) if the supply is on a purchase order—the supply complies with section 90 (Supplying medicines on purchase orders); and

(g) if the supply is on a standing order—the medicine is supplied in accordance with the standing order and, if a primary pack of the medicine is supplied, the pack—

(i) complies with section 181 (Packaging of supplied primary packs of medicines—Act, s 49 (1) (b)); and

(ii) is labelled in accordance with section 102 (Labelling medicines supplied on standing orders—Act, s 65 (c)).

(2) In this section:

authorised prescriber—see section 70 (3).

Division 4.2.2 Dispensing medicines

70 How medicines are dispensed

(1) A pharmacist, or a student pharmacist under the direct supervision of a pharmacist, may dispense a medicine on a prescription only if—

(a) the prescription is issued by an authorised prescriber; and

Note ***Authorised prescriber***—see s (3).

(b) the medicine is dispensed in accordance with the prescription (including the prescription as changed by the pharmacist at the oral direction of the prescriber); and

Note 1 ***Dispensed in accordance with the prescription***—see s (3).

Note 2 For changes to a prescription by the dispenser, see the Act, s 26 (3).

(c) the prescription complies with the applicable provisions of part 3.2 (Prescriptions); and

(d) the package of the medicine dispensed is labelled in accordance with section 71.

(2) However, a pharmacist may dispense a prescription that does not comply with the applicable provision mentioned in subsection (1) (c) if—

(a) the prescription is issued by an authorised prescriber; and

(b) the medicine is dispensed in accordance with the prescription (including the prescription as changed by the pharmacist at the oral direction of the prescriber); and

(c) the package of the medicine dispensed is labelled in accordance with section 71; and

(d) the pharmacist is satisfied that, because of a circumstance affecting the prescriber or the person for whom the medicine is to be dispensed, it is not practicable for a complying prescription to be issued for the medicine.

Note ***Pharmacist*** does not include student pharmacist (see dict).

(3) In this section:

authorised prescriber, in relation to a prescription, means—

(a) a person who is authorised to issue the prescription under the Act or another territory law; or

(b) for a medicine other than a controlled medicine—a person who is—

(i) registered (however described) as a dentist, doctor or veterinary surgeon (however described), other than a student dentist, student doctor or student veterinary surgeon (however described), under a law of a State; and

Note ***State*** includes the Northern Territory (see Legislation Act, dict, pt 1).

(ii) authorised (however described) under a law of the State to prescribe the medicine.

Examples

1 A NSW registered doctor practising in Queanbeyan is authorised under a NSW law to prescribe medicines. The doctor gives a patient a prescription for a controlled medicine and another prescription for a prescription only medicine. The prescription only medicine can be dispensed in the ACT because the prescription was issued by a person who is authorised under a corresponding law to prescribe the medicine. The prescription for the controlled medicine can not be dispensed in the ACT because the doctor is not registered in the ACT.

2 If the doctor in example 1 is registered in both the ACT and NSW, the prescription for the controlled medicine can be dispensed in the ACT.

3 A special event exemption under the *Health Professionals (Special Events Exemptions) Act 2000* authorises a visiting health professional to prescribe a medicine, including a controlled medicine. A Victorian registered doctor who is a visiting health professional within the meaning of that Act prescribes a controlled medicine. The prescription can be dispensed in the ACT.

Note 1 An example is part of the regulation, is not exhaustive and may extend, but does not limit, the meaning of the provision in which it appears (see Legislation Act, s 126 and s 132).

Note 2 A reference to a health professional in schedule 1 is a reference to a health professional who is registered under the *Health Professionals Act 2004*. See, for example, the Legislation Act, dictionary, part 1, definition of ***dentist***.

dispensed in accordance with the prescription, for a prescribed medicine, includes dispensing another brand of the medicine that is bioequivalent to the prescribed medicine.

71 Labelling dispensed medicines—Act, s 56 (c)

A package of a dispensed medicine must have a label that includes the following:

(a) the name of the person for whom the medicine is dispensed;

(b) if the prescriber is a dentist—the words 'for dental treatment only';

(c) if the prescriber is an optometrist—the words 'for optometry use only';

(d) if the prescriber is a veterinary surgeon—

(i) the words 'for animal treatment only'; and

(ii) the species of the animal for which the medicine is dispensed; and

(iii) if a way of identifying the animal is stated on the prescription—the way of identifying the animal;

(e) the medicine's approved name and brand name;

Note ***Approved name***—see the medicines and poisons standard, pt 1, par 1 (1).

(f) the form, strength and quantity of the medicine dispensed;

(g) if the package of the dispensed medicine is not a primary pack—the medicine's batch number and expiry date;

(h) the date the medicine is dispensed;

(i) the name and the business address and telephone number of the pharmacy from which the medicine is dispensed;

(j) if more than 1 pharmacist or student pharmacist is dispensing at the pharmacy when the medicine is dispensed—

(i) the initials or other identification of the dispensing pharmacist; or

(ii) if the dispensing pharmacist is a student pharmacist—the initials or other identification of the pharmacist supervising the student pharmacist;

Note A student pharmacist may dispense only under the direct supervision of a pharmacist (see sch 1).

(k) a number that is different from the number given to all other prescriptions dispensed at the pharmacy;

(l) directions about the use of the medicine that are adequate to allow the medicine to be taken safely, including any warning statement in the medicines and poisons standard, appendix K (Drugs required to be labelled with a sedation warning) applying to the medicine;

(m) words to the effect of 'keep out of the reach of children'.

Example—par (e) and (f)

Warfarin tablets (Coumadin) 5mg 50

Note An example is part of the regulation, is not exhaustive and may extend, but does not limit, the meaning of the provision in which it appears (see Legislation Act, s 126 and s 132).

72 Marking dispensed prescriptions—Act, s 57 (1) (b) and (2) (c)

(1) A dispensed paper-based prescription for a medicine must be marked with—

(a) if the prescription is a single prescription or the last repeat of a repeat prescription—the word 'cancelled' on the front of the prescription; and

(b) the prescribed particulars.

(2) A dispensed electronic prescription for a medicine must be marked with—

(a) if the prescription is a single prescription or the last repeat of a repeat prescription—the word 'cancelled'; and

(b) a link to an electronic document containing the prescribed particulars.

(3) In this section:

paper-based prescription includes a faxed copy of a prescription.

prescribed particulars, for a dispensed prescription for a medicine, means—

(a) the date the medicine is dispensed; and

(b) the name and business address of the dispensing pharmacy; and

(c) if the medicine is dispensed at a place other than a hospital and another brand of the medicine is dispensed for the prescribed medicine—the brand name of the medicine dispensed; and

(d) for a repeat prescription—the number of the repeat dispensed; and

(e) the prescription's number under section 71 (k); and

(f) if the medicine is dispensed by a pharmacist—the pharmacist's initials or signature; and

(g) if the medicine is dispensed by a student pharmacist—the initials or signature of the pharmacist supervising the student pharmacist.

single prescription means a prescription that is not a repeat prescription.

73 Recording dispensing of medicines—Act, s 28 (a), s 29 (1) (a) and (b)

(1) The responsible pharmacist for the dispensing of a medicine must ensure that a written record of the following information in relation to the dispensing of the medicine is made:

(a) the pharmacist's name;

(b) the date of the prescription;

(c) the prescriber's name;

(d) the date the prescription is dispensed;

(e) for a repeat prescription—the number of times the medicine has been dispensed under the prescription;

(f) the name and address of the person for whom the medicine is dispensed;

(g) the medicine's approved name and brand name;

Note ***Approved name***—see the medicines and poisons standard, pt 1, par 1 (1).

(h) the form, strength and quantity of the medicine dispensed.

Note ***Written*** includes in electronic form (see dict).

(2) The pharmacist in charge of the pharmacy from which the medicine is dispensed must ensure that the record of the dispensing is kept.

Note The record must be kept for at least 2 years (see Act, s 29 (1) (c)).

(3) In this section:

responsible pharmacist, for the dispensing of a medicine, means—

(a) if the medicine is dispensed by a pharmacist—the pharmacist; or

(b) if the medicine is dispensed by a student pharmacist—the pharmacist supervising the student pharmacist.

Note A student pharmacist may dispense only under the direct supervision of a pharmacist (see sch 1).

74 Additional requirement for prescriptions faxed to pharmacists

(1) In this section:

pharmacist includes a student pharmacist.

(2) A pharmacist commits an offence if—

(a) the pharmacist dispenses a medicine on a faxed copy of a prescription; and

(b) the pharmacist does not, not later than 7 days after the day the medicine is dispensed, receive the prescription; and

(c) the pharmacist does not, within 24 hours after the end of the 7-day period, tell the chief health officer, in writing, of the failure to receive the prescription.

Maximum penalty: 30 penalty units.

(3) An offence against this section is a strict liability offence.

Division 4.2.3 Supplying medicines on requisition

Note For authorisation to issue a requisition, see s 140.

80 Supplying medicines on requisition

(1) In this section:

approved person, in relation to a medicine, means—

(a) if supplying the medicine on requisition is included in schedule 1, column 3 in relation to the person—the person; or

(b) a person supplying the medicine on requisition under the direct supervision of a pharmacist.

Note ***Pharmacist*** does not include student pharmacist (see dict).

supplied in accordance with the requisition, for a requisitioned medicine, includes supplying another brand of the medicine that is bioequivalent to the requisitioned medicine.

(2) An approved person may supply a medicine on requisition only if—

(a) the medicine is supplied in accordance with the requisition (including the requisition as changed by the person supplying the medicine at the oral direction of the person issuing the requisition); and

Note For changes to a requisition by the person supplying a medicine on a requisition, see the Act, s 26 (3).

(b) if the requisition is a written requisition—

(i) the requisition is in accordance with section 81; and

(ii) the requisition includes the particulars mentioned in section 82 on the front of the requisition; and

(c) if the requisition is an oral requisition—the requisition includes the particulars mentioned in section 82; and

(d) the package of the medicine supplied is labelled in accordance with section 83.

(3) However, if the requisition does not comply with section 81 or section 82 (as appropriate), an approved person is authorised to supply the medicine on the requisition if satisfied that, because of a circumstance affecting the requisitioner or the person for whom the medicine is to be supplied, it is not practicable for a complying requisition to be issued for the medicine.

81 General requirements for written requisitions—Act, s 59 (2) (c)

A written requisition for a medicine must be—

(a) signed by the person (the ***issuer***) issuing the requisition; and

Note The requisition must be signed with the issuer's usual signature (see Act, dict, def ***signs***).

(b) if the issuer amends the requisition—initialed and dated by the issuer beside the amendment.

Note ***Written*** includes in electronic form (see dict).

82 Particulars for requisitions—Act, s 59 (2) (c)

A requisition must include the following particulars:

(a) the name of the person issuing the requisition;

(b) the capacity in which the person is issuing the requisition;

(c) the date the requisition is issued;

(d) the medicine, and the form, strength and quantity of the medicine, to be supplied on the requisition;

(e) the pharmacy or ward to which the medicine is to be supplied.

83 Labelling medicines supplied on requisition—Act, s 61 (c)

A package of a medicine supplied on requisition must have a label that includes the following:

(a) the medicine's approved name and brand name;

Note ***Approved name***—see the medicines and poisons standard, pt 1, par 1 (1).

(b) the form, strength and quantity of the medicine;

(c) if the package of the supplied medicine is not a primary pack—the medicine's batch number and expiry date;

(d) the name or other identifier of the pharmacy or ward from which the medicine is supplied;

(e) a number that is different from the number given to each other requisition supplied from the pharmacy or ward.

Example—par (a) and (b)

Warfarin tablets (Coumadin) 5mg 50

Note An example is part of the regulation, is not exhaustive and may extend, but does not limit, the meaning of the provision in which it appears (see Legislation Act, s 126 and s 132).

84 Marking filled requisitions—Act, s 62 (1) (b) and (2) (c)

(1) A filled paper-based requisition for a medicine must be marked with—

(a) the word 'cancelled' on the front of the requisition; and

(b) the requisition's number under section 83 (e); and

(c) the prescribed particulars.

(2) A filled electronic requisition for a medicine must be marked with—

(a) the word 'cancelled'; and

(b) a link to an electronic document containing—

(i) the requisition's number under section 83 (e); and

(ii) the prescribed particulars.

(3) However, subsection (1) (b) and (2) (b) (i) do not apply to a requisition filled at a pharmacy in an institution.

(4) In this section:

prescribed particulars, for a filled requisition for a medicine, means—

(a) the medicine's name; and

(b) the name or other identifier of the pharmacy or ward from which the medicine is supplied; and

(c) the supplier's initials or signature.

85 Recording supply of medicines on requisitions—Act, s 28 (a), s 29 (1) (a) and (b)

(1) A person who supplies a medicine to someone else on requisition must make a written record of the following information:

(a) the date of the requisition;

(b) the name of the person who issued the requisition;

(c) the date the requisition is filled;

(d) the medicine's approved name;

(e) the form, strength and quantity of the medicine supplied;

(f) the name or initials of the person supplying the medicine.

Note ***Written*** includes in electronic form (see dict).

(2) The pharmacist in charge of the pharmacy that filled the requisition must ensure that the record of the supply of the medicine is kept.

Note The record must be kept for at least 2 years (see Act, s 29 (1) (c)).

Division 4.2.4 Supplying medicines on purchase orders

Note For authorisation to issue a purchase order, see s 140.

90 Supplying medicines on purchase orders

A person may supply a medicine on a purchase order to someone else (the ***buyer***) only if—

(a) the purchase order complies with section 91; and

(b) the medicine is supplied in primary packs that comply with section 181 (Packaging of supplied primary packs of medicines—Act, s 49 (1) (b)); and

(c) the primary packs are labelled in accordance with section 182 (Labelling supplied medicines—Act, s 50 (1) (b)); and

(d) the primary packs are securely wrapped and packed; and

(e) if the medicine is personally delivered to the buyer by the supplier—the delivery is acknowledged by the adult taking delivery signing and dating a copy of the purchase order; and

(f) if the medicine is not personally delivered to the buyer by the supplier—the medicine is delivered to the buyer by a person whose procedures require the delivery of the medicine to be signed for by the buyer or an adult employee of the buyer.

91 Requirements for medicines purchase orders

(1) A purchase order for a medicine must be—

(a) signed by the person (the ***issuer***) issuing the order; and

Note The purchase order must be signed with the issuer's usual signature (see Act, dict, def ***signs***).

(b) if the issuer amends the order—initialed and dated by the issuer beside the amendment.

(2) A purchase order for a medicine must include the following:

(a) the issuer's name and business address and telephone number;

(b) the issuer's authority to issue the order;

(c) the medicine, and the form, strength and quantity of the medicine, to be supplied on the order.

92 Recording supply of medicines on purchase orders—Act, s 28 (a), s 29 (1) (a) and (b)

(1) A person who supplies a medicine to someone else on a purchase order must make a written record of the following information:

(a) the date of the order;

(b) the name, and the business address and telephone number, of the person to whom the medicine is supplied;

(c) the date the order is supplied;

(d) the medicine, and the form, strength and quantity of the medicine, supplied.

Note ***Written*** includes in electronic form (see dict).

(2) The person in charge of the business that filled the purchase order must ensure that the record of the supply of the medicine is kept.

Note The record must be kept for at least 2 years (see Act, s 29 (1) (c)).

93 Delivery acknowledgement required for certain medicines purchased on purchase orders

(1) In this section:

relevant medicine means—

(a) pseudoephedrine; or

(b) a prescription only medicine; or

(c) a controlled medicine.

(2) A person (the ***buyer***) commits an offence if—

(a) the buyer obtains a relevant medicine on a purchase order; and

(b) the supplier does not personally deliver the medicine to the buyer; and

(c) the buyer fails to send the supplier, not later than 24 hours after the buyer receives the medicine, a document signed by the buyer acknowledging receipt of the medicine.

Maximum penalty: 30 penalty units.

(3) A person (the ***supplier***) commits an offence if—

(a) the supplier supplies a relevant medicine to a person (the ***buyer***) on a purchase order; and

(b) the supplier does not personally deliver the medicine to the buyer; and

(c) the supplier does not, not later than 7 days after the day the medicine is delivered to the buyer, receive a document signed by the buyer acknowledging receipt of the medicine; and

(d) the supplier does not, within 24 hours after the end of the 7-day period, tell the chief health officer, in writing, of the failure to receive the receipt for the delivery of the medicine.

Maximum penalty: 30 penalty units.

(4) An offence against this section is a strict liability offence.

94 Keeping delivery acknowledgements for certain medicines purchased on purchase orders—Act, s 29 (1) (b)

(1) A document acknowledging delivery of a relevant medicine is prescribed.

(2) In this section:

relevant medicine—see section 93 (1).

95 Keeping filled purchase orders for medicines—Act, s 52 (1) (a) and (2) (a)

Medicines are prescribed.

Note The effect of this section is that filled purchase orders for medicines must be kept at the supplier's business premises for at least 2 years after the day the order is filled.

Division 4.2.5 Supplying medicines on standing orders

Note 1 For authorisation to issue a standing order for the supply of a medicine, see s 130.

Note 2 ***Supply*** does not include administer (see Act, s 18).

100 Recording supply of medicines on standing orders—Act, s 28 (a), s 29 (1) (a) and (b)

(1) A person (the ***supplier***) who supplies a medicine to a person (the ***patient***) on a standing order must make a written record of the following information:

(a) the supplier's name;

(b) the patient's name and address;

(c) the date the medicine is supplied;

(d) the medicine's approved name and brand name;

(e) the form, strength and quantity of the medicine supplied;

(f) the date of the standing order.

Note ***Written*** includes in electronic form (see dict).

(2) However, subsection (1) (b) does not apply if the record is made in the patient's medical records.

(3) The supplier must ensure that the record of the supply of the medicine is kept.

Note The record must be kept for at least 2 years (see Act, s 29 (1) (c)).

101 Notifying prescriber of supply of medicines on standing orders

(1) A person commits an offence if—

(a) the person supplies a medicine to a person (the ***recipient***) under a standing order; and

(b) the person does not give the prescriber who would ordinarily have prescribed the medicine for the recipient the required information for the supply in writing not later than 24 hours after supplying the medicine.

Maximum penalty: 30 penalty units.

Note ***Written*** includes in electronic form (see dict).

(2) This section does not apply if the person is the person who would ordinarily have prescribed the medicine for the recipient.

(3) In this section:

required information, for the supply of a medicine on a standing order, means—

(a) the supplier's name; and

(b) the date the medicine is supplied; and

(c) the name and address of the person to whom the medicine is supplied; and

(d) the medicine's approved name and brand name; and

(e) the form, strength and quantity of the medicine supplied.

102 Labelling medicines supplied on standing order—Act, s 65 (c)

A package of a medicine supplied on a standing order must have a label that includes the following:

(a) the name of the person to whom the medicine is to be supplied;

(b) the date the medicine is supplied;

(c) the medicine, and the form, strength and quantity of the medicine, supplied;

(d) if the package of the medicine supplied is not a primary pack—the medicine's batch number and expiry date;

(e) the name, and the business address and telephone number, of the person who supplied the medicine;

(f) directions about the use of the medicine that are adequate to allow the medicine to be taken safely, including any warning statement in the medicines and poisons standard, appendix K (Drugs required to be labelled with a sedation warning) applying to the medicine;

(g) words to the effect of 'keep out of the reach of children'.

Part 4.3 Authorisation for certain prescribers to supply packages of medicines

110 Meaning of *prescriber*—pt 4.3

In this part:

prescriber does not include a student dentist, student doctor or student veterinary surgeon.

111 Authorisation of certain prescribers to supply manufacturers packages of medicines

(1) A prescriber is authorised to supply a medicine if—

(a) the prescriber is authorised under section 30 to prescribe the medicine; and

(b) if the medicine is supplied for human use—the medicine is supplied in accordance with the quality use of medicines principles in section 16; and

(c) the medicine is supplied—

(i) to a patient, or an animal's owner, during a consultation; and

(ii) in the manufacturer's original package; and

(d) the supplied package is labelled in accordance with section 112 (Labelling of medicines supplied by certain prescribers).

Example—par (c) (ii)

a doctor gives a patient a starter pack of an antibiotic

Note An example is part of the regulation, is not exhaustive and may extend, but does not limit, the meaning of the provision in which it appears (see Legislation Act, s 126 and s 132).

(2) In this section:

animal owner—see section 21.

112 Labelling of medicines supplied by certain prescribers

The label for the package of medicine supplied by a prescriber under section 111 must include the following:

(a) the name of the person to whom the medicine is supplied;

(b) the date the medicine is supplied;

(c) the prescriber's name and business address and telephone number;

(d) the medicine's approved name and brand name;

Note ***Approved name***—see the medicines and poisons standard, pt 1, par 1 (1).

(e) the form, strength and quantity of the medicine;

(f) directions about the use of the medicine that are adequate to allow the medicine to be taken safely, including any warning statement in the medicines and poisons standard, appendix K (Drugs required to be labelled with a sedation warning) applying to the medicine;

(g) words to the effect of 'keep out of the reach of children';

(h) if the prescriber is a dentist—the words 'for dental treatment only';

(i) if the prescriber is an optometrist—the words 'for optometry use only';

(j) if the prescriber is a veterinary surgeon—

(i) the words 'for animal treatment only'; and

(ii) the species of the animal for which the medicine is supplied; and

(iii) if possible, a way of identifying the animal.

Example—par (d) and (e)

Warfarin tablets (Coumadin) 5mg 50

Note An example is part of the regulation, is not exhaustive and may extend, but does not limit, the meaning of the provision in which it appears (see Legislation Act, s 126 and s 132).

113 Recording medicines supplied by certain prescribers—Act, s 28 (a), s 29 (1) (a) and (b)

(1) A prescriber must make a written record of the following information in the medical records of the person or animal to whom the consultation mentioned in section 111 (1) (c) (i) (Authorisation of certain prescribers to supply packages of medicines) related:

(a) the date the medicine is supplied;

(b) the medicine's approved name and brand name;

Note ***Approved name***—see the medicines and poisons standard, pt 1, par 1 (1).

(c) the form, strength and quantity of the medicine;

(d) the directions given to the person for the use of the medicine.

Note ***Written*** includes in electronic form (see dict).

(2) The prescriber must ensure that the record of the supply of the medicine is kept.

Note The record must be kept for at least 2 years (see Act, s 29 (1) (c)).

114 Information for CHO about controlled medicines—Act, s 30 (2) (a) and (b) and (3)

(1) This section applies if a prescriber supplies a controlled medicine to a person under section 111 (Authorisation of certain prescribers to supply manufacturers packages of medicines).

(2) The prescriber must, not later than 7 days after the end of the month when the controlled medicine is supplied, give the chief health officer the following information in writing:

(a) the prescriber's name and business address and telephone number;

(b) the name and address of the person to whom the medicine is supplied;

(c) the date of supply;

(d) the medicine, and the form, strength and quantity of the medicine, supplied.

Part 4.4 Authorisation to supply without prescription in emergencies

120 Meaning of *designated prescription only medicine*—pt 4.4

In this part:

designated prescription only medicine means a prescription only medicine other than—

(a) an anabolic steroid; or

(b) an appendix D medicine; or

(c) a benzodiazepine.

Note Prescription only medicines do not include controlled medicines.

121 Authorisation to supply designated prescription only medicines without prescription in emergencies

(1) A pharmacist is authorised to supply a designated prescription only medicine to someone else without being given a prescription for the medicine only if—

(a) the pharmacist is satisfied that—

(i) the person is undergoing treatment essential to the person's health or wellbeing; and

(ii) the designated prescription only medicine has previously been prescribed for the person's treatment by a prescriber; and

(iii) the person is in immediate need of the medicine to continue the treatment; and

(iv) because of an emergency affecting the person, it is not practicable for the person to obtain a prescription for the medicine from a prescriber; and

(b) the quantity supplied is—

(i) if the medicine is a liquid, aerosol, cream, ointment or anovulant tablet packaged in a primary pack—the smallest primary pack in which the liquid, aerosol, cream, ointment or anovulant tablet is generally available; or

(ii) in any other case—not more than the quantity required for 3 days' treatment for the person; and

(c) if the medicine is supplied in a primary pack—the package of the medicine complies with section 181 (Packaging of supplied primary packs of medicines—Act, s 49 (1) (b)); and

(d) the supplied package of the medicine is labelled with the relevant particulars.

Note ***Pharmacist*** does not include student pharmacist (see dict).

(2) In this section:

relevant particulars, for a label for a supplied package of medicine, means the following:

(a) the name of the person to whom the medicine is supplied;

(b) the date the medicine is supplied;

(c) the name and the business address and telephone number of the pharmacy from which the medicine is supplied;

(d) if more than 1 pharmacist or student pharmacist is dispensing at the pharmacy when the medicine is supplied—

(i) the initials or other identification of the pharmacist supplying the medicine; or

(ii) if the supplying pharmacist is a student pharmacist—the initials or other identification of the pharmacist supervising the student pharmacist;

Note A student pharmacist may dispense only under the direct supervision of a pharmacist (see sch 1).

(e) the medicine's approved name and brand name;

Note ***Approved name***—see the medicines and poisons standard, pt 1, par 1 (1).

(f) the form, strength and quantity of the medicine;

(g) if the package of the supplied medicine is not a primary pack—the medicine's batch number and expiry date;

(h) directions about the use of the medicine that are adequate to allow the medicine to be taken safely, including any warning statement in the medicines and poisons standard, appendix K (Drugs required to be labelled with a sedation warning) applying to the medicine;

(i) words to the effect of 'keep out of the reach of children'.

Example—par (c) and (d)

Warfarin tablets (Coumadin) 5mg 3

Note An example is part of the regulation, is not exhaustive and may extend, but does not limit, the meaning of the provision in which it appears (see Legislation Act, s 126 and s 132).

122 Recording supply of designated prescription only medicines—Act, s 28 (a), s 29 (1) (a) and (b)

(1) A pharmacist who supplies a designated prescription only medicine to a person under section 121 must make a written record of the following information in relation to the supply of the medicine:

(a) the pharmacist's name;

(b) the name of the prescriber who would ordinarily have prescribed the medicine;

(c) the date the medicine is supplied;

(d) the name and address of the person to whom the medicine is supplied;

(e) the medicine's approved name and brand name;

(f) the form, strength and quantity of the medicine supplied.

Note ***Written*** includes in electronic form (see dict).

(2) The pharmacist in charge of the pharmacy from which the medicine is supplied must ensure that the record of the supply of the medicine is kept.

Note The record must be kept for at least 2 years (see Act, s 29 (1) (c)).

123 Notifying usual prescriber of supply of designated prescription only medicines

(1) A pharmacist commits an offence if—

(a) the pharmacist supplies a designated prescription only medicine to a person (the ***recipient***) under section 121; and

(b) the pharmacist does not give the prescriber who would ordinarily have prescribed the medicine for the recipient the required information for the supply in writing not later than 24 hours after supplying the medicine.

Maximum penalty: 30 penalty units.

Note ***Written*** includes in electronic form (see dict).

(2) In this section:

required information, for the supply of a designated prescription only medicine, means—

(a) the pharmacist's name; and

(b) the date the medicine is supplied; and

(c) the name and address of the person to whom the medicine is supplied; and

(d) the medicine's approved name and brand name; and

(e) the form, strength and quantity of the medicine supplied.

Chapter 5 Other medicines authorisations

Part 5.1 Authorisations to issue standing orders

130 Authorisation of CHO to issue standing orders for supply of medicines

(1) The chief health officer is authorised to issue a standing order for the supply of a medicine in an emergency relating to public health.

Note A standing order must be in writing (see Act, dict, def ***standing order***).

(2) To remove any doubt, a standing order may be issued under subsection (1) even if an emergency declaration under the *Public Health Act 1997* is not in force.

131 Authorisation of CHO to issue standing orders for administration of medicines

(1) The chief health officer is authorised to issue a standing order for the administration of a medicine in relation to a public health matter if the order includes—

(a) a description of the public health matter to which the order relates; and

(b) the relevant particulars for the order; and

(c) the date of effect of the order and the date (not longer than 2 years after the date of effect) when the order ends.

Note A standing order must be in writing (see Act, dict, def ***standing order***).

(2) In this section:

relevant particulars, for a standing order for the administration of a medicine, are as follows:

(a) the clinical circumstances when the medicine may be administered;

(b) a description of the people to whom the medicine may be administered;

(c) the medicine's approved name and, if applicable, brand name;

Note ***Approved name***—see the medicines and poisons standard, pt 1, par 1 (1).

(d) if applicable, the form and strength of the medicine;

(e) the dose and route of administration;

(f) if applicable, the frequency of administration.

Example—par (c) and (d)

Adrenaline (EpiPen) 300 micrograms in 0.3mL pre-filled syringe

Note An example is part of the regulation, is not exhaustive and may extend, but does not limit, the meaning of the provision in which it appears (see Legislation Act, s 126 and s 132).

132 Authorisation of doctors to issue standing orders for administration of medicines at institutions

(1) A doctor is authorised to issue a standing order for the administration of a medicine to patients of an institution if—

(a) a medicines and therapeutics committee (the ***approving committee***) for the institution has approved the order and given an approval number for the order; and

(b) the order includes the following:

(i) the relevant particulars for the order;

(ii) the ward where the order applies;

(iii) the date of effect of the order and the date (not longer than 2 years after the date of effect) when the order ends;

(iv) the approval number for the order;

(v) the signature of the chair of the approving committee.

Note ***Doctor*** does not include student doctor (see dict).

(2) In this section:

medicines and therapeutics committee, for an institution, means a body—

(a) established by the institution to approve standing orders for the administration of medicines to patients at the institution; and

(b) that includes at least a doctor, nurse and pharmacist.

Note 1 ***Doctor*** and ***pharmacist*** do not include student doctors and student pharmacists (see dict).

Note 2 ***Nurse*** does not include an enrolled nurse (see Legislation Act, dict, pt 1).

relevant particulars, for a standing order for the administration of a medicine—see section 131.

Part 5.2 Authorisations for other dealings with medicines—sch 1

140 Other authorisations to deal with medicines—sch 1

(1) In this section:

prescribed administration witness means a person prescribed under section 234 (Prescribed witnesses for administration of controlled medicines—Act, s 43 (a) and (b)) for the administration of a controlled medicine.

relevant dealing, with a medicine, means any of the following:

(a) manufacturing the medicine;

(b) obtaining the medicine;

(c) possessing the medicine;

(d) administering the medicine;

(e) issuing a requisition for the medicine;

(f) issuing a purchase order for the medicine.

(2) A person mentioned in schedule 1, column 2 is authorised for a relevant dealing with a medicine if—

(a) the dealing is included in the schedule, column 3 in relation to the person; and

(b) the dealing is consistent with any condition or restriction for the dealing mentioned in the schedule, column 3; and

(c) if the dealing is the administration of a controlled medicine—the administration is witnessed by a prescribed administration witness or, if a prescribed administration witness is not reasonably available to witness the administration, the administration is witnessed by another person; and

Note The witness must sign the record of the administration as witness (see Act, s 67 (2) (e)).

(d) if the dealing is issuing a written requisition for the medicine—

(i) the requisition is in accordance with section 81 (General requirements for written requisitions—Act, s 59 (2) (c)); and

(ii) the requisition includes the particulars mentioned in section 82 (Particulars for requisitions—Act, s 59 (2) (c)); and

(e) if the dealing is issuing an oral requisition for the medicine—

(i) the person reasonably believes that issuing the requisition is reasonably necessary for emergency treatment; and

(ii) the quantity of the medicine requisitioned is not more than the amount reasonably necessary for the emergency; and

(iii) the requisition includes the particulars mentioned in section 82 (Particulars for requisitions—Act, s 59 (2) (c)); and

(f) if the dealing is issuing a purchase order for the medicine—the purchase order complies with section 91 (Requirements for medicines purchase orders).

Note A purchase order must be in writing (see Act, dict, def ***purchase order***).

Part 5.3 Wholesale supply of medicines under corresponding laws

141 Restrictions on wholesalers under corresponding laws supplying medicines—Act, s 17 (4) (b)

(1) This section applies to a person (the ***interstate wholesaler***) who is authorised under the Act, section 17 (4) (Meaning of *authorised*) to supply a medicine by wholesale.

(2) The interstate wholesaler must comply with, and must ensure that the interstate wholesaler's agents and employees comply with—

(a) the Australian code of good wholesaling practice for therapeutic goods for human use; and

(b) the medicines Australia code of conduct.

Note ***Australian code of good wholesaling practice for therapeutic goods for human use*** and ***Medicines Australia code of conduct***—see the dictionary.

(3) The interstate wholesaler must not supply the medicine to someone else (the ***buyer***) unless—

(a) the buyer is authorised to possess the medicine; and

(b) the supply is in accordance with—

(i) section 90 (Supplying medicines on purchase orders); or

(ii) the medicines Australia code of conduct.

Note See s 92 to s 95 for other requirements in relation to supply of medicines on purchase orders.

Chapter 6 Supply authorities generally

160 Cancellation of invalid supply authorities—Act, s 27 (2) (b)

(1) A paper-based supply authority is ***cancelled*** by a person if the person—

(a) marks the word 'cancelled', the person's name and business address and the date on the front of the supply authority; and

(b) signs the cancellation of the authority.

(2) An electronic supply authority is ***cancelled*** by a person if the person—

(a) marks the word 'cancelled' on the supply authority; and

(b) attaches or links, by electronic means, a document that includes the person's name and business address, the date and person's signature.

161 Information for CHO about controlled medicines supplied on supply authorities—Act, s 30 (1) (a) and (b) and (3)

A person (the ***supplier***) who supplies a controlled medicine on a supply authority must, not later than 7 days after the end of the month in which the medicine is supplied, give the chief health officer the following information in writing:

(a) the supplier's name and business address and telephone number;

(b) the name of the person who issued the supply authority;

(c) the date of the supply authority;

(d) the name and address of the person to whom the medicine is supplied;

(e) the date of supply;

(f) the medicine, and the form, strength and quantity of the medicine, supplied.

Chapter 7 Administration and disposal of medicines

Note 1 For authorisation to administer a medicine, see s 140 and sch 1.

Note 2 For authorisations to issue standing orders to administer medicines, see s 131 and s 132.

170 Recording and witnessing controlled medicines administration—Act, s 67 (2) (a), (b) and (d)

The administration of a controlled medicine to a person (the ***patient***) must be—

(a) witnessed by a person prescribed under section 234 (Prescribed witnesses for administration of controlled medicines—Act, s 43 (a) and (b)); and

(b) recorded in—

(i) the patient's medical records; and

(ii) the applicable controlled medicines register mentioned in section 233 (2) (Making entries in controlled medicines registers—Act, s 41 (1) (b)).

171 Recording administration authorised by standing order—Act, s 67 (1) (a) and (c)

A person who administers a medicine to a person (the ***patient***) in accordance with a standing order must record the administration in the patient's medical records.

172 Disposal of controlled medicines—Act, s 35 (1) (a)

(1) A controlled medicine must be disposed of by a prescribed disposal witness in the presence of another prescribed disposal witness.

Note 1 The disposal must be recorded in a controlled medicines register (see s 233 (1) (j)).

Note 2 See also the *Crimes (Medicines, Poisons and Drugs Enforcement) Act 1989*, div 11.4 about the disposal of seized substances.

(2) However, subsection (1) is subject to section 23 (Exemption for disposal of residue of administered medicines—Act, s 175 (1) (a)).

(3) Also, a person who is authorised to administer a controlled medicine may dispose of the residue of the medicine after administration in the presence of a person who is not a prescribed disposal witness if no other prescribed disposal witness is reasonably available to witness the disposal.

(4) In this section:

dispose of, in relation to a controlled medicine, means to destroy the medicine so that it is unable to be used.

prescribed disposal witness means a person prescribed under section 235 (Prescribed witnesses for disposal of controlled medicines—Act, s 44 (a) and (b)) for the disposal of a controlled medicine.

Note A medicine must not be disposed of in a way that creates a risk to the health or safety of people or is likely to cause damage to property or the environment (see Act, s 35 (3) (c)).

Chapter 8 Packaging and labelling of medicines generally

180 When pharmacy medicines and pharmacist only medicines to be supplied in primary packs—Act, s 49 (1) (b)

(1) In this section:

health professional does not include a pharmacist, or student pharmacist, at a hospital.

supply does not include dispense.

(2) If a health professional, or an employee acting under the direction of a health professional, supplies a pharmacy medicine or pharmacist only medicine, the medicine must be supplied in a whole primary pack of the medicine.

Note ***Primary pack*** means the pack in which medicine and its immediate container or immediate wrapper or measure pack are presented for sale or supply (see the medicines and poisons standard).

(3) If a rural communities pharmacy medicines licence-holder, or an employee acting under the direction of the licence-holder, sells a pharmacy medicine to which the licence applies, the medicine must be supplied in a whole primary pack of the medicine.

181 Packaging of supplied primary packs of medicines—Act, s 49 (1) (b)

A primary pack of a medicine supplied must be packaged—

(a) in accordance with the medicines and poisons standard, part 2 (Labels and containers), paragraphs 21 to 28; or

(b) in a container approved under the Act, section 178 (Approval of non-standard packaging and labelling by chief health officer); or

(c) in a container in which the medicine may be sold under a corresponding law.

182 Labelling supplied medicines—Act, s 50 (1) (b)

(1) In this section:

supply, for a medicine, does not include—

(a) dispense the medicine; or

(b) supply the medicine on a requisition or standing order.

Note See the following labelling provisions:

- s 71 (Labelling dispensed medicines—Act, s 56 (c))
- s 83 (Labelling medicines supplied on requisition—Act, s 61 (c))
- s 102 (Labelling medicines supplied on standing order—Act, s 65 (c)).

(2) A primary pack of a supplied medicine must be labelled in accordance with—

(a) the medicines and poisons standard, part 2 (Labels and containers), paragraphs 3 to 19; or

(b) an approval under the Act, section 178 (Approval of non-standard packaging and labelling by chief health officer); or

(c) a corresponding law.

(3) If the primary pack is a pharmacy medicine or pharmacist only medicine sold by retail at a community pharmacy, the label must also include the pharmacy's name and business address and telephone number.

(4) If the primary pack is a pharmacy medicine sold at premises licensed under a rural communities pharmacy medicines licence, the label must also include the licence-holder's name and business address and telephone number.

Chapter 9 Storage of medicines

Part 9.1 Preliminary

190 Meaning of *personal custody*—ch 9

In this chapter:

personal custody, of a key by a person, includes keeping the key in a combination-operated key safe, the combination of which the person keeps confidential.

191 Meaning of *prescribed person*—ch 9

For this chapter, each of the following is a ***prescribed person***:

(a) a dentist, doctor, optometrist, podiatrist or veterinary surgeon;

Note ***Dentist***, ***doctor*** and ***veterinary surgeon*** do not include a student dentist etc (see dict).

(b) a pharmacist in charge of a pharmacy;

(c) an approved analyst;

Note ***Approved analyst***—see the dictionary.

(d) a medicines and poisons inspector (other than a police officer);

(e) a medicines research and education program licence-holder;

(f) a person in charge of any of the following:

(i) an ambulance service (whether or not operated by the Commonwealth, the Territory or a State);

(ii) a child residential centre;

(iii) a correctional centre;

(iv) a residential aged care facility without a pharmacy;

(v) a residential disability care facility without a pharmacy;

(vi) a ward (including an opioid dependency treatment centre).

Note 1 ***Child residential centre*** and ***residential disability care facility***—see this regulation, dictionary.

Note 2 ***Residential aged care facility***—see the Act, dictionary.

Note 3 ***State*** includes a territory (see Legislation Act, dict, pt 1).

Part 9.2 Storage of medicines generally

200 Storage of medicines generally—Act, s 51 (b) and (c)

(1) This section applies to the following people in relation to a medicine in the person's possession:

(a) a prescribed person;

(b) a medicines wholesalers licence-holder;

(c) a person authorised under the Act, section 17 (4) (Meaning of *authorised*) to supply the medicine by wholesale.

Note 1 ***Possession*** includes having control over disposition (see Act, s 18).

Note 2 ***Prescribed person***—see s 191.

(2) The person must store the medicine—

(a) within the manufacturer's recommended storage temperature range; and

(b) in any other condition that is necessary to preserve the medicine's stability and therapeutic quality.

(3) To remove any doubt, this section does not apply to a prescribed person mentioned in section 191 (f) if the person does not have control over the disposition of the medicine.

Example of when person does not have control over disposition of medicine

a medicine in the personal possession of a resident of a residential aged care facility who is in an independent living unit within the facility

Note An example is part of the regulation, is not exhaustive and may extend, but does not limit, the meaning of the provision in which it appears (see Legislation Act, s 126 and s 132).

201 Removal of medicines at institutions from storage receptacles for administration—Act, s 66 (a)

The following medicines are prescribed:

(a) appendix D medicines;

(b) controlled medicines.

Part 9.3 Additional storage requirements for medicines other than controlled medicines

210 Storage of medicines other than controlled medicines in community pharmacies—Act, s 51 (b) and (c)

(1) A pharmacist in charge of a community pharmacy must ensure that each pharmacy medicine at the pharmacy is stored—

(a) if the medicine is for retail sale—within 4m of, and in sight of, the pharmacy's dispensary; and

(b) in any other case—so that public access to the medicine is restricted.

(2) A pharmacist in charge of a community pharmacy must ensure that each pharmacist only medicine and prescription only medicine at the pharmacy is stored—

(a) in a part of the premises to which the public does not have access; and

(b) so that only a pharmacist, or a person under the direct supervision of a pharmacist, has access to the medicine.

Note ***Pharmacist*** does not include student pharmacist (see dict).

211 Storage of medicines other than controlled medicines by other people—Act, s 51 (b) and (c)

(1) This section applies to the following people in relation to a medicine (other than a controlled medicine) in the person's possession:

(a) a prescribed person (other than a pharmacist in charge of a community pharmacy);

(b) a medicines wholesalers licence-holder;

(c) a person authorised under the Act, section 17 (4) (Meaning of *authorised*) to supply the medicine by wholesale.

Note 1 ***Possession*** includes having control over disposition (see Act, s 18).

Note 2 ***Prescribed person***—see s 191.

(2) A person to whom this section applies must ensure that the medicine is stored so that public access to it is restricted.

(3) To remove any doubt, this section does not apply to a prescribed person mentioned in section 191 (f) if the person does not have control over the disposition of the medicine.

Example of when person does not have control over disposition of medicine

a medicine in the personal possession of a resident of a residential aged care facility who is in an independent living unit within the facility

Note An example is part of the regulation, is not exhaustive and may extend, but does not limit, the meaning of the provision in which it appears (see Legislation Act, s 126 and s 132).

212 Storage of pharmacy medicines by rural communities pharmacy medicines licence-holders—Act, s 51 (b) and (c)

A rural communities pharmacy medicines licence-holder must store a pharmacy medicine for retail sale so that public access to the medicine is restricted.

Part 9.4 Additional storage requirements for controlled medicines

220 Storage of controlled medicines by wholesalers—Act, s 51 (b) and (c)

(1) In this section:

wholesaler means—

(a) a medicines wholesalers licence-holder; or

(b) a person authorised under the Act, section 17 (4) (Meaning of *authorised*) to supply a medicine by wholesale.

(2) A wholesaler must store a controlled medicine in the person's possession (other than a controlled medicine required for immediate supply) in the following way:

(a) the medicine must be stored in a vault that complies with, or is more secure than, the requirements for a vault in schedule 5, section 5.8 (Requirements for vaults);

(b) the vault must be fitted with an alarm system.

(3) However, if the chief health officer is satisfied that the total amount of controlled medicines held by the wholesaler at any time is not large enough to need to be stored in a vault, the chief health officer may approve, in writing, the storage of the controlled medicine in a safe or strong room.

(4) If the chief health officer gives an approval under subsection (3)—

(a) if the approval is for a safe—the safe must comply with, or be more secure than a safe that complies with, the requirements for a safe in schedule 5, section 5.6 (Requirements for safes); and

(b) if the approval is for a strong room—the strong room must comply with, or be more secure than a strong room that complies with, the requirements for a strong room in schedule 5, section 5.7 (Requirements for strong rooms); and

(c) the safe or strong room must be fitted with an alarm system.

221 Storage of controlled medicines by certain prescribers etc—Act, s 51 (b) and (c)

(1) In this section:

designated person means—

(a) a dentist, doctor or veterinary surgeon; or

(b) an ambulance officer employed by the Commonwealth, the Territory or a State; or

(c) a first-aid kit licence-holder.

Note 1 ***Dentist***, ***doctor*** and ***veterinary surgeon*** do not include a student dentist etc (see dict).

Note 2 ***State*** includes a territory (see Legislation Act, dict, pt 1).

(2) A designated person who possesses a controlled medicine must store the controlled medicine as follows:

(a) the person must ensure that the controlled medicine is stored in—

(i) a locked container that prevents ready access to the container's contents and that is securely attached to a building; or

(ii) a locked drawer, cupboard, room, vehicle or first-aid kit;

(b) if the medicine is kept in a container that is unlocked by a combination lock—the person must keep the combination confidential;

(c) if the medicine is kept in a container that is unlocked by a key—the person must keep personal custody of the key;

(d) if the medicine is kept in a drawer, cupboard, room, vehicle or first-aid kit—the person must keep personal custody of the key to the drawer, cupboard, room, vehicle or first-aid kit.

(3) However, subsection (2) does not apply to—

(a) a controlled medicine being carried by a designated person in a locked first-aid kit; or

(b) a controlled medicine in a first-aid kit if the kit is being used by a designated person.

222 Storage of controlled medicines by other people—Act, s 51 (b) and (c)

(1) A prescribed person (other than a dentist, doctor or veterinary surgeon) is prescribed in relation to a controlled medicine in the person's possession, other than a controlled medicine for immediate administration.

Note 1 ***Possession*** includes having control over disposition (see Act, s 18).

Note 2 ***Prescribed person***—see s 191.

(2) A prescribed person (other than a dentist, doctor or veterinary surgeon) must ensure that—

(a) the controlled medicine is stored in a medicines cabinet, safe, strong room or vault (a ***storage receptacle***) that complies with, or is more secure than a storage receptacle that complies with, the requirements for the receptacle in schedule 5 (Minimum requirements for secure store receptacles); and

(b) the storage receptacle is kept securely locked when not in immediate use; and

(c) if the storage receptacle is unlocked by a combination lock—the person keeps the combination confidential; and

(d) if the storage receptacle is unlocked by a key—the person keeps personal custody of the key; and

(e) if the prescribed person is the chief pharmacist in an institution—the receptacle is fitted with an alarm system.

(3) To remove any doubt, this section does not apply to a prescribed person mentioned in section 191 (f) if the person does not have control over the disposition of the medicine.

Example of when person does not have control over disposition of medicine

a medicine in the personal possession of a resident of a residential aged care facility who is in an independent living unit within the facility

Note An example is part of the regulation, is not exhaustive and may extend, but does not limit, the meaning of the provision in which it appears (see Legislation Act, s 126 and s 132).

Chapter 10 Controlled medicines registers

230 Keeping of controlled medicines registers by certain people—Act, s 38 and s 40 (b)

(1) A person mentioned in table 230, column 2 who possesses a controlled medicine is prescribed.

(2) However, the person is not prescribed in relation to a controlled medicine in a first-aid kit kept by the person.

Note ***First-aid kit***—see the dictionary.

(3) A person prescribed under subsection (1) must keep a controlled medicines register for a controlled medicine for which the person is prescribed at the place prescribed in table 230, column 3 for the person.

Table 230 Keeping controlled medicines registers

column 1 item	column 2 prescribed person	column 3 place where register to be kept
1	ambulance service (whether or not operated by the Commonwealth, the Territory or a State)—person in charge	the premises where the controlled medicine is kept
2	approved analyst	the analyst's laboratory
3	child residential centre—person in charge	the centre
4	correctional centre—person in charge	the centre
5	dentist	the dentist's surgery

column 1 item	column 2 prescribed person	column 3 place where register to be kept
6	doctor	the doctor's surgery
7	medicines wholesalers licence-holder	the licensed premises under section 352
8	medicines and poisons inspector (other than police officer)	the place directed by the chief health officer
9	person authorised under the Act, section 17 (4) (Meaning of *authorised*) to supply medicine by wholesale	the person's business premises
10	pharmacist in charge for the time being of a pharmacy	the pharmacy
11	residential aged care facility without pharmacy—person in charge for the time being of facility	the facility
12	residential disability care facility without pharmacy—person in charge for the time being of facility	the facility
13	supervisor of program under medicines research and education program licence	the premises where program is being conducted
14	veterinary surgeon	the veterinary surgeon's surgery
15	ward (including an opioid dependency treatment centre)—person in charge for the time being of ward	the ward

231 Keeping of controlled medicines registers by first-aid kit holders—Act, s 38 and s 40 (b)

(1) In this section:

designated person means—

(a) a dentist, doctor or veterinary surgeon; or

(b) an ambulance officer employed by the Commonwealth, the Territory or a State; or

(c) a first-aid kit licence-holder.

Note 1 ***Dentist***, ***doctor*** and ***veterinary surgeon*** do not include a student dentist etc (see dict).

Note 2 ***State*** includes a territory (see Legislation Act, dict, pt 1).

(2) A designated person who possesses a first-aid kit containing a controlled medicine must keep a controlled medicines register for the controlled medicine with the first-aid kit.

Note ***First-aid kit***—see the dictionary.

232 Not keeping controlled medicines registers—Act, s 39 (b)

(1) A controlled medicines register must be kept—

(a) in English; and

(b) in writing; and

(c) in a way that is easily retrievable.

Note ***Written*** includes in electronic form (see dict).

(2) Each page in a controlled medicines register must relate to a single form and strength of a controlled medicine.

233 Making entries in controlled medicines registers—Act, s 41 (1) (b)

(1) The following details for a dealing with a controlled medicine are prescribed:

(a) the nature of the dealing;

(b) the date of the dealing;

(c) the medicine, and the form, strength and quantity of the medicine, dealt with;

(d) if the dealing is receiving the medicine—the name and address of the supplier;

(e) if the dealing is supplying the medicine—the name and address of the person to whom it is supplied;

(f) if the medicine is prescribed—the prescriber's name and suburb and the prescription's number under section 71 (k);

(g) if the medicine is supplied on a requisition—the requisition's number under section 83 (e);

(h) if the medicine is supplied on a purchase order—the date of the purchase order;

(i) if the Act, section 43 (Registers—witnessing administration of medicines) applies to the dealing—the prescribed administration particulars;

(j) if the dealing is disposing of the controlled medicine—the prescribed disposal particulars;

(k) the quantity of the medicine held after the dealing.

(2) A dealing with a controlled medicine must be entered in—

(a) if the dealing happens at a pharmacy in an institution—the controlled medicines register kept at the pharmacy; or

(b) if the dealing happens in a ward in an institution—the controlled medicines register kept at the ward; or

(c) if the person must keep both a controlled medicines register for a first-aid kit and another controlled medicines register—

(i) for a dealing with a controlled medicine to which the first-aid kit relates—the controlled medicines register for the kit; or

(ii) for any other dealing by the person—the other controlled medicines register the person must keep; or

(d) in any other case—the controlled medicines register the person must keep.

(3) In this section:

prescribed administration particulars, for a controlled medicine, means—

(a) the name of the person to whom the medicine is administered; and

(b) the signature of the person who administered the medicine and the person who witnessed its administration.

prescribed disposal particulars, for a controlled medicine, means the signature of the person who disposed of the medicine and the person who witnessed its disposal.

234 Prescribed witnesses for administration of controlled medicines—Act, s 43 (a) and (b)

The following people are prescribed as witnesses in relation to the administration of a controlled medicine:

(a) if the medicine is administered by a student doctor—a dentist, doctor, midwife, nurse, nurse practitioner or pharmacist;

(b) if the medicine is administered by a person who is not a student doctor—

(i) a person mentioned in paragraph (a); or

(ii) a student doctor, enrolled nurse (medications) or student pharmacist.

Note 1 ***Dentist***, ***doctor*** and ***pharmacist*** do not include students (see the definitions of these terms in the dictionary).

Note 2 ***Nurse*** does not include an enrolled nurse (see Legislation Act, dict, pt 1).

235 Prescribed witnesses for disposal of controlled medicines—Act, s 44 (a) and (b)

The following people are prescribed as witnesses in relation to the disposal of a controlled medicine:

(a) an ambulance officer employed by the Commonwealth, the Territory or a State;

(b) an approved analyst;

(c) a dentist;

(d) a doctor;

(e) a medicines and poisons inspector (other than a police officer);

(f) a midwife;

(g) a nurse;

(h) a nurse practitioner;

(i) a pharmacist;

(j) a veterinary surgeon.

Note 1 ***Approved analyst***—see the dictionary.

Note 2 ***Dentist***, ***doctor***, ***pharmacist*** and ***veterinary surgeon*** do not include a student doctor etc (see dict).

Note 3 ***Nurse*** does not include an enrolled nurse (see Legislation Act, dict, pt 1).

236 Changes etc to entries in controlled medicines registers—Act, s 45 (2) (b)

(1) An entry in a paper-based controlled medicines register may be amended by the person who made the entry by—

(a) the person signing and dating a marginal note or footnote that gives the date of the amendment and the amended details; and

(b) if the entry relates to administering a controlled medicine—the amendment being witnessed by a person prescribed under section 234 (Prescribed witnesses for administration of controlled medicines—Act, s 44 (1) (a) and (b)); and

(c) if the entry relates to disposing of a controlled medicine—the amendment being witnessed by a person prescribed under section 235 (Prescribed witnesses for disposal of controlled medicines—Act, s 44 (a) and (b)).

(2) An entry in an electronic controlled medicines register may be amended by the person who made the entry by the person attaching or linking, by electronic means, a document (the ***correcting document***) that includes—

(a) the person's signature, the date and the amended details; and

(b) if the entry relates to administering a controlled medicine—the signature as witness of a person prescribed under section 234; and

(c) if the entry relates to disposing of a controlled medicine—the signature as witness of a person prescribed under section 235.

Chapter 11 Controlled medicines and appendix D medicines approvals

Part 11.1 Controlled medicines approvals

Division 11.1.1 Preliminary

240 Meaning of *controlled medicines approval*—regulation

In this regulation:

controlled medicines approval means an approval to prescribe a controlled medicine under any of the following:

(a) section 250 (Standing approvals to prescribe controlled medicines for hospital patients);

(b) section 251 (Standing approvals to prescribe controlled medicines for short-term treatment);

(c) section 252 (Standing approval to prescribe buprenorphine and methadone for opioid dependency treatment centres);

(d) division 11.1.3 (Chief health officer controlled medicines approvals).

241 Meaning of *designated prescriber*—pt 11.1

In this part:

designated prescriber means a prescriber (other than a veterinary surgeon) in relation to whom prescribing a controlled medicine is included in schedule 1, column 3.

Division 11.1.2 Standing controlled medicines approvals

250 Standing approvals to prescribe controlled medicines for hospital patients

A designated prescriber is approved to prescribe a controlled medicine for a patient of the prescriber if the patient is an in-patient in a hospital.

Note A hospice is a hospital (see *The Macquarie Dictionary*, 3rd ed, def ***hospice***).

251 Standing approvals to prescribe controlled medicines for short-term treatment

A designated prescriber is approved to prescribe a controlled medicine for a patient of the prescriber if—

(a) the prescriber believes, on reasonable grounds, that the patient is not a drug-dependant person in relation to a controlled medicine or prohibited substance; and

(b) the prescriber believes, on reasonable grounds, that the patient has not been prescribed a controlled medicine by someone else within the period of 2 months before the prescriber prescribes the medicine; and

(c) the prescriber prescribes the controlled medicine for the patient's use for a period of 2 months or less.

252 Standing approval to prescribe buprenorphine and methadone for opioid dependency treatment centres

(1) In this section:

doctor includes a student doctor acting under the direct supervision of a doctor.

(2) A doctor is approved (the ***interim approval***) to prescribe buprenorphine or methadone if—

(a) the doctor is employed at an opioid dependency treatment centre; and

(b) the doctor prescribes the buprenorphine or methadone for a patient of the centre; and

(c) the buprenorphine or methadone is prescribed in accordance with the guidelines approved under section 380 (Guidelines for treatment of opioid dependency); and

(d) the doctor makes an application under section 260 (Applications for CHO controlled medicines approvals) to prescribe the medicine not later than 72 hours after the doctor first prescribes buprenorphine or methadone for the patient.

(3) The interim approval ends—

(a) if the chief health officer approves the application under division 11.1.3—when the doctor is given notice of the approval; or

(b) if the application under section 260 is withdrawn—on the withdrawal of the application; or

(c) if the chief health officer refuses to approve the application and the 7-day period mentioned in section 266 (2) (Applications for review of unfavourable CHO decisions) ends without an application for review being made—at the end of the 7-day period; or

(d) if the chief health officer refers the application to the medicines advisory committee or an application is made to the committee under section 266—when the doctor is given notice of the chief health officer's decision under section 274 (Medicines advisory committee—directions to chief health officer).

Division 11.1.3 Chief health officer controlled medicines approvals

260 Applications for CHO controlled medicines approvals

(1) A designated prescriber may apply to the chief health officer for approval to prescribe a controlled medicine.

(2) An application under subsection (1)—

(a) may be made—

(i) on the applicant's own behalf; or

(ii) on the applicant's own behalf and on behalf of other named designated prescribers; or

(iii) on behalf of a group of designated prescribers that includes the applicant and who practise at the same business address; and

(b) must be for approval to prescribe a controlled medicine for a single individual; and

(c) must be made in a way determined by the chief health officer.

Example—par (a) (iii)

the doctors practising at a suburban medical practice so that if a person's usual doctor is unavailable another doctor at the practice can, under the approval, prescribe the controlled medicine

Examples—par (c)

telephone, email and fax

Note 1 An example is part of the regulation, is not exhaustive and may extend, but does not limit, the meaning of the provision in which it appears (see Legislation Act, s 126 and s 132).

Note 2 If a form is approved under the Act, s 184 for this provision, the form must be used.

(3) A determination is a notifiable instrument.

Note A notifiable instrument must be notified under the Legislation Act.

261 Requirements for CHO controlled medicines approval applications

(1) An application by a designated prescriber for an approval to prescribe a controlled medicine for a patient must include the following:

(a) the designated prescriber's name and address;

(b) if the application is made on behalf of a group of designated prescribers—the names of the designated prescribers or a description of the group;

(c) the medicine, and the form, strength and quantity of the medicine, to be prescribed;

Note For morphine or oxycodone for a terminally ill person, see s (2).

(d) the daily dose of the medicine and, if more than 1 form or strength of the medicine is to be prescribed, the dose for each form or strength;

(e) the patient's name and home address;

(f) the condition from which the patient is suffering that, in the designated prescriber's opinion, requires treatment by the medicine;

(g) whether, in the designated prescriber's opinion, based on reasonable grounds, the patient is a drug-dependent person in relation to a controlled medicine or prohibited substance.

(2) However, for subsection (1) (c), if the controlled medicine is morphine or oxycodone for a person with a terminal illness, the application may be made for all forms, strengths and quantities of the medicine.

(3) To remove any doubt, the application may include any other information the designated prescriber considers relevant.

(4) The chief health officer may ask the designated prescriber for any other information reasonably required to decide the application, including, for example, further information about the patient's treatment.

Note An example is part of the regulation, is not exhaustive and may extend, but does not limit, the meaning of the provision in which it appears (see Legislation Act, s 126 and s 132).

262 CHO decision on applications to prescribe controlled medicines

(1) On application under section 260, the chief health officer must—

(a) approve the application in the terms applied for; or

(b) approve the application in terms different from those applied for; or

Note An approval may include conditions (see s 271).

(c) refuse to approve the application; or

(d) refer the application to the medicines advisory committee.

Note For the form of a controlled medicines approval by the chief health officer, see s 272.

(2) However, the chief health officer need not decide the application if the chief health officer has asked for information under section 261 (4) and the information has not been given.

(3) For subsection (1), the chief health officer must comply with any restrictions on the chief health officer's powers under section 263.

(4) The chief health officer must give the applicant written notice of the chief health officer's decision not later than 7 days after the day the decision is made.

(5) If the decision is made under subsection (1) (b) or (c), the notice must include information about the applicant's right to seek review of the decision under section 266 (Applications for review of unfavourable CHO decisions for approvals).

263 Restrictions on CHO power to approve applications for approvals

In making a decision under section 262, the chief health officer—

(a) must comply with any applicable guidelines made under section 275 (Medicines advisory committee—guidelines for CHO decisions on approval applications); and

(b) must not approve an application to prescribe all forms, strengths and quantities of morphine or oxycodone for the treatment of a person who is terminally ill unless satisfied—

(i) a specialist has diagnosed the person as being terminally ill; and

(ii) the medicine is for use by the person for therapeutic purposes only; and

Note ***Specialist***—see the dictionary.

(c) must not approve an application to prescribe buprenorphine or methadone to treat a drug-dependent person's drug-dependency unless the applicant is—

(i) a doctor or student doctor employed at an opioid dependency treatment centre; or

(ii) a doctor who holds an endorsement under section 282 (CHO decisions on applications for endorsement to treat drug-dependency).

Note ***Doctor*** does not include student doctor (see dict).

264 Term of CHO controlled medicines approvals

A controlled medicines approval under this division is for the period (not longer than 1 year) stated in the approval.

265 Written application required for CHO oral approvals

(1) A person commits an offence if—

(a) the chief health officer gives the person a controlled medicines approval on an oral application; and

(b) the person does not give the chief health officer a written application in accordance with this division for the approval not later than 7 days after the day the approval is given.

Maximum penalty: 30 penalty units.

(2) An offence against this section is a strict liability offence.

266 Applications for review of unfavourable CHO decisions for approvals

(1) This section applies if, under section 262 (CHO decision on applications to prescribe controlled medicines), the chief health officer—

(a) approves an application for a controlled medicines approval in terms different from those applied for; or

(b) refuses to approve the application for an approval.

(2) The applicant for the approval may, not later than 7 days after the day the person receives written notice of the decision, apply to the medicines advisory committee for review of the decision.

(3) The application for review—

(a) must be in writing signed by the applicant; and

(b) must set out the grounds for the application; and

(c) may include any information that the applicant considers appropriate for the review.

267 Medicines advisory committee—referred applications and review of unfavourable CHO decisions

(1) This section applies to an application—

(a) for approval to prescribe a controlled medicine referred to the medicines advisory committee under section 262 (1) (d) (CHO decision on applications to prescribe controlled medicines); or

(b) under section 266 for review of a decision of the chief health officer on an application for a controlled medicines approval.

(2) The medicines advisory committee may, in writing, ask the applicant to give the committee further information about the treatment of the person to whom the application relates not later than a stated reasonable time.

(3) After considering the application and any further information provided in accordance with a notice under subsection (2), the medicines advisory committee must—

(a) for an application for review of a decision by the chief health officer—

(i) direct the chief health officer to confirm the decision made; or

(ii) do both of the following:

(A) direct the chief health officer to revoke the decision made;

(B) give the chief health officer a direction under paragraph (b) (i), (ii) or (iii); or

(b) direct the chief health officer—

(i) to approve the application to prescribe a controlled medicine in the terms applied for; or

(ii) to approve the application in terms different from those applied for; or

(iii) to refuse to approve the application.

Note 1 The medicines advisory committee may direct the chief health officer to include conditions in the approval (see s 271 (2)).

Note 2 The chief health officer must comply with a direction (see s 274).

(4) A direction must be in writing.

268 Amendment and revocation of controlled medicines approvals

(1) The chief health officer may amend or revoke a controlled medicines approval on the chief health officer's own initiative and without consulting the medicines advisory committee.

(2) The medicines advisory committee may direct the chief health officer to amend or revoke a controlled medicines approval, whether or not the approval was given at the direction of the committee.

Note The chief health officer must comply with a direction (see s 274).

(3) A direction under subsection (2) must be in writing.

(4) The chief health officer must give the approval-holder written notice of the chief health officer's decision not later than 7 days after the day the decision is made.

(5) If the decision is to amend or revoke a controlled medicines approval under subsection (1), the notice must include information about the approval-holder's right to seek review of the decision under section 269.

(6) In this section:

amend, a controlled medicines approval, includes imposing a condition on, or changing a condition of, the approval.

269 Application for review of amendment and revocation on CHO initiative

(1) This section applies if the chief health officer amends or revokes a controlled medicines approval under section 268 (1).

(2) The person to whom the approval was given may, not later than 7 days after the day the person is given written notice of the

amendment or revocation, apply to the medicines advisory committee for review of the decision.

(3) The application for review—

(a) must be in writing signed by the applicant; and

(b) must set out the grounds for the application; and

(c) may include any information that the applicant considers appropriate for the review.

(4) To remove any doubt, the decision to which the application relates continues to operate despite the making of the application until the day the chief health officer's decision on direction under section 270 (3) takes effect.

270 Medicines advisory committee—review of amendment or revocation decisions on CHO initiative

(1) This section applies if an application is made to the medicines advisory committee under section 269 to review a decision (the ***original decision***) of the chief health officer to amend or revoke a controlled medicines approval.

(2) The medicines advisory committee may, in writing, ask the designated prescriber to give the committee further information about the treatment of the person to whom the application relates not later than a stated reasonable time.

(3) After considering the application for review and any further information provided in accordance with a notice under subsection (2), the medicines advisory committee must direct the chief health officer to—

(a) confirm the original decision; or

(b) revoke the original decision; or

(c) revoke the original decision and approve the application as directed by the committee.

Note 1 The medicines advisory committee may direct the chief health officer to include conditions in the approval (see s 271 (2)).

Note 2 The chief health officer must comply with a direction (see s 274).

(4) A direction under subsection (3) must be in writing.

271 Conditional controlled medicines approvals

(1) The chief health officer may include conditions for the safe or proper use of a controlled medicine in a controlled medicines approval.

(2) The medicines advisory committee may direct the chief health officer to include conditions for the safe or proper use of a controlled medicine in a controlled medicines approval.

Note The chief health officer must comply with a direction (see s 274).

272 Form of CHO controlled medicines approvals

(1) A controlled medicines approval given by the chief health officer must include the following:

(a) the name of the controlled medicine to which the approval relates;

(b) the maximum quantity of the medicine that may be prescribed under the approval;

Note 1 For morphine or oxycodone for a person with a terminal illness, see s (2).

Note 2 For buprenorphine or methadone for a drug-dependent person, see s (3).

(c) the form and strength of the medicine that may be prescribed under the approval;

Note Other forms and strengths may be prescribed in accordance with s 31.

(d) the period when the medicine may be prescribed under the approval or when the approval ends;

(e) an identifying number for the approval;

(f) any condition to which the approval is subject.

(2) However, for subsection (1) (b) and (c), if the controlled medicines approval relates to the treatment of a person with a terminal illness, the approval may provide that all forms, strengths and quantities of morphine or oxycodone are approved.

(3) Also, for subsection (1) (b), if the controlled medicines approval relates to the treatment of a drug-dependent person with buprenorphine or methadone for their drug-dependency, the approval may state the maximum daily dose that may be prescribed for the person.

273 When controlled medicines approvals etc take effect

(1) A controlled medicines approval takes effect when the applicant receives notice of the approval or, if the approval states a later day, on the later day.

(2) An amendment or revocation of a controlled medicines approval takes effect when the applicant receives notice of the amendment or revocation or, if the notice of the amendment or states a later day, on the later day.

274 Medicines advisory committee—directions to CHO

(1) This section applies if the medicines advisory committee directs the chief health officer to make a decision in relation to—

(a) an application for a controlled medicines approval; or

(b) a controlled medicines approval; or

(c) an application under section 281 (Applications for CHO endorsement to treat drug-dependency).

(2) The chief health officer must—

(a) make the decision in accordance with the direction; and

(b) give the applicant or approval holder written notice of the decision not later than 7 days after the day the chief health officer makes the decision.

275 Medicines advisory committee—guidelines for CHO decisions on approval of applications

(1) The medicines advisory committee may issue guidelines for the chief health officer in relation to decisions on applications under section 260 (Applications for CHO controlled medicines approvals).

Note The chief health officer must comply with any applicable guidelines (see s 263 (a)).

(2) A guideline is a notifiable instrument.

Note A notifiable instrument must be notified under the Legislation Act.

Division 11.1.4 Endorsements to treat drug-dependency

280 Meaning of *endorsement*—div 11.1.4

In this division:

endorsement means an endorsement under section 282 (CHO decisions on applications for endorsement to treat drug-dependency) to prescribe buprenorphine and methadone to treat a drug-dependent person's drug-dependency.

281 Applications for CHO endorsement to treat drug-dependency

(1) A doctor may, in writing, apply to the chief health officer for an endorsement.

Note ***Doctor*** does not include student doctor (see dict).

(2) The application must include the following:

(a) the doctor's name and business address and telephone number;

(b) the doctor's qualifications and experience in treating drug-dependency.

Note If a form is approved under the Act, s 184 for this provision, the form must be used.

(3) The chief health officer may ask the doctor for any other information reasonably required to decide the application.

282 CHO decisions on applications for endorsement to treat drug-dependency

(1) The chief health officer must give, or refuse to give, an applicant under section 281 an endorsement.

(2) The chief health officer may give a doctor an endorsement only if satisfied that the doctor has the qualifications and experience to treat drug-dependency.

(3) An endorsement is subject to any condition included in the endorsement by the chief health officer.

(4) The chief health officer must give the doctor written notice of the chief health officer's decision not later than 7 days after the day the decision is made.

(5) If the chief health officer refuses the application, the notice must include information about the doctor's right to seek review of the decision under section 284.

283 Form of CHO endorsements to treat drug-dependency

An endorsement by the chief health officer must include the following:

(a) the doctor's name;

(b) an identifying number for the endorsement;

(c) any condition to which the endorsement is subject.

284 Medicines advisory committee—review of CHO decisions to refuse endorsements to treat drug-dependency

(1) This section applies if the chief health officer refuses to give an endorsement to an applicant under section 281.

(2) The applicant may, not later than 28 days after the day the applicant receives written notice of the decision, apply to the medicines advisory committee for review of the decision.

(3) The application for review—

(a) must be in writing signed by the applicant; and

(b) must set out the grounds for the application; and

(c) may include any information that the applicant considers appropriate for the review.

(4) The medicines advisory committee may, in writing, ask the applicant to give the committee further information that the committee reasonably needs to decide the application.

(5) After considering the application and any further information provided in accordance with a notice under subsection (4), the medicines advisory committee must—

(a) direct the chief health officer to confirm the decision made; or

(b) direct the chief health officer to revoke the decision made and approve the application as directed by the committee.

Note The chief health officer must comply with a direction (see s 274).

(6) A direction must be in writing.

Part 11.2 Appendix D medicines approvals

290 Meaning of *appendix D approval*—regulation

In this regulation:

appendix D medicines approval means—

(a) an approval under section 291; or

(b) an approval under section 293 (CHO decisions on applications to prescribe appendix D medicines).

291 Standing approvals to prescribe appendix D medicines

A doctor is approved to prescribe an appendix D medicine if—

(a) the medicine is mentioned in schedule 3, part 3.2 in relation to the doctor; and

(b) if the schedule, part 3.2, column 3 contains a restriction on the doctor prescribing the medicine—the doctor prescribes the medicine in accordance with the restriction.

Example—par (b)

If schedule 3, part 3.2, column 3 includes a condition requiring a doctor to advise a woman of child-bearing age to avoid becoming pregnant during or for a certain period after the completion of treatment, the doctor is authorised to prescribe the medicine only if the doctor gives the patient the advice.

Note 1 An example is part of the regulation, is not exhaustive and may extend, but does not limit, the meaning of the provision in which it appears (see Legislation Act, s 126 and s 132).

Note 2 ***Doctor*** does not include student doctor (see dict).

292 Applications for CHO approval to prescribe appendix D medicines

(1) A doctor may, in writing, apply to the chief health officer for approval to prescribe an appendix D medicine.

Note ***Doctor*** does not include student doctor (see dict).

(2) The application must include the following:

(a) the medicine's name;

(b) the doctor's name and business address and telephone number;

(c) if the doctor is a specialist—the specialist area in which the doctor practises;

(d) if the doctor is not a specialist—the doctor's qualifications and experience in relation to the medicine.

Note If a form is approved under the Act, s 184 for this provision, the form must be used.

(3) The chief health officer may ask the doctor for any other information reasonably required to decide the application.

293 CHO decisions on applications to prescribe appendix D medicines

(1) The chief health officer must approve, or refuse to approve, an application by a doctor under section 292 for approval to prescribe an appendix D medicine.

(2) An approval under subsection (1) to prescribe an appendix D medicine is subject to the following conditions:

(a) that the doctor complies with any conditions or restrictions in schedule 3, column 3 for the medicine;

(b) any other condition included in the approval by the chief health officer.

Example—par (a)

If schedule 3, part 3.2, column 3 includes a condition requiring a doctor to advise a woman of child-bearing age to avoid becoming pregnant during or for a certain period after the completion of treatment, the doctor is authorised to prescribe the medicine only if the doctor gives the patient the advice.

Note An example is part of the regulation, is not exhaustive and may extend, but does not limit, the meaning of the provision in which it appears (see Legislation Act, s 126 and s 132).

(3) For this section, the chief health officer—

(a) must have regard to the specialist area (if any) in which the doctor practises and the requirements (if any) stated in the medicines and poisons standard, appendix D for the medicine to which the application relates; and

(b) may have regard to anything else the chief health officer considers appropriate.

(4) The chief health officer must give the doctor written notice of the chief health officer's decision not later than 7 days after the day the decision is made.

294 Form of CHO appendix D medicines approvals

An appendix D medicines approval given by the chief health officer must include the following:

(a) the doctor's name;

(b) the name of the medicine to which the approval relates;

(c) an identifying number for the approval;

(d) any condition included in the approval by the chief health officer.

Chapter 12 Medicines licences

Part 12.1 Medicines licences generally

300 Medicines licences—Act, s 85 (2)

The following licences for medicines may be issued:

(a) a licence for medicines for first-aid kits (a ***first-aid kit licence***);

(b) a licence for a program of research or education in relation to a medicine (a ***medicines research and education program licence***);

(c) a licence for the treatment of opioid dependency with buprenorphine or methadone (an ***opioid dependency treatment licence***);

(d) a licence for the sale by retail of pharmacy medicines by a person who is not a pharmacist (a ***rural communities pharmacy medicines licence***);

(e) a licence for the supply by wholesale of a medicine (a ***medicines wholesalers licence***).

Part 12.2 First-aid kit licences

310 Applications for first-aid kit licences

(1) An application for a first-aid kit licence must be in writing signed by the applicant and include the following:

(a) the full name, address and occupation of the applicant;

(b) the full name, address and occupation of each other person proposed to be authorised to deal with a medicine under the licence;

(c) the prescription only medicines and controlled medicines (each of which are ***relevant medicines***), and the form and strength of the relevant medicines, for which the licence is sought;

Note Pharmacy medicines and pharmacist only medicines are authorised for the kit under s 0.

(d) the maximum quantity of the relevant medicines that would be possessed under the licence at any time;

(e) the situations in which it is proposed the medicines in the first-aid kit will be used;

(f) the period for which the licence is sought.

Note 1 A fee may be determined under the Act, s 183 for this section.

Note 2 If a form is approved under the Act, s 184 for this provision, the form must be used.

(2) The application must be accompanied by—

(a) evidence of the qualifications mentioned in section 311 (a) for the applicant and each person included in the application under subsection (1) (b); and

(b) a letter of support from a doctor who will provide medical direction and support to the applicant.

311 Restrictions on issuing of first-aid kit licences—Act, s 92 (1) (a)

The chief executive must not issue a first-aid kit licence to a person unless—

(a) each person to be authorised under the licence has successfully completed a course that qualifies the person to be registered as a nurse or employed as an ambulance paramedic; and

(b) the chief executive is satisfied that the person provides first-aid services to the community, for example, at a workplace or as part of a privately operated ambulance service; and

(c) the medicines to which the licence application relates are reasonably necessary to provide the first-aid services.

Note An example is part of the regulation, is not exhaustive and may extend, but does not limit, the meaning of the provision in which it appears (see Legislation Act, s 126 and s 132).

312 Authorisations under first-aid kit licences—Act, s 17 (1) (a)

(1) In this section:

authorised medicine, in relation to a first-aid kit, means—

(a) a medicine stated in the first-aid kit licence for the kit; and

(b) a pharmacy medicine and pharmacist only medicine for the kit.

(2) A first-aid kit licence authorises—

(a) the licence-holder to—

(i) issue a complying purchase order for an authorised medicine for the first-aid kit; and

Note ***Complying purchase order***—see the dictionary.

(ii) obtain an authorised medicine for the first-aid kit; and

(b) the licence-holder, and anyone else authorised to deal with a medicine by the licence, to—

(i) possess an authorised medicine as part of the first-aid kit for the emergency treatment of a person's medical condition; and

(ii) supply an authorised medicine to someone else who is authorised under the licence to administer the medicine; and

(iii) administer an authorised medicine in the first-aid kit if the person reasonably believes that the administration of the medicine is necessary for the emergency treatment of a person's medical condition.

313 Additional information for first-aid kit licences—Act, s 95 (1) (k)

(1) The following additional information is prescribed for a first-aid kit licence:

(a) the full name and residential address of each person who is authorised to deal with a medicine under the licence;

(b) the maximum quantity of each relevant medicine that may be possessed under the licence at any time;

(c) the total quantity of each relevant medicine that may be possessed during the period of the licence;

(d) the form and strength in which each relevant medicine may be obtained, possessed and administered under the licence.

(2) In this section:

relevant medicines—see section 310.

Part 12.3 Medicines research and education program licences

320 Applications for medicines research and education program licences

(1) An application for a medicines research and education program licence for a medicine must be in writing signed by the applicant and include the following:

(a) the full name, address and academic, professional or other relevant qualifications of—

(i) the person who is to supervise the program; and

(ii) the person who is to conduct the program;

(b) the name of the recognised body at or under which the program is proposed to be conducted;

Note ***Recognised body***—see the Act, dictionary.

(c) whether the program will be conducted at, or under the authority of, the recognised body;

(d) the medicine, and the form and strength of the medicine, for which the licence is sought;

(e) the maximum quantity of the medicine that would be possessed under the licence at any time;

(f) a description of the program, including an explanation of why the program can not be carried out satisfactorily without the use of the medicine;

(g) the supervision arrangements for the program;

(h) the period for which the licence is sought.

Note 1 A fee may be determined under the Act, s 183 for this section.

Note 2 If a form is approved under the Act, s 184 for this provision, the form must be used.

(2) The application must be accompanied by a written approval of the program by the person in charge of the recognised body.

321 Restrictions on issuing of medicines research and education program licences—Act, s 92 (1) (a)

The chief executive must not issue a medicines research and education program licence to a person unless—

(a) the program to which the licence relates will be conducted at, or under the authority of, a recognised body; and

(b) the program is approved by the person in charge of the recognised body; and

(c) satisfied that the program—

(i) can not be carried out without the use of the medicine to which the licence application relates; and

(ii) will be adequately supervised.

322 Authorisations under medicines research and education program licences—Act, s 17 (1) (a)

(1) A medicines research and education program licence authorises—

(a) the licence-holder to obtain the licensed medicine on a complying purchase order for the program; and

Note ***Complying purchase order***—see the dictionary.

(b) the program's supervisor, and anyone taking part in the program, to deal with the licensed medicine as authorised by the licence at the premises stated in the licence.

(2) In this section:

licensed medicine, in relation to a medicines research and education program licence, means a medicine stated in the licence.

323 Additional information for medicines research and education licences—Act, s 95 (1) (k)

The following additional information is prescribed for a medicines research and education licence:

(a) the research or education program for which the licence is issued;

(b) the name of the program's supervisor;

(c) the dealings with a medicine authorised by the licence;

(d) the maximum quantity of the medicine that may be possessed at any time for the program;

(e) the total quantity of the medicine that may be possessed for the program during the period of the licence;

(f) the form and strength of the medicine that may be obtained and possessed for the program.

Part 12.4 Opioid dependency treatment licences

330 Applications for opioid dependency treatment licences

An application for an opioid dependency treatment licence must be in writing signed by the applicant and include the applicant's full name and business address.

Note 1 A fee may be determined under the Act, s 183 for this section.

Note 2 If a form is approved under the Act, s 184 for this provision, the form must be used.

331 Restrictions on issuing of opioid dependency treatment licences—Act, s 92 (1) (a)

The chief executive must not issue an opioid dependency treatment licence to a person unless the person is a pharmacist at a community pharmacy.

332 Authorisations under opioid dependency treatment licences—Act, s 17 (1) (a)

(1) An opioid dependency treatment licence authorises the licence-holder, and any other pharmacist at the community pharmacy (the ***licensed pharmacy***) to which the licence relates, to do any of the following for the purpose of treating a person's drug-dependency:

(a) issue a complying purchase order for buprenorphine or methadone;

Note ***Complying purchase order***—see the dictionary.

(b) obtain buprenorphine or methadone on a complying purchase order;

(c) possess buprenorphine and methadone;

(d) dispense buprenorphine and methadone in accordance with a prescription;

(e) supply buprenorphine and methadone to a nurse at the licensed pharmacy for administration at the pharmacy under the supervision of a pharmacist;

Note ***Nurse*** does not include an enrolled nurse (see Legislation Act, dict, pt 1).

(f) administer buprenorphine and methadone at the licensed pharmacy in accordance with—

(i) a prescription; or

(ii) the approved opioid dependency treatment guidelines.

(2) An opioid dependency treatment licence authorises a nurse to administer buprenorphine and methadone at the licensed pharmacy under the supervision of a pharmacist and in accordance with—

(a) a prescription; or

(b) the approved opioid dependency treatment guidelines.

Note ***Nurse*** does not include an enrolled nurse (see Legislation Act, dict, pt 1).

(3) In this section:

approved opioid dependency treatment guidelines means the guidelines approved under section 380 (Guidelines for treatment of opioid dependency)

333 Statutory licence condition for opioid dependency treatment licences—Act, s 96 (d)

(1) An opioid dependency treatment licence is subject to the condition that the licence-holder must ensure that a person to whom buprenorphine or methadone is administered under the licence signs an acknowledgement that the medicine has been administered to the person.

(2) The acknowledgement must includes the following:

(a) the name of the medicine administered;

(b) the form, strength and quantity of the medicine administered;

(c) the date the medicine is administered.

334 Witnessing not required for administration under opioid dependency treatment licence—Act, s 175 (1) (a)

The Act, section 43 (e) (Registers—witnessing administration of medicines) does not apply to the administration of buprenorphine or methadone under an opioid dependency treatment licence if section 333 is complied with in relation to the administration.

Part 12.5 Rural communities pharmacy medicines licences

340 Applications for rural communities pharmacy medicines licences

An application for a rural communities pharmacy medicines licence must be in writing signed by the applicant and include the applicant's full name and business address and telephone number.

Note 1 A fee may be determined under the Act, s 183 for this section.

Note 2 If a form is approved under the Act, s 184 for this provision, the form must be used.

341 Restrictions on issuing of rural communities pharmacy medicines licences—Act, s 92 (1) (a)

The chief executive must not issue a rural communities pharmacy medicines licence to a person unless—

(a) the person is carrying on the business of selling goods by retail; and

(b) the premises from which the medicines will be sold under the licence is more than 25km by the shortest practical route to the nearest community pharmacy.

342 Authorisations under rural communities pharmacy medicines licences—Act, s 17 (1) (a)

(1) A rural communities pharmacy medicines licence authorises—

(a) the licence-holder to—

(i) issue a complying purchase order for pharmacy medicines to which the licence relates; and

Note ***Complying purchase order***—see the dictionary.

(ii) obtain the medicines on a complying purchase order; and

(iii) possess the medicines for sale by retail; and

(iv) sell the medicines by retail from the licensed premises; and

(b) an employee of the licence-holder to—

(i) possess the medicines for sale by retail from the licensed premises; and

(ii) sell the medicines by retail.

(2) In this section:

licensed premises means the premises stated in the licence.

Part 12.6 Medicines wholesalers licences

350 Applications for medicines wholesalers licences

(1) An application for a medicines wholesalers licence must be in writing signed by the applicant and include the following:

(a) the medicines to which the application relates;

(b) the full name of the applicant;

(c) the applicant's ABN (if any);

(d) if the applicant is a corporation—the corporation's ACN;

(e) the location of the premises where the applicant proposes to deal with the medicines under the licence;

(f) the security arrangements proposed for the premises;

(g) the name of an individual who is to supervise the dealings to be authorised under the licence.

Note 1 A fee may be determined under the Act, s 183 for this section.

Note 2 If a form is approved under the Act, s 184 for this provision, the form must be used.

(2) The application must be accompanied by a plan of the premises that shows—

(a) where it is proposed to store the medicines; and

(b) the location and nature of security devices.

351 Restrictions on issuing of medicines wholesalers licences—Act, s 92 (1) (a)

(1) The chief executive must not issue a medicines wholesalers licence to a person unless dealings with medicines under the licence will be supervised by an individual nominated by the applicant and approved, in writing, by the chief executive.

(2) The chief executive must not approve the nominated individual unless satisfied that the individual—

(a) is a suitable person to hold a medicines wholesalers licence; and

(b) has qualifications in chemistry, pharmacy or pharmacology or experience appropriate for the sale of medicines.

Note For changes of nominated individuals, see the Act, s 100.

(3) In this section:

suitable person, to hold a licence—see the Act, section 88.

352 Authorisations under medicines wholesalers licences—Act, s 17 (1) (a)

(1) A medicines wholesalers licence authorises the holder to do any of the following in relation to a medicine (the ***licensed medicine***) stated in the licence at the premises (the ***licensed premises***) stated in the licence:

(a) obtain a licensed medicine on a complying purchase order for sale by wholesale;

Note ***Complying purchase order***—see the dictionary.

(b) possess a licensed medicine for sale by wholesale;

(c) sell by wholesale (whether or not for resale) a licensed medicine on a complying purchase order to—

(i) a person authorised to issue a purchase order for the medicine; or

(ii) someone in another State who may obtain the medicine by wholesale under the law of the other State; or

(iii) someone in another country who may lawfully obtain the medicine by wholesale in the other country;

Note The medicines must be sold on a purchase order in accordance with s 90 (see s 353).

(d) supply a licensed medicine (other than a controlled medicine) in accordance with the medicines Australia code of conduct provisions for product starter packs.

Note ***Medicines Australia code of conduct***—see the dictionary.

(2) However, an authorisation under subsection (1) does not apply if the licence states that it does not apply.

(3) Also, subsection (1) (c) (iii) does not apply in relation to a licensed medicine that is a prohibited export under the *Customs Act 1901* (Cwlth).

353 Statutory licence conditions for medicines wholesalers licences—Act, s 96 (d)

(1) A medicines wholesalers licence is subject to the following conditions:

(a) that the dealings with medicines authorised by the licence will be carried out under the supervision of an individual approved under section 351 (1) (Restrictions on issuing of medicines wholesalers licences—Act, s 92 (1) (a));

(b) that the licence-holder complies with, and the licence-holder ensures that the licence-holder's agents and employees comply with—

(i) the Australian code of good wholesaling practice for therapeutic goods for human use; and

(ii) the medicines Australia code of conduct;

Note ***Australian code of good wholesaling practice for therapeutic goods for human use*** and ***Medicines Australia code of conduct***—see the dictionary.

(c) that medicines sold under the licence will be sold on a purchase order in accordance with section 90 (Supplying medicines on purchase orders).

(2) In this section:

suitable person, to hold a licence—see the Act, section 88.

354 Additional information for medicines wholesalers licences—Act, s 95 (1) (k)

The name of the person nominated by the licence-holder to supervise the dealings with medicines authorised by the licence is prescribed for a medicines wholesalers licence.

Chapter 13 Medicines—other provisions

Part 13.1 Opioid dependency treatment guidelines

380 Guidelines for treatment of opioid dependency

(1) The Minister may approve guidelines for the treatment of opioid dependency.

(2) Without limiting subsection (1), approved guidelines may make provision in relation to the prescribing and administration of buprenorphine and methadone to drug-dependent people.

(3) An approval is a notifiable instrument.

Note A notifiable instrument must be notified under the Legislation Act.

Part 13.2 Medicines advisory committee

Note The medicines advisory committee is established under the Act, s 179.

390 Medicines advisory committee—membership

(1) The medicines advisory committee consists of the following members appointed by the Minister:

(a) a chair;

(b) 2 other members.

Note 1 For the making of appointments (including acting appointments), see the Legislation Act, pt 19.3.

Note 2 Certain Ministerial appointments require consultation with an Assembly committee and are disallowable (see Legislation Act, div 19.3.3).

(2) A person is not eligible for appointment to the medicines advisory committee unless the person is a doctor.

Note ***Doctor*** does not include student doctor (see dict).

(3) The medicines advisory committee must include—

(a) at least 1 member who has had experience in the teaching or practice of psychiatry; and

(b) 1 member nominated by the Australian Capital Territory Branch of the Australian Medical Association.

391 Medicines advisory committee—term of appointments

(1) The appointment of a medicines advisory committee member must not be for longer than 3 years.

Note A person may be reappointed to a position if the person is eligible to be appointed to the position (see Legislation Act, s 208 and dict, pt 1, def ***appoint***).

(2) The instrument appointing, or evidencing the appointment of, a medicines advisory committee member must state whether the person is appointed as the chair or a member of the committee.

392 Medicines advisory committee—conditions of appointments

The conditions of appointment of a medicines advisory committee member are the conditions agreed between the Minister and the member, subject to any determination under the *Remuneration Tribunal Act 1995*.

393 Medicines advisory committee—time and place of meetings

(1) Meetings of the medicines advisory committee are to be held when and where the committee decides.

(2) The chair of the medicines advisory committee may at any time call a meeting.

(3) The chair must give the other members reasonable notice of the time and place of a meeting called by the chair.

(4) The medicines advisory committee may adjourn a proceeding, for any reason it considers appropriate, to a time and place decided by the committee.

394 Medicines advisory committee—presiding member

(1) The chair presides at a meeting of the medicines advisory committee.

(2) If the chair is absent, the member chosen by the members present presides.

395 Medicines advisory committee—quorum

Business may be carried out at a meeting of the medicines advisory committee only if at least 2 members are present.

396 Medicines advisory committee—voting

(1) At a meeting of the medicines advisory committee each member has a vote on each question to be decided.

(2) A question is decided by a majority of the votes of members present and voting but, if the votes are equal, the presiding member has the deciding vote.

397 Medicines advisory committee—conduct of meetings

(1) The medicines advisory committee may conduct its meetings as the committee considers appropriate.

(2) A meeting of the medicines advisory committee may be held using a method of communication, or a combination of methods of communication, that allows each member taking part to hear what each other member taking part says without the members being in each other's presence.

Examples

a phone link, a satellite link

Note An example is part of the regulation, is not exhaustive and may extend, but does not limit, the meaning of the provision in which it appears (see Legislation Act, s 126 and s 132).

(3) A medicines advisory committee member who takes part in a meeting conducted under subsection (2) is taken to be present at the meeting.

(4) A resolution is a valid resolution of the medicines advisory committee, even if it is not passed at a meeting of the committee, if all members agree to the proposed resolution in writing.

Note ***Written*** includes in electronic form (see dict).

(5) The medicines advisory committee must keep minutes of its meetings.

398 Medicines advisory committee—disclosure of interests by members

(1) If a medicines advisory committee member has a material interest in an issue being considered, or about to be considered, by the committee, the member must disclose the nature of the interest at a committee meeting as soon as possible after the relevant facts have come to the member's knowledge.

(2) The disclosure must be recorded in the medicines advisory committee's minutes and, unless the committee otherwise decides, the member must not—

(a) be present when the medicines advisory committee considers the issue; or

(b) take part in a decision of the committee on the issue.

Example

David, Emile and Fiona are members of the medicines advisory committee. They have an interest in an issue being considered at a committee meeting and they disclose the interest as soon as they become aware of it. David's and Emile's interests are minor but Fiona has a direct financial interest in the issue.

The medicines advisory committee considers the disclosures and decides that because of the nature of the interests:

- David may be present when the committee considers the issue but not take part in the decision
- Emile may be present for the consideration and take part in the decision.

The medicines advisory committee does not make a decision allowing Fiona to be present or take part in the committee's decision. Accordingly, Fiona can not be present for the consideration of the issue or take part in the decision.

Note An example is part of the regulation, is not exhaustive and may extend, but does not limit, the meaning of the provision in which it appears (see Legislation Act, s 126 and s 132).

(3) Any other medicines advisory committee member who also has a material interest in the issue must not be present when the committee is considering its decision under subsection (2).

(4) For the purposes of deciding under subsection (2) whether a member may be present when the medicines advisory committee decides the issue or take part in a decision of the committee on the issue, and despite section 395 (Medicines advisory committee—quorum), the committee may consist of 1 member.

Example

if 2 members are present at a meeting and 1 member discloses a material interest, the other member may decide whether the member who made the disclosure can take part in a decision by the committee

(5) In this section:

associate, of a person, means—

(a) the person's business partner; or

(b) a close friend of the person; or

(c) a family member of the person.

executive officer, of a corporation, means a person (however described) who is concerned with, or takes part in, the corporation's management (whether or not the person is a director of the corporation).

indirect interest—without limiting the kind of indirect interest a person may have, a person has an ***indirect interest*** in an issue if any of the following has an interest in the issue:

(a) an associate of the person;

(b) a corporation with not more than 100 members that the person, or an associate of the person, is a member of;

(c) a subsidiary of a corporation mentioned in paragraph (b);

(d) a corporation that the person, or an associate of the person, is an executive officer of;

(e) the trustee of a trust that the person, or an associate of the person, is a beneficiary of;

(f) a member of a firm or partnership that the person, or an associate of the person, is a member of;

(g) someone else carrying on a business if the person, or an associate of the person, has a direct or indirect right to participate in the profits of the business.

material interest—a medicines advisory committee member has a ***material interest*** in an issue if the member has—

(a) a direct or indirect financial interest in the issue; or

(b) a direct or indirect interest of any other kind if the interest could conflict with the proper exercise of the member's functions in relation to the committee's consideration of the issue.

399 Medicines advisory committee—ending appointments

(1) The Minister may end the appointment of a medicines advisory committee member—

(a) if the member contravenes a territory law; or

(b) for misbehaviour; or

(c) if the member becomes bankrupt or executes a personal insolvency agreement; or

(d) if the member is convicted, in the ACT, of an offence punishable by imprisonment for at least 1 year; or

(e) if the member is convicted outside the ACT, in Australia or elsewhere, of an offence that, if it had been committed in the ACT, would be punishable by imprisonment for at least 1 year; or

(f) if the member contravenes section 398 (Medicines advisory committee—disclosure of interests by members).

Note A member's appointment also ends if the member resigns (see Legislation Act, s 210).

(2) The Minister must end the appointment of a medicines advisory committee member—

(a) if the member ceases to be a doctor; or

(b) if, on 3 consecutive occasions, the member fails, without leave, to make himself or herself available for a proposed meeting of the committee; or

(c) if the member fails to take all reasonable steps to avoid being placed in a position where a conflict of interest arises during the exercise of the member's functions; or

(d) for physical or mental incapacity, if the incapacity substantially affects the exercise of the member's functions.

Chapter 14 Low and moderate harm poisons

500 Meaning of *relevant law*—ch 14

In this chapter:

relevant law means—

(a) a corresponding law; or

(b) the *Agricultural and Veterinary Chemicals Act 1994* (Cwlth); or

(c) the *Therapeutic Goods Act 1989* (Cwlth).

Note 1 ***Corresponding law*** includes a law of a State that corresponds, or substantially corresponds, to the Act (see Act, dictionary).

Note 2 ***State*** includes a territory (see Legislation Act, dict, pt 1).

501 Authorisation to manufacture low and moderate harm poisons—Act, s 17 (1) (d)

A person is authorised to manufacture a low harm poison or moderate harm poison if—

(a) the person is authorised to manufacture the poison under a relevant law; and

(b) if a condition or restriction applies to the person under the relevant law—the person manufactures the poison in accordance with each condition and restriction.

502 Packaging of supplied low and moderate harm poisons—Act, s 70 (1) (b)

A primary pack of a supplied low harm poison or moderate harm poison must be packaged—

(a) in accordance with the medicines and poisons standard, part 2 (Labels and containers), paragraphs 21 to 28; or

(b) in a container approved under the Act, section 178 (Approval of non-standard packaging and labelling by chief health officer); or

(c) in a container in which the poison may be sold under a relevant law.

503 Labelling of supplied low and moderate harm poisons—Act, s 71 (1) (b)

A primary pack of a supplied low harm poison or moderate harm poison must be labelled in accordance with—

(a) the medicines and poisons standard, part 2 (Labels and containers), paragraphs 3 to 19; or

(b) an approval under the Act, section 178 (Approval of non-standard packaging and labelling by chief health officer); or

(c) a relevant law.

Chapter 15 Dangerous poisons authorisations

Part 15.1 Overview of dangerous poisons authorisations

510 General overview of authorisations for dangerous poisons

(1) The Act requires that a person must not deal with a dangerous poison in a particular way unless the person is authorised to deal with the poison.

Example

the Act, section 32 about obtaining certain substances (which include dangerous poisons)

Note 1 Under the Act, s 16, a person ***deals*** with a dangerous poison if—

(a) the person manufactures, obtains, possesses, supplies, administers or disposes of the poison; or

(b) the person issues a purchase order for the poison; or

(c) the poison otherwise comes into, or goes out of, the person's possession.

Note 2 An example is part of the regulation, is not exhaustive and may extend, but does not limit, the meaning of the provision in which it appears (see Legislation Act, s 126 and s 132).

(2) The Act, section 17 (Meaning of *authorised*) sets out when a person is authorised to deal with a dangerous poison.

(3) This regulation—

(a) authorises certain dealings with dangerous poisons; and

(b) prescribes dealings with dangerous poisons that need not be authorised; and

(c) exempts certain regulated substances from the Act (see s 780).

Example—par (b)

the transport and delivery of a dangerous poison supplied on a purchase order (see s 521)

(4) An authorisation may be subject to limitations under this regulation.

Example

a purchase order issued by a person mentioned in schedule 4, column 2 must comply with s 581 (see s 530 (2) (c))

Note For the power to impose other limitations, see the Act, ch 6 (Restrictions on dealing with regulated substances).

511 Overview of provisions authorising dealings with dangerous poisons

(1) The following provisions of this regulation give authorisations to deal with dangerous poisons:

(a) section 530 (Particular authorisations for dangerous poisons—Act, s 17 (2) (a));

(b) chapter 16 (Dangerous poisons licences).

Part 15.2 Dangerous poisons authorisations—when not required

520 Exemption for possession of dangerous poisons—Act, s 175 (1) (a)

(1) A person is exempt from the Act, section 33 (Possession of certain part 3.2 substances) in relation to possessing a dangerous poison if—

(a) the person is authorised to obtain the poison; and

(b) the person obtains the poison from someone who is authorised to supply the poison to the person.

(2) Subsection (1) applies in relation to a person whether the dangerous poison is obtained by the person for the person's own use or as agent for someone else.

521 Exemption for transport and delivery of dangerous poisons—Act, s 175 (1) (a)

(1) This section applies to an adult (a ***delivery person***) who is—

(a) engaged to transport or deliver a dangerous poison supplied on a purchase order; or

(b) acting for a person mentioned in paragraph (a).

(2) A delivery person is exempt from the following provisions of the Act to the extent necessary to transport and deliver the dangerous poison as engaged:

(a) section 23 (Supply of part 3.2 substances);

(b) section 32 (Obtaining certain part 3.2 substances);

(c) section 33 (Possession of certain part 3.2 substances).

522 Exemption for supply of dangerous poisons to dangerous poisons suppliers licence-holder for disposal—Act, s 175 (1) (a)

A person is exempt from the Act, section 23 (Supply of part 3.2 substances) in relation to the supply of a dangerous poison to a dangerous poisons suppliers licence-holder for disposal.

Part 15.3 Dangerous poisons authorisations generally

530 Particular authorisations for dangerous poisons—Act, s 17 (2) (a)

(1) In this section:

relevant dealing, with a dangerous poison, means any of the following:

(a) obtaining the poison;

(b) possessing the poison;

(c) issuing a purchase order for the poison.

(2) A person mentioned in schedule 4 (Dangerous poisons—particular authorisations), column 2, is authorised for a relevant dealing with a dangerous poison mentioned in column 3 in relation to the person if—

(a) the poison is for the purpose mentioned in column 4 in relation to the person; and

(b) the dealing is consistent with any condition or restriction for the dealing mentioned in the schedule, column 3; and

(c) if the dealing is issuing a purchase order for the poison—the purchase order complies with section 581 (Requirements for dangerous poisons purchase orders).

Note A purchase order must be in writing (see Act, dict, def ***purchase order***).

531 Restrictions on wholesalers under corresponding laws supplying dangerous poisons—Act, s 17 (4) (b)

A person (the ***seller***) who is authorised under the Act, section 17 (4) (Meaning of *authorised*) to supply a dangerous poison by wholesale must not supply the poison to someone else (the ***buyer***) unless—

(a) the buyer is authorised to possess the poison; and

(b) the supply is in accordance with section 580 (Supplying dangerous poisons on purchase orders); and

(c) the poison is supplied for a non-household (including a non-household garden) purpose only; and

(d) if the poison is liquid containing paraquat—the poison is coloured blue or green and has an offensive smell.

Note 1 A purchase order must be in writing (see Act, dict, def ***purchase order***).

Note 2 See s 582 to s 585 for other requirements in relation to supply of dangerous poisons on purchase orders.

Chapter 16 Dangerous poisons licences

Part 16.1 Dangerous poisons licences generally

540 Kinds of dangerous poisons licences—Act, s 85 (2)

The following licences for dangerous poisons may be issued:

(a) a licence for the manufacture of a dangerous poison (a ***dangerous poisons manufacturers licence***);

(b) a licence for a program of research or education in relation to a dangerous poison (a ***dangerous poisons research and education program licence***);

(c) a licence for the supply of dangerous poisons (a ***dangerous poison suppliers licence***).

Part 16.2 Dangerous poisons manufacturers licences

550 Applications for dangerous poisons manufacturers licences

(1) An application for a dangerous poisons manufacturers licence must be in writing signed by the applicant and include the following:

(a) the dangerous poisons to which the application relates;

(b) the full name of the applicant;

(c) the applicant's ABN (if any);

(d) if the applicant is a corporation—the corporation's ACN;

(e) the location of the premises where the applicant proposes to deal with the poisons under the licence;

(f) the security arrangements proposed for the premises;

(g) the name of an individual who is to supervise the dealings to be authorised under the licence.

Note 1 A fee may be determined under the Act, s 183 for this section.

Note 2 If a form is approved under the Act, s 184 for this provision, the form must be used.

(2) The application must be accompanied by a plan of the premises that shows—

(a) each part of the premises where a process in the manufacture of the dangerous poisons is proposed to be carried out and the nature of the process; and

(b) where it is proposed to store the dangerous poisons to which the application relates and any other dangerous poisons obtained for the manufacture of those dangerous poisons; and

(c) the location and nature of security devices.

551 Restrictions on issuing of dangerous poisons manufacturers licences—Act, s 92 (1) (a)

(1) The chief executive must not issue a dangerous poisons manufacturers licence to a person unless dealings with dangerous poisons under the licence will be supervised by an individual nominated by the applicant and approved, in writing, by the chief executive.

(2) The chief executive must not approve the nominated individual unless satisfied that the individual—

(a) is a suitable person to hold a dangerous poisons manufacturers licence; and

(b) has qualifications in chemistry, pharmacy or pharmacology or experience appropriate for the manufacture of dangerous poisons.

Note For changes of nominated individuals, see the Act, s 100.

(3) In this section:

suitable person, to hold a licence—see the Act, section 88.

552 Authorisations under dangerous poisons manufacturers licences—Act, s 17 (1) (b)

(1) A dangerous poisons manufacturers licence authorises the holder to do any of the following in relation to a dangerous poison (the ***licensed dangerous poison***) stated in the licence at the premises (the ***licensed premises***) stated in the licence:

(a) manufacture a licensed dangerous poison;

(b) possess a licensed dangerous poison for sale by wholesale;

(c) sell by wholesale (whether or not for resale) a licensed dangerous poison on a complying purchase order to—

(i) a person authorised to issue a purchase order for the dangerous poison; or

(ii) someone in another State who may obtain the dangerous poison under the law of the other State; or

(iii) someone in another country who may lawfully obtain the dangerous poison in the other country;

Note The dangerous poisons must be sold on a purchase order in accordance with s 580 (see s 553).

(d) obtain a dangerous poison, other than a licensed dangerous poison, on a complying purchase order for manufacturing a licensed dangerous poison at the licensed premises;

Note ***Complying purchase order***—see the dictionary.

(e) possess a dangerous poison, other than a licensed dangerous poison, at the licensed premises for manufacturing a licensed dangerous poison.

(2) However, an authorisation under subsection (1) does not apply if the licence states that it does not apply.

(3) Also, subsection (1) (c) (iii) does not apply in relation to a licensed dangerous poison that is a prohibited export under the *Customs Act 1901* (Cwlth).

553 Statutory licence conditions for dangerous poisons manufacturers licences—Act, s 96 (d)

(1) A dangerous poisons manufacturers licence is subject to the following conditions:

(a) that the dealings with dangerous poisons authorised by the licence will be carried out under the supervision of an individual approved under section 551 (1) (Restrictions on issuing of dangerous poisons manufacturers licences—Act, s 92 (1) (a));

(b) that dangerous poisons sold under the licence will be sold on a purchase order in accordance with section 580 (Supplying dangerous poisons on purchase orders);

(c) that licensed dangerous poisons will be supplied for a non-household (including a non-household garden) purpose only;

(d) if a licensed dangerous poison is liquid containing paraquat—the poison is coloured blue or green and has an offensive smell.

(2) In this section:

suitable person, to hold a licence—see the Act, section 88.

554 Additional information for dangerous poisons manufacturers licences—Act, s 95 (1) (k)

The name of the person nominated by the licence-holder to supervise the dealings with dangerous poisons authorised by the licence is prescribed for a dangerous poisons manufacturers licence.

Part 16.3 Dangerous poison research and education program licences

560 Applications for dangerous poisons research and education program licences

(1) An application for a dangerous poisons research and education program licence for a dangerous poison must be in writing signed by the applicant and include the following:

(a) the full name, address and academic, professional or other relevant qualifications of—

(i) the person who is to supervise the program; and

(ii) the person who is to conduct the program;

(b) the name of the recognised body at or under which the program is proposed to be conducted;

Note ***Recognised body***—see the Act, dictionary.

(c) whether the program will be conducted at, or under the authority of, the recognised body;

(d) the dangerous poison, and the form and strength of the poison, for which the licence is sought;

(e) the maximum quantity of the dangerous poison that would be possessed under the licence at any time;

(f) a description of the program, including an explanation of why the program can not be carried out satisfactorily without the use of the dangerous poison;

(g) the supervision arrangements for the program;

(h) the period for which the licence is sought.

Note 1 A fee may be determined under the Act, s 183 for this section.

Note 2 If a form is approved under the Act, s 184 for this provision, the form must be used.

(2) The application must be accompanied by a written approval of the program by the person in charge of the recognised body.

561 Restrictions on issuing of dangerous poisons research and education program licences—Act, s 92 (1) (a)

The chief executive must not issue a dangerous poisons research and education program licence to a person unless—

(a) the program to which the licence relates will be conducted at, or under the authority of, a recognised body; and

(b) the program is approved by the person in charge of the recognised body; and

(c) satisfied that the program—

(i) can not be carried out without the use of the dangerous poison to which the licence application relates; and

(ii) will be adequately supervised.

562 Authorisations under dangerous poisons research and education program licences—Act, s 17 (1) (a)

(1) A dangerous poisons research and education program licence authorises—

(a) the licence-holder to obtain the licensed dangerous poison on a complying purchase order for the program; and

Note ***Complying purchase order***—see the dictionary.

(b) the program's supervisor, and anyone taking part in the program, to deal with the licensed dangerous poison as authorised by the licence at the premises stated in the licence.

(2) In this section:

licensed dangerous poison, in relation to a dangerous poisons research and education program licence, means a dangerous poison stated in the licence.

563 Additional information for dangerous poisons research and education licences—Act, s 95 (1) (k)

The following additional information is prescribed for a dangerous poisons research and education licence:

(a) the research or education program for which the licence is issued;

(b) the name of the program's supervisor;

(c) the dealings with a dangerous poison authorised by the licence;

(d) the maximum quantity of the dangerous poison that may be possessed at any time for the program;

(e) the total quantity of the dangerous poison that may be possessed for the program during the period of the licence;

(f) the form and strength of the dangerous poison that may be obtained and possessed for the program.

Part 16.4 Dangerous poisons suppliers licences

570 Applications for dangerous poisons suppliers licences

(1) An application for a dangerous poisons suppliers licence must be in writing signed by the applicant and include the following:

(a) the dangerous poisons to which the application relates;

(b) the full name of the applicant;

(c) the applicant's ABN (if any);

(d) if the applicant is a corporation—the corporation's ACN;

(e) the location of the premises where the applicant proposes to deal with the poisons under the licence;

(f) the security arrangements proposed for the premises;

(g) the name of an individual who is to supervise the dealings to be authorised under the licence.

Note 1 A fee may be determined under the Act, s 183 for this section.

Note 2 If a form is approved under the Act, s 184 for this provision, the form must be used.

(2) The application must be accompanied by a plan of the premises that shows—

(a) where it is proposed to store the dangerous poisons; and

(b) the location and nature of security devices.

571 Restrictions on issuing of dangerous poisons suppliers licences—Act, s 92 (1) (a)

(1) The chief executive must not issue a dangerous poisons suppliers licence to a person unless dealings with dangerous poisons under the licence will be supervised by an individual nominated by the applicant and approved, in writing, by the chief executive.

(2) The chief executive must not approve the nominated individual unless satisfied that the individual—

(a) is a suitable person to hold a dangerous poisons suppliers licence; and

(b) has qualifications in chemistry, pharmacy or pharmacology or experience appropriate for the sale of dangerous poisons.

Note For changes of nominated individuals, see the Act, s 100.

(3) In this section:

suitable person, to hold a licence—see the Act, section 88.

572 Authorisations under dangerous poisons suppliers licences—Act, s 17 (1) (b)

(1) A dangerous poisons suppliers licence authorises the holder to do any of the following in relation to a dangerous poison (the ***licensed dangerous poison***) stated in the licence at the premises (the ***licensed premises***) stated in the licence:

(a) obtain a licensed dangerous poison on a complying purchase order for the purpose of sale;

Note ***Complying purchase order***—see the dictionary.

(b) possess a licensed dangerous poison for the purpose of sale;

(c) sell a licensed dangerous poison on a purchase order to—

(i) a person authorised to issue a purchase order for the dangerous poison; or

(ii) someone in another State who may obtain the dangerous poison under the law of the other State; or

(iii) someone in another country who may lawfully obtain the dangerous poison in the other country.

Note The dangerous poisons must be sold on a purchase order in accordance with s 580 (see s 573).

(2) However, an authorisation under subsection (1) does not apply if the licence states that it does not apply.

(3) Also, subsection (1) (c) (iii) does not apply in relation to a licensed dangerous poison that is a prohibited export under the *Customs Act 1901* (Cwlth).

573 Statutory licence conditions for dangerous poisons suppliers licences—Act, s 96 (d)

(1) A dangerous poisons suppliers licence is subject to the following conditions:

(a) that the dealings with dangerous poisons authorised by the licence will be carried out under the supervision of an individual approved under section 571 (1) (Restrictions on issuing of dangerous poisons suppliers licences—Act, s 92 (1) (a));

(b) that dangerous poisons supplied under the licence will be supplied on a purchase order in accordance with section 580 (Supplying dangerous poisons on purchase orders);

(c) that licensed dangerous poisons will be supplied for a non-household (including a non-household garden) purpose only;

(d) if the dangerous poison is subject to the medicines and poisons standard, appendix J (Conditions for availability and use of schedule 7 poisons), condition 3—that the poison will be supplied only to a person who is allowed to use the poison under the condition;

(e) if a licensed dangerous poison is liquid containing paraquat—the poison is coloured blue or green and has an offensive smell.

(2) In this section:

licensed dangerous poison—see section 572.

Chapter 17 Dangerous poisons—other provisions

Part 17.1 Supplying dangerous poisons on purchase orders

580 Supplying dangerous poisons on purchase orders

A person may supply a dangerous poison on a purchase order to someone else (the ***buyer***) only if—

(a) the purchase order complies with section 581; and

(b) the dangerous poison is supplied in primary packs that comply with section 591 (Packaging of supplied primary packs of dangerous poisons—Act, s 49 (1) (b)); and

(c) the primary packs are labelled in accordance with section 592 (Labelling supplied dangerous poisons—Act, s 50 (1) (b)); and

(d) the primary packs are securely wrapped and packed; and

(e) if the dangerous poison is personally delivered to the buyer by the supplier—the delivery is acknowledged by the adult taking delivery by signing and dating a copy of the purchase order; and

(f) if the dangerous poison is not personally delivered to the buyer by the supplier—the dangerous poison is delivered to the buyer by a person whose procedures require the delivery of the dangerous poison to be signed for by the buyer or an adult employee of the buyer.

581 Requirements for dangerous poisons purchase orders

(1) A purchase order for a dangerous poison must be—

(a) signed by the person (the ***issuer***) issuing the order; and

Note The purchase order must be signed with the issuer's usual signature (see Act, dict, def ***signs***).

(b) if the issuer amends the order—initialed and dated by the issuer beside the amendment.

(2) A purchase order for a dangerous poison must include the following:

(a) the issuer's name and business address and telephone number;

(b) the issuer's authority to issue the order;

(c) the dangerous poison, and the form, strength and quantity of the poison, to be supplied on the order.

582 Recording supply of dangerous poisons on purchase orders—Act, s 28 (a), s 29 (1) (a) and (b)

(1) A person who supplies a dangerous poison to someone else on a purchase order must make a written record of the following information:

(a) the date of the order;

(b) the name, and the business address and telephone number, of the person to whom the dangerous poison is supplied;

(c) the date the order is supplied;

(d) the dangerous poison, and the form, strength and quantity of the poison, supplied.

Note ***Written*** includes in electronic form (see dict).

(2) The person in charge of the business that filled the purchase order must ensure that the record of the supply of the dangerous poison is kept.

Note The record must be kept for at least 2 years (see Act, s 29 (1) (c)).

583 Delivery acknowledgement required for certain dangerous poisons purchased on purchase orders

(1) A person (the ***buyer***) commits an offence if—

(a) the buyer obtains a dangerous poison on a purchase order; and

(b) the supplier does not personally deliver the dangerous poison to the buyer; and

(c) the buyer fails to send the supplier, not later than 24 hours after the buyer receives the dangerous poison, a document signed by the buyer acknowledging receipt of the dangerous poison.

Maximum penalty: 30 penalty units.

(2) A person (the ***supplier***) commits an offence if—

(a) the supplier supplies a dangerous poison to a person (the ***buyer***) on a purchase order; and

(b) the supplier does not personally deliver the dangerous poison to the buyer; and

(c) the supplier does not, not later than 7 days after the day the dangerous poison is delivered to the buyer, receive a document signed by the buyer acknowledging receipt of the dangerous poison; and

(d) the supplier does not, within 24 hours after the end of the 7-day period, tell the chief health officer, in writing, of the failure to receive the receipt for the delivery of the dangerous poison.

Maximum penalty: 30 penalty units.

(3) An offence against this section is a strict liability offence.

584 Keeping delivery acknowledgements for certain dangerous poisons purchased on purchase orders—Act, s 29 (1) (b)

A document acknowledging delivery of a dangerous poison is prescribed.

585 Keeping filled purchase orders for dangerous poisons—Act, s 52 (1) (a) and (2) (a)

Dangerous poisons are prescribed.

Note The effect of this section is that filled purchase orders for dangerous poisons must be kept at the supplier's business premises for at least 2 years after the day the order is filled.

Part 17.2 Packaging and labelling of dangerous poisons

590 Meaning of *relevant law*—pt 17.2

In this part:

relevant law means—

(a) a corresponding law; or

(b) the *Agricultural and Veterinary Chemicals Act 1994* (Cwlth); or

(c) the *Therapeutic Goods Act 1989* (Cwlth).

Note 1 ***Corresponding law*** includes a law of a State that corresponds, or substantially corresponds, to the Act (see Act, dictionary).

Note 2 ***State*** includes a territory (see Legislation Act, dict, pt 1).

591 Packaging of supplied dangerous poisons—Act, s 49 (1) (b)

A primary pack of a supplied dangerous poison must be packaged—

(a) in accordance with the medicines and poisons standard, part 2 (Labels and containers), paragraphs 21 to 28; or

(b) in a container approved under the Act, section 178 (Approval of non-standard packaging and labelling by chief health officer); or

(c) in a container in which the poison may be sold under a relevant law.

592 Labelling of supplied dangerous poisons—Act, s 50 (1) (b)

A primary pack of supplied dangerous poison must be labelled in accordance with—

(a) the medicines and poisons standard, part 2 (Labels and containers), paragraphs 3 to 19; or

(b) an approval under the Act, section 178 (Approval of non-standard packaging and labelling by chief health officer); or

(c) a relevant law.

Part 17.3 Storage of dangerous poisons

600 Storage of dangerous poisons—Act, s 51 (b) and (c)

(1) A person mentioned in table 610 (Keeping dangerous poisons registers), column 2 who possess a dangerous poison is prescribed.

(2) The dangerous poison must be kept—

(a) in a part of the premises to which the public does not have access; and

(b) so that only the prescribed person, or an employee of the prescribed person under the supervision of the prescribed person, has access to the poison.

Part 17.4 Dangerous poisons registers

610 Keeping of dangerous poisons registers by certain people—Act, s 38 and s 40 (b)

(1) A person mentioned in table 610, column 2 who possesses a dangerous poison is prescribed.

(2) A person prescribed under subsection (1) must keep a dangerous poisons register for a dangerous poison for which the person is prescribed at the place prescribed in table 610, column 3 for the person.

Table 610 Keeping dangerous poisons registers

column 1 item	column 2 prescribed person	column 3 place where register to be kept
1	approved analyst	the analyst's laboratory
2	dangerous poisons manufacturers licence-holder	the licensed premises under section 552
3	dangerous poisons suppliers licence-holder	the licensed premises under section 572
4	medicines and poisons inspector (other than police officer)	the place directed by the chief health officer
5	person authorised under the Act, section 17 (4) (Meaning of *authorised*) to supply a dangerous poison by wholesale	the person's business premises

column 1 item	column 2 prescribed person	column 3 place where register to be kept
6	person mentioned in schedule 4 (Dangerous poisons—particular manufacturing authorisations), column 2	the person's business premises
7	supervisor under dangerous poisons research and education program licence	the premises where program is being conducted

611 Not keeping dangerous poisons registers—Act, s 39 (b)

(1) A dangerous poisons register must be kept—

(a) in English; and

(b) in writing; and

(c) in a way that is easily retrievable.

Note ***Written*** includes in electronic form (see dict).

(2) Each page in a dangerous poisons register must relate to a single form and strength of a dangerous poison.

612 Making entries in dangerous poisons registers—Act, s 41 (1) (b)

(1) The following details for a dealing with a dangerous poison are prescribed:

(a) the nature of the dealing;

(b) the date of the dealing;

(c) the dangerous poison, and the form, strength and quantity of the poison, dealt with;

(d) if the dealing is receiving the poison—the name and address of the supplier;

(e) if the dealing is supplying the poison—the name and address of the person to whom it is supplied;

(f) if the poison is supplied on a purchase order—the date of the purchase order;

(g) if the dealing is disposing of the poison—the signature of the person who disposed of the poison;

(h) the quantity of the poison held after the dealing.

(2) A dealing with a dangerous poison must be entered in the dangerous poisons register the person must keep.

613 Prescribed witnesses for disposal of dangerous poisons—Act, s 44 (a) and (b)

An adult is prescribed as a witness in relation to the disposal of a dangerous poison.

614 Changes etc to entries in dangerous poisons registers—Act, s 45 (2) (b)

(1) An entry in a paper-based dangerous poisons register may be amended by the person who made the entry by—

(a) the person signing and dating a marginal note or footnote that gives the date of the amendment and the amended details; and

(b) if the entry relates to disposing of a dangerous poison—the amendment being witnessed by a person mentioned in section 613.

(2) An entry in an electronic dangerous poisons register may be amended by the person who made the entry by the person attaching or linking, by electronic means, a document (the ***correcting document***) that includes—

(a) the person's signature, the date and the amended details; and

(b) if the entry relates to disposing of a dangerous poison—the signature as witness of a person mentioned in section 613.

Chapter 18 Paints

650 Manufacture, supply and use of paints containing white lead—Act, s 78 (2)

A paint containing basic lead carbonate (white lead) may be manufactured, supplied or used for application as a mirror backing if the paint—

(a) contains no more than 15% lead in the non-volatile content of the paint; and

(b) is applied no more than 40µm thick; and

Note ***µm*** is the symbol for micrometer.

(c) is covered by a paint that does not contain lead.

651 Manufacture, supply and use of paints for certain purposes—Act, s 79 (1) and (3)

(1) A first schedule paint must not be manufactured, supplied or used for application to—

(a) a roof or other surface to be used for the collection or storage of potable water; or

(b) furniture; or

(c) a fence, wall, post, gate or building (including the interior of a building), other than a building that is used only for industrial purposes or mining or as an oil terminal; or

(d) premises used for the manufacture, processing, preparation, packing or serving of products intended for human or animal consumption.

Note ***First schedule paint***—see the medicines and poisons standard, pt 1, par 1 (1).

(2) A third schedule paint must not be manufactured, supplied or used for application to—

(a) a roof or other surface to be used for the collection or storage of potable water; or

(b) furniture; or

(c) a fence, wall, post, gate, building (including the interior of a building), bridge, pylon, pipeline, storage tank or similar structure; or

(d) premises, equipment or utensils used for the manufacture, processing, preparation, packing or serving of products intended for human or animal consumption.

Note ***Third schedule paint***—see the medicines and poisons standard, pt 1, par 1 (1).

652 Manufacture, supply and use of paints for toys—Act, s 80 (2)

A paint that complies with the specification for coating materials in Australian Standard 1647, *Childrens Toys (Safety Requirements)*, part 3, as in force from time to time, may be manufactured, supplied or used for application to toys.

653 Manufacture, supply and use of paints containing pesticides—Act, s 81 (2)

The following pesticides are prescribed:

(a) an algicide;

(b) an antifouling agent;

(c) a bactericide;

(d) a fungicide.

Note ***Pesticide***—see the medicines and poisons standard, pt 1, par 1 (1).

Chapter 19 Prohibited and appendix C substances

Part 19.1 Preliminary

700 Meaning of *prohibited substance*—ch 19

In this chapter:

prohibited substance includes an appendix C substance.

Note ***Appendix C substance*** and ***prohibited substance***—see the Act, s 15.

701 Prohibited substances licences—Act, s 85 (2)

A licence for a program of research or education in relation to a prohibited substance (a ***prohibited substances research and education program licence***) may be issued.

Part 19.2 Prohibited substances research and education program licences

Division 19.2.1 Issue of prohibited substances research and education program licences

710 Applications for prohibited substances research and education program licences

(1) An application for a prohibited substances research and education program licence for a prohibited substance must be in writing signed by the applicant and include the following:

(a) the full name, address and academic, professional or other relevant qualifications of—

(i) the person who is to supervise the program; and

(ii) the person who is to conduct the program;

(b) the name of the recognised body at or under which the program is proposed to be conducted;

Note ***Recognised body***—see the Act, dictionary.

(c) whether the program will be conducted at, or under the authority of, the recognised body;

(d) the prohibited substance, and the form and strength of the substance, for which the licence is sought;

(e) the maximum quantity of the prohibited substance that would be possessed under the licence at any time;

(f) a description of the program, including an explanation of why the program can not be carried out satisfactorily without the use of the prohibited substance;

(g) the supervision arrangements for the program;

(h) the period for which the licence is sought.

Note 1 A fee may be determined under the Act, s 183 for this section.

Note 2 If a form is approved under the Act, s 184 for this provision, the form must be used.

(2) The application must be accompanied by a written approval of the program by the person in charge of the recognised body.

711 Restrictions on issuing of prohibited substances research and education program licences— Act, s 92 (1) (a)

The chief executive must not issue a prohibited substances research and education program licence to a person unless—

(a) the program to which the licence relates will be conducted at, or under the authority of, a recognised body; and

(b) the program is approved by the person in charge of the recognised body; and

(c) satisfied that the program—

(i) can not be carried out without the use of the prohibited substance to which the licence application relates; and

(ii) will be adequately supervised.

712 Authorisations under prohibited substances research and education program licences—Act, s 17 (1) (a)

(1) A prohibited substances research and education program licence authorises—

(a) the licence-holder to obtain the licensed prohibited substance on a complying purchase order for the program; and

Note ***Complying purchase order***—see the dictionary.

(b) the program's supervisor, and anyone taking part in the program, to deal with the licensed prohibited substance as authorised by the licence at the premises stated in the licence.

(2) In this section:

licensed prohibited substance, in relation to a prohibited substances research and education program licence, means a prohibited substance stated in the licence.

713 Additional information for prohibited substances research and education licences—Act, s 95 (1) (k)

The following additional information is prescribed for a prohibited substances research and education licence:

(a) the research or education program for which the licence is issued;

(b) the name of the program's supervisor;

(c) the dealings with a prohibited substance authorised by the licence;

(d) the maximum quantity of the prohibited substance that may be possessed at any time for the program;

(e) the total quantity of the prohibited substance that may be possessed for the program during the period of the licence;

(f) the form and strength of the prohibited substance that may be obtained and possessed for the program.

Division 19.2.2 Other provisions—prohibited substances research and education program licences

720 Approvals of dealings for prohibited substances research and education program licences—Act, s 17 (1) (c)

(1) In this section:

relevant dealing, with a prohibited substance for a prohibited substances research and education program licence, means any of the following:

(a) obtaining the substance;

(b) possessing the substance;

(c) issuing a purchase order for the substance;

(d) supplying the substance on a purchase order to the licence-holder.

(2) The chief executive may approve a person (the ***supplier***) for a relevant dealing with a prohibited substance to which a prohibited substances research and education program licence relates.

(3) An approval—

(a) must be in writing; and

(b) may be conditional; and

(c) may apply for a stated period or until a stated event happens.

721 Information for CHO about supplied prohibited substances research and education program licences—Act, s 30 (2) (a) and (b) and (3)

(1) This section applies if a person supplies a prohibited substance to a prohibited substances research and education program licence-holder.

(2) The person must, not later than 7 days after the end of the month when the prohibited substance is supplied, give the chief health officer the following information in writing:

(a) the person's name and business address and telephone number;

(b) the name and address of the person to whom the substance is supplied;

(c) the date of supply;

(d) the prohibited substance, and the form, strength and quantity of the substance, supplied.

Part 19.3 Prohibited substances registers

730 Keeping of prohibited substances registers by certain people—Act, s 38 and s 40 (b)

(1) A person mentioned in table 730, column 2 who possesses a prohibited substance is prescribed.

(2) A person prescribed under subsection (1) must keep a prohibited substances register for a prohibited substance for which the person is prescribed at the place prescribed in table 730, column 3 for the person.

Table 730 Keeping prohibited substances registers

column 1 item	column 2 prescribed person	column 3 place where register to be kept
1	approved analyst	the analyst's laboratory
2	medicines and poisons inspector (other than police officer)	the place directed by the chief health officer
3	supervisor under prohibited substances research and education program licence	the premises where program is being conducted

731 Not keeping prohibited substances registers—Act, s 39 (b)

(1) A prohibited substances register must be kept—

(a) in English; and

(b) in writing; and

(c) in a way that is easily retrievable.

Note ***Written*** includes in electronic form (see dict).

(2) Each page in a prohibited substances register must relate to a single form and strength of a prohibited substance.

732 Making entries in prohibited substances registers—Act, s 41 (1) (b)

(1) The following details for a dealing with a prohibited substance are prescribed:

(a) the nature of the dealing;

(b) the date of the dealing;

(c) the prohibited substance, and the form, strength and quantity of the substance, dealt with;

(d) if the dealing is receiving the substance—the name and address of the supplier;

(e) if the dealing is supplying the substance—the name and address of the person to whom it is supplied;

(f) if the dealing is disposing of the prohibited substance—the signature of the person who disposed of the substance;

(g) the quantity of the substance held after the dealing.

(2) A dealing with a prohibited substance must be entered in the prohibited substances register the person must keep.

733 Prescribed witnesses for disposal of prohibited substances—Act, s 44 (a) and (b)

The following people are prescribed as witnesses in relation to the disposal of a prohibited substance:

(a) an approved analyst;

(b) a medicines and poisons inspector.

Note ***Approved analyst***—see the dictionary.

734 Changes etc to entries in prohibited substances registers—Act, s 45 (2) (b)

(1) An entry in a paper-based prohibited substances register may be amended by the person who made the entry by—

(a) the person signing and dating a marginal note or footnote that gives the date of the amendment and the amended details; and

(b) if the entry relates to disposing of a prohibited substance—the amendment being witnessed by a person prescribed under section 613.

(2) An entry in an electronic prohibited substances register may be amended by the person who made the entry by the person attaching or linking, by electronic means, a document (the ***correcting document***) that includes—

(a) the person's signature, the date and the amended details; and

(b) if the entry relates to disposing of a prohibited substance—the signature as witness of a person prescribed under section 613.

Chapter 20 Review of administrative decisions

750 Decisions reviewable by AAT

(1) A person mentioned in table 750, column 3 may apply to the administrative appeals tribunal for review of a decision by the chief executive mentioned in column 2 for the person.

(2) A person who is refused an approval under section 220 (3) to store a controlled medicine in a safe or strongroom may apply to the administrative appeals tribunal for review of the chief health officer's decision.

Table 750 Chief executive decisions reviewable by AAT

column 1 item	column 2 decision	column 3 affected person
1	section 351 (1)—refuse approval of nominated individual for medicines wholesales licence	applicant for licence
2	section 551 (1)—refuse approval of nominated individual for dangerous poisons manufacturers licence	applicant for licence
3	section 571 (1)—refuse approval of nominated individual for dangerous poisons suppliers licence	applicant for licence

751 Notice of reviewable decisions

(1) The chief executive must give written notice of a decision mentioned in table 750, column 2 to the affected person mentioned in column 3 for the decision.

(2) The chief health officer must give written notice of a decision mentioned in section 750 (2) to the applicant for the approval.

(3) A notice under subsection (1) or (2) must be in accordance with the requirements of the code of practice in force under the *Administrative Appeals Tribunal Act 1989*, section 25B (1).

Chapter 21 Exemptions from Act

780 Exempt regulated substances—Act, s 175 (1) (a)

The Act does not apply to a medicine or poison—

(a) in a product mentioned in the medicines and poisons standard, appendix A (General exemptions); or

(b) to which the drugs and poisons standard, appendix G (Dilute preparations) applies.

Note The drugs and poisons standard, appendix B (Substance considered not to require control by scheduling) lists substances that have not been included in any of the schedules to the standard. As such, the substances are not regulated substances (see Act, s 12).

Chapter 22 Miscellaneous

800 Regulated substances—authorisations for approved analysts

To the extent necessary to exercise a function under a law of the Commonwealth, the Territory or a State and, if employed, within the scope of employment, an approved analyst is authorised to do any of the following:

(a) issue a purchase order for a regulated substance;

(b) obtain a regulated substance;

(c) manufacture a regulated substance;

(d) possess a regulated substance;

(e) supply a regulated substance to a person authorised to obtain the substance.

Note 1 ***Approved analyst***—see the dictionary.

Note 2 ***State*** includes a territory (see Legislation Act, dict, pt 1).

801 Regulated substances—authorisations for medicines and poisons inspectors

To the extent necessary to exercise a function under the Act and within the scope of employment, a medicines and poisons inspector is authorised to do any of the following:

(a) obtain a regulated substance;

(b) possess a regulated substance;

(c) supply a regulated substance to a person authorised to obtain the substance.

802 Certain containers not to be used for human use substances—Act, 75 (1) (b)

A container of a kind mentioned in the medicines and poisons standard, part 2 (Labels and containers), paragraph 21, paragraph 22 or paragraph 23 is prescribed.

803 Disapplication of Legislation Act, s 47 (6)—Act, s 180 (1) (h)

The following are prescribed:

(a) Australian code of good wholesaling practice for therapeutic goods for human use;

(b) Australian Standard 1647, *Childrens Toys (Safety Requirements)*;

(c) medicines Australia code of conduct;

(d) the shared care model between the Optometrists Registration Board under the *Optometrists Act 1930* (NSW), the Australian and New Zealand College of Ophthalmologists and the School of Vision Science, University of New South Wales.

Note 1 ***Australian code of good wholesaling practice for therapeutic goods for human use*** and ***Medicines Australia code of conduct***—see the dictionary.

Note 2 ***Shared care model***—see sch 2 (Optometry medicines), table 2.2.

Note 3 The text of an applied, adopted or incorporated instrument, whether applied as in force from time to time or at a particular time, is taken to be a notifiable instrument if the operation of the Legislation Act, s 47 (5) or (6) is not disapplied (see s 47 (7)).

Note 4 A reference to an Act includes a reference to the statutory instruments made or in force under the Act, including any regulation (see Legislation Act, s 104).

Schedule 1 Medicines—particular authorisations

(see s 30, s 60 and s 140)

Part 1.1 Ambulance services and officers

column 1 item	column 2 person authorised	column 3 authorisation
1	ambulance officer employed by Commonwealth, Territory or State	in course of employment, do any of the following: (a) obtain medicines; (b) possess medicines; (c) administer medicines.
2	ambulance service operated by Commonwealth, Territory or State—person in charge of ambulance service	in course of employment, do any of the following: (a) issue purchase orders for medicines; (b) obtain medicines mentioned in paragraph (a); (c) possess medicines mentioned in paragraph (a); (d) supply medicines to ambulance officers in ambulance service.

Part 1.2 Child residential and correctional centres

column 1 item	column 2 person authorised	column 3 authorisation
1	child residential centre employee correctional centre employee	within the scope of employment, and for medicines dispensed for people at centre or supplied for people at centre by person authorised to supply them, do any of the following: (a) obtain medicines; (b) possess medicines at centre; (c) administer medicines at centre.

Part 1.3 Dentists, dental hygienists and dental therapists

column 1 item	column 2 person authorised	column 3 authorisation
1	dentist	to the extent necessary to practise dentistry and, if employed, within the scope of employment, do any of the following: (a) issue purchase orders and requisitions for medicines; (b) obtain medicines; (c) possess medicines; (d) administer medicines; (e) prescribe medicines; (f) supply medicines for administration to patients at dental surgery to people authorised to administer them. *Note* For authorisation to supply medicines to patients, see s 111.
	Note ***Dentist*** does not include student dentist (see dict).	
2	student dentist	to the extent necessary to practise dentistry or undertake training, and under supervision of dentist, do any of the following: (a) possess medicines; (b) administer medicines in accordance with prescription (whether or not issued by themself or dentist); (c) prescribe medicines for administration at institution or dental surgery.

column 1 item	column 2 person authorised	column 3 authorisation
3	dental hygienist	within the scope of employment, to the extent necessary to practice as dental hygienist, and under supervision of dentist, do any of the following: (a) obtain medicines from dentist authorised to possess them; (b) possess medicines mentioned in paragraph (a); (c) administer medicines mentioned in paragraph (a) in accordance with dentist's prescription.
4	dental therapist	within the scope of employment, to the extent necessary to practice as dental therapist, and under supervision of dentist, do any of the following: (a) issue purchase orders and requisitions for medicines for topical dental use and for local anaesthetics; (b) obtain medicines mentioned in paragraph (a); (c) possess medicines mentioned in paragraph (a); (d) administer medicines mentioned in paragraph (a).

Part 1.4 Doctors

column 1 item	column 2 person authorised	column 3 authorisation
1	doctor	to the extent necessary to practise medicine and, if employed, within the scope of employment, do any of the following: (a) issue purchase orders and requisitions for medicines; (b) obtain medicines; (c) possess medicines; (d) administer medicines; (e) prescribe medicines; (f) supply medicines for administration to patients to people authorised to administer them. *Note 1* For authorisation to supply medicines to patients, see s 111. *Note 2* For authorisation to issue standing orders for administration of medicines at institutions, see s 132.

Note ***Doctor*** does not include student doctor (see dict).

column 1 item	column 2 person authorised	column 3 authorisation
2	student doctor	to the extent necessary to practise medicine or undertake training or supervised practice, and under supervision of doctor, do any of the following: (a) possess medicines; (b) administer medicines in accordance with prescription (whether or not issued by themself or another prescriber); (c) prescribe medicines for administration at institution or surgery; (d) supply dispensed medicines to patients on discharge from institution.

Part 1.5 Midwives

column 1 item	column 2 person authorised	column 3 authorisation
1	midwife	to the extent necessary to practise midwifery and, if employed, within the scope of employment, do any of the following: (a) issue requisitions for medicines; (b) obtain medicines on requisition; (c) possess medicines; (d) administer medicines in accordance with prescription or standing order; (e) supply medicines in accordance with standing order issued by chief health officer.

Part 1.6 Nurses

column 1 item	column 2 person authorised	column 3 authorisation
1	nurse	to the extent necessary to practise nursing and, if employed, within the scope of employment, do any of the following: (a) issue requisitions for medicines; (b) obtain medicines on requisition; (c) possess medicines; (d) administer medicines in accordance with prescription or standing order; (e) supply medicines in accordance with standing order issued by chief health officer.
	Note ***Nurse*** does not include enrolled nurse (see Legislation Act, dict, pt 1).	
2	student nurse	if successfully completed pharmacology units of nursing studies, to the extent necessary to practise nursing as student nurse or undertake training, and under supervision of nurse, nurse practitioner or midwife, do any of the following: (a) possess medicines; (b) administer medicines (other than controlled medicines) to patients in accordance with prescription.

column 1 item	column 2 person authorised	column 3 authorisation
3	enrolled nurse	to the extent necessary to practise nursing as enrolled nurse and, if employed, within the scope of employment, do any of the following: (a) possess medicines; (b) administer medicines (other than controlled medicines) in accordance with prescription.
4	enrolled nurse (medications)	to the extent necessary to practise nursing as enrolled nurse and, if employed, within the scope of employment, do any of the following: (a) possess medicines; (b) administer medicines in accordance with prescription.

column 1 item	column 2 person authorised	column 3 authorisation
5	nurse practitioner	to the extent necessary to practise nursing and, if employed, within the scope of employment, do any of the following: (a) issue requisitions for medicines; (b) obtain medicines on requisition; (c) possess medicines; (d) prescribe medicines (other than controlled medicines) in accordance with approved scope of practice under the *Health Regulation 2004*, section 11 (Scope of practice for nurse practitioner position); (e) administer medicines in accordance with prescription (whether or not issued by issued by themself or another prescriber) or standing order; (f) supply medicines in accordance with standing order issued by chief health officer. *Note* For authorisation to supply medicines to patients, see s 111.

Part 1.7 Opioid dependency treatment centres

column 1 item	column 2 person authorised	column 3 authorisation
1	person in charge of centre opioid dependency treatment centre	to the extent necessary to treat patients of centre and within the scope of employment, do any of the following: (a) issue purchase orders and requisitions for buprenorphine and methadone; (b) obtain buprenorphine and methadone on purchase orders and requisitions; (c) supply buprenorphine and methadone to health professionals at centre for patients of centre.
2	doctor or nurse at opioid dependency treatment centre	to the extent necessary to treat patients of centre and within the scope of employment, supply buprenorphine and methadone to patients of centre for self-administration outside centre if— (a) supply is in accordance with prescription or standing order; and (b) medicine is labelled as if dispensed medicine; and (c) labelled medicine checked by another health professional before supply. *Note* For authorisation of doctor to issue standing orders for administration of medicines at centre, see s 132.

Part 1.8 Optometrists

column 1 item	column 2 person authorised	column 3 authorisation
1	optometrist	to the extent necessary to practise optometry and, if employed, within the scope of employment, do any of the following: (a) deal with optometry medicines mentioned in schedule 2, table 2.1, column 2 for a purpose mentioned in column 3 for the medicine in relation to medicines as follows: (i) issue purchase orders or requisitions for the medicines; (ii) obtain the medicines; (iii) possess the medicines; (iv) administer the medicines; (b) if holder of optometrist drug authority under *Health Professionals Act 2004* to treat eye condition, deal with optometry medicines mentioned in schedule 2, table 2.2 for treatment of condition as follows: (i) issue purchase orders or requisitions for the medicines; (ii) obtain the medicines; (iii) possess the medicines; (iv) administer the medicines; (v) prescribe the medicines. *Note* For authorisation to supply medicines to patients, see s 111.

Part 1.9 Pharmacists and employees

column 1 item	column 2 person authorised	column 3 authorisation
1	pharmacist	to the extent necessary to practise pharmacy and, if employed, within the scope of employment, do any of the following: (a) issue purchase orders and requisitions for medicines; (b) obtain medicines; (c) possess medicines; (d) dispense medicines; (e) administer medicines; (f) supply pharmacy medicines; (g) if pharmacist at institution—supply pharmacist only medicines without prescription; (h) if pharmacist at community pharmacy—supply pharmacist only medicines without prescription but in accordance with quality use of medicines principles in section 16; (i) supply medicines on purchase order, requisition or standing order. *Note* Certain actions by pharmacists are taken not to be manufacture and therefore do not require authorisation (see Act, s 19).

Note ***Pharmacist*** does not include student pharmacist (see dict).

column 1 item	column 2 person authorised	column 3 authorisation
2	student pharmacist	to the extent necessary to practise pharmacy or undertake training or supervised practice, do any of the following: (a) under direct supervision of pharmacist— (i) dispense medicines; (ii) administer medicines; (iii) if student pharmacist at institution—supply pharmacist only medicines without prescription; (iv) if student pharmacist at community pharmacy—supply pharmacist only medicines without prescription but in accordance with quality use of medicines principles in section 16; (b) under supervision of pharmacist, do any of the following: (i) possess medicines; (ii) supply pharmacy medicines; (iii) supply medicines on requisition.

column 1 item	column 2 person authorised	column 3 authorisation
3	pharmacist's employee public employee assisting pharmacist who is public employee	within the scope of employment and under supervision of pharmacist, do any of the following: (a) obtain medicines from pharmacist if pharmacist authorised to possess them; (b) possess medicines mentioned in paragraph (a); (c) supply pharmacy medicines without prescription; (d) supply medicines on requisition. *Note* For delivery and sale of certain medicines by community pharmacy employees, see s 24.

Part 1.10 Podiatrists

column 1 item	column 2 person authorised	column 3 authorisation
1	podiatrist	to the extent necessary to practise podiatry and, if employed, within the scope of employment, do any of the following: (a) issue purchase orders and requisitions for adrenaline and local anaesthetics; (b) obtain adrenaline and local anaesthetics; (c) possess adrenaline and local anaesthetics; (d) administer adrenaline and local anaesthetics.

Part 1.11 Residential care facilities

column 1 item	column 2 person authorised	column 3 authorisation
1	director of nursing for residential aged care facility without pharmacy medical superintendent for residential aged care facility without pharmacy	within the scope of employment, do any of the following: (a) issue purchase orders for following medicines for emergency administration to residents at facility under direction of prescriber: (i) pharmacy medicines, pharmacist only medicines and prescription only medicines; (ii) not more than 5 ampoules, each of 1mL or less, of morphine sulfate, at a concentration of 30mg or less of morphine sulfate per mL; (b) obtain medicines mentioned in paragraph (a). *Note 1* No authorisation is required for certain dealings with residents' own medicines, see s 20. *Note 2* For authorisation of doctor to issue standing orders for administration of medicines at facility, see s 132.

column 1 item	column 2 person authorised	column 3 authorisation
2	director of nursing for residential disability care facility without pharmacy medical superintendent for residential disability care facility without pharmacy	within the scope of employment, do any of the following: (a) issue purchase orders for medicines (other than controlled medicines) for emergency administration to residents at facility under direction of prescriber; (b) obtain medicines mentioned in paragraph (a). *Note* See item 1, notes 1 and 2.

Part 1.12 Sales representatives for medicines manufacturers and wholesalers

column 1 item	column 2 person authorised	column 3 authorisation
1	representative of person authorised under corresponding law to manufacture medicines representative of person authorised to supply medicines by wholesale	for purpose of supplying medicines (other than controlled medicines) under medicines Australia code of conduct, and within the scope of employment, do any of the following: (a) obtain starter packs of medicines (other than controlled medicines) from manufacturer or wholesaler; (b) possess medicines obtained under paragraph (a); (c) supply starter packs of medicines in accordance with medicines Australia code of conduct.

Part 1.13 Veterinary surgeons and employees

column 1 item	column 2 person authorised	column 3 authorisation
1	veterinary surgeon	to the extent necessary to practise veterinary medicine and, if employed, within the scope of employment, do any of the following: (a) issue purchase orders for medicines; (b) obtain medicines; (c) possess medicines; (d) administer medicines; (e) prescribe medicines; (f) supply medicines. *Note* For authorisation to supply medicines to animal owners, see s 111.

Note ***Veterinary surgeon*** does not include student veterinary surgeon (see dict).

column 1 item	column 2 person authorised	column 3 authorisation
2	student veterinary surgeon	to the extent necessary to practise veterinary medicine or undertake training, and under supervision of veterinary surgeon, do any of the following: (a) possess medicines; (b) administer medicines in accordance with prescription (whether or not issued by themself or veterinary surgeon); (c) prescribe medicines for administration at veterinary surgery.
3	veterinary surgeon's employee public employee assisting veterinary surgeon who is public employee	within the scope of employment and under supervision of veterinary surgeon, do any of the following: (a) obtain medicines from veterinary surgeon if veterinary surgeon authorised to possess them; (b) possess medicines mentioned in paragraph (a); (c) administer medicines mentioned in paragraph (a) in accordance with veterinary surgeon's prescription; (d) supply pharmacy medicines without prescription if labelled for animal use. Note For delivery and sale of certain medicines by employee of veterinary surgeon, see s 24.

Schedule 2 Optometry medicines

(see sch 1)

Table 2.1 General optometry medicines

column 1 item	column 2 general optometry medicine	column 3 prescribed purpose
1	cycloplegic medicines	paralysing accommodation of eye
2	local anaesthetics	tonometry
		fitting contact lens
3	miotic medicines	instilling into eye after use of mydriatic substance
4	mydriatic medicines	enlarging pupil

Table 2.2 Restricted optometry medicines

column 1 item	column 2 medicine group	column 3 restricted optometry medicine
1	Topical ocular anti-infective agents (anti-bacterial, anti-viral)	Choramphenicol
		Gramicidin
		Framycetin
		Neomycin
		Polymixin
		Tetracycline

column 1 item	column 2 medicine group	column 3 restricted optometry medicine
2	Topical ocular anti-allergy agents (anti-histamine, mast cell stabilisers)	Cromoglycate
		Ketotifen
		Levocabastine
		Lodoxamide
		Olopatadine
3	Topical ocular non-steroidal anti-inflammatory agents (NSAIDS)	Diclofenac
		Flurbiprofen
		Ketorolac
4	Topical ocular steroid preparations	Fluorometholone
		Hydrocortisone
5	Topical glaucoma preparations in accordance with shared care model between Optometrists Registration Board under *Optometrists Act 1930* (NSW), Australian and New Zealand College of Ophthalmologists and School of Vision Science, University of New South Wales, as in force from time to time	Apraclonidine
		Betaxolol
		Bimatoprost
		Brimonidine
		Brinzolamide
		Carbachol
		Dipivefrine
		Dorzolamide
		Latanoprost
		Levobunolol
		Pilocarpine
		Timolol
		Travoprost

column 1 item	column 2 medicine group	column 3 restricted optometry medicine
6	Mydriatics and cycloplegics	Atropine
		Cyclopentolate
		Homatropine
		Phenylephrine
		Tropicamide
7	Topical local anaesthetics	Amethocaine
		Oxybuprocaine
		Proxymetacaine

Schedule 3 Appendix D medicines standing approvals

(see s 291 and s 293)

Part 3.1 Approval conditions

3.1 Definitions—sch 3

In this schedule:

condition 1, for a doctor prescribing or supplying an appendix D medicine to a woman of child-bearing age, means the doctor must ensure that the possibility of pregnancy by the woman has been excluded prior to commencement of treatment.

condition 2, for a doctor prescribing or supplying an appendix D medicine to a woman of child-bearing age, means the doctor must advise the woman to avoid becoming pregnant during, or for a period of 1 month after the completion of, treatment.

condition 3, for a doctor prescribing or supplying an appendix D medicine to a woman of child-bearing age, means the doctor must advise the woman to avoid becoming pregnant during, or for a period of 3 months after the completion of, treatment.

condition 4, for a doctor prescribing or supplying an appendix D medicine to a woman of child-bearing age, means the doctor must advise the woman to avoid becoming pregnant during, or for a period of 24 months after the completion of, treatment.

Part 3.2 Standing approvals for appendix D medicines

column 1 item	column 2 doctor	column 3 appendix D medicine and conditions (if any)
1	specialist practising in specialist area of dermatology	acitretin for human use (conditions 1 and 4)
		alefacept
		bexarotene (conditions 1 and 2)
		etretinate for human use (conditions 1 and 4)
		isotretinoin for human oral use (conditions 1 and 2)
		thalidomide for human use (conditions 1 and 2)
2	specialist practising in specialist area of endocrinology, gynaecology or obstetrics	clomiphene for human use
		cyclofenil for human use
		dinoprost for human use
		dinoprostone for human use
		follitropin alpha (recombinant human follicle-stimulating hormone) for human use
		luteinising hormone for human use
		urofollitrophin (human follicle-stimulating hormone) for human use

column 1 item	column 2 doctor	column 3 appendix D medicine and conditions (if any)
3	specialist practising in specialist area of mental health doctor employed by Territory and working under supervision of chief psychiatrist under *Mental Health (Treatment and Care) Act 1994*	clozapine for human use
4	specialist physician	acitretin for human use (conditions 1 and 4) etretinate for human use (conditions 1 and 4) bexarotene (conditions 1 and 2) bosentan (conditions 1 and 3) isotretinoin for human oral use (conditions 1 and 2) teripraritide for human use thalidomide for human use (conditions 1 and 2) tretinoin for human oral use (conditions 1 and 2)
5	doctor authorised by Secretary of Commonwealth Department of Health and Ageing	dronabinol

Note ***Specialist*** includes a doctor training in a specialist area—see the dictionary.

Schedule 4 Dangerous poisons—particular authorisations

(see s 530)

column 1 item	column 2 people	column 3 dangerous poison	column 4 prescribed purpose
1	manufacturers of glass	arsenic	manufacturing glass
	metallurgists		manufacturing alloys
2	manufacturers of dyes or pharmaceuticals	benzene	manufacturing dyes or pharmaceuticals
	manufacturers of lacquers, linoleum, protective cloths or varnishes		manufacturing lacquers, linoleum, protective cloths or varnishes
3	manufacturers of chemicals or pharmaceuticals	carbon tetrachloride	manufacturing chemicals or pharmaceuticals
	manufacturers of lacquers, paints or varnishes		manufacturing lacquers, paints or varnishes
4	managers of swimming pools, other than domestic swimming pools	chlorine	purifying water in pools
	manufacturers of chemicals, plastics or synthetic rubber		manufacturing chemicals, plastics or synthetic rubber
	metallurgists		cleaning metals
	people working at sewage treatment centres		treating sewage at treatment centres
	people working at water treatment centres		purifying water at treatment centres

column 1 item	column 2 people	column 3 dangerous poison	column 4 prescribed purpose
5	electroplaters	cyanides	electroplating
	jewellers		manufacturing gold jewellery
	miners		extracting or processing gold
6	manufacturers of lacquers, paints or varnishes	epichlorohydrin	manufacturing lacquers, paints or varnishes
7	manufacturers of chemicals or detergents	ethylene oxide	manufacturing chemicals or detergents
	sterilising technologists		sterilising surgical instruments
8	glass workers	hydrofluoric acid	etching glass
	masons		cleaning building materials
	metal workers		cleaning or etching metals
	miners		extracting or processing gold
	potters		cleaning ceramics
9	dentists or dental workers	mercury	making amalgams
	manufacturers of lamps, mirrors or scientific instruments		manufacturing of lamps, mirrors or scientific instruments
	manufacturers of mercury salts or organic compounds		manufacturing mercury salts or organic compounds
	miners		extracting metals from ores

column 1 item	column 2 people	column 3 dangerous poison	column 4 prescribed purpose
10	manufacturers of plastics	4, 4'-methylenebis [2-chloroaniline] (MOCA)	manufacturing plastics
11	manufacturers of detergents, lubricants or organic compounds	propylene oxide	manufacturing detergents, lubricants or organic compounds
12	manufacturers of organic compounds, paints, rust removers or varnishes	tetrachloroethane	manufacturing organic compounds, paints, rust removers or varnishes
13	manufacturers of dyes	ortho-tolidine	manufacturing dyes
14	manufacturers of disinfectants, household cleaners or industrial deodorants	trichloroisocyanuric acid	manufacturing disinfectants, household cleaners or industrial deodorants

Schedule 5 Minimum requirements for storage receptacles

(see s 220 and s 222)

Part 5.1 Medicines cabinets

5.1 Medicines cabinets—general requirements

A medicines cabinet must be constructed to prevent ready access to the cabinet's contents by cutting, sawing or unbolting.

5.2 Medicines cabinets—body requirements

(1) The body of a medicines cabinet must be constructed of a single layer of black mild steel plate at least 10mm thick and with continuous welding of all joints.

(2) The body must have, for installation—

(a) 4 suitably sized holes in the cabinet's back plate; or

(b) 2 suitably sized holes in the back plate and 2 suitably sized holes in the cabinet's base.

5.3 Medicines cabinets—door requirements

(1) The door of a medicines cabinet must be constructed of black mild steel plate at least 10mm thick.

(2) When the medicines cabinet door is closed, the door must—

(a) fit flush with the cabinet; and

(b) have a clearance around the door of no more than 1.5mm.

(3) The door must be fitted with a fixed locking bar, welded to the inside face of the door near the hinge edge, that engages in a rebate in the cabinet when closed.

(4) The hinges on the door must be—

(a) constructed of heavy duty steel; and

(b) continuous welded to the door and body of the cabinet.

5.4 Medicines cabinets—lock requirements

(1) A medicines cabinet lock must be—

(a) a 6-lever pick-proof lock; or

(b) a lock mechanism of a level of security equal to, or greater than, a 6-lever pick-proof lock.

(2) The lock must securely attached to the inside face of the door.

5.5 Medicines cabinets—mounting requirements

(1) A medicines cabinet must be—

(a) embedded in a floor of reinforced concrete of at least 10mpa compressive strength; or

(b) securely fixed to a wall or floor (or both) in accordance with this section.

(2) If the wall and floor are brick or concrete, the medicines cabinet must be fixed to the wall or floor (or both) by at least 4 expanding bolts.

(3) If the wall is timber, but the floor is brick or concrete, the medicines cabinet must be fixed—

(a) to the floor by at least 4 expanding bolts; and

(b) to the wall by at least 2 coach screws into the studs as close to the top of the wall face as is possible.

(4) If the wall and floor are timber, the medicines cabinet must be fixed to the timber frame of the wall or floor in a way that will ensure that the cabinet can not be removed from the floor or wall within 30 minutes.

(5) The bolts and coach screws must be at least 10mm in diameter.

Part 5.2 Safes, strong rooms and vaults

5.6 Requirements for safes

(1) A safe must be constructed to prevent ready access to the safe's contents by cutting, sawing or unbolting.

(2) When locked, a safe must reasonably be expected to resist attempts to gain entry by tools, torch or explosives for at least 30 minutes.

(3) A safe—

(a) may be freestanding if it weighs more that 350kg; or

(b) must be securely attached to, or embedded in, a concrete floor or a concrete or brick wall in a way that will ensure that the cabinet can not be removed within from the floor or wall within 30 minutes.

5.7 Requirements for strong rooms

(1) The walls, floor and ceiling of a strong room must be brick or concrete.

(2) The strong room must be fitted with a door.

(3) When locked, the strong room must reasonably be expected to resist attempts to gain entry by tools, torch or explosives for at least 1 hour.

5.8 Requirements for vaults

(1) The walls, floor and ceiling of a vault must be reinforced concrete.

(2) The vault must be fitted with a door.

(3) When locked, the vault must reasonably be expected to resist attempts to gain entry by tools, torch or explosives for at least 1 hour.

Dictionary

(see s 3)

Note 1 The Legislation Act contains definitions and other provisions relevant to this regulation.

Note 2 For example, the Legislation Act, dict, pt 1, defines the following terms:

- child
- dentist
- doctor
- nurse
- nurse practitioner
- optometrist
- writing.

Note 3 Terms used in this regulation have the same meaning that they have in the *Medicines and Poisons Act 2006* (see Legislation Act, s 148). For example, the following terms are defined in the *Medicines and Poisons Act 2006*, dictionary:

- controlled medicine
- dangerous poison
- institution
- medicines and poisons inspector
- pharmacist only medicine
- pharmacy medicine
- prescription only medicine
- prohibited substance
- regulated substance
- standing order.

appendix D medicine means a medicine listed in the medicines and poisons standard, appendix D if the medicine is subject to the medicines and poisons standard, schedule 4 or schedule 8.

appendix D medicines approval—see section 290.

approved analyst means—

(a) an authorised analyst under the Act, section 122; or

(b) an analyst appointed or authorised under—

(i) another territory law; or

(ii) a law of the Commonwealth, a State or another Territory.

Australian code of good wholesaling practice for therapeutic goods for human use means the *Australian Code of Good Wholesaling Practice for Therapeutic Goods for Human Use* prepared by the National Coordinating Committee on Therapeutic Goods, as in force from time to time.

Note The code is available at www.tga.gov.au.

child residential centre means an attendance centre, institution, shelter or other place that children and young people may be detained under the *Children and Young People Act 1999*.

CHO means chief health officer.

community pharmacy means a pharmacy at a place other than an institution.

complying purchase order means—

(a) for a dangerous poison—a purchase order that complies with section 581 (Requirements for dangerous poisons purchase orders); or

(b) for a medicine—a purchase order that complies with section 91 (Requirements for medicines purchase orders).

condition 1, for a doctor prescribing or supplying an appendix D medicine to a woman of child-bearing age, for schedule 3 (Appendix D medicines standing approvals)—see schedule 3, section 3.1.

condition 2, for a doctor prescribing or supplying an appendix D medicine to a woman of child-bearing age, for schedule 3—see schedule 3, section 3.1.

condition 3, for a doctor prescribing or supplying an appendix D medicine to a woman of child-bearing age, for schedule 3—see schedule 3, section 3.1.

condition 4, for a doctor prescribing or supplying an appendix D medicine to a woman of child-bearing age, for schedule 3—see schedule 3, section 3.1.

controlled medicines approval—see section 240.

controlled medicines register means a register for controlled medicines.

correctional centre—see the *Crimes (Sentence Administration) Act 2005*.

dangerous poisons manufacturers licence—see section 540.

dangerous poisons register means a register for dangerous poisons.

dangerous poisons research and education program licence—see section 540.

dangerous poisons suppliers licence—see section 540.

day hospital means a facility where a person is admitted for surgical or medical treatment and discharged on the same day.

dentist does not include a student dentist.

Note See the definition of ***student***.

designated prescriber, for part 11.1 (Controlled medicines approvals)—see section 241.

designated prescription only medicine, for part 4.4 (Authorisation to supply without prescription in emergencies)—see section 120.

disability care means care that is provided to a person with a disability in a residential facility in which the person is also provided with accommodation that includes—

(a) appropriate staff to meet the nursing and personal care needs of the person; and

(b) meals and cleaning services; and

(c) furnishings, furniture and equipment for the provision of the care and accommodation.

doctor does not include a student doctor.

Note See the definition of ***student***.

endorsement, for division 11.1.4 (Endorsements to treat drug-dependency)—see section 280.

enrolled nurse includes an enrolled nurse (medications).

enrolled nurse (medications) means an enrolled nurse who is registered under the *Health Professionals Act 2004* in the specialist area of enrolled nurse (medications).

first-aid kit includes a portable bag or container of medicines and other medical supplies kept by a person for health care or emergency treatment.

first-aid kit licence—see section 300.

health profession—see the *Health Professionals Act 2004*, dictionary.

health professional means a person who is registered under the *Health Professionals Act 2004*.

medical records, for a person, includes the person's clinical records and a medication chart for the person in an institution.

medicines research and education program licence—see section 300.

medicines wholesalers licence—see section 300.

medicines Australia code of conduct means the *Medicines Australia Code of Conduct*, authorised by the Australian Competition and Consumer Commission, as in force from time to time.

Note The medicines Australia code of conduct is available at www.medicinesaustralia.com.au.

opioid dependency treatment licence—see section 300.

personal custody, of a key by a person, for chapter 9 (Storage of medicines)—see section 190.

pharmacist does not include a student pharmacist.

Note See the definition of ***student***.

prescribed person, for chapter 9 (Storage of medicines)—see section 191.

prescriber, in relation to a medicine, means—

(a) for this Act generally—a person in relation to whom prescribing the medicine is included in schedule 1, column 3 in relation to the person; and

(b) for part 4.3 (Authorisation for certain prescribers to supply packages of medicines)—see section 110.

prescription, for chapter 4 (Authorisations to supply medicines)—see section 51.

prohibited substance, for chapter 19 (Prohibited and appendix C substances)—see section 700.

prohibited substances register means a register for prohibited substances.

prohibited substances research and education program licence—see section 701.

relevant law—

(a) for chapter 14 (Low and moderate harm poisons)—see section 500; and

(b) for part 17.2 (Packaging and labelling of dangerous poisons)—see section 590.

requisition includes issue a requisition.

residential disability care facility—

(a) means a residential facility that provides disability care to people with disabilities; but

(b) does not include a residential aged care facility.

Note ***Residential aged care facility***—see the Act, dictionary.

rural communities pharmacy medicines licence—see section 300.

scope of employment includes scope of engagement as a contractor.

specialist means—

(a) a medical practitioner admitted to a specialist area of a health profession; or

(b) a doctor who is undergoing a course of training under the supervision of a person mentioned in paragraph (a), the successful completion of which will qualify the person to be admitted to a specialist area.

specialist area, for a health profession—see the *Health Professionals Regulation 2004*, dictionary.

student, in relation to a health professional, means a person who is conditionally registered as a health professional to allow the person to undertake a period of supervised practice or course of training or both to allow the person to become registered to practice without supervision.

Examples of references to student

student dentist, student doctor, student nurse, student pharmacist and student veterinary surgeon

Note An example is part of the regulation, is not exhaustive and may extend, but does not limit, the meaning of the provision in which it appears (see Legislation Act, s 126 and s 132).

terminal illness—a person has a ***terminal illness*** if a specialist diagnoses the person as having a terminal illness and estimates the person's life expectancy to be less than 1 year.

Note ***Specialist*** includes a doctor training in a specialist area—see the definition above.

veterinary surgeon does not include a student veterinary surgeon.

Note See the definition of ***student***.

written includes in electronic form.

Endnotes

1 Notification

Notified under the Legislation Act on 2007.

2 Republications of amended laws

For the latest republication of amended laws, see www.legislation.act.gov.au.