Western Australia

Medicines and Poisons Act 2014

Medicines and Poisons Regulations 2016

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Medicines and Poisons Regulations 2016

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Defined terms

Medicines and Poisons Regulations 2016

Part 1 — Preliminary

1. Citation

These regulations are the *Medicines and Poisons Regulations 2016*.

2. Commencement

These regulations come into operation on the day on which section 131 of the Act comes into operation.

3. Terms used

(1) In these regulations —

acute care means immediate, short-term treatment for an injury, episode of illness or urgent medical condition;

approved electronic prescribing system means an electronic system approved under regulation 19(4);

approved form means a form approved by the CEO;

approved needle and syringe programme means a needle and syringe programme approved under regulation 108;

current Poisons Standard has the meaning given in the *Therapeutic Goods Act 1989* (Commonwealth) section 3(1);

dispense means to supply in accordance with a prescription;

exempt substance means each of the following —

(a) a preparation that contains a poison listed in the current Poisons Standard Appendix G Column 1 at a concentration that is the same as or less than the concentration specified in Column 2 of the Appendix;

(b) a poison in a product listed in the current Poisons Standard Appendix A;

hospital means a private hospital or a public hospital;

medical practitioner means a person registered under the *Health Practitioner Regulation National Law (Western Australia)* in the medical profession;

medication chart means a chart recording medicines used, or to be used, for the treatment of a patient in a hospital, that is —

(a) in a form developed by the Australian Council for Safety and Quality in Health Care; or

(b) in a form approved by the clinical governance committee of the hospital; or

(c) in a form approved by the CEO;

patient in a hospital means a person who is admitted as a patient to the hospital;

pharmaceutical sample means a sample package —

(a) that contains a medicine that is a Schedule 2, 3 or 4 poison; and

(b) that is —

(i) up to one-third of the size of the smallest trade pack of the medicine; or

(ii) if it is not practical to produce a pack that is one-third of the size of the smallest trade pack of the medicine — the smallest trade pack of the medicine;

private hospital has the meaning given in the *Private Hospitals and Health Services Act 1927* section 2(1);

public health programme means a programme designed to prevent injury and reduce the spread of disease;

public health service has the meaning given in the *Health Services Act 2016* section 6;

public hospital has the meaning given in the *Health Services Act 2016* section 6;

residential care chart means a chart recording medicines used, or to be used, for the treatment of a care recipient in a residential care facility that is —

(a) in a form developed by the Australian Council for Safety and Quality in Health Care; or

(b) a medication chart prescription as defined in the *National Health (Pharmaceutical Benefits) Regulations 1960* (Commonwealth) regulation 19AA(1);

residential care facility means any premises used to provide residential care to care recipients by an approved provider as defined in the *Aged Care Act 1997* (Commonwealth);

restricted Schedule 3 poison means pseudoephedrine as included in Schedule 3;

section means section of the Act;

structured administration and supply arrangement (SASA) means a document —

(a) that sets out the circumstances in which a health professional specified, or of a class specified, in the document may administer or supply a medicine specified in the document; and

(b) that is issued in accordance with regulation 33(1), 34(2) or 35(1).

(2) For the purposes of these regulations, the definitions and interpretation provisions in the current Poisons Standard apply to the interpretation of the current Poisons Standard.

(3) Unless the contrary intention appears, a reference in these regulations to a Schedule is a reference to a Schedule referred to in section 4(1).

[Regulation 3 amended: Gazette 13 Nov 2018 p. 4429; 15 Mar 2019 p. 787; 19 Nov 2019 p. 4051; SL 2023/3 r. 4 and 7.]

4. Needle and syringe programme prescribed

An approved needle and syringe programme is prescribed as a type of needle and syringe programme for the purposes of section 17(b).

5. Fees

(1) For the purposes of section 38(2), the application fee and the licence fee for a licence are the fees set out in Schedule 1 Division 1 to these regulations for a licence of that type.

(2) For the purposes of section 38(2), the application fee and the permit fee for a permit are the fees set out in Schedule 1 Division 2 to these regulations for a permit of that type.

(3) For the purposes of a provision listed in Schedule 1 Division 3 to these regulations, the fee is the fee set out in that Division in respect of that provision.

Part 2 — Classification of substances as poisons

6. Classification of substances as poisons included in Schedules (s. 4)

Each substance, other than an exempt substance or nicotine, described in an item in the Table is classified as a poison included in the Schedule specified in that item.

Table

Item	Schedule	Description of substance
1.	Schedule 2	A substance listed in the current Poisons Standard Schedule 2
2.	Schedule 3	A substance listed in the current Poisons Standard Schedule 3
3.	Schedule 4	A substance listed in the current Poisons Standard Schedule 4 SCAEVOLA SPINESCENS
4.	Schedule 5	A substance listed in the current Poisons Standard Schedule 5
5.	Schedule 6	A substance listed in the current Poisons Standard Schedule 6
6.	Schedule 7	A substance listed in the current Poisons Standard Schedule 7
7.	Schedule 8	A substance listed in the current Poisons Standard Schedule 8

Item	Schedule	Description of substance
8.	Schedule 9	A substance listed in the current Poisons Standard Schedule 9 A substance listed in Schedule 2 to these regulations

[Regulation 6 amended: SL 2023/3 r. 7; SL 2024/218 r. 4.]

6A. Classification of nicotine as poison (s. 4)

(1) In this regulation —

included in the Register has the meaning given in the *Therapeutic Goods Act 1989* (Commonwealth) section 3;

oromucosal administration means oromucosal use as defined in the current Poisons Standard section 6;

therapeutic use has the meaning given in the current Poisons Standard section 6;

transdermal administration means transdermal use as defined in the current Poisons Standard section 6.

(2) Each substance described in an item in the Table is classified as a poison included in the Schedule specified in that item.

Table

Item	Schedule	Description of substance
1.	Schedule 4	NICOTINE in preparations for human use **except**: (a) in preparations for oromucosal or transdermal administration for human therapeutic use when included in the Register as an aid in withdrawal either from

Item	Schedule	Description of substance
		tobacco smoking or nicotine vaping; or (b) in tobacco prepared and packed for smoking.
2.	Schedule 7	NICOTINE **except**: (a) when included in Schedule 4; or (b) in preparations for oromucosal or transdermal administration for human therapeutic use when included in the Register as an aid in withdrawal either from tobacco smoking or nicotine vaping; or (c) in tobacco prepared and packed for smoking.

[Regulation 6A inserted: SL 2024/218 r. 5.]

7. Classification of substances as strictly controlled substances (s. 5)

Each substance listed in the current Poisons Standard Schedule 10 is classified as a strictly controlled substance.

[Regulation 7 amended: SL 2023/3 r. 7.]

Part 3 — Supply and use of strictly controlled substances

8. Authorisation to supply or use strictly controlled substance

(1) The CEO may, for the purposes of section 18(1)(a)(ii) or (2)(a)(ii), authorise a person to supply or use a strictly controlled substance if the CEO is satisfied that —

(a) the supply or use of the substance is for educational or research purposes; and

(b) the supply or use of the substance will be conducted in a manner that protects the health, safety and welfare of the public.

(2) The authorisation —

(a) must be in writing; and

(b) may be subject to conditions; and

(c) may, at any time, be amended, suspended or revoked by the CEO.

9. Authorisation to supply or use amygdalin

(1) In this regulation —

legally imported amygdalin means amygdalin that has been imported in accordance with permission granted under the *Customs (Prohibited Imports) Regulations 1956* (Commonwealth) regulation 5H and Schedule 8 item 12AA.

(2) For the purposes of section 18(2)(a)(i), a person is authorised to use legally imported amygdalin if the person uses the amygdalin on the direction of a medical practitioner.

Part 4 — Prescriptions and prescribing

Division 1 — Requirements for prescriptions

10. Requirements for prescriptions generally

(1) For the purposes of paragraph (c) of the definition of ***prescription*** in section 7(1), a document must —

(a) include the following information —

(i) the name, address and telephone number of the prescriber;

(ii) the date on which the document is issued;

(iii) the name and address of the patient for whom the medicine is prescribed or, in the case of a medicine that is prescribed for veterinary use, the species of animal to be treated and the name and address of the person who has the care of the animal;

(iv) if the document is for the supply of a medicine that is a Schedule 8 poison and is not for veterinary use — the date of birth of the patient;

(v) a description and the quantity, dose, strength and form of each medicine that is to be supplied;

(vi) precise directions for use of each medicine that is to be supplied;

(vii) if the document provides for the medicine to be supplied on more than one occasion — the maximum number of times it may be supplied;

(viii) if the document is for the supply of a medicine that is a Schedule 8 poison on more than one occasion — the intervals at which it may be supplied;

and

(b) be issued by a prescriber in a form described in regulation 11(1).

(2) A prescription must not be for the supply of both a medicine that is a Schedule 4 poison and a medicine that is a Schedule 8 poison.

(3) A prescription that is issued by a veterinarian must include the words "For veterinary use only" or "For animal treatment only".

(4) However, the requirements in this regulation do not apply in respect of a document if the document —

(a) is issued for a purpose set out in regulations 12, 13 or 14; and

(b) complies with the requirements in the relevant regulation for a document issued for that purpose.

[Regulation 10 amended: SL 2022/93 r. 5.]

11. Form of prescription

(1) For the purposes of regulation 10(1)(b), a document can be in any of the following forms —

(a) an electronic document issued by the prescriber by means of an approved electronic prescribing system;

(b) a printed form that is —

(i) generated by means of a computer system that satisfies the requirements set out in subregulation (2); and

(ii) signed by the prescriber;

(c) a document —

(i) with the details referred to in regulation 10(1)(a)(ii) to (viii) written in ink by the prescriber; and

(ii) signed by the prescriber.

(2) For the purposes of subregulation (1)(b)(i), a computer system must be designed so that —

(a) only a prescriber may generate the form; and

(b) the form when printed indicates the total number of items to be supplied, or is scored, hatched or otherwise marked to prevent any other item being added to the form after it is generated; and

(c) a prescriber must determine, on each occasion, the specific directions for use of each medicine that is to be supplied; and

(d) the form contains a number which uniquely identifies it; and

(e) particulars of the form are included in the clinical or prescription record of the person or animal to be supplied with the items identified in the form; and

(f) the clinical or prescription record of the person or animal to be supplied with the items identified in the form is —

(i) in the case of an item that is a medicine that is a Schedule 4 poison — preserved for at least 2 years from the date on which the form is generated; and

(ii) in the case of an item that is a medicine that is a Schedule 8 poison — preserved for at least 5 years from the date on which the form is generated.

12. Medication chart for patient in hospital

For the purposes of paragraph (c) of the definition of ***prescription*** in section 7(1), a document that is issued for the purpose of supplying a medicine that is a Schedule 4 or 8 poison

for the use of a patient in a hospital may be in the form of a medication chart if —

(a) all the details about the patient and the medicine required by the medication chart have been completed; and

(b) the medication chart is completed in a printed or written form or by means of an approved electronic prescribing system; and

(c) each entry in the medication chart about the medicine is signed by a prescriber.

13. Medication chart for patient discharged from hospital

For the purposes of paragraph (c) of the definition of ***prescription*** in section 7(1), a document that is issued for the purpose of supplying a medicine that is a Schedule 4 or 8 poison on the discharge of a patient from a hospital may be in the form of a medication chart if —

(a) all the details about the patient and the medicine required by the medication chart have been completed in writing on the medication chart; and

(b) an authorisation for the medicine to be dispensed for discharge is —

(i) written on the medication chart in ink by a prescriber; and

(ii) dated and signed by the prescriber.

14. Chart for patient in residential care

For the purposes of paragraph (c) of the definition of ***prescription*** in section 7(1), a document that is issued for the purpose of supplying a medicine that is a Schedule 4 poison for

the use of a person who is a care recipient in a residential care facility may be in the form of a residential care chart if —

(a) all the details about the person and the medicine required by the residential care chart have been completed in writing on the residential care chart; and

(b) each entry in the residential care chart about the medicine is —

(i) written in ink by a prescriber; and

(ii) dated and signed by the prescriber.

Division 2 — Directions by prescriber

15. Direction by prescriber to administer medicine that is Schedule 4 or 8 poison

(1) A prescriber may give a direction for an authorised health professional to administer a medicine that is a Schedule 4 or 8 poison to a particular person (the ***patient***).

(2) The direction may be given —

(a) by entering in the clinical record of the patient any details referred to in regulation 10(1)(a)(i) to (v) that are not already included in the clinical record and signing the entry; or

(b) by entering all the details about the patient and the medicine required by the medication chart or the residential care chart for the patient and signing the entry; or

(c) to an authorised health professional orally or by telephone or other electronic means.

(3) If a prescriber gives a direction to an authorised health professional in a form described in subregulation (2)(c), the prescriber must, within 24 hours of giving the direction —

(a) enter all the details about the patient and the medicine required by the medication chart or the residential care chart for the patient and sign the entry; or

(b) enter in the clinical record of the patient any details referred to in regulation 10(1)(a)(i) to (v) that are not already included in the clinical record and sign the entry.

16. Direction by prescriber to administer medicine that is Schedule 4 or 8 poison to animal

(1) A prescriber may give a direction for an authorised health professional to administer a medicine that is a Schedule 4 or 8 poison to a particular animal (the ***animal***).

(2) The direction may be given —

(a) by entering in the clinical record of the animal any details referred to in regulation 10(1)(a)(i) to (v) that are not already included in the clinical record and signing the entry; or

(b) to an authorised health professional orally or by telephone or other electronic means.

(3) If a prescriber gives a direction to an authorised health professional in a form described in subregulation (2)(b), the prescriber must, within 24 hours of giving the direction enter in the clinical record of the animal any details referred to in regulation 10(1)(a)(i) to (v) that are not already included in the clinical record and sign the entry.

16A. Direction by prescriber to supply medicine that is Schedule 2, 3 or 4 poison

(1) A prescriber may give a direction for an authorised health professional to supply a medicine that is a Schedule 2, 3 or 4 poison to a particular person (the ***patient***).

(2) The direction may be given —

(a) by entering in the clinical record of the patient any details referred to in regulation 10(1)(a)(i) to (vii) that are not already included in the clinical record and signing the entry; or

(b) to an authorised health professional orally or by telephone or other electronic means.

(3) If a prescriber gives a direction to an authorised health professional in a form described in subregulation (2)(b), the prescriber must, within 24 hours of giving the direction, enter in the clinical record of the patient any details referred to in regulation 10(1)(a)(i) to (vii) that are not already included in the clinical record and sign the entry.

[Regulation 16A inserted: Gazette 15 Mar 2019 p. 787.]

17. Direction by prescriber to supply medicine that is Schedule 4 or 8 poison in emergency

(1) A prescriber may give a direction for a pharmacist to supply a medicine that is a Schedule 4 or 8 poison to a person.

(2) The direction —

(a) may be given orally or by telephone or other electronic means; and

(b) may only be given in an emergency.

(3) If a direction is given under subregulation (1), the prescriber must —

(a) prepare a document for the supply of the medicine in accordance with the requirements in regulation 10(1); and

(b) mark the document to show that it is a confirmation of a direction given orally or by telephone or other electronic means; and

(c) send the document within 24 hours to the pharmacist.

(4) A pharmacist who supplies a medicine that is a Schedule 8 poison on a direction given under subregulation (1) must notify the CEO if the pharmacist does not receive the document for the supply of the medicine required under subregulation (3) within 5 working days of the supply of the medicine.

Penalty for this subregulation: a fine of $1 000.

Division 3 — Electronic prescribing systems

18. Terms used

(1) In this Division —

access code, of a person, means a password or other means by which the person gains access to an electronic system;

personal information has the meaning given in the *Freedom of Information Act 1992* in the Glossary clause 1;

system identifier, of a person, means the code by which the identity of the person is recorded by an electronic system.

(2) For the purposes of this Division, an entry is made in an electronic system if —

(a) a prescription is issued, amended or cancelled using the system; or

(b) the system is used for the purpose of dispensing a medicine that is a Schedule 4 or 8 poison; or

(c) information is otherwise entered into or retrieved from the system in relation to —

(i) issuing, amending or cancelling a prescription using the system; or

(ii) the use of the system for the purpose of dispensing a medicine that is a Schedule 4 or 8 poison.

19. Approval of electronic system

(1) A person may apply to the CEO for approval of an electronic system to be used for the purpose of issuing prescriptions for medicines that are Schedule 4 or 8 poisons and for the dispensing of those medicines.

(2) An application must be in an approved form.

(3) The CEO may by written notice require an applicant to provide further information in relation to an application.

(4) The CEO may approve an electronic system to be used for issuing prescriptions for medicines that are Schedule 4 or 8 poisons and for the purpose of dispensing those medicines if satisfied that the system —

(a) is sufficiently secure; and

(b) is designed so that, to the extent practicable, for a particular medicine —

(i) only a prescriber can use the system to issue a prescription for the medicine; and

(ii) only a pharmacist, or an assistant under the direct personal supervision of a pharmacist, can use the system for the purpose of dispensing the medicine;

and

(c) complies substantially with the criteria in regulation 20; and

(d) complies with any other criteria the CEO thinks relevant.

(5) Before being satisfied that an electronic system is sufficiently secure, the CEO must be satisfied that, to the extent practicable —

(a) personal information included in the system is protected; and

(b) access to and use of the system is controlled by appropriate procedures; and

(c) only persons permitted to have access to the system according to those procedures can have access to the system; and

(d) the system records in a way that cannot be amended or erased every occurrence of —

(i) a prescription being issued or amended using the system; and

(ii) the use of the system for the purpose of dispensing a medicine.

(6) Subregulation (5) does not limit the matters that the CEO may take into account for the purposes of subregulation (4)(a).

20. Criteria for electronic system

For the purposes of regulation 19(4)(c), the criteria for an electronic system are that the system must be designed so that —

(a) only an individual can be given an access code; and

(b) the system records in a way that cannot be amended or erased —

(i) each person who is given an access code; and

(ii) the date that the access code is given; and

(iii) if the access code is cancelled — the date that it is cancelled;

and

(c) each entry made in the system is given a unique sequential number; and

(d) for each entry made in the system, the system records in a way that cannot be amended or erased —

(i) the time and date the entry is made; and

(ii) the system identifier of the person whose access code is used to make the entry;

and

(e) the system requires that persons with access to the system change their access code in accordance with standard industry practice; and

(f) appropriate backup arrangements are in place; and

(g) the system records the details of each person who is an administrator of the system and retains those details for 7 years after the person ceases to be an administrator; and

(h) the system can generate appropriate reports from its records including reports of —

(i) persons who have been given an access code and have access to the system during a particular period; and

(ii) entries made in the system during a particular period; and

(iii) entries made in the system sorted according to medicine type, strength or dose or according to patient; and

(iv) corrections to entries made in the system during a particular period;

and

(i) the records of the system can be produced on demand.

21. System to have administrator

An approval given under regulation 19(4) has no effect during any period for which there is no individual designated by the CEO as the administrator of the electronic system.

22. Offences

(1) In this regulation —

inappropriate use, in relation to an approved electronic prescribing system, includes using the system in a way that is not in accordance with the procedures that control access to and use of the system;

unauthorised person, in relation to an approved electronic prescribing system, means a person who is not permitted to access the system in accordance with the procedures that control access to and use of the system.

(2) A person must not make inappropriate use of an approved electronic prescribing system.

Penalty for this subregulation: a fine of $5 000.

(3) A person who has an access code for an approved electronic prescribing system must not —

(a) reveal the person's access code to another person; or

(b) do anything to allow an unauthorised person to gain access to the system.

Penalty for this subregulation: a fine of $5 000.

(4) An administrator of an approved electronic prescribing system must, to the extent practicable, ensure that —

(a) only one access code is given to each person who is permitted to have access to the system; and

(b) each person who is responsible to the administrator for the operation and control of the system does not make inappropriate use of the system.

Penalty for this subregulation: a fine of $5 000.

Part 5 — Supplying medicine that is Schedule 4 or 8 poison

23. Dispensing medicine that is Schedule 4 or 8 poison

(1) A pharmacist who dispenses a medicine that is a Schedule 4 or 8 poison must —

(a) be satisfied that —

(i) the prescription is completed and issued in accordance with the requirements in Part 4; and

(ii) the class of health professional of which the person issuing the prescription is a member, is a class that is authorised to prescribe the medicine;

and

(b) comply with the directions on the prescription; and

(c) on each occasion on which the medicine is dispensed —

(i) if an approved electronic prescribing system is used for the purpose of dispensing the medicine — provide the information referred to in subregulation (2) by means of the approved electronic prescribing system; or

(ii) in all other cases — mark on the prescription the information referred to in subregulation (2);

and

(d) record the dispensing of the medicine in accordance with Part 12; and

(e) in the case of a prescription for a medicine that is a Schedule 8 poison —

(i) retain the prescription; or

(ii) with the approval of the CEO, transfer the prescription to another pharmacist.

(2) The information to be provided or marked on a prescription is the following —

(a) the prescription reference number;

(b) the amount of the medicine that is dispensed;

(c) the date on which the medicine is dispensed;

(d) the name and address of the pharmacy where the medicine is dispensed.

(3) A pharmacist must not dispense a medicine that is a Schedule 4 or 8 poison if —

(a) the prescription —

(i) in the case of a prescription for a medicine that is a Schedule 4 poison — is more than 12 months old; or

(ii) in the case of a prescription for a medicine that is a Schedule 8 poison — is more than 6 months old;

or

(b) the prescription is illegible or appears to have been altered by a person other than the prescriber who issued it; or

(c) the prescription is cancelled in accordance with regulation 26.

24. Repeat dispensing of medicine that is Schedule 4 or 8 poison

(1) A pharmacist who dispenses a medicine that is a Schedule 4 poison to a person must, if the prescription is for the supply of the medicine on more than one occasion, prepare and provide to the person —

(a) a duplicate of the prescription; and

(b) a form that specifies the remaining number of occasions on which the medicine is authorised to be supplied in accordance with the prescription (a ***repeat form***).

(2) A pharmacist who dispenses a medicine that is a Schedule 8 poison must, if the prescription is for the supply of the medicine on more than one occasion, prepare and retain —

(a) a duplicate of the prescription; and

(b) a form that specifies the remaining number of occasions on which the medicine is authorised to be supplied in accordance with the prescription (a ***repeat form***).

(3) A duplicate prescription with a repeat form that authorises the supply of a medicine on at least one occasion is taken to be a prescription for the purpose of dispensing the medicine.

25. Pharmacist to confirm details of prescription for medicine that is Schedule 8 poison

(1) A pharmacist who is presented with a prescription for the supply of a medicine that is a Schedule 8 poison must take reasonable steps to confirm —

(a) the authenticity of the prescription; and

(b) the identity of the person who issued the prescription; and

(c) the bona fides of the person wishing to have the medicine supplied in accordance with the prescription.

(2) If, despite taking reasonable steps, a pharmacist is unable to confirm the matters referred to in subregulation (1)(a) to (c) in respect of a prescription, the pharmacist may supply a quantity of the medicine required to provide treatment for 2 days in accordance with the directions for use for the medicine included in the prescription.

(3) This regulation does not apply in respect of a prescription issued using an approved electronic prescribing system.

26. Cancelling prescription or document

(1) A pharmacist must cancel a prescription for a medicine that is a Schedule 4 or 8 poison in the following circumstances —

(a) the medicine has been dispensed on one occasion and the prescription does not clearly indicate the maximum number of occasions on which the medicine is to be dispensed;

(b) the medicine is a Schedule 8 poison that has been dispensed on one occasion and the prescription does not clearly indicate the intervals at which the medicine is to be dispensed;

(c) the medicine has already been dispensed on the maximum number of occasions specified in the prescription.

Penalty for this subregulation: a fine of $1 000.

(2) A pharmacist must cancel a document that is presented as a prescription for the supply of a medicine that is a Schedule 4 or 8 poison if the pharmacist is satisfied that the document —

(a) is not completed or issued in accordance with the requirements in Part 4; or

(b) was not issued by a person who was authorised to prescribe the medicine; or

(c) is false in a material particular.

Penalty for this subregulation: a fine of $1 000.

(3) A prescription or document must be cancelled —

(a) in the case of a prescription or document that is issued using an approved electronic prescribing system — by the means provided by the approved electronic prescribing system; or

(b) in any other case — by marking the word “cancelled” across the prescription or document.

(4) If a pharmacist cancels a document under subregulation (2)(c), the pharmacist must —

(a) inform the CEO that the document has been cancelled; and

(b) advise the CEO of the reasons for cancelling the document.

Penalty for this subregulation: a fine of $1 000.

27. Dispensing medicine that is Schedule 8 poison to drug dependent or oversupplied person

A pharmacist may dispense a medicine that is a Schedule 8 poison, other than an opioid pharmacotherapy, to a drug dependent person or an oversupplied person.

28. Dispensing opioid pharmacotherapy for drug dependent person or oversupplied person

(1) The CEO may authorise a pharmacy to dispense opioid pharmacotherapies to drug dependent persons or oversupplied persons.

(2) The authorisation —

(a) must be in writing; and

(b) may be subject to conditions; and

(c) may, at any time, be amended, suspended or revoked by the CEO.

(3) A pharmacist may, at a pharmacy, dispense an opioid pharmacotherapy to a drug dependent person or an oversupplied person if —

(a) an authorisation has been given under subregulation (1) in respect of the pharmacy; and

(b) the pharmacist does so in accordance with the authorisation.

29. Supplying medicine that is Schedule 4 poison in emergency

(1) A pharmacist may supply a medicine that is a Schedule 4 poison to a person if the pharmacist is satisfied on reasonable grounds that —

(a) the person is under regular treatment with the medicine; and

(b) it is not practical for the person to obtain a prescription in sufficient time to allow for treatment with the medicine to continue uninterrupted; and

(c) interruption of treatment with the medicine is likely to cause harm to the person.

(2) The maximum quantity of a medicine that may be supplied under subregulation (1) is the quantity required for 3 days of the regular treatment of the person.

30. Supplying medicine that is Schedule 4 poison for emergency veterinary use

(1) A pharmacist may supply a medicine that is a Schedule 4 poison to a person if the pharmacist is satisfied on reasonable grounds that —

(a) the person requires the medicine for treatment of an animal which is under regular treatment with the medicine; and

(b) it is not practical for the person to obtain a prescription in sufficient time to allow for treatment with the medicine to continue uninterrupted; and

(c) interruption of treatment with the medicine is likely to cause harm to the animal.

(2) The maximum quantity of a medicine that may be supplied under subregulation (1) is the quantity required for 3 days of the regular treatment of the animal.

31. Supplying medicine that is Schedule 4 or 8 poison on direction of prescriber

A pharmacist may supply a medicine that is a Schedule 4 or 8 poison on a direction given under regulation 17(1).

32. Supplying medicine that is Schedule 4 or 8 poison to authorised health professional

A pharmacist must not supply a medicine that is a Schedule 4 or 8 poison to an authorised health professional unless —

(a) the medicine is supplied in accordance with a prescription; or

(b) the pharmacist —

(i) is satisfied that the supply is for the purpose of administration or supply of the medicine by the health professional in the lawful practice of their profession; and

(ii) obtains from the health professional a written request specifying the quantity, dose, strength and form of the medicine that is to be supplied.

Part 6 — Structured administration and supply arrangement

33. SASA issued by CEO

(1) The CEO may issue a SASA that applies throughout the State.

(2) A SASA issued by the CEO must —

(a) be in writing; and

(b) specify the following —

(i) the class of health professional to which it applies;

(ii) a description of each medicine to which it applies;

(iii) the circumstances in which the medicine may be administered or supplied by a health professional.

(3) For the purposes of subregulation (2)(b)(i), a class of health professional may be identified by reference to any of the following —

(a) a qualification held by the health professional;

(b) the employment circumstances of the health professional;

(c) any other criteria the CEO thinks relevant.

(4) A SASA issued by the CEO must be published on the Department's website.

[Regulation 33 amended: Gazette 13 Nov 2018 p. 4429.]

34. SASA issued for health organisation

(1) In this regulation —

clinical governance committee means a committee constituted by at least 3 members including a medical practitioner, a registered nurse and a pharmacist.

(2) The chief executive officer of a health organisation may issue a SASA that applies in respect of the practice of authorised health professionals of a specified class who —

(a) are employed in the organisation; or

(b) provide services to the organisation under a contract for services.

(3) Each SASA issued by the chief executive officer of a health organisation must apply to only one medicine.

(4) A SASA issued by the chief executive officer of a health organisation must —

(a) be in writing; and

(b) specify the following —

(i) the class of authorised health professional to which it applies;

(ii) a description of the medicine to which it applies;

(iii) the circumstances in which the medicine may be administered or supplied by an authorised health professional;

and

(c) be signed by the most senior medical practitioner employed in the organisation; and

(d) be approved by a clinical governance committee established by the chief executive officer of the organisation; and

(e) be made available to each health professional to whom it applies.

(5) For the purposes of subregulation (4)(b)(iii), the circumstances in which a medicine may be administered or supplied can only be circumstances relating to the acute care of a patient of the organisation or the implementation of a public health programme conducted by the organisation.

(6) A SASA issued by the chief executive officer of a health organisation —

(a) expires at the end of the period of 2 years beginning on the day it is issued unless earlier withdrawn; and

(b) cannot be reissued unless a review of the SASA has been carried out by the most senior medical practitioner employed in the organisation.

(7) The chief executive officer of a health organisation must, as soon as reasonably practicable after issuing a SASA in respect of the organisation, provide a copy of the SASA to the CEO.

Penalty for this subregulation: a fine of $1 000.

(8) The chief executive officer of a health organisation must withdraw a SASA issued in respect of the organisation on the written direction of the CEO.

Penalty for this subregulation: a fine of $5 000.

35. SASA issued by medical practitioner

(1) A medical practitioner may issue a SASA that applies in respect of the practice of a specified authorised health professional employed by the medical practitioner.

(2) A SASA issued by a medical practitioner must —

(a) be in writing; and

(b) specify the following —

(i) the name of the authorised health professional employed by the medical practitioner to which it applies;

(ii) a description of each medicine to which it applies;

(iii) the circumstances in which the medicine may be administered or supplied by the authorised health professional;

and

(c) be signed by the medical practitioner.

(3) For the purposes of subregulation (2)(b)(iii), the circumstances in which a medicine may be administered or supplied can only be circumstances relating to the acute care of a patient of the medical practitioner or the implementation of a public health programme in which the medical practitioner is participating.

(4) A SASA issued by a medical practitioner —

(a) expires at the end of the period of 2 years beginning on the day it is issued unless earlier withdrawn; and

(b) cannot be reissued unless a review of the SASA has been carried out by the medical practitioner.

(5) A medical practitioner who issues a SASA must make it available to the CEO on request.

Penalty for this subregulation: a fine of $1 000.

(6) A medical practitioner must withdraw a SASA issued by the medical practitioner on the written direction of the CEO.

Penalty for this subregulation: a fine of $2 000.

36. Requirement for SASA applying to medicine that is Schedule 8 poison

A SASA that relates to the administration or supply of a medicine that is a Schedule 8 poison must not include provisions that are inconsistent with Part 11.

Part 7 — Authorisation of health professionals

Division 1 — Preliminary

37. Terms used

In this Part —

Aboriginal and Torres Strait Islander health practitioner means a person registered under the *Health Practitioner Regulation National Law (Western Australia)* whose name is entered on the Register of Aboriginal and Torres Strait Islander Health Practitioners kept under that Law;

Aboriginal and Torres Strait Islander health worker means a person employed —

(a) by an Aboriginal Health Service to provide health care to Aboriginal or Torres Strait Islander people; or

(b) to provide a public health service to Aboriginal or Torres Strait Islander people;

Aboriginal Health Service means a health service that is a member of the Aboriginal Health Council of Western Australia (ACN 114 220 478);

anaesthetic technician means a person employed in a hospital to assist an anaesthetist in the hospital;

dental hygienist means a person registered under the *Health Practitioner Regulation National Law (Western Australia)* whose name is entered on the Dental Hygienist Division of the Register of Dental Practitioners kept under that Law;

dental therapist means a person registered under the *Health Practitioner Regulation National Law (Western Australia)* whose name is entered on the Dental Therapist Division of the Register of Dental Practitioners kept under that Law;

dentist means a person registered under the *Health Practitioner Regulation National Law (Western Australia)* whose name is

entered on the Dentists Division of the Register of Dental Practitioners kept under that Law;

domestic commercial vessel has the meaning given in the Marine Safety (Domestic Commercial Vessel) National Law section 6 as set out in the *Marine Safety (Domestic Commercial Vessel) National Law Act 2012* (Commonwealth) Schedule 1;

endorsed midwife means a person registered under the *Health Practitioner Regulation National Law (Western Australia)* in the midwifery profession whose registration is endorsed under section 94 of that Law;

endorsed optometrist means an optometrist whose registration is endorsed under the *Health Practitioner Regulation National Law (Western Australia)* section 94;

endorsed podiatrist means a podiatrist whose registration is endorsed under the *Health Practitioner Regulation National Law (Western Australia)* section 94;

enrolled nurse means a person registered under the *Health Practitioner Regulation National Law (Western Australia)* in the nursing profession whose name is entered on Division 2 of the Register of Nurses kept under that Law as an enrolled nurse;

first aid provider (vessel) means a person on a vessel —

(a) whose duties include the provision of acute care for persons or animals who suffer a medical or veterinary condition on the vessel; and

(b) who is authorised by the captain of the vessel to obtain medicines for use on the vessel;

foreign vessel has the meaning given in the *Navigation Act 2012* (Commonwealth) section 14;

health organisation means any of the following —

(a) a public hospital;

(b) a private hospital;

(c) an organisation that is the holder of a health service permit;

health service permit means a permit of a type referred to in item 1, 2 or 3 of the Table to regulation 79(2);

medic —

(a) means a person who provides emergency health services, including ambulance services, in a location other than a hospital, and who is covered by one or more of the following —

(i) the person is employed by a medical practitioner to provide the services;

(ii) the person is employed, or engaged under a contract for services, by a health organisation to provide the services;

(iii) the person is under the supervision of a health organisation in respect of the provision of the services;

but

(b) does not include a paramedic;

midwife means a person registered under the *Health Practitioner Regulation National Law (Western Australia)* in the midwifery profession;

nurse practitioner means a person registered under the *Health Practitioner Regulation National Law (Western Australia)* in the nursing profession whose registration under that Law is endorsed as nurse practitioner;

optometrist means a person registered under the *Health Practitioner Regulation National Law (Western Australia)* in the optometry profession;

oral health therapist means a person registered under the *Health Practitioner Regulation National Law (Western Australia)* whose name is entered on the Oral Health Therapist Division of the Register of Dental Practitioners kept under that Law;

paramedic means a person registered under the *Health Practitioner Regulation National Law (Western Australia)* in the paramedicine profession;

PBS means the document "Schedule of Pharmaceutical Benefits" published from time to time, for the purposes of the *National Health Act 1953* (Commonwealth), by the Department of State of the Commonwealth that is administered by the Commonwealth Minister administering that Act;

PBS medicine means a medicine that —

(a) is listed in any of the following Schedules of the PBS —

(i) General Pharmaceutical Benefits;

(ii) Palliative Care;

but

(b) is not listed in any of the following Schedules of the PBS —

(i) Highly Specialised Drugs Program (Private Hospital);

(ii) Highly Specialised Drugs Program (Public Hospital);

(iii) Highly Specialised Drugs Program (Community Access);

podiatrist means a person registered under the *Health Practitioner Regulation National Law (Western Australia)* in the podiatry profession;

racing yacht means a yacht participating in a race departing from the State;

registered nurse means a person registered under the *Health Practitioner Regulation National Law (Western Australia)* in the nursing profession whose name is entered on Division 1 of the Register of Nurses kept under that Law as a registered nurse;

regulated Australian vessel has the meaning given in the *Navigation Act 2012* (Commonwealth) section 15;

remote clinic means a medical clinic, nursing post or similar facility —

(a) operated by a health service that satisfies the conditions specified in the *National Health (Remote Area Aboriginal Health Services Program) Special Arrangement 2017* (Commonwealth) section 9(2); or

(b) approved by the CEO under regulation 39A;

supply does not include dispense;

vessel means each of the following —

(a) a domestic commercial vessel;

(b) a foreign vessel;

(c) a racing yacht;

(d) a regulated Australian vessel;

veterinary nurse has the meaning given in the *Veterinary Practice Act 2021* section 3.

[Regulation 37 amended: Gazette 13 Nov 2018 p. 4429-30; 15 Mar 2019 p. 787-8; SL 2022/93 r. 4.]

38. Classes of persons prescribed as health professionals

The following classes of persons are prescribed for the purposes of the definition of ***health professional*** in section 3 —

(a) Aboriginal and Torres Strait Islander health workers;

(b) anaesthetic technicians;

(c) first aid providers (vessel);

(d) medics;

(e) veterinary nurses.

[Regulation 38 amended: Gazette 13 Nov 2018 p. 4430.]

39. Veterinary medicine not for human use

Nothing in this Part authorises the administration to a human or supply for human use of a poison which is prepared for veterinary use.

39A. Approval of remote clinic

(1) In this regulation —

ASGS means the document "Australian Statistical Geography Standard (ASGS): Volume 5 - Remoteness Structure, July 2016" published by the Australian Bureau of Statistics.

(2) The CEO may approve a medical clinic, nursing post or similar facility as a remote clinic if it is in an area of the State classified as Remote Australia or Very Remote Australia under the ASGS.

(3) The approval —

(a) must be in writing; and

(b) may be subject to conditions; and

(c) may, at any time, be amended, suspended or revoked by the CEO.

[Regulation 39A inserted: Gazette 15 Mar 2019 p. 788.]

Division 2 — Authorisation of Aboriginal and Torres Strait Islander health professionals

40. Classes of Aboriginal and Torres Strait Islander health professional prescribed for s. 25(1)(a)

The following classes of health professional are prescribed for the purposes of section 25(1)(a) —

(a) Aboriginal and Torres Strait Islander health practitioner;

(b) Aboriginal and Torres Strait Islander health worker.

41. Authorisation of Aboriginal and Torres Strait Islander health practitioners

(1) For the purposes of section 25(1)(b), a medicine that is a Schedule 2 or 3 poison is a medicine that an Aboriginal and Torres Strait Islander health practitioner, acting in the lawful practice of their profession, may supply.

(2) For the purposes of section 25(1)(b), a medicine that is a Schedule 4 poison is a medicine that an Aboriginal and Torres Strait Islander health practitioner, acting in the lawful practice of their profession, may —

(a) administer; or

(b) possess; or

(c) supply.

(3) The supply by an Aboriginal and Torres Strait Islander health practitioner of a medicine that is a Schedule 2, 3 or 4 poison is subject to the condition that the supply is —

(a) in the circumstances described in subregulation (3A); or

(b) in the circumstances identified in a SASA that applies to the Aboriginal and Torres Strait Islander health practitioner in respect of the medicine.

(3A) For the purposes of subregulation (3)(a), the circumstances are as follows —

(a) the medicine is a PBS medicine;

(b) the place of supply is a remote clinic;

(c) when the supply occurs there is no pharmacy within 25 km of the place of supply that is open and accessible by the person to whom the medicine is supplied;

(d) the supply is not for the purposes of acute care or treatment relating to the implementation of a public health programme;

(e) the person to whom the medicine is supplied has consulted with a medical practitioner, in the period of 6 months before the day on which the supply occurs, about the medical condition to which the supply relates;

(f) the supply is on a direction given under regulation 16A(1) in respect of that particular supply;

(g) the Aboriginal and Torres Strait Islander health practitioner has completed a course of training approved by the CEO for the purposes of this subregulation.

(4) The administration by an Aboriginal and Torres Strait Islander health practitioner of a medicine that is a Schedule 4 poison is subject to the condition that the administration —

(a) is on a direction given under regulation 15(1); or

(b) is in the circumstances identified in a SASA that applies to the Aboriginal and Torres Strait Islander health practitioner in respect of the medicine.

(5) The possession by an Aboriginal and Torres Strait Islander health practitioner of a medicine that is a Schedule 4 poison is subject to the condition that the possession is for the purpose of administering or supplying the medicine in accordance with this regulation.

[Regulation 41 amended: Gazette 15 Mar 2019 p. 788-9.]

42. Authorisation of Aboriginal and Torres Strait Islander health workers

(1) For the purposes of section 25(1)(b), a medicine that is a Schedule 2 or 3 poison is a medicine that an Aboriginal and Torres Strait Islander health worker, acting in the lawful practice of their profession, may supply.

(2) For the purposes of section 25(1)(b), a medicine that is a Schedule 4 poison is a medicine that an Aboriginal and Torres

Strait Islander health worker, acting in the lawful practice of their profession, may —

(a) administer; or

(b) possess; or

(c) supply.

(3) The supply by an Aboriginal and Torres Strait Islander health worker of a medicine that is a Schedule 2, 3 or 4 poison is subject to the condition that the supply is —

(a) in the circumstances described in subregulation (3A); or

(b) in the circumstances identified in a SASA that applies to the Aboriginal and Torres Strait Islander health worker in respect of the medicine.

(3A) For the purposes of subregulation (3)(a), the circumstances are as follows —

(a) the medicine is a PBS medicine;

(b) the place of supply is a remote clinic;

(c) when the supply occurs there is no pharmacy within 25 km of the place of supply that is open and accessible by the person to whom the medicine is supplied;

(d) the supply is not for the purposes of acute care or treatment relating to the implementation of a public health programme;

(e) the person to whom the medicine is supplied has consulted with a medical practitioner, in the period of 6 months before the day on which the supply occurs, about the medical condition to which the supply relates;

(f) the supply is on a direction given under regulation 16A(1) in respect of that particular supply;

(g) the Aboriginal and Torres Strait Islander health worker has completed a course of training approved by the CEO for the purposes of this subregulation.

(4) The administration by an Aboriginal and Torres Strait Islander health worker of a medicine that is a Schedule 4 poison is subject to the condition that the administration —

(a) is on a direction given under regulation 15(1); or

(b) is in the circumstances identified in a SASA that applies to the Aboriginal and Torres Strait Islander health worker in respect of the medicine.

(5) The possession by an Aboriginal and Torres Strait Islander health worker of a medicine that is a Schedule 4 poison is subject to the condition that the possession is for the purpose of administering or supplying the medicine in accordance with this regulation.

[Regulation 42 amended: Gazette 15 Mar 2019 p. 789-90.]

Division 3 — Authorisation of anaesthetic technicians

43. Anaesthetic technician prescribed for s. 25(1)(a)

Anaesthetic technician is prescribed as a class of health professional for the purposes of section 25(1)(a).

44. Authorisation of anaesthetic technicians

(1) For the purposes of section 25(1)(b), a medicine that is a Schedule 4 or 8 poison is a medicine that an anaesthetic technician, acting in the lawful practice of their profession, may —

(a) administer; or

(b) possess.

(2) The administration by an anaesthetic technician of a medicine that is a Schedule 4 or 8 poison is subject to the condition that the administration —

(a) is on a direction given by a medical practitioner under regulation 15(1); or

(b) is in the circumstances identified in a SASA that applies to the anaesthetic technician in respect of the medicine.

(3) The possession by an anaesthetic technician of a medicine that is a Schedule 4 or 8 poison is subject to the condition that the possession is for the purpose of —

(a) administering the medicine in accordance with this regulation; or

(b) assisting an anaesthetist in a hospital.

Division 4 — Authorisation of dental professionals

45. Classes of dental professional prescribed for s. 25(1)(a)

The following classes of health professional are prescribed for the purposes of section 25(1)(a) —

(a) dentist;

(b) dental hygienist;

(c) dental therapist;

(d) oral health therapist.

46. Authorisation of dentists

(1) For the purposes of section 25(1)(b), a medicine that is a Schedule 2 or 3 poison is a medicine that a dentist, acting in the lawful practice of their profession, may supply.

(2) For the purposes of section 25(1)(b), a medicine that is a Schedule 4 or 8 poison is a medicine that a dentist, acting in the lawful practice of their profession, may —

(a) administer; or

(b) possess; or

(c) prescribe; or

(d) supply.

(3) The prescription or supply by a dentist of a medicine that is a Schedule 8 poison is subject to Part 11.

47. Authorisation of other dental staff

(1) In this regulation —

dental worker means each of the following —

(a) a dental hygienist;

(b) a dental therapist;

(c) an oral health therapist.

(2) For the purposes of section 25(1)(b), a medicine that is a Schedule 2 or 3 poison is a medicine that a dental worker, acting in the lawful practice of their profession, may supply.

(3) For the purposes of section 25(1)(b), a medicine that is a Schedule 4 or 8 poison is a medicine that a dental worker, acting in the lawful practice of their profession, may —

(a) administer; or

(b) possess.

(4) The supply by a dental worker of a medicine that is a Schedule 2 or 3 poison is subject to the condition that the supply is in the circumstances identified in a SASA that applies to the dental worker in respect of the medicine.

(5) The administration by a dental worker of a medicine that is a Schedule 4 or 8 poison is subject to the condition that the administration —

(a) is on a direction given by a dentist under regulation 15(1); or

(b) is in the circumstances identified in a SASA that applies to the dental worker in respect of the medicine.

(6) The possession by a dental worker of a medicine that is a Schedule 4 or 8 poison is subject to the condition that the

possession is for the purpose of administering the medicine in accordance with this regulation.

Division 5 — Authorisation of first aid providers (vessel)

48. First aid provider (vessel) prescribed for s. 25(1)(a)

First aid provider (vessel) is prescribed as a class of health professional for the purposes of section 25(1)(a).

49. Authorisation of first aid providers (vessel)

(1) In this regulation —

livestock export standard means —

(a) *Australian Standards for the Export of Livestock (Version 2.3) 2011* published by the Department of Agriculture, Fisheries and Forestry of the Commonwealth; or

(b) *Marine Orders — Part 43 (Cargo and cargo handling — livestock) 2006* that is in effect under the *Navigation Act 2012* (Commonwealth).

(2) For the purposes of section 25(1)(b), a medicine that is a Schedule 2 or 3 poison is a medicine that a first aid provider (vessel), acting in the lawful practice of their profession, may supply.

(3) For the purposes of section 25(1)(b), a medicine that is a Schedule 4 or 8 poison listed in the Table in respect of a type of vessel is a medicine that a first aid provider (vessel) on that type of vessel, acting in the lawful practice of their profession, may —

(a) administer; or

(b) possess; or

(c) supply.

Table

Type of vessel	Medicines
Domestic commercial vessel	A medicine that is a Schedule 4 or 8 poison that is necessary for the vessel to comply with the requirements of the *National Standard for Commercial Vessels* published by the Australian Maritime Safety Authority
Foreign vessel	A medicine that is a Schedule 4 or 8 poison that is necessary for the vessel to comply with the *International Medical Guide for Ships*, Third Edition published by the World Health Organisation
Racing yacht	A medicine that is a Schedule 4 or 8 poison that is necessary for the yacht to comply with the requirements of the *Racing Rules of Sailing* made by Australian Sailing Ltd
Regulated Australian vessel	A medicine that is a Schedule 4 or 8 poison that is necessary for the vessel to comply with the requirements of *Marine Order 11 (Living and working conditions on vessels) 2015* that is in effect under the *Navigation Act 2012* (Commonwealth)
Regulated Australian vessel carrying livestock for export	A medicine that is a Schedule 4 poison that is necessary for compliance with a requirement relating to veterinary treatment set out in a livestock export standard

(4) The administration or supply by a first aid provider (vessel) of a medicine that is a Schedule 4 or 8 poison is subject to the condition that the administration or supply is for the treatment of a person or animal on the vessel.

(5) The possession by a first aid provider (vessel) of a medicine that is a Schedule 4 or 8 poison is subject to the condition that the possession is for the purpose of administering or supplying the medicine in accordance with this regulation.

Division 6 — Authorisation of medical practitioners

50. Medical practitioner prescribed for s. 25(1)(a)

Medical practitioner is a class of health professional prescribed for the purposes of section 25(1)(a).

51. Authorisation of medical practitioners

(1) For the purposes of section 25(1)(b), a medicine that is a Schedule 2 or 3 poison is a medicine that a medical practitioner, acting in the lawful practice of their profession, may supply.

(2) For the purposes of section 25(1)(b), a medicine that is a Schedule 4 or 8 poison is a medicine that a medical practitioner, acting in the lawful practice of their profession, may —

(a) administer; or

(b) possess; or

(c) prescribe; or

(d) supply.

(3) The prescription or supply by a medical practitioner of a medicine that is a Schedule 8 poison is subject to Part 11.

Division 7 — Authorisation of nurses and midwives

52. Classes of nurse and midwife prescribed for s. 25(1)(a)

The following classes of health professional are prescribed for the purposes of section 25(1)(a) —

(a) nurse practitioner;

(b) registered nurse;

(c) enrolled nurse;

(d) midwife.

53. Authorisation of nurse practitioners

(1) For the purposes of section 25(1)(b), a medicine that is a Schedule 2 or 3 poison is a medicine that a nurse practitioner, acting in the lawful practice of their profession, may supply.

(2) For the purposes of section 25(1)(b), a medicine that is a Schedule 4 or 8 poison is a medicine that a nurse practitioner, acting in the lawful practice of their profession, may —

(a) administer; or

(b) possess; or

(c) prescribe; or

(d) supply.

(3) The prescription or supply by a nurse practitioner of a medicine that is a Schedule 8 poison is subject to Part 11.

54. Authorisation of registered nurses

(1) For the purposes of section 25(1)(b), a medicine that is a Schedule 2 or 3 poison is a medicine that a registered nurse, acting in the lawful practice of their profession, may supply.

(2) For the purposes of section 25(1)(b), a medicine that is a Schedule 4 poison is a medicine that a registered nurse, acting in the lawful practice of their profession, may —

(a) administer; or

(b) possess; or

(c) supply.

(3) For the purposes of section 25(1)(b), a medicine that is a Schedule 8 poison is a medicine that a registered nurse, acting in the lawful practice of their profession, may —

(a) administer; or

(b) possess.

(4) The supply by a registered nurse of a medicine that is a Schedule 2, 3 or 4 poison is subject to the condition that the supply is —

(a) in the circumstances described in subregulation (4A); or

(b) in the circumstances identified in a SASA that applies to the registered nurse in respect of the medicine.

(4A) For the purposes of subregulation (4)(a), the circumstances are as follows —

(a) the medicine is a PBS medicine;

(b) the place of supply is a remote clinic;

(c) when the supply occurs there is no pharmacy within 25 km of the place of supply that is open and accessible by the person to whom the medicine is supplied;

(d) the supply is not for the purposes of acute care or treatment relating to the implementation of a public health programme;

(e) the person to whom the medicine is supplied has consulted with a medical practitioner, in the period of 6 months before the day on which the supply occurs, about the medical condition to which the supply relates;

(f) the supply is on a direction given under regulation 16A(1) in respect of that particular supply.

(5) The administration by a registered nurse of a medicine that is a Schedule 4 or 8 poison is subject to the condition that the administration —

(a) is on a direction given under regulation 15(1); or

(b) is in the circumstances identified in a SASA that applies to the registered nurse in respect of the medicine.

(6) The possession by a registered nurse of a medicine that is a Schedule 4 or 8 poison is subject to the condition that the possession is for the purpose of administering or supplying the medicine in accordance with this regulation.

[Regulation 54 amended: Gazette 15 Mar 2019 p. 790-1.]

55. Authorisation of enrolled nurses

(1) For the purposes of section 25(1)(b), a medicine that is a Schedule 2 or 3 poison is a medicine that an enrolled nurse, acting in the lawful practice of their profession, may supply.

(2) For the purposes of section 25(1)(b), a medicine that is a Schedule 4 poison is a medicine that an enrolled nurse, acting in the lawful practice of their profession, may —

(a) administer; or

(b) possess; or

(c) supply.

(3) For the purposes of section 25(1)(b), a medicine that is a Schedule 8 poison is a medicine that an enrolled nurse, acting in the lawful practice of their profession, may —

(a) administer; or

(b) possess.

(4) The supply by an enrolled nurse of a medicine that is a Schedule 2, 3 or 4 poison is subject to the condition that the supply is —

(a) in the circumstances described in subregulation (4A); or

(b) in the circumstances identified in a SASA that applies to the enrolled nurse in respect of the medicine.

(4A) For the purposes of subregulation (4)(a), the circumstances are as follows —

(a) the medicine is a PBS medicine;

(b) the place of supply is a remote clinic;

(c) when the supply occurs there is no pharmacy within 25 km of the place of supply that is open and accessible by the person to whom the medicine is supplied;

(d) the supply is not for the purposes of acute care or treatment relating to the implementation of a public health programme;

(e) the person to whom the medicine is supplied has consulted with a medical practitioner, in the period of 6 months before the day on which the supply occurs, about the medical condition to which the supply relates;

(f) the supply is on a direction given under regulation 16A(1) in respect of that particular supply.

(5) The administration by an enrolled nurse of a medicine that is a Schedule 4 or 8 poison is subject to the condition that the administration —

(a) is on a direction given under regulation 15(1); or

(b) is in the circumstances identified in a SASA that applies to the enrolled nurse in respect of the medicine.

(6) The possession by an enrolled nurse of a medicine that is a Schedule 4 or 8 poison is subject to the condition that the

possession is for the purpose of administering or supplying the medicine in accordance with this regulation.

[Regulation 55 amended: Gazette 15 Mar 2019 p. 791.]

56. Authorisation of midwives

(1) For the purposes of section 25(1)(b), a medicine that is a Schedule 2 or 3 poison is a medicine that a midwife, acting in the lawful practice of their profession, may supply.

(2) For the purposes of section 25(1)(b), a medicine that is a Schedule 4 poison is a medicine that a midwife, acting in the lawful practice of their profession, may —

(a) administer; or

(b) possess; or

(c) supply.

(3) For the purposes of section 25(1)(b), a medicine that is a Schedule 8 poison is a medicine that a midwife, acting in the lawful practice of their profession, may —

(a) administer; or

(b) possess.

(4) The supply by a midwife of a medicine that is a Schedule 2, 3 or 4 poison is subject to the condition that the supply is —

(a) in the circumstances described in subregulation (4A); or

(b) in the circumstances identified in a SASA that applies to the midwife in respect of the medicine.

(4A) For the purposes of subregulation (4)(a), the circumstances are as follows —

(a) the medicine is a PBS medicine;

(b) the place of supply is a remote clinic;

(c) when the supply occurs there is no pharmacy within 25 km of the place of supply that is open and accessible by the person to whom the medicine is supplied;

(d) the supply is not for the purposes of acute care or treatment relating to the implementation of a public health programme;

(e) the person to whom the medicine is supplied has consulted with a medical practitioner, in the period of 6 months before the day on which the supply occurs, about the medical condition to which the supply relates;

(f) the supply is on a direction given under regulation 16A(1) in respect of that particular supply.

(5) The administration by a midwife of a medicine that is a Schedule 4 or 8 poison is subject to the condition that the administration —

(a) is on a direction given under regulation 15(1); or

(b) is in the circumstances identified in a SASA that applies to the midwife in respect of the medicine.

(6) The possession by a midwife of a medicine that is a Schedule 4 or 8 poison is subject to the condition that the possession is for the purpose of administering or supplying the medicine in accordance with this regulation.

[Regulation 56 amended: Gazette 15 Mar 2019 p. 792.]

57. Authorisation of endorsed midwives

(1) For the purposes of section 25(1)(b), a medicine that is a Schedule 2 or 3 poison is a medicine that an endorsed midwife, acting in the lawful practice of their profession, may supply.

(2) For the purposes of section 25(1)(b), a medicine that is a Schedule 4 or 8 poison is a medicine that an endorsed midwife, acting in the lawful practice of their profession, may —

(a) administer; or

(b) possess; or

(c) prescribe; or

(d) supply.

(3) The prescription or supply by an endorsed midwife of a medicine that is a Schedule 8 poison is subject to Part 11.

(4) The prescription by an endorsed midwife of a medicine that is a Schedule 8 poison is subject to the condition that the prescription is not for the purpose of the administration of the medicine by a person other than the midwife.

(5) The possession by an endorsed midwife of a medicine that is a Schedule 4 or 8 poison is subject to the condition that the possession is for the purpose of administering or supplying the medicine in accordance with this regulation.

(6) This regulation applies in addition to regulation 56.

[Regulation 57 amended: Gazette 19 Nov 2019 p. 4051-2.]

Division 8 — Authorisation of optometrists

58. Optometrist prescribed for s. 25(1)(a)

Optometrist is a class of health professional prescribed for the purposes of section 25(1)(a).

59. Authorisation of optometrists

(1) In this regulation —

Optometry guidelines means the *Optometry guidelines for use of scheduled medicines* published by the Optometry Board of Australia.

(2) For the purposes of section 25(1)(b), a medicine that is a Schedule 2 or 3 poison is a medicine that an optometrist, acting in the lawful practice of their profession, may supply.

(3) For the purposes of section 25(1)(b), a medicine that is a Schedule 4 poison is a medicine that an optometrist, acting in the lawful practice of their profession, may —

(a) administer; or

(b) possess.

(4) The supply by an optometrist of a medicine that is a Schedule 2 or 3 poison is subject to the condition that the supply is in accordance with the Optometry guidelines.

(5) The administration by an optometrist of a medicine that is a Schedule 4 poison is subject to the condition that the administration is in accordance with the Optometry guidelines.

(6) The possession by an optometrist of a medicine that is a Schedule 4 poison is subject to the condition that the possession is for the purpose of administering the medicine in accordance with this regulation.

60. Authorisation of endorsed optometrists

(1) In this regulation —

Standard for Optometrists means the *Endorsement for Scheduled Medicines Registration Standard* Table 1 approved by the Australian Health Workforce Ministerial Council.

(2) For the purposes of section 25(1)(b), a medicine that is a Schedule 4 poison listed in the Standard for Optometrists is a medicine that an endorsed optometrist, acting in the lawful practice of their profession, may —

(a) administer; or

(b) possess; or

(c) prescribe; or

(d) supply.

(3) The administration, prescription or supply by an endorsed optometrist of a medicine listed in the Standard for Optometrists that is a Schedule 4 poison is subject to the condition that the administration, prescription or supply complies with any restrictions or conditions set out in the Standard for Optometrists in respect of the medicine.

(4) The possession by an endorsed optometrist of a medicine listed in the Standard for Optometrists that is a Schedule 4 poison is subject to the condition that the possession is for the purpose of administering or supplying the medicine in accordance with this regulation.

(5) This regulation applies in addition to regulation 59.

Division 9 — Authorisation of paramedics

61. Paramedic prescribed for s. 25(1)(a)

Paramedic is prescribed as a class of health professional for the purposes of section 25(1)(a).

62. Authorisation of paramedics

(1) For the purposes of section 25(1)(b), a medicine that is a Schedule 2 or 3 poison is a medicine that a paramedic, acting in the lawful practice of their profession, may supply.

(2) For the purposes of section 25(1)(b), a medicine that is a Schedule 4 or 8 poison is a medicine that a paramedic, acting in the lawful practice of their profession, may —

(a) administer; or

(b) possess; or

(c) supply.

(3) The supply by a paramedic of a medicine is subject to the condition that the supply is in the circumstances identified in a SASA that applies to the paramedic in respect of the medicine.

(4) The administration by a paramedic of a medicine that is a Schedule 4 or 8 poison is subject to the condition that the administration —

(a) is on a direction given under regulation 15(1); or

(b) is in the circumstances identified in a SASA that applies to the paramedic in respect of the medicine.

(5) The possession by a paramedic of a medicine that is a Schedule 4 or 8 poison is subject to the condition that the possession is for the purpose of administering or supplying the medicine in accordance with this regulation.

Division 9A — Authorisation of medics

[Heading inserted: Gazette 13 Nov 2018 p. 4431.]

62A. Medic prescribed for s. 25(1)(a)

Medic is prescribed as a class of health professional for the purposes of section 25(1)(a).

[Regulation 62A inserted: Gazette 13 Nov 2018 p. 4431.]

62B. Authorisation of medics

(1) For the purposes of section 25(1)(b), a medicine that is a Schedule 2 or 3 poison is a medicine that a medic, acting in the lawful practice of their profession, may supply.

(2) For the purposes of section 25(1)(b), a medicine that is a Schedule 4 or 8 poison is a medicine that a medic, acting in the lawful practice of their profession, may —

(a) administer; or

(b) possess; or

(c) supply.

(3) The supply by a medic of a medicine is subject to the condition that the supply is in the circumstances identified in a SASA that applies to the medic in respect of the medicine.

(4) The administration by a medic of a medicine that is a Schedule 4 or 8 poison is subject to the condition that the administration —

(a) is on a direction given under regulation 15(1); or

(b) is in the circumstances identified in a SASA that applies to the medic in respect of the medicine.

(5) The possession by a medic of a medicine that is a Schedule 4 or 8 poison is subject to the condition that the possession is for the purpose of administering or supplying the medicine in accordance with this regulation.

[Regulation 62B inserted: Gazette 13 Nov 2018 p. 4431.]

Division 10 — Authorisation of pharmacists

63. Pharmacist prescribed for s. 25(1)(a)

Pharmacist is prescribed as a class of health professional for the purposes of section 25(1)(a).

64. Authorisation of pharmacists

(1) For the purposes of section 25(1)(b), a medicine that is a Schedule 2 or 3 poison is a medicine that a pharmacist, acting in the lawful practice of their profession, may supply.

(2) For the purposes of section 25(1)(b), a medicine that is a Schedule 4 or 8 poison is a medicine that a pharmacist, acting in the lawful practice of their profession, may —

(a) administer; or

(b) dispense; or

(c) possess; or

(d) supply.

(3) The administration by a pharmacist of a medicine that is a Schedule 4 or 8 poison is subject to the condition that the administration is in the circumstances identified in a SASA that applies to the pharmacist in respect of the medicine.

(4) The dispensing by a pharmacist of a medicine that is a Schedule 4 or 8 poison is subject to the condition that —

(a) the medicine is dispensed to a person (the ***patient***) and —

(i) the medicine was prescribed for the patient by a prescriber; and

(ii) the pharmacist reasonably believes that the patient will use the medicine in accordance with the instructions of the prescriber;

or

(b) the medicine is dispensed to a person (the ***agent***) and —

(i) the medicine is dispensed to the agent for the purpose of it being administered or supplied to another person or to an animal (the ***patient***); and

(ii) the medicine was prescribed for the patient by a prescriber; and

(iii) the pharmacist reasonably believes that the medicine will be administered or supplied to the patient in accordance with the instructions of the prescriber.

(5) The supply by a pharmacist of a medicine that is a Schedule 4 or 8 poison is subject to the condition that the supply —

(a) is in the circumstances identified in a SASA that applies to the pharmacist in respect of the medicine; or

(b) is to an authorised health professional in accordance with regulation 32.

Division 11 — Authorisation of podiatrists

65. Podiatrist prescribed for s. 25(1)(a)

Podiatrist is a class of health professional prescribed for the purposes of section 25(1)(a).

66. Authorisation of podiatrists

(1) For the purposes of section 25(1)(b), a medicine that is a Schedule 2 or 3 poison is a medicine that a podiatrist, acting in the lawful practice of their profession, may supply.

(2) For the purposes of section 25(1)(b), a medicine that is a Schedule 4 poison is a medicine that a podiatrist, acting in the lawful practice of their profession, may —

(a) administer; or

(b) possess; or

(c) supply.

(3) The supply by a podiatrist of a medicine that is a Schedule 2, 3 or 4 poison is subject to the condition that the supply is in the circumstances identified in a SASA that applies to the podiatrist in respect of the medicine.

(4) The administration by a podiatrist of a medicine that is a Schedule 4 poison is subject to the condition that the administration —

(a) is on a direction given under regulation 15(1); or

(b) is in the circumstances identified in a SASA that applies to the podiatrist in respect of the medicine.

(5) The possession by a podiatrist of a medicine that is a Schedule 4 poison is subject to the condition that the possession is for the purpose of administering or supplying the medicine in accordance with this regulation.

67. Authorisation of endorsed podiatrists

(1) In this regulation —

Medicines List means the *National Podiatry Scheduled Medicines List* that is Appendix B to the *Guidelines for Endorsement for Scheduled Medicines* issued by the Podiatry Board of Australia.

(2) For the purposes of section 25(1)(b), a medicine listed in the Medicines List is a medicine that an endorsed podiatrist, acting in the lawful practice of their profession, may —

(a) administer; or

(b) possess; or

(c) prescribe; or

(d) supply.

(3) The administration, prescription or supply by an endorsed podiatrist of a medicine listed in the Medicines List is subject to the condition that the administration, prescription or supply complies with any conditions or restrictions set out in the Medicines List in respect of the medicine.

(4) The possession by an endorsed podiatrist of a medicine listed in the Medicines List that is a Schedule 4 or 8 poison is subject to the condition that the possession is for the purpose of administering or supplying the medicine in accordance with this regulation.

(5) This regulation applies in addition to regulation 66.

Division 12 — Authorisation of veterinary professionals

68. Classes of veterinary professional prescribed for s. 25(1)(a)

The following classes of health professional are prescribed for the purposes of section 25(1)(a) —

(a) veterinarian;

(b) veterinary nurse.

[Regulation 68 amended: SL 2022/93 r. 5.]

69. Authorisation of veterinarians

(1) For the purposes of section 25(1)(b), a medicine that is a Schedule 4 or 8 poison is a medicine that a veterinarian, acting in the lawful practice of their profession, may —

(a) administer; or

(b) possess; or

(c) prescribe; or

(d) supply.

(2) The prescription by a veterinarian of a medicine that is a Schedule 8 poison is subject to the condition that the prescription does not provide for the poison to be dispensed on more than one occasion.

[Regulation 69 amended: SL 2022/93 r. 5.]

70. Authorisation of veterinary nurses

(1) For the purposes of section 25(1)(b), a medicine that is a Schedule 4 or 8 poison is a medicine that a veterinary nurse, acting in the lawful practice of their profession, may —

(a) administer; or

(b) possess.

(2) The administration by a veterinary nurse of a medicine that is a Schedule 4 or 8 poison is subject to the condition that the administration is on the direct instruction of a veterinarian to administer the medicine to a particular animal.

(3) The possession by a veterinary nurse of a medicine that is a Schedule 4 or 8 poison is subject to the condition that the possession is for the purpose of administering the medicine in accordance with this regulation.

[Regulation 70 amended: SL 2022/93 r. 5.]

Part 8 — Licences and permits

Division 1 — Preliminary

71. Term used: specified

In this Part —

specified, in relation to a licence or permit, means specified in the licence or permit.

72. Purposes for licence or permit for Schedule 9 poison

(1) For the purposes of section 35(a), the following are prescribed as purposes for which the manufacture or supply of a Schedule 9 poison may be authorised by a licence —

(a) chemical analysis;

(b) treatment or anaesthesia of exotic animals;

(c) training animals to detect Schedule 9 poisons.

(2) For the purposes of section 37, the following are prescribed as purposes for which the use of a Schedule 9 poison may be authorised by a permit —

(a) chemical analysis;

(b) treatment or anaesthesia of exotic animals;

(c) training animals to detect Schedule 9 poisons.

73. Information to be recorded in register for licences and permits

For the purposes of section 75(3), the information that must be recorded in the register for each current licence or permit is the following —

(a) the name of the licensee or permit holder;

(b) contact details for the licensee or permit holder including address, telephone numbers and any email address;

(c) the type of licence or permit;

(d) details of any matters that are specified in the licence or permit;

(e) the dates of grant and expiry of the licence or permit;

(f) if the licence or permit has been suspended — the period of the suspension.

Division 2 — Licences

74. Types of licence

(1) In this regulation —

permitted purpose, in relation to a Schedule 9 poison, means a purpose referred to in section 35(a) or regulation 72(1).

(2) The types of licences that may be granted under the Act and the activities that may be authorised by each type of licence are set out in the Table.

Table

Item	Type of licence	Activities that may be authorised by licence
1.	Indent licence	To supply specified poisons from premises other than the licensee's premises
2.	Schedule 2 retail licence	To supply by retail sale specified medicines that are Schedule 2 poisons from specified premises
3.	Schedule 7 retail licence	To supply by retail sale specified Schedule 7 poisons from specified premises

Item	Type of licence	Activities that may be authorised by licence
4.	Schedule 9 licence	To manufacture or supply Schedule 9 poisons for a specified permitted purpose at or from specified premises
5.	Wholesaler's/ manufacturer's licence	To manufacture and supply by wholesale specified poisons at or from specified premises

75. Condition on Schedule 7 retail licence: records to be kept

(1) A Schedule 7 retail licence is subject to the condition that the licensee must comply with subregulations (2) and (3).

(2) A record of the retail sale of a Schedule 7 poison must be made in accordance with the current Poisons Standard Part 2 Division 6.

(3) A record of the retail sale of a Schedule 7 poison must —

(a) be kept for a period of 5 years commencing on the day the poison is supplied; and

(b) be produced for inspection on the request of an investigator.

[Regulation 75 amended: SL 2023/3 r. 5.]

76. Condition on wholesaler's/manufacturer's licence: responsible person

(1) In this regulation —

responsible person, in relation to a wholesaler's/manufacturer's licence, means —

(a) the person specified as responsible for supervision of activities carried out under the licence; or

(b) a person authorised for the licence under subregulation (3).

(2) A wholesaler's/manufacturer's licence is subject to the condition that any manufacture or supply of a poison under the licence must be carried out by or under the direction of a responsible person.

(3) If a person specified as responsible for supervision of activities carried out under a wholesaler's/manufacturer's licence is no longer able to supervise those activities, the CEO may, by written notice, authorise another person to be the responsible person for the licence.

77. Condition on wholesaler's/manufacturer's licence: supply of Schedule 4 or 8 poison

A wholesaler's/manufacturer's licence is subject to the condition that any supply of a Schedule 4 or 8 poison is only to a person —

(a) who is —

(i) authorised by a professional authority or an appropriate licence to manufacture or supply the poison; or

(ii) the holder of an appropriate permit that authorises the person to be in possession of the poison;

and

(b) who has provided the licensee with a written request specifying the quantity, strength and form of the medicine that is to be supplied.

78. Condition on wholesaler's/manufacturer's licence: records to be kept for Schedule 2, 3, 4 or 7 poisons

(1) A wholesaler's/manufacturer's licence that relates to the manufacture or supply of a Schedule 2, 3 or 4 poison is subject

to the condition that the licensee must comply with subregulations (3), (5) and (6).

(2) A wholesaler's/manufacturer's licence that relates to the manufacture or supply of a Schedule 7 poison is subject to the condition that the licensee must comply with subregulations (4) to (6).

(3) A record of the supply of a medicine that is a Schedule 2, 3 or 4 poison must —

(a) be made in an approved form on the day the medicine is supplied; and

(b) include the following details —

(i) the day on which the medicine is supplied;

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

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

(iv) the reference number on the invoice or other document evidencing the supply.

(4) A record of the supply of a Schedule 7 poison must be made in accordance with the current Poisons Standard Part 2 Division 6.

(5) The record of the supply of a poison must —

(a) be kept —

(i) in the case of a medicine that is a Schedule 2, 3 or 4 poison — for a period of 2 years commencing on the day the medicine is supplied; and

(ii) in the case of a Schedule 7 poison — for a period of 5 years commencing on the day the poison is supplied;

and

(b) be produced for inspection on the request of an investigator.

(6) Particulars of any details included in the record of the supply of a poison must, on the written request of the CEO, be provided to the CEO as follows —

(a) if the request relates to details recorded in the period of 2 months before the request — within 7 days of the request;

(b) otherwise — within 28 days of the request.

[Regulation 78 amended: SL 2023/3 r. 6.]

Division 3 — Permits

79. Types of permit

(1) In this regulation —

permitted purpose, in relation to a Schedule 9 poison, means —

(a) a purpose referred to in section 37; or

(b) a purpose referred to in regulation 72(2);

public sector agency means an agency as defined in the *Public Sector Management Act 1994* section 3(1).

(2) The types of permits that may be granted under the Act and the uses that may be authorised by each type of permit are set out in the Table.

Table

Item	Type of permit	Uses that may be authorised by permit
1.	Health service permit	To use specified medicines in providing health services at specified premises

Item	Type of permit	Uses that may be authorised by permit
2.	Health service permit — Department/ hospital	To use specified medicines in providing health services on behalf of the Department or at specified public hospitals including supply of the medicines in connection with providing the health services
3.	Health service permit — Public sector agency	To use specified medicines in providing health services on behalf of a specified public sector agency
4.	Government permit	To use specified poisons for the purpose of carrying out the activities of a specified public sector agency
5.	Industrial permit	To use a specified poison in a specified business
6.	Pharmaceutical samples permit	To carry and supply pharmaceutical samples of medicines that are Schedule 2, 3 or 4 poisons as a representative of a specified manufacturer or wholesale supplier

Item	Type of permit	Uses that may be authorised by permit
7.	Research/ Education permit	To use specified poisons for the purpose of education or research on behalf of a specified school, university, government department or research organisation
8.	Schedule 9 permit	To use specified Schedule 9 poisons for specified permitted purposes
9.	Stockfeed manufacture permit	To use specified medicines in the manufacture of stockfeed mixes and the supply of stockfeed mixes containing those medicines
10.	Veterinary practice permit	To use medicines in providing veterinary services

80. Condition on stockfeed manufacture permit: stockfeed mix containing antibiotic or sulphonamide

(1) A stockfeed manufacture permit is subject to the condition that the permit holder must comply with subregulations (2) and (3).

(2) Any supply by retail of a stockfeed mix containing an antibiotic or sulphonamide must be on a written order for the stockfeed mix that —

(a) is signed by a veterinarian; and

(b) is in respect of the supply of the stockfeed mix on a single occasion.

(3) The written order —

(a) must be kept by the permit holder for at least 2 years from the day the stockfeed mix is supplied; and

(b) must be produced for inspection on the request of an investigator.

[Regulation 80 amended: SL 2022/93 r. 5.]

81. Conditions on pharmaceutical samples permit

(1) A pharmaceutical samples permit is subject to the condition that the permit holder must not supply a pharmaceutical sample of a medicine to a person unless —

(a) the person is an authorised health professional who is authorised to administer, possess, prescribe, supply or use the medicine; and

(b) the person has given the permit holder a written request for the supply of the sample that is signed by the person.

(2) A pharmaceutical samples permit is subject to the condition that the permit holder must comply with the following requirements in relation to the transport and storage of pharmaceutical samples —

(a) the samples must be stored at the specified premises except when the permit holder is carrying them in a vehicle in the course of the permit holder's business;

(b) the samples must be stored at the specified premises in a locked cabinet or refrigerator;

(c) not more than 100 samples of any single medicine or samples of not more than 5 different medicines may be stored at the specified premises at any one time;

(d) not more than 25 samples of any single medicine or samples of not more than 5 different medicines may be carried in a vehicle at any one time.

(3) The CEO may, by written notice, vary the condition referred to in subregulation (2) to authorise the transport or storage of pharmaceutical samples in another specified manner.

(4) A pharmaceutical samples permit is subject to the condition that the permit holder must —

(a) make a written record of every pharmaceutical sample received or supplied by the permit holder; and

(b) keep the record together with consignment notes, invoices, advice notes and request forms relating to the record for a period of at least 2 years commencing on the day the sample is received or supplied; and

(c) on the written request of the CEO submit the record and supporting documentation to the CEO.

Part 9 — Requirements relating to manufacture, supply, handling, storage, transport and disposal of poisons

Division 1 — General requirements for containers and labels

82. Container and its labels to comply with current Poisons Standard

A poison must not be stored, supplied or transported unless —

(a) the immediate container in which the poison is stored, supplied or transported complies with the current Poisons Standard Part 2 or its use is authorised under regulation 84; and

(b) the container bears or has securely fixed to it a label which complies with the current Poisons Standard Part 2 or the use of which is authorised under regulation 84; and

(c) the container and the label comply with any other requirements in this Division.

[Regulation 82 amended: SL 2023/3 r. 7.]

83. Use of certain containers prohibited

A paper or plastic bag or envelope or a cardboard box must not be used as a container for a medicine or a Schedule 9 poison unless —

(a) within the container, the medicine or poison is individually sealed in measured amounts in a form commonly described as strip packaging; or

(b) the use of the container is authorised under regulation 84.

84. Authorisation of container or label

(1) In this regulation —

Appendix K poison means a poison listed in the current Poisons Standard Appendix K.

(2) The label for a medicine containing an Appendix K poison for human internal use that is not labelled with a sedation warning as required under the current Poisons Standard Part 2 is authorised if —

(a) the medicine is stored, supplied or transported by a person who is the holder of a licence that authorises the manufacture or supply of the medicine; or

(b) the medicine is supplied for the treatment of a patient in a hospital.

(3) The label for a medicine that is a Schedule 4 or 8 poison is authorised if —

(a) the medicine is supplied by an authorised health professional; and

(b) the immediate container in which the medicine is supplied bears, or has securely fixed to it, a label which complies with the current Poisons Standard Appendix L.

(4) The CEO may authorise the use of a container which does not comply with regulation 82(a) or 83(a) if the CEO is satisfied that, having regard to the nature of the poison and the purpose for which it is to be used, the use of the container is unlikely to adversely affect public safety.

(5) The CEO may authorise the use of a label which does not comply with regulation 82(b) if the CEO is satisfied that, having regard to the nature of the poison and the purpose for which it is to be used, the use of the label is unlikely to adversely affect public safety.

(6) An authorisation under subregulation (4) or (5) —

(a) must be in writing; and

(b) may be subject to conditions; and

(c) may, at any time, be amended, suspended or revoked by the CEO.

[Regulation 84 amended: SL 2023/3 r. 7.]

85. Suspending or prohibiting use of container or label

(1) In this regulation —

non-compliant container or label means —

(a) a container that does not comply with regulation 82(a); or

(b) a label that does not comply with regulation 82(b).

(2) The CEO may, by notice given to a person, direct the person to immediately suspend or stop the use of a container or label if the CEO is satisfied that —

(a) the container or label is a non-compliant container or label; and

(b) the use of the container or label may adversely affect public safety.

(3) The notice —

(a) must be in writing; and

(b) may be subject to conditions; and

(c) may, at any time, be amended, suspended or revoked by the CEO.

(4) A person must comply with a notice given to the person under subregulation (2).

Penalty for this subregulation: a fine of $5 000.

Division 2 — Requirements for medicine that is Schedule 2 poison

86. Storage of medicine that is Schedule 2 poison

(1) In this regulation —

Schedule 2 retail licence means a licence of a type referred to in item 2 of the Table to regulation 74(2).

(2) A medicine that is a Schedule 2 poison that is stored for supply by retail sale must be stored —

(a) in premises specified in a Schedule 2 retail licence or in a pharmacy; and

(b) in an area or in a manner that prevents physical access to the medicine by any person other than a person who is employed in the pharmacy or employed by the licensee.

(3) A medicine that is a Schedule 2 poison that is stored other than for supply by retail sale must be stored —

(a) so that it is not visible to members of the public; and

(b) in an area or in a manner that prevents physical access to the medicine by members of the public.

Division 3 — Requirements for medicine that is Schedule 3 poison

87. Storage of medicine that is Schedule 3 poison

(1) A medicine that is a Schedule 3 poison that is stored for supply by retail sale must be stored —

(a) in a pharmacy; and

(b) in an area or in a manner that prevents physical access to the medicine by any person other than a person who is employed in the pharmacy.

(2) A restricted Schedule 3 poison must not be stored in any part of the retail area of a pharmacy.

(3) A medicine that is a Schedule 3 poison that is stored other than for supply by retail sale must be stored —

(a) so that it is not visible to members of the public; and

(b) in an area or in a manner that prevents physical access to the medicine by members of the public.

88. Supply by retail sale of medicine that is Schedule 3 poison

(1) In this regulation —

pharmacy intern means a person who is undertaking supervised practice approved by the Pharmacy Board of Australia;

pharmacy technician means a person who assists a pharmacist in the preparation, dispensing and supply of medicines.

(2) A medicine that is a Schedule 3 poison must not be supplied by retail sale unless it is supplied —

(a) personally by a pharmacist; or

(b) by a pharmacy intern under the personal supervision of a pharmacist; or

(c) by a pharmacy technician under the personal supervision of a pharmacist.

(3) A restricted Schedule 3 poison must not be supplied by retail sale in a pharmacy unless the identity of the purchaser —

(a) is known to the pharmacist, intern or technician; or

(b) is verified by the pharmacist, intern or technician by means of photographic evidence provided by the purchaser.

(4) A restricted Schedule 3 poison that is supplied by retail sale must be labelled with —

(a) the name and address of the pharmacy from which it is supplied; and

(b) the number or code allocated under regulation 142(2)(b).

89. Advertising medicine that is Schedule 3 poison

(1) In this regulation —

Australian Register of Therapeutic Goods means the register maintained under the *Therapeutic Goods Act 1989* (Commonwealth) section 9A;

listed name, in relation to a medicine that is a Schedule 3 poison, means a name of the medicine that is listed in the Australian Register of Therapeutic Goods.

(2) A medicine that is a Schedule 3 poison must not be advertised unless the advertisement is in a publication that is normally sold or intended for sale or circulation only to health professionals or persons licensed to manufacture or supply medicines.

(3) Subregulation (2) does not apply to a medicine that is listed in the current Poisons Standard Appendix H and advertised by its listed name.

[Regulation 89 amended: SL 2023/3 r. 7.]

Division 4 — Requirements for medicine that is Schedule 4 poison

90. Storage of medicine that is Schedule 4 poison

(1) A medicine that is a Schedule 4 poison must be stored for supply by retail sale —

(a) in a pharmacy; and

(b) in an area or in a manner that prevents physical access to the medicine by any person other than a person who is employed in the pharmacy.

(2) A medicine that is a Schedule 4 poison supplied to an authorised health professional for the purposes of administration or supply in accordance with a professional authority must be stored at the

health professional's usual place of practice in a container, cabinet or room that —

(a) is kept locked; and

(b) is accessible only by an authorised health professional or a person who is personally supervised by an authorised health professional.

(3) However, an authorised health professional who attends patients at a place other than the health professional's usual place of practice may carry a medicine that is a Schedule 4 poison for the purpose of treatment of those patients if —

(a) the quantity of the medicine carried is an amount reasonably required by the health professional for the treatment of the patients; and

(b) the medicine is in the possession of the health professional at all times; and

(c) the health professional takes reasonable steps to protect the medicine from being lost or stolen.

91. Advertising medicine that is Schedule 4 poison

A medicine that is a Schedule 4 poison must not be advertised unless the advertisement is in a publication that is normally sold or intended for sale or circulation only to health professionals or persons licensed to manufacture or supply medicines.

Division 5 — Requirements for Schedule 5, 6 or 7 poison

92. Storage, transport and disposal of Schedule 5, 6 or 7 poison

A Schedule 5, 6 or 7 poison must be stored, transported and disposed of in accordance with the current Poisons Standard Part 2.

[Regulation 92 amended: SL 2023/3 r. 7.]

93. Manufacture and supply of Schedule 5, 6 or 7 poison

(1) A Schedule 5, 6 or 7 poison must be manufactured and supplied in accordance with the current Poisons Standard Part 2.

(2) A Schedule 5, 6 or 7 poison must not be supplied to a person who is apparently under 16 years of age.

[Regulation 93 amended: SL 2023/3 r. 7.]

Division 6 — Requirements for medicine that is Schedule 8 poison or for Schedule 9 poison

Subdivision 1 — Preliminary

94. Terms used

In this Division —

approved alternative storage arrangement means an arrangement approved by the CEO under regulation 102;

AS/NZS 3809:1998 means Australian/New Zealand Standard 3809:1998 *Safes and strongrooms* jointly published by Standards Australia and Standards New Zealand;

detection device, in relation to a safe or strongroom, means a continuously monitored system —

(a) to detect the presence of a person who interferes, or attempts to interfere, with a safe or strongroom or any security measures associated with the safe or strongroom; and

(b) that complies with the requirements in AS 2201.3-1991 *Intruder alarm systems, Part 3: Detection devices for internal use* published by Standards Australia;

dose, in relation to a medicine that is a Schedule 8 poison, means —

(a) an individual human dose of the medicine in the form of a tablet, capsule, ampoule, vial or sachet or in a similar form; or

(b) if the medicine is not in a form referred to in paragraph (a) — an amount that is equivalent to the smallest available individual human dose of the medicine;

large safe means a safe —

(a) that —

(i) is determined in accordance with AS/NZS 3809:1998 to have a resistance grading of at least II; or

(ii) complies with the requirements for a large safe set out in the Table to Schedule 3 clause 2 of these regulations;

and

(b) that is kept locked at all times except when items are being placed in or removed from it; and

(c) that is located in an area that is not accessible by members of the public;

secure cabinet means a cupboard or drawer that —

(a) is made from hardwood or metal; and

(b) is lockable; and

(c) is securely fixed to a floor or wall; and

(d) is kept locked at all times except when items are being placed in or removed from it;

small safe means a safe —

(a) that is —

(i) determined in accordance with AS/NZS 3809:1998 to have a resistance grading of at least I; or

(ii) complies with the requirements for a small safe set out in the Table to Schedule 3 clause 1 of these regulations;

and

(b) that is kept locked at all times except when items are being placed in or removed from it; and

(c) that is located in an area that is not accessible by members of the public;

strongroom means a strongroom that is determined in accordance with AS/NZS 3809:1998 to have a resistance grading of at least VII.

Subdivision 2 — Requirements for medicine that is Schedule 8 poison

95. Storage and carriage of medicine that is Schedule 8 poison: authorised health professional or permit holder

(1) In this regulation —

relevant premises means any of the following —

(a) premises, other than a hospital or a pharmacy, at which an authorised health professional carries out the lawful practice of their profession;

(b) premises that are specified in a permit that authorises the use of a medicine that is a Schedule 8 poison.

(2) A medicine that is a Schedule 8 poison stored at relevant premises must be stored as follows —

(a) if there are not more than 250 doses of medicines that are Schedule 8 poisons stored at the premises —

(i) in a small safe; or

(ii) in accordance with an approved alternative storage arrangement;

(b) if there are more than 250 doses but not more than 500 doses of medicines that are Schedule 8 poisons stored at the premises —

(i) in a small safe with a detection device; or

(ii) in accordance with an approved alternative storage arrangement;

(c) if there are more than 500 doses of medicines that are Schedule 8 poisons stored at the premises —

(i) in a large safe with a detection device; or

(ii) in accordance with an approved alternative storage arrangement.

(3) An authorised health professional who attends patients at a place other than the health professional's usual place of practice may carry a medicine that is a Schedule 8 poison for the purpose of treatment of those patients if —

(a) the quantity of the medicine carried is a quantity reasonably required by the health professional for the treatment of the patients; and

(b) the medicine is in the possession of the health professional at all times; and

(c) the health professional takes reasonable steps to protect the medicine from being lost or stolen.

96. Storage of medicine that is Schedule 8 poison: pharmacy

(1) A medicine that is a Schedule 8 poison stored in a pharmacy or the pharmacy department of a hospital must be stored —

(a) in a secure cabinet access to which is supervised at all times by a pharmacist; or

(b) in a large safe with a detection device; or

(c) in accordance with an approved alternative storage arrangement.

(2) A pharmacist who is supervising access to a secure cabinet in which a medicine that is a Schedule 8 poison is stored must —

(a) if access to the secure cabinet is by use of a key — keep immediate and personal possession of the key; or

(b) if access to the secure cabinet is by way of an access code — take all reasonable measures to ensure that the access code is not given to any other person.

97. Storage of medicine that is Schedule 8 poison: hospital

(1) A medicine that is a Schedule 8 poison stored at a hospital must be stored —

(a) in the pharmacy department of the hospital in accordance with regulation 96; or

(b) in a ward or patient care location in the hospital as follows —

(i) when the ward or patient care location is being supervised by an authorised health professional — in a secure cabinet;

(ii) when the ward or patient care location is not supervised by an authorised health professional — in accordance with subregulation (2).

(2) A medicine that is a Schedule 8 poison stored in a ward or patient care location in a hospital when it is not supervised by an authorised health professional must be stored as follows —

(a) if there are not more than 250 doses of medicines that are Schedule 8 poisons stored in the ward or patient care location —

(i) in a small safe; or

(ii) in accordance with an approved alternative storage arrangement;

(b) if there are more than 250 doses but not more than 500 doses of medicines that are Schedule 8 poisons stored in the ward or patient care location —

(i) in a small safe with a detection device; or

(ii) in accordance with an approved alternative storage arrangement;

(c) if there are more than 500 doses of medicines that are Schedule 8 poisons stored in the ward or patient care location —

(i) in a large safe with a detection device; or

(ii) in accordance with an approved alternative storage arrangement.

(3) An authorised health professional who is supervising a ward or patient care location in a hospital in which a medicine that is a Schedule 8 poison is stored in a secure cabinet must —

(a) if access to the secure cabinet is by use of a key — keep immediate and personal possession of the key; or

(b) if access to the secure cabinet is by way of an access code — take all reasonable measures to ensure that the access code is not given to any other person.

98. Storage of medicine that is Schedule 8 poison: licensed premises

A medicine that is a Schedule 8 poison stored on premises that are specified in a wholesaler's/manufacturer's licence must be stored —

(a) in a strongroom with a detection device; or

(b) in accordance with an approved alternative storage arrangement.

99. Packaging medicine that is Schedule 8 poison for transport

A medicine that is a Schedule 8 poison that is transported for commercial purposes must be transported in a package —

(a) that does not contain goods other than medicines that are Schedule 8 poisons; and

(b) that is secure and sturdy without any exterior writing that might indicate the contents of the package; and

(c) that is clearly addressed to a person who is authorised to be in possession of the medicine.

100. Advertising medicine that is Schedule 8 poison

A medicine that is a Schedule 8 poison must not be advertised unless the advertisement is in a publication that is normally sold or intended for sale or circulation only to health professionals or persons licensed to manufacture or supply medicines.

Subdivision 3 — Requirements for Schedule 9 poison

101. Storage of Schedule 9 poison

A Schedule 9 poison must be stored —

(a) in a large safe with a detection device; or

(b) in accordance with an approved alternative storage arrangement.

Subdivision 4 — Approval of alternative storage arrangement

102. Approval of alternative storage arrangement for medicine that is Schedule 8 poison or for Schedule 9 poison

(1) The CEO may, by notice given to a person who stores a Schedule 9 poison or a medicine that is a Schedule 8 poison, approve an arrangement for the storage of the poison or medicine if the CEO is satisfied that the arrangement provides for the secure storage of the poison or medicine.

(2) The approval —

(a) must be in writing; and

(b) may be subject to conditions; and

(c) may, at any time, be amended, suspended or revoked by the CEO.

Division 7 — Vending machines

103. Supply of medicine from vending machine

For the purposes of section 24(2), a medicine may be supplied from a vending machine that has been placed in premises in accordance with regulation 104 if the person who removes the medicine from the machine —

(a) is authorised to access the machine; and

(b) has gained access to the machine in accordance with the procedures for access to the machine referred to in regulation 105(5)(a).

104. Placement of vending machine

For the purposes of section 24(4), a vending machine may be placed in premises if —

(a) the premises —

(i) are premises at which an authorised health professional carries out the lawful practice of their profession; or

(ii) are specified in a licence or permit;

and

(b) the placement of the vending machine is approved by the CEO under regulation 105(4).

105. Approval of placement of vending machine

(1) A person may apply to the CEO for approval to place a vending machine in premises.

(2) An application must be in an approved form.

(3) The CEO may by written notice require an applicant to provide further information in relation to an application.

(4) The CEO may approve the placement of a vending machine in premises if satisfied that —

(a) the machine is sufficiently secure; and

(b) the machine is designed so that, to the extent practicable, for any particular medicine, only an authorised health professional who has authority to administer or supply the medicine can access the machine to remove the medicine; and

(c) the proposed placement complies with any other criteria the CEO thinks relevant.

(5) The CEO cannot be satisfied that a vending machine is sufficiently secure unless satisfied that, to the extent practicable —

(a) access to the machine to remove any particular medicine from the machine is controlled by appropriate procedures; and

(b) only persons permitted to have access to the machine according to those procedures can have access to the machine for the purpose of removing a particular medicine from the machine; and

(c) every occurrence of the removal, or attempted removal, of a medicine from the machine is recorded electronically by the machine in a way that cannot be amended or erased.

(6) Subregulation (5) does not limit the matters the CEO may take into account for the purposes of subregulation (4).

Division 8 — Miscellaneous

106. CEO to be notified of loss or theft of certain poisons

A person who is an authorised health professional, a licensee or a permit holder must, as soon as is reasonably practicable, notify the CEO in writing if —

(a) the person loses a Schedule 7 or 9 poison or a medicine that is a Schedule 4 or 8 poison; or

(b) a Schedule 7 or 9 poison or a medicine that is a Schedule 4 or 8 poison is stolen from the person.

Penalty: a fine of $5 000.

107. CEO may give direction about storage or use of poison

(1) In this regulation —

specified means specified in a direction.

(2) If the CEO is satisfied that a person is storing or using a poison in a manner that may cause a serious danger to public health, the CEO may direct the person —

(a) to secure the poison in a specified place and by specified means and not to remove the poison until further directed by the CEO; or

(b) to destroy, or otherwise dispose of, the poison in a specified way; or

(c) not to use the poison (either generally or in a specified way); or

(d) to deliver the poison to a specified person at a specified time and place.

(3) The direction —

(a) must be in writing; and

(b) may be subject to conditions; and

(c) may, at any time, be amended, suspended or revoked by the CEO.

(4) A person must comply with a direction given under subregulation (2).

Penalty for this subregulation: a fine of $5 000.

Part 10 — Needle and syringe programmes

108. Approval of needle and syringe programme

(1) A person may apply to the CEO for approval of a needle and syringe programme.

(2) An application must —

(a) be in an approved form; and

(b) nominate a person to be the coordinator of the programme.

(3) The CEO may by written notice require an applicant to provide further information in relation to an application.

(4) An approval of a needle and syringe programme must —

(a) be given by written notice signed by the CEO; and

(b) clearly identify the programme that is being approved by reference to the activity or activities, and the persons or class of persons engaging in the activity or activities, that constitute the programme; and

(c) specify the period during which the programme is approved; and

(d) specify any conditions that apply to the approval.

(5) The CEO must not approve a needle and syringe programme unless the CEO is satisfied that the coordinator of the programme —

(a) is at least 18 years of age; and

(b) is a person of good character and repute; and

(c) is a fit and proper person to coordinate the programme; and

(d) understands their duties as the coordinator of the programme.

109. Copy of approval to be provided to programme coordinator

The CEO must give a copy of the notice of approval to the coordinator of the approved needle and syringe programme.

110. Condition of approval: programme coordinator's duties

The approval of a needle and syringe programme is subject to the condition that the coordinator of the programme must —

(a) keep a register of all persons engaged in the conduct of the programme; and

(b) ensure that persons engaged in the conduct of the programme understand the requirements of these regulations and are appropriately instructed and trained; and

(c) submit to the CEO an annual report on the programme by a date specified by the CEO; and

(d) report to the CEO any irregularities that occur in the conduct of the programme.

111. Condition of approval: used needles and syringes

(1) The approval of a needle and syringe programme is subject to the following conditions —

(a) a used hypodermic needle or a used hypodermic syringe must not be accepted in the course of the conduct of the programme unless the needle or syringe has been exhausted;

(b) a used hypodermic needle or a used hypodermic syringe received in the course of the conduct of the programme must be placed immediately in a receptacle of a type approved by the CEO.

(2) For the purposes of subregulation (1)(a), a hypodermic needle or a hypodermic syringe is taken to have been exhausted if it contains no more than the residue of any Schedule 8 or 9 poison.

112. Condition of approval: conduct of programme

(1) The CEO may approve a needle and syringe programme subject to the condition that the programme only be conducted —

(a) at a specified place or specified places; or

(b) between specified times.

(2) If the CEO is of the opinion that a person is not a suitable person to be engaged in the conduct of an approved needle and syringe programme, the CEO may, by written notice given to that person and to the coordinator of the programme, direct the person not to participate in the conduct of the programme.

(3) The approval of a needle and syringe programme is subject to the condition that a person who has been given a direction under subregulation (2) must not participate in the conduct of the programme.

113. Breach of condition of approval

(1) The CEO may, by written notice given to the coordinator of an approved needle and syringe programme, revoke an approval given under regulation 108 in respect of the programme if the CEO is satisfied that a condition of the approval has been breached.

(2) A person does not have possession of a used hypodermic needle, used hypodermic syringe or another used thing for the purpose of disposing of it in accordance with an approved needle and syringe programme if the possession by the person of the syringe, needle or other thing is in breach of a condition of the approval.

Part 11 — Prescription and supply of medicine that is Schedule 8 poison

Division 1 — Preliminary

114. Terms used

In this Part —

cannabis-based product means a medicine —

(a) that is a Schedule 8 poison; and

(b) that contains cannabis or a tetrahydrocannibinol;

custodial facility means —

(a) a prison as defined in the *Prisons Act 1981* section 3(1); or

(b) a detention centre as defined in the *Young Offenders Act 1994* section 3;

opioid pharmacotherapy means any of the following substances when used for the treatment of drug dependency —

(a) methadone or buprenorphine;

(b) any of the salts of methadone or buprenorphine;

(c) any preparation or admixture containing methadone or buprenorphine or any of their salts;

prescribing code means the *Schedule 8 Medicines Prescribing Code* approved by the CEO and published on the Department's website;

stimulant means any of the following substances —

(a) dexamfetamine, lisdexamfetamine or methylphenidate;

(b) any of the salts of dexamfetamine, lisdexamfetamine or methylphenidate;

(c) any preparation or admixture containing dexamfetamine, lisdexamfetamine or methylphenidate or any of their salts.

115. Application of Part

This Part does not apply to dispensing a medicine that is a Schedule 8 poison.

Division 2 — General requirements

116. Requirements for prescription or supply of medicine that is Schedule 8 poison

(1) This regulation does not apply to the prescription or supply of a medicine that is a Schedule 8 poison for the treatment of a patient who is a drug dependent person or an oversupplied person.

(2) An authorised health professional may prescribe or supply a medicine that is a Schedule 8 poison for the treatment of a patient if —

(a) the medicine is not a cannabis-based product or a stimulant and the prescription or supply complies with the requirements for prescribing or supplying the medicine set out in the prescribing code; or

(b) the medicine is a cannabis-based product and the health professional is authorised under Division 3 to prescribe or supply the medicine and the prescription or supply is in accordance with the authorisation; or

(c) the medicine is a stimulant and the health professional is authorised under Division 4 to prescribe or supply the medicine and the prescription or supply is in accordance with the authorisation; or

(d) the health professional is authorised under regulation 118 to prescribe or supply the medicine for the patient and the prescription or supply is in accordance with the authorisation.

117. Administration, prescription or supply of medicine that is Schedule 8 poison to drug dependent person or oversupplied person

(1) An authorised health professional may administer a medicine that is a Schedule 8 poison for the treatment of a patient who is a drug dependent person or an oversupplied person.

(2) An authorised health professional may prescribe or supply a medicine that is a Schedule 8 poison for the treatment of a patient who is a drug dependent person or an oversupplied person if —

(a) the health professional is authorised under regulation 118 to prescribe or supply the medicine for the patient and the prescription or supply is in accordance with the authorisation; or

(b) the health professional is authorised under Division 5 to prescribe the medicine for the purpose of treatment of drug dependence and the prescription or supply is in accordance with the authorisation.

118. CEO may authorise prescribing of specified medicine that is Schedule 8 poison to specified patient

(1) In this regulation —

specified means specified in an authorisation.

(2) The CEO may, on the request of an authorised health professional, authorise the health professional to prescribe or supply a specified medicine that is a Schedule 8 poison for the treatment of a specified patient if the CEO is satisfied that it is reasonable to prescribe or supply the medicine for the patient.

(3) The authorisation —

(a) must be in writing; and

(b) may be subject to conditions; and

(c) may, at any time, be amended, suspended or revoked by the CEO.

(4) If an authorisation is given under subregulation (2), another authorised health professional may prescribe or supply the medicine in accordance with the authorisation if that health professional —

(a) is a member of the same medical practice as the health professional to whom the authorisation was given; and

(b) has access to the clinical records of the practice relating to the specified patient.

Division 3 — Authorising prescription or supply of cannabis-based product

119. Terms used

In this Division —

cannabis-based product prescriber means a medical practitioner designated as a cannabis-based product prescriber under regulation 121(1);

cannabis-based product co-prescriber, in relation to a patient, means a medical practitioner appointed under regulation 122(1) as a co-prescriber for the patient;

current cannabis-based product prescriber, in relation to a patient, means the current cannabis-based product prescriber for the patient under regulation 124(1).

120. Prescribing or supplying cannabis-based product

(1) A medical practitioner is authorised to prescribe or supply a cannabis-based product for the treatment of a patient if —

(a) the medical practitioner is a cannabis-based product prescriber; and

(b) the prescription or supply complies with the requirements for prescribing or supplying the cannabis-based product set out in the prescribing code.

(2) A medical practitioner is authorised to prescribe or supply a cannabis-based product for the treatment of a patient if —

(a) the medical practitioner is a cannabis-based product co-prescriber for the patient; and

(b) the prescription or supply complies with —

(i) the requirements for prescribing or supplying the cannabis-based product set out in the prescribing code; and

(ii) the appointment of the medical practitioner as a cannabis-based product co-prescriber for the patient.

(3) A medical practitioner whose practice includes treating patients who are patients in a hospital or in custody in a custodial facility is authorised to prescribe or supply a cannabis-based product for the treatment of such a patient if —

(a) the patient has previously been treated using cannabis-based products; and

(b) the prescription or supply is consistent with the form and dosage of the previous treatment; and

(c) the medical practitioner is satisfied that it is safe to prescribe the cannabis-based product for the patient; and

(d) the prescription or supply is for treatment of the patient for a period that does not exceed 3 months.

121. Designating cannabis-based product prescriber

(1) The CEO may designate a medical practitioner as a cannabis-based product prescriber.

(2) The designation —

(a) must be in writing; and

(b) may be subject to conditions; and

(c) may, at any time, be amended, suspended or revoked by the CEO.

122. Appointing cannabis-based product co-prescriber

(1) A cannabis-based product prescriber may appoint another medical practitioner to be a co-prescriber for a patient who is being treated by the cannabis-based product prescriber.

(2) The appointment —

(a) must be in writing; and

(b) must specify the type, form and dosage of the cannabis-based product that the co-prescriber may prescribe for or supply to the patient; and

(c) may be subject to conditions; and

(d) may, at any time, be amended, suspended or revoked by the cannabis-based product prescriber.

(3) A cannabis-based product prescriber must, as soon as is reasonably practicable, notify the CEO if the prescriber appoints a medical practitioner under subregulation (1) or amends, suspends or revokes an appointment.

Penalty for this subregulation: a fine of $1 000.

(4) A cannabis-based product prescriber must, on a written direction given to the prescriber by the CEO, suspend or revoke an appointment made under subregulation (1).

Penalty for this subregulation: a fine of $2 000.

(5) A cannabis-based product prescriber must notify a medical practitioner if the prescriber appoints the medical practitioner under subregulation (1) or amends, suspends or revokes the appointment.

Penalty for this subregulation: a fine of $1 000.

123. CEO to be notified of treatment of patient with cannabis-based product

(1) If a cannabis-based product prescriber commences the treatment of a patient with a cannabis-based product, the prescriber must notify the CEO.

Penalty for this subregulation: a fine of $1 000.

(2) The notification must be in an approved form and include the following information —

(a) the name, date of birth and address of the patient;

(b) details of the type, form and dosage of the product.

124. Current cannabis-based product prescriber for patient

(1) When the CEO receives a notification about a patient under regulation 123(1) from a cannabis-based product prescriber, the prescriber becomes the patient's current cannabis-based product prescriber.

(2) When the CEO receives a notification about a patient under regulation 123(1), the CEO must give written notice to any person who was the current cannabis-based product prescriber for the patient immediately before the notification was received.

(3) A person who is given a notice under subregulation (2) must give a copy of it —

(a) to any cannabis-based product co-prescriber for the patient; and

(b) if the person is aware that the patient is being treated by a medical practitioner as permitted under regulation 120(3) — to the medical practitioner.

Penalty for this subregulation: a fine of $1 000.

(4) Despite regulation 120, a person who is given a notice under subregulation (2) or a copy of a notice under subregulation (3) about a patient must not, without the written approval of the

CEO, prescribe or supply a cannabis-based product for the treatment of the patient.

Division 4 — Authorising prescription or supply of stimulant

125. Terms used

In this Division —

clinic prescriber means a medical practitioner who practices at a stimulant clinic;

current stimulant clinic, in relation to a patient, means the current stimulant clinic for the patient under regulation 132(1);

current stimulant prescriber, in relation to a patient, means the current stimulant prescriber for the patient under regulation 131(1);

stimulant clinic means a clinic approved under regulation 127(2);

stimulant co-prescriber, in relation to a patient, means a medical practitioner appointed under regulation 129(1) as a co-prescriber for the patient;

stimulant prescriber means a medical practitioner designated as a stimulant prescriber under regulation 128(1).

126. Prescribing or supplying stimulant

(1) A medical practitioner is authorised to prescribe or supply a stimulant for the treatment of a patient if —

(a) the medical practitioner is —

(i) a clinic prescriber; or

(ii) a stimulant prescriber;

and

(b) the prescription or supply is in accordance with the requirements for the stimulant set out in the prescribing code.

(2) A medical practitioner is authorised to prescribe or supply a stimulant for the treatment of a patient if —

(a) the medical practitioner is a stimulant co-prescriber for the patient; and

(b) the prescription or supply complies with —

(i) the requirements for prescribing or supplying the stimulant set out in the prescribing code; and

(ii) the appointment of the medical practitioner as a stimulant co-prescriber for the patient.

(3) A medical practitioner whose practice includes treating patients who are patients in a hospital or in custody in a custodial facility is authorised to prescribe or supply a stimulant for the treatment of such a patient if —

(a) the patient has previously been treated using stimulants; and

(b) the prescription or supply is consistent with the form and dosage of that previous treatment; and

(c) the medical practitioner is satisfied that it is safe to prescribe the stimulant for the patient; and

(d) the prescription or supply is for treatment of the patient for a period that does not exceed 3 months.

127. Approval of stimulant clinic

(1) In this regulation —

public health service facility has the meaning given in the *Health Services Act 2016* section 6.

(2) The CEO may approve a public health service facility as a stimulant clinic if —

(a) patients are treated with stimulants at the facility; and

(b) there is at least one stimulant prescriber employed at the facility.

(3) The approval —

(a) must be in writing; and

(b) may be subject to conditions; and

(c) may, at any time, be amended, suspended or revoked by the CEO.

128. Designating stimulant prescriber

(1) The CEO may designate a medical practitioner as a stimulant prescriber.

(2) The designation —

(a) must be in writing; and

(b) may be subject to conditions; and

(c) may, at any time, be amended, suspended or revoked by the CEO.

129. Appointing stimulant co-prescriber

(1) A stimulant prescriber may appoint another medical practitioner to be a co-prescriber for a patient of the stimulant prescriber.

(2) The appointment —

(a) must be in writing; and

(b) must specify the type, form and dosage of the stimulant that the co-prescriber may prescribe for or supply to the patient; and

(c) may be subject to conditions; and

(d) may, at any time, be amended, suspended or revoked by the stimulant prescriber.

(3) A stimulant prescriber must, as soon as is reasonably practicable, notify the CEO if the prescriber appoints a medical practitioner under this regulation or amends, suspends or revokes an appointment.

Penalty for this subregulation: a fine of $1 000.

(4) A stimulant prescriber must, on a written direction given to the prescriber by the CEO, suspend or revoke an appointment made under subregulation (1).

Penalty for this subregulation: a fine of $2 000.

(5) A stimulant prescriber must notify a medical practitioner if the prescriber appoints the medical practitioner under this regulation or amends, suspends or revokes the appointment.

Penalty for this subregulation: a fine of $1 000.

130. CEO to be notified of treatment of patient with stimulant

(1) If a stimulant prescriber commences the treatment of a patient with a stimulant, the prescriber must notify the CEO.

(2) The notification must be in an approved form and include the following information —

(a) the name, date of birth and address of the patient;

(b) details of the type, form and dosage of the stimulant.

131. Current stimulant prescriber for patient

(1) When the CEO receives a notification about a patient under regulation 130(1) from a stimulant prescriber, the prescriber becomes the patient's current stimulant prescriber.

(2) When the CEO receives a notification about a patient under regulation 130(1), the CEO must give written notice to any person who was the current stimulant prescriber for the patient immediately before the notification was received.

(3) A person who is given a notice under subregulation (2) must give a copy of it —

(a) to any stimulant co-prescriber for the patient; and

(b) if the person is aware that the patient is being treated by a medical practitioner as permitted under regulation 126(3) — to that medical practitioner.

Penalty for this subregulation: a fine of $1 000.

(4) Despite regulation 126, a person who is given a notice under subregulation (2) or a copy of a notice under subregulation (3) about a patient must not, without the written approval of the CEO, prescribe or supply a stimulant for the treatment of the patient.

132. Current stimulant clinic for patient

(1) When the CEO receives a notification about a patient under regulation 130(1) from a clinic prescriber, the stimulant clinic at which the prescriber practices becomes the patient's current stimulant clinic.

(2) When the CEO receives a notification about a patient under regulation 130(1), the CEO must give written notice to the person in charge of any stimulant clinic which was the current stimulant clinic for the patient immediately before the notification was received.

(3) A person in charge of a stimulant clinic who is given a notice under subregulation (2) about a patient must ensure that systems are in place to ensure that each medical practitioner who practices at the clinic is notified about, and has access to a copy of, the notice before treating the patient.

Penalty for this subregulation: a fine of $1 000.

(4) If a notice about a patient is given to the person in charge of a stimulant clinic under subregulation (2), a medical practitioner who practices at the clinic must not, without the written approval of the CEO, prescribe or supply a stimulant for the treatment of the patient.

Division 5 — Authorising prescription or supply of opioid pharmacotherapy for treatment of drug dependency

Subdivision 1 — Preliminary

133. Terms used

In this Division —

co-prescriber, in relation to a patient, means a medical practitioner who is appointed as a co-prescriber for the patient under regulation 138(1);

current detoxification prescriber, in relation to a patient, means the current detoxification prescriber for the patient under regulation 136(1);

detoxification prescriber means a medical practitioner designated as a detoxification prescriber under regulation 134(3);

opioid pharmacotherapy prescriber means a medical practitioner or nurse practitioner designated as an opioid pharmacotherapy prescriber under regulation 134(1);

specialist prescriber means an opioid pharmacotherapy prescriber designated as a specialist prescriber under regulation 134(2).

134. Designation of opioid pharmacotherapy prescriber, specialist prescriber and detoxification prescriber

(1) The CEO may designate a medical practitioner or a nurse practitioner as an opioid pharmacotherapy prescriber.

(2) The CEO may designate an opioid pharmacotherapy prescriber as a specialist prescriber.

(3) The CEO may designate a medical practitioner as a detoxification prescriber.

(4) A designation under subregulation (1), (2) or (3) —

(a) must be in writing; and

(b) may be subject to conditions; and

(c) may, at any time, be amended, suspended or revoked by the CEO.

Subdivision 2 — Detoxification treatment using opioid pharmacotherapy

135. Detoxification treatment using opioid pharmacotherapy

(1) In this regulation —

detoxification treatment means the use of opioid pharmacotherapy for the purpose of opiate withdrawal.

(2) A medical practitioner is authorised to administer or supply an opioid pharmacotherapy for the purpose of detoxification treatment of a patient if the medical practitioner —

(a) is a detoxification prescriber; and

(b) does so in accordance with the requirements relating to detoxification treatment set out in the prescribing code.

(3) A detoxification prescriber must notify the CEO before commencing detoxification treatment of a patient.

(4) The notification must be in an approved form and include the following information —

(a) the name, date of birth and address of the patient; and

(b) details of the treatment provided.

136. Current detoxification prescriber for patient

(1) When the CEO receives a notification about a patient under regulation 135(3) from a detoxification prescriber, the prescriber giving the notification becomes the patient's current detoxification prescriber.

(2) When the CEO receives a notification about a patient under subregulation (1), the CEO must give written notice to —

(a) any person who was the current detoxification prescriber for the patient immediately before the notification was received; and

(b) any person who the CEO believes, on reasonable grounds has been, or may be, requested to administer or supply a medicine that is a Schedule 8 poison to the patient.

(3) A person who is given a notice under subregulation (2) about a patient must not, without the written approval of the CEO, administer or supply a medicine that is a Schedule 8 poison for the treatment of the patient.

Subdivision 3 — Opioid pharmacotherapy for treatment of drug dependency

137. Appointing opioid pharmacotherapy prescriber for drug dependent person

(1) The CEO may appoint an opioid pharmacotherapy prescriber to be the opioid pharmacotherapy prescriber for a patient who is a drug dependent person.

(2) The appointment is for the period specified in the instrument of appointment.

(3) The appointment —

(a) must be in writing; and

(b) may be subject to conditions; and

(c) may, at any time, be amended, suspended or revoked by the CEO.

138. Appointing co-prescriber for drug dependent person

(1) A specialist prescriber who is the opioid pharmacotherapy prescriber for a patient who is a drug dependent person may

appoint a medical practitioner (who need not be an opioid pharmacotherapy prescriber) to be a co-prescriber for the patient.

(2) The appointment —

(a) is for the period specified in the instrument of appointment, which cannot be more than 12 months; and

(b) ceases on the earlier of —

(i) the end of the period of appointment; or

(ii) the specialist prescriber ceasing to be the opioid pharmacotherapy prescriber for the patient.

(3) The appointment —

(a) must be in writing; and

(b) may be subject to conditions; and

(c) may, at any time, be amended, suspended or revoked by the specialist prescriber.

(4) A specialist prescriber who makes an appointment under subregulation (1) must, as soon as is reasonably practicable, give a copy of the appointment to the CEO.

Penalty for this subregulation: a fine of $1 000.

(5) A specialist prescriber must, on a written direction given to the prescriber by the CEO, suspend or revoke an appointment made under subregulation (1).

Penalty for this subregulation: a fine of $2 000.

(6) A specialist prescriber must notify a medical practitioner if any of the following occurs —

(a) the prescriber appoints the medical practitioner as a co-prescriber for a patient under subregulation (1);

(b) the prescriber amends, suspends or revokes the appointment;

(c) the prescriber has appointed the medical practitioner as a co-prescriber for a patient and the prescriber ceases to be the opioid pharmacotherapy prescriber for the patient.

Penalty for this subregulation: a fine of $1 000.

139. Prescribing opioid pharmacotherapy for treatment of drug dependency

(1) A medical practitioner or nurse practitioner is authorised to prescribe an opioid pharmacotherapy for the treatment of a patient who is a drug dependent person if —

(a) the medical practitioner or nurse practitioner is appointed under regulation 137(1) as the opioid pharmacotherapy prescriber for the patient; and

(b) the medical practitioner or nurse practitioner prescribes the opioid pharmacotherapy in accordance with the appointment; and

(c) the prescription complies with the requirements for prescribing the opioid pharmacotherapy set out in the prescribing code.

(2) A medical practitioner or nurse practitioner is authorised to prescribe an opioid pharmacotherapy for the treatment of a patient who is a drug dependent person if —

(a) the medical practitioner or nurse practitioner is an opioid pharmacotherapy prescriber; and

(b) the medical practitioner or nurse practitioner is a member of the same medical practice as the opioid pharmacotherapy prescriber appointed under regulation 137(1) for the patient; and

(c) the medical practitioner or nurse practitioner has access to the clinical records of the practice relating to the patient; and

(d) the medical practitioner or nurse practitioner prescribes the opioid pharmacotherapy in accordance with the

appointment of the opioid pharmacotherapy prescriber for the patient; and

(e) the prescription complies with the requirements for prescribing the opioid pharmacotherapy set out in the prescribing code.

(3) A medical practitioner is authorised to prescribe an opioid pharmacotherapy for the treatment of a patient who is a drug dependent person if —

(a) the medical practitioner is a co-prescriber for the patient; and

(b) the medical practitioner prescribes the opioid pharmacotherapy in accordance with —

(i) the appointment as a co-prescriber; and

(ii) the appointment of the opioid pharmacotherapy prescriber for the patient;

and

(c) the prescription complies with the requirements for prescribing the opioid pharmacotherapy set out in the prescribing code.

(4) A prescription for the supply of an opioid pharmacotherapy under subregulation (3) must not cover a period of more than 3 months.

140. Prescribing opioid pharmacotherapy for treatment of drug dependent person in hospital or custody

(1) A medical practitioner whose practice includes treating drug dependent persons who are patients in a hospital or in custody in a custodial facility is authorised to prescribe an opioid pharmacotherapy for the treatment of such a patient if —

(a) an opioid pharmacotherapy prescriber is appointed under regulation 137(1) for the patient; and

(b) the medical practitioner is satisfied that it is safe to prescribe an opioid pharmacotherapy for the patient; and

(c) the medical practitioner prescribes the opioid pharmacotherapy in accordance with the appointment of the opioid pharmacotherapy prescriber for the patient; and

(d) the prescription complies with the requirements for prescribing the opioid pharmacotherapy set out in the prescribing code; and

(e) the prescription is for the treatment of the patient for a period that does not exceed 1 month.

(2) Subregulation (1) does not authorise the medical practitioner to prescribe an opioid pharmacotherapy unless it will be administered to a person while the person is a patient in the hospital or in custody in the custodial facility.

141. Prescribing opioid pharmacotherapy for treatment of drug dependent person in certain circumstances

(1) A specialist prescriber is authorised to prescribe an opioid pharmacotherapy for the treatment of a patient who is a drug dependent person if —

(a) an opioid pharmacotherapy prescriber is appointed under regulation 137(1) for the patient; and

(b) the specialist prescriber —

(i) is satisfied that the patient is unable to obtain a prescription for an opioid pharmacotherapy under regulation 139 or 140; and

(ii) is satisfied that it is safe to prescribe an opioid pharmacotherapy for the treatment of the patient; and

(iii) does so in accordance with the appointment of the opioid pharmacotherapy prescriber for the patient;

and

(c) the prescription complies with the requirements for prescribing the opioid pharmacotherapy set out in the prescribing code; and

(d) the prescription is for the treatment of the patient for a period that does not exceed 1 month.

(2) A specialist prescriber who prescribes an opioid pharmacotherapy for the treatment of a patient under subregulation (1) must, as soon as is reasonably practicable, notify the CEO and the opioid pharmacotherapy prescriber appointed for the patient.

Part 12 — Record keeping and reporting

142. Record of supply by retail sale of medicine that is restricted Schedule 3 poison

(1) In this regulation —

approved system means a recording system approved in writing by the CEO for the purposes of this regulation.

(2) A pharmacist who supplies a medicine that is a restricted Schedule 3 poison by retail sale must —

(a) record in an approved system the following information —

(i) the date of sale;

(ii) the name and address of the purchaser;

(iii) if the medicine is intended for the use of a person other than the purchaser — the name and address of the person;

(iv) the name and quantity of the medicine supplied;

and

(b) allocate to each sale a unique identification number or alpha-numerical code, and record the number or code in the system.

(3) The information recorded under subregulation (2) must —

(a) be kept for at least 2 years from the date on which the medicine is supplied; and

(b) be produced for inspection on the request of the CEO or an investigator.

[Regulation 142 amended: SL 2020/214 r. 4.]

143. Record of administration or supply of medicine that is Schedule 4 or 8 poison

(1) An authorised health professional who administers or supplies a medicine that is a Schedule 4 or 8 poison for the treatment of a person or an animal must ensure that the following information is recorded on the clinical record for the person or animal —

(a) the name, quantity, strength and form of the medicine supplied or administered;

(b) the address of the person treated or the name and address of the owner of the animal treated;

(c) the date on which the medicine is supplied or administered;

(d) if the medicine is supplied in accordance with a prescription —

(i) the prescription reference number; and

(ii) the date of issue of the prescription;

(e) if the medicine is a Schedule 8 poison administered or supplied for the treatment of a person — the date of birth of the person;

(f) if the medicine is a Schedule 8 poison — the name and address of the prescriber.

(2) The information recorded under subregulation (1) must —

(a) be provided to the CEO in the manner and form and at the times specified by the CEO; and

(b) in the case of a medicine that is a Schedule 4 poison — be kept for at least 2 years from the date on which the medicine is administered or supplied; and

(c) in the case of a medicine that is a Schedule 8 poison — be kept for at least 5 years from the date on which the medicine is administered or supplied; and

(d) be produced for inspection on the request of the CEO or an investigator.

[Regulation 143 amended: SL 2020/214 r. 5.]

143A. Record of prescription of medicine that is Schedule 4 or 8 poison

(1) An authorised health professional who prescribes a medicine that is a Schedule 4 or 8 poison for the treatment of a person or an animal must ensure that the following information is recorded on the clinical record for the person or animal —

(a) the name and address of the authorised health professional;

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

(c) if the medicine is prescribed for the treatment of a person —

(i) the name and address of the person; and

(ii) if the medicine is a Schedule 8 poison — the date of birth of the person;

(d) if the medicine is prescribed for the treatment of an animal —

(i) the name and address of the owner of the animal; and

(ii) the species of the animal;

(e) the date on which the medicine is prescribed.

(2) The information recorded under subregulation (1) must —

(a) be provided to the CEO in the manner and form and at the times specified by the CEO; and

(b) in the case of a medicine that is a Schedule 4 poison — be kept for at least 2 years from the date on which the medicine is prescribed; and

(c) in the case of a medicine that is a Schedule 8 poison — be kept for at least 5 years from the date on which the medicine is prescribed; and

(d) be produced for inspection on the request of the CEO or an investigator.

[Regulation 143A inserted: SL 2020/214 r. 6.]

144. Requirement to keep register of Schedule 9 poisons and medicines that are Schedule 8 poisons

(1) In this regulation —

authorised person means each of the following —

(a) a person authorised under a licence or a permit to manufacture, supply or use a Schedule 9 poison or a medicine that is a Schedule 8 poison and who has possession of the poison or medicine for that purpose;

(b) a person authorised by a professional authority to manufacture or supply a medicine that is a Schedule 8 poison and who has possession of the medicine for the purpose of that supply;

recordable event, in relation to a Schedule 9 poison or a medicine that is a Schedule 8 poison, means each occasion on which the poison or medicine is received, supplied, used, administered or transported by or on behalf of an authorised person.

(2) An authorised person must keep a register of the Schedule 9 poisons and the medicines that are Schedule 8 poisons manufactured, received, stored, supplied, administered or transported by or on behalf of the person.

(3) The register must be —

(a) kept for each premises at which the authorised person manufactures, or from which the authorised person supplies, a Schedule 9 poison or a medicine that is a Schedule 8 poison; and

(b) kept on the premises to which it relates.

(4) The following information must be recorded in the register —

(a) the name, quantity, form and date of manufacture of a Schedule 9 poison or a medicine that is a Schedule 8 poison that is manufactured;

(b) for each recordable event for a Schedule 9 poison or a medicine that is a Schedule 8 poison —

(i) the name, quantity, strength and form of the poison or medicine involved; and

(ii) the date of the recordable event; and

(iii) the name and address of each other person involved in the recordable event; and

(iv) if the recordable event involves the supply or administration of a poison or medicine — the name of the person who issued the prescription, order or other authority for the poison or medicine; and

(v) if the recordable event involves the supply or administration of a medicine in accordance with a prescription — the prescription reference number of the prescription; and

(vi) if the recordable event involves the supply of a medicine or poison on an order or other authority — the identifying number for the order or other authority on which the poison or medicine is supplied; and

(vii) the quantity of the poison or medicine remaining on hand after the recordable event;

(c) for each inventory made by the authorised person under regulation 148 —

(i) the date the inventory is made; and

(ii) the name, quantity, strength and form of the Schedule 9 poisons and medicines that are

Schedule 8 poisons at the premises for which the register is kept when the inventory is made.

(5) Information must be recorded in a register as follows —

(a) in the case of information referred to in subregulation (4)(b) — at the time a recordable event occurs;

(b) in the case of information referred to in subregulation (4)(c) — on the day an inventory is made.

(6) Each entry in a register must be signed by the authorised person who is responsible for keeping the register.

(7) Information on a register must be kept for at least 5 years from the date on which the information is recorded.

(8) A register for premises must be kept in such a way that the quantity of each Schedule 9 poison and each medicine that is a Schedule 8 poison at the premises at any time is clearly identifiable.

(9) An authorised person must —

(a) provide details of the register to the CEO in the manner and form and the times specified by the CEO; and

(b) produce the register for inspection on the request of an investigator.

145. Destruction of Schedule 9 poison or medicine that is Schedule 8 poison

(1) In this regulation —

qualified person means a person who is in one or more of the following categories —

(a) a health professional;

(b) an investigator;

(c) a police officer.

(2) A Schedule 9 poison or a medicine that is a Schedule 8 poison must not be wilfully destroyed unless —

(a) it is destroyed by or on behalf of —

(i) a qualified person who is authorised to possess the poison or medicine; or

(ii) a licensee or a permit holder who is authorised to possess the poison or medicine;

and

(b) the destruction is witnessed by a qualified person who is not the person by or on behalf of whom the medicine or poison is destroyed.

(3) A person who wilfully destroys a Schedule 9 poison or a medicine that is a Schedule 8 poison must keep a register of the poisons or medicines destroyed by or on behalf of the person.

(4) The following information must be recorded in the register —

(a) the name, contact details and signature of the person by or on behalf of whom the poison or medicine is destroyed;

(b) details of the basis on which the person is authorised to destroy the medicine or poison or have it destroyed;

(c) the date of destruction;

(d) the name, quantity, strength and form of the poison or medicine destroyed;

(e) the reason for destruction;

(f) the method of destruction;

(g) the name, contact details and signature of the witness to the destruction and details of the category under which the witness is a qualified person.

146. Registers generally

(1) A register kept for the purposes of regulation 144(2) or 145(3) must be kept in a manner and form approved by the CEO.

(2) The CEO must not approve the keeping of a register by means of an electronic system unless the CEO is satisfied that the system will comply with the requirements in regulation 147.

147. Requirements for electronic register

(1) In this regulation —

access code, for a person, means a password or other means by which the person gains access to a register;

authorised person, in relation to a register, means the person who is required under regulation 144(2) or 145(3) to keep the register;

register means a register kept electronically for the purposes of regulation 144(2) or 145(3);

system identifier, of a person, means the code or identifier by which the identity of the person is recorded by a register.

(2) The requirements for an electronic system for the keeping of a register are as follows —

(a) entries in the register cannot be deleted;

(b) entries in the register cannot be made by any person who does not use a system identifier issued by the authorised person for the register;

(c) information recorded or stored in the register —

(i) remains in the form in which it is originally recorded; and

(ii) is capable of being reproduced on paper in a written form;

(d) a system identifier must be used in combination with an access code for the person to whom the system identifier is issued;

(e) the system identifier of a person is automatically recorded in the register when the person makes an entry in the register;

(f) a record is kept of the system identifiers issued to persons who use the system in a form that cannot be changed.

148. Inventory of Schedule 9 poisons and medicines that are Schedule 8 poisons

(1) An authorised person who is required under regulation 144(2) to keep a register of Schedule 9 poisons or medicines that are Schedule 8 poisons in respect of premises must, at intervals of not more than 1 month, make an inventory of the Schedule 9 poisons or medicines that are Schedule 8 poisons at the premises.

(2) If the inventory does not agree with the information recorded under regulation 144(4)(b)(vii) in the register for the premises at the time the inventory is made, the authorised person must immediately give written notice of the discrepancy to the CEO.

Penalty for this subregulation: a fine of $1 000.

Part 12A — Infringement notices

[Heading inserted: SL 2024/224 r. 4.]

148A. Prescribed offences and modified penalties

(1) The offences specified in Schedule 4 to these regulations are offences for which an infringement notice may be issued under the *Criminal Procedure Act 2004* Part 2.

(2) The modified penalty specified opposite an offence in Schedule 4 to these regulations is the modified penalty for that offence for the purposes of the *Criminal Procedure Act 2004* section 5(3).

[Regulation 148A inserted: SL 2024/224 r. 4.]

148B. Authorised officers and approved officers

(1) The CEO may, in writing, appoint persons or classes of persons to be authorised officers or approved officers for the purposes of the *Criminal Procedure Act 2004* Part 2 in relation to infringement notices issued under that Part for an offence specified in Schedule 4 to these regulations.

(2) The CEO must issue to each person appointed as an authorised officer under subregulation (1) a certificate, badge or identity card identifying the officer as a person authorised to issue infringement notices.

(3) A person appointed as an authorised officer under subregulation (1) may show that they are an authorised officer by producing the certificate, badge or identity card issued to them under subregulation (2).

[Regulation 148B inserted: SL 2024/224 r. 4.]

148C. Forms

For the purposes of the *Criminal Procedure Act 2004* Part 2, the forms set out in Schedule 5 to these regulations are prescribed in relation to the matters specified in those forms.

[Regulation 148C inserted: SL 2024/224 r. 4.]

Part 12B — Miscellaneous

[Heading inserted: SL 2024/224 r. 4.]

148D. Term used: Schedule 6 nitrous oxide

In this Part —

Schedule 6 nitrous oxide means nitrous oxide classified as a Schedule 6 poison under regulation 6.

[Regulation 148D inserted: SL 2024/224 r. 4.]

148E. Supply of Schedule 6 nitrous oxide

(1) For the purposes of section 15(1)(b), a person does not commit an offence under section 15(1) of supplying Schedule 6 nitrous oxide if the supply is —

(a) from a manufacturer to a wholesaler or retailer; or

(b) from a wholesaler to a wholesaler or retailer; or

(c) in an immediate container also containing sulfur dioxide; or

(d) to an approved recipient in an immediate container containing 10 g or less of nitrous oxide.

(2) For the purposes of subregulation (1)(d), each of the following is an ***approved recipient*** —

(a) the proprietor (as defined in the *Food Act 2008* section 8) of a food business registered under the *Food Act 2008* Part 9;

(b) the holder of a licence granted under the *Liquor Control Act 1988* (other than a liquor store licence as defined in section 3(1) of that Act);

(c) a college established under the *Vocational Education and Training Act 1996* section 35;

(d) a government school, or a non-government school, as those terms are defined in the *School Education Act 1999* section 4;

(e) a university established under a written law;

(f) a person who carries on a business of providing cooking education and training.

[Regulation 148E inserted: SL 2024/224 r. 4.]

148F. Record of supply of Schedule 6 nitrous oxide

(1) A person who supplies Schedule 6 nitrous oxide must keep a proper record of the supply.

Penalty for this subregulation: a fine of $5 000.

(2) For the purposes of subregulation (1), a proper record of a supply is kept if a written record is —

(a) made of the following information —

(i) the date on which the nitrous oxide is supplied;

(ii) the brand, form and quantity of the nitrous oxide supplied;

(iii) the name, business address and delivery address (if applicable) of the person to whom the nitrous oxide is supplied;

and

(b) kept for at least 2 years from the date on which the nitrous oxide is supplied.

[Regulation 148F inserted: SL 2024/224 r. 4.]

Part 13 — Transitional matters

149. Terms used

In this Part —

commencement day has the meaning given in section 140;

repealed Act has the meaning given in section 140;

repealed regulations means the *Poisons Regulations 1965* as in force immediately before commencement day.

150. Continuation of licences and permits (s. 141)

(1) For the purposes of section 141(1), a licence of a type referred to in column 1 of an item in the Table is taken to be a licence of a type referred to in column 2 of the Table for the same item.

Table

Item	Column 1 Type of licence under repealed Act	Column 2 Type of licence under Act
1.	Wholesaler's licence referred to in regulation 3 of the repealed regulations	Wholesaler's/ manufacturer's licence
2.	Retailer's licence to sell Schedule 2 poisons referred to in regulation 7 of the repealed regulations	Schedule 2 retail licence

Item	Column 1 Type of licence under repealed Act	Column 2 Type of licence under Act
3.	Retailer's licence to sell Schedule 7 poisons referred to in regulation 8 of the repealed regulations	Schedule 7 retail licence

(2) For the purposes of section 141(2), a permit of a type referred to in column 1 of an item in the Table is taken to be a permit of a type referred to in column 2 of the Table for the same item.

Table

Item	Column 1 Type of permit under repealed Act	Column 2 Type of permit under Act
1.	Permit referred to in regulation 8A of the repealed regulations	Pharmaceutical samples permit
2.	Permit referred to in regulation 9 of the repealed regulations other than a permit referred to in item 3	Industrial permit
3.	Permit referred to in regulation 9 of the repealed regulations with conditions relating to the treatment of animals	Veterinary practice permit

Item	Column 1 Type of permit under repealed Act	Column 2 Type of permit under Act
4.	Permit referred to in regulation 10 of the repealed regulations	Research/ Education permit
5.	Permit referred to in regulation 10AA of the repealed regulations	Health service permit
6.	Permit referred to in regulation 10A of the repealed regulations other than a permit referred to in item 7 or 8	Health service permit — Department/ hospital
7.	Permit referred to in regulation 10A of the repealed regulations with conditions relating to the provision of health services on behalf of a public sector agency	Health service permit — Public sector agency
8.	Permit referred to in regulation 10A of the repealed regulations with conditions relating to the carrying out of activities of a public sector agency	Government permit

Item	Column 1 Type of permit under repealed Act	Column 2 Type of permit under Act
9.	Permit referred to in regulation 39A(3) of the repealed regulations	Stockfeed manufacture permit

151. Manufacture, supply and use of Schedule 9 poisons for research

(1) A person who, immediately before commencement day, was authorised by an order made under section 41 of the repealed Act to manufacture or supply a Schedule 9 poison is taken to be the holder of a Schedule 9 licence for the period of 12 months beginning on commencement day.

(2) A person who is taken to be the holder of a licence under subregulation (1) is not eligible to apply for the renewal of the licence.

(3) A person who, immediately before commencement day, was authorised by an order made under section 41 of the repealed Act to use a Schedule 9 poison is taken to be the holder of a Schedule 9 permit for the period of 12 months beginning on commencement day.

(4) A person who is taken to be the holder of a permit under subregulation (3) is not eligible to apply for the renewal of the permit.

(5) Nothing in this regulation prevents a person from applying for a Schedule 9 licence or a Schedule 9 permit.

152. Containers and labels

(1) In this regulation —

exemption means an exemption given under section 50(3) of the repealed Act that is in force immediately before commencement day;

non-compliant container or label means —

(a) a container that does not comply with regulation 82(a) or 83(a); or

(b) a label that does not comply with regulation 82(b).

(2) If an exemption authorises a person to use a non-compliant container or label, the exemption is taken, on and from commencement day, to be an authorisation for the purposes of regulation 84(4) or (5) to the extent that the exemption authorises the use of a non-compliant container or label.

(3) An approval of a container or label given under regulation 25 of the repealed regulations that is in force immediately before commencement day is taken, on and from commencement day, to be an authorisation for the purposes of regulation 84(4) or (5) to the extent that the approval authorises the use of a non-compliant container or label.

153. Directions about storage or use of poisons

A direction given under section 55E of the repealed Act that is in force immediately before commencement day (the ***existing direction***) is taken, on and from commencement day, to be a direction about the storage or use of the poison given under regulation 107(2) in the same terms as the existing direction.

154. Approvals

An approval of a type referred to in column 1 of the Table that is in force immediately before commencement day (the ***existing approval***), is taken, on and from commencement day, to be an approval referred to in column 2 of the Table for the same item on the same terms and conditions as the existing approval.

Table

Item	Column 1 Type of approval under repealed Act	Column 2 Type of approval under Act
1.	Approval given under regulation 12A(4) of the repealed regulations	Approval of needle and syringe programme given under regulation 108(4)
2.	Approval of system of electronic prescribing given under regulation 32B(1) of the repealed regulations	Approval of electronic system given under regulation 19(4)
3.	Approval to install electronic storage and supply unit given under regulation 32G(1) of the repealed regulations	Approval to place vending machine given under regulation 105(4)
4.	Approval of recording system for pseudoephedrine given for the purposes of regulation 35A of the repealed regulations	Approval of recording system given for the purposes of regulation 142

Item	Column 1 Type of approval under repealed Act	Column 2 Type of approval under Act
5.	Approval of alternative recording method given for the purposes of regulation 44B(1) of the repealed regulations	Approval of recording system given for the purposes of regulation 146
6.	Approval of clinic given under regulation 51FJ(1) of the repealed regulations	Approval of stimulant clinic given under regulation 127(2)

155. Appointments, authorisations, designations and nominations

An appointment, authorisation, designation or nomination of a type referred to in column 1 of an item in the Table that is in force immediately before commencement day (the ***existing authority***), is taken, on and from commencement day, to be an appointment, authorisation or designation referred to in column 2 of the Table for the same item on the same terms and conditions as the existing authority.

Table

Item	Column 1 Type of appointment, authorisation, designation or nomination under repealed Act	Column 2 Type of appointment, authorisation or designation under Act
1.	Authorisation to prescribe or supply drug of addiction for treatment of drug addict given under regulation 51BA(2) of the repealed regulations	Authorisation to prescribe or supply specified medicine that is a Schedule 8 poison given under regulation 118(2)
2.	Designation as authorised prescriber under regulation 51C(1) of the repealed regulations	Designation as an opioid pharmacotherapy prescriber under regulation 134(1)
3.	Designation as specialist prescriber under regulation 51C(2) of the repealed regulations	Designation as a specialist prescriber under regulation 134(2)
4.	Appointment of authorised prescriber for drug addict under regulation 51CA(1) of the repealed regulations	Appointment of opioid pharmacotherapy prescriber for drug dependent person under regulation 137(1)

Item	Column 1 Type of appointment, authorisation, designation or nomination under repealed Act	Column 2 Type of appointment, authorisation or designation under Act
5.	Appointment of co-prescriber for drug addict under regulation 51CB(1) of the repealed regulations	Appointment of co-prescriber for drug dependent person under regulation 138(1)
6.	Authorisation to dispense pharmacotherapies given under regulation 51EA(1) of the repealed regulations	Authorisation to dispense opioid pharmacotherapies given under regulation 28(1)
7.	Authorisation to write, issue or authorise a prescription or document or to supply poison included in Schedule 8 given under regulation 51F of the repealed regulations	Authorisation given to prescribe specified medicine that is a Schedule 8 poison given under regulation 118(2)
8.	Authorisation to supply or prescribe stimulant given under regulation 51FC(2) of the repealed regulations	Authorisation to prescribe or supply specified medicine that is a Schedule 8 poison given under regulation 118(2)

Item	Column 1 Type of appointment, authorisation, designation or nomination under repealed Act	Column 2 Type of appointment, authorisation or designation under Act
9.	Authorisation to supply and prescribe stimulant given under regulation 51FG(1) of the repealed regulations	Designation as stimulant prescriber under regulation 128(1)
10.	Authorisation to supply or prescribe stimulant given under regulation 51FG(3) of the repealed regulations	Authorisation to prescribe or supply specified medicine that is a Schedule 8 poison given under regulation 118(2)
11.	Nomination of co-prescriber for patient under regulation 51FH(1) of the repealed regulations	Appointment of stimulant co-prescriber for patient under regulation 129(1)
12.	Authorisation to supply flunitrazepam or write or authorise prescription for flunitrazepam given under regulation 51GB(1) of the repealed regulations	Authorisation to prescribe or supply specified medicine that is a Schedule 8 poison given under regulation 118(2)

Item	Column 1 Type of appointment, authorisation, designation or nomination under repealed Act	Column 2 Type of appointment, authorisation or designation under Act
13.	Authorisation in respect of poison included in Schedule 8 given under regulation 51H(2) of the repealed regulations	Authorisation to prescribe or supply specified medicine that is a Schedule 8 poison given under regulation 118(2)

156. Approval of storage arrangements

If, immediately before commencement day, a person has permission given under regulation 56(3)(b) of the repealed regulations to store a drug of addiction in a manner and with security arrangements specified by the CEO (the ***existing permission***), the person is taken, on and from commencement day, to have been given approval under regulation 102 to store a Schedule 9 poison or a medicine that is a Schedule 8 poison in accordance with the security arrangements specified in the existing permission.

Schedule 1 — Fees

[r. 5]

[Heading inserted: SL 2024/91 r. 15.]

Division 1 — Fees for licences

[Heading inserted: SL 2024/91 r. 15.]

Item	Type of licence	Application fee $	Licence fee $
1.	Indent licence	162	109
2.	Schedule 2 retail licence	109	109
3.	Schedule 7 retail licence	218	162
4.	Schedule 9 licence	218	162
5.	Wholesaler's/manufacturer's licence	329	274

[Division 1 inserted: SL 2024/91 r. 15.]

Division 2 — Fees for permits

[Heading inserted: SL 2024/91 r. 15.]

Item	Type of permit	Application fee $	Permit fee $
1.	Health service permit	218	162
2.	Health service permit — Department/hospital	nil	nil
3.	Health service permit — Public sector agency	218	162
4.	Government permit	162	109

Item	Type of permit	Application fee $	Permit fee $
5.	Industrial permit	191	136
6.	Pharmaceutical samples permit	109	109
7.	Research/education permit	162	109
8.	Schedule 9 permit	218	162
9.	Stockfeed manufacture permit	109	109
10.	Veterinary practice permit	163	109

[Division 2 inserted: SL 2024/91 r. 15.]

Division 3 — Other fees

[Heading inserted: SL 2024/91 r. 15.]

Item	Provision of Act	Description of matter	Fee $
1.	s. 48(3)(b)	Application to vary licence or permit	87
2.	s. 52(2)(b)	Application to vary conditions imposed on licence or permit	87
3.	s. 55(2)(b)	Application for approval of proposed change of management	87
4.	s. 57(2)(b)	Application for approval after change of management	87
5.	s. 67	Issue of replacement licence or permit	44
6.	s. 68(1)	Provision of certified copy of licence or permit	87

Item	Provision of Act	Description of matter	Fee $
7.	s. 76(3)	Provision of copy of all or part of the register	44
8.	s. 76(3)	Provision of certified copy of all or part of the register	87
9.	s. 91(3)	Provision of copy of information included on the drugs of addiction record in relation to a person	87
10.	s. 91(3)	Provision of certified copy of information included on the drugs of addiction record in relation to a person	132

[Division 3 inserted: SL 2024/91 r. 15.]

Schedule 2 — List of additional substances that are Schedule 9 poisons

[r. 6]

N-(ADAMANTAN-1-YL)-1-(5-FLUOROPENTYL)-1H-INDOLE-3-CARBOXAMIDE (STS-135)
N-((3S,5S,7S)-ADAMANTAN-1-YL)-1-(5-FLUOROPENTYL)-1H-INDAZOLE-3-CARBOXAMIDE (5-F AKB48 OR 5-F APINACA)
N-(1-ADAMANTYL)-1-PENTYL-1H-INDOLE-3-CARBOXAMIDE (2NE1 OR SDB-001)
N-(1-ADAMANTYL)-1-PENTYL-1H-INDAZOLE-3-CARBOXAMIDE (AKB48 OR APINACA)
ALPHA-PYRROLIDINOVALEROPHENONE (ALPHA-PVP)
N-[1-(AMINOCARBONYL)-2,2-DIMETHYLPROPYL]-1-PENTYL-1H-INDAZOLE-3-CARBOXAMIDE (ADB-PINACA)
N-[1-(AMINOCARBONYL)-2-METHYLPROPYL]-1-(CYCLOHEXYLMETHYL)-1H-INDAZOLE-3-CARBOXAMIDE (AB-CHMINACA)
N-[(1S)-1-(AMINOCARBONYL)-2-METHYLPROPYL]-1-(5-FLUOROPENTYL)-1H-INDAZOLE-3-CARBOXAMIDE (5F-AB-PINACA)
N-[(1S)-1-(AMINOCARBONYL)-2-METHYLPROPYL]-1-(5-FLUOROPENTYL)-1H-PYRROLO[2,3-B]PYRIDINE-3-CARBOXAMIDE (5F-AB-P7AICA)
N-[(1S)-1-(AMINOCARBONYL)-2-METHYLPROPYL]-1-[(4-FLUOROPHENYL)METHYL]-1H-INDAZOLE-3-CARBOXAMIDE (AB-FUBINACA)
N-[(1S)-1-(AMINOCARBONYL)-2-METHYLPROPYL]-1-PENTYL-1H-INDAZOLE-3-CARBOXAMIDE (AB PINACA)
6-(2-AMINOPROPYL)BENZOFURAN (6-APB)

N-(1-AMINO-3,3-DIMETHYL-1-OXOBUTAN-2-YL)-1 -(CYCLOHEXYLMETHYL)-1H-INDAZOLE-3-CARBOXAMIDE (MAB-CHMINACA or ADB-CHMINACA)
N-(1-AMINO-3,3-DIMETHYL-1-OXOBUTAN-2-YL)-1-(5-FLUOROPENTYL)-1H-INDOLE-3-CARBOXAMIDE (5F-ADBICA)
N-(1-AMINO-3-METHYL-1-OXOBUTAN-2-YL)-1-(5-FLUOROPENTYL)-1H-INDOLE-3-CARBOXAMIDE (5F-ABICA)
1-BUTYL-N-(2-PHENYLPROPAN-2-YL)-1H-INDOLE-3-CARBOXAMIDE (CUMYL-BICA)
[3-(3-CARBAMOYLPHENYL)PHENYL]N-CYCLOHEXYLCARBAMATE (URB-597)
(E)-4-CHLORO-N-(1-(4-NITROPHENETHYL)PIPERIDIN-2-YLIDENE)BENZENESULFONAMIDE (W-18)
(1R,2S,3S,5S)-3-(4-CHLOROPHENYL)-8-METHYL-2-[3-(4-METHYLPHENYL)-5-ISOXAZOLYL]-8-AZABICYCLO[3.2.1]OCTANE (RTI-336)
1-(4-CYANOBUTYL)-N-(1-METHYL-1-PHENYLETHYL)-1H-INDAZOLE-3-CARBOXAMIDE (SGT-78; 4-CN-CUMYL-BINACA; CUMYL-CB-PINACA; CUMYL-CYBINACA; 4-CYANO CUMYL-BUTINACA)
CYCLOHEXYL-[1,1-BIPHENYL]-3-YLCARBAMATE (URB-602)
1-CYCLOHEXYL-4-(1,2-DIPHENYLETHYL)PIPERAZINE (MT-45; IC-6)
1-(CYCLOHEXYLMETHYL)-1H-INDOLE-3-CARBOXYLIC ACID 8-QUINOLINYL ESTER (BB-22)
1-CYCLOHEXYLETHYL-3-(2-METHOXYPHENYLACETYL)INDOLE (RCS-8)

DESOXYPIPRADROL (2-DPMP)
2,5-DIHYDRO-2-(1-METHYL-1-PHENYLETHYL)-5-PENTYL-1H-PYRIDO[4,3-B]INDOL-1-ONE (CUMYL-PEGACLONE; SGT-151)
DIPHENIDINE
1-(5-FLUOROPENTYL)-1H-INDOLE-3-CARBOXYLIC ACID 8-QUINOLINYL ESTER (5F-PB22)
[1-(5-FLUOROPENTYL)-1H-INDOL-3-YL]-(2,2,3,3-TETRAMETHYL CYCLOPROPYL)METHANONE (XLR11 OR 5-FLUORO UR144)
1-(5-FLUOROPENTYL)-3-(4-METHYL-1-NAPHTHOYL)INDOLE (MAM-2201)
1-(5-FLUOROPENTYL)-N-(1-METHYL-1-PHENYLETHYL)-1H-INDAZOLE-3-CARBOXAMIDE (SGT-25)
1-(5-FLUOROPENTYL)-3-(1-NAPHTHOYL)INDOLE (AM-2201)
5-(5-FLUOROPENTYL)-2-(2-PHENYLPROPAN-2-YL)-2,5-DIHYDRO-1H-PYRIDO[4,3-B]INDOL-1-ONE (5F-CUMYL-PEGACLONE; 5F SGT-151)
2-(2-FLUOROPHENYL)-2-METHYLAMINO-CYCLOHEXANONE (2-FLUORODESCHLOROKETAMINE; 2FDCK)
1-HEXYL-3-(1-NAPHTHOYL)INDOLE (JWH-019)
9-(HYDROXYMETHYL)-6,6-DIMETHYL-3-(2-METHYLOCTAN-2-YL)-6A,7,10,10A-TETRAHYDROBENZO[C]CHROMEN-1-OL (HU-210)
N-(2-METHOXYLBENZYL)-2,5-DIMETHOXY-4-BROMOPHENETHYLAMINE (25B-NBOME)
N-(2-METHOXYLBENZYL)-2,5-DIMETHOXY-4-CHLOROPHENETHYLAMINE (25C-NBOME)

N-(2-METHOXYLBENZYL)-2,5-DIMETHOXY-4-IODOPHENETHYL AMINE (25I-NBOME)
2-METHOXYDIPHENIDINE (2-MXP or MXP)
4-METHOXYPHENYL(1-BUTYL-1H-INDOL-3-YL)-METHANONE (RCS-4 (C4))
2-(4-METHOXYPHENYL)-1-(1-PENTYL-1H-INDOL-3-YL)-ETHANONE (JWH-201)
2-(3-METHOXYPHENYL)-1-(1-PENTYLINDOL-3-YL)ETHANONE (JWH-302)
METHYL 2-(9-(CYCLOHEXYLMETHYL)-9H-CARBAZOLE-3-CARBOXAMIDO)-3,3-DIMETHYLBUTANOATE (MDMB-CHMCZCA)
METHYL 2-[1-(4-FLUOROBENZYL)-1H-INDOLE-3-CARBOXAMIDO]-3-METHYLBUTANOATE (MMB-FUBICA; AMB-FUBICA)
METHYL 2-[[1-(4-FLUOROBUTYL)INDAZOLE-3-CARBONYL]AMINO]-3,3-DIMETHYL-BUTANOATE (4F-MDMB-BINACA; 4F-MDMB-BUTINACA)
METHYL (S)-2-[1-(5-FLUOROPENTYL)-1H-INDAZOLE-3-CARBOXAMIDO]-3,3-DIMETHYLBUTANOATE (5F-ADB)
METHYL 2-(1-(5-FLUOROPENTYL)-1H-INDAZOLE-3-CARBOXAMIDO)-3-METHYLBUTANOATE (5F-AMB)
METHYL 2-[[1-(5-FLUOROPENTYL)INDOLE-3-CARBONYL]AMINO]-3,3-DIMETHYL-BUTANOATE (5-FLUORO MDMB-PICA; 5F-MDMB-PICA)

5,6-METHYLENEDIOXY-2AMINOINDANE (MDAI)
4-METHYLETHYLCATHINONE (4-MEC)
1-[(N-METHYLPIPERIDIN-2-YL)METHYL]-3-(1-ADAMANTOYL)INDOLE (AM-1248)
1-[(N-METHYLPIPERIDIN-2-YL)METHYL]3-(2-IODOBENZOYL)INDOLE (AM-2233)
1-[(N-METHYLPIPERIDIN-2-YL)METHYL]3-(4-METHYL-1-NAPHTHOYL)INDOLE (MAM-1220)
1-[(N-METHYLPIPERIDIN-2-YL)METHYL]3-(1-NAPHTHOYL)INDOLE (AM-1220)
N-METHYL-1-(THIOPHEN-2-YL)PROPAN-2-AMINE (METHIOPROPAMINE; MPA)
[1-(2-MORPHOLIN-4-YLETHYL)-1H-INDOL-3-YL]-(2,2,3,3-TETRAMETHYLCYCLOPROPYL)METHANONE (A796,260)
N-(1-NAPHTHYL)-1-(5-FLUOROPENTYL)-1H-INDOLE-3-CARBOXAMIDE (5F-NNEI; 5F-MN-24)
N-(1-NAPHTHYL)-1-PENTYL-1H-INDOLE-3-CARBOXAMIDE (NNEI)
1-PENTYL-3-(1-ADAMANTOYL)INDOLE (AB-001)
1-PENTYL-3-(4-CHLORO-1-NAPHTHOYL)INDOLE (JWH-398)
1-PENTYL-3-(2-CHLOROPHENYLACETYL)INDOLE (JWH-203)
1-PENTYL-3-(4-ETHYL-1-NAPHTHOYL)INDOLE (JWH-210)
1-PENTYL-1H-INDOLE-3-CARBOXYLIC ACID 8-QUINOLINYL ESTER (PB22)
1-PENTYL-3-[(4-METHOXY)-BENZOYL]INDOLE (RCS-4)

1-PENTYL-3-(2-METHOXYBENZOYL)INDOLE (RCS-4 (2-METHOXY ISOMER))
1-PENTYL-3-(4-METHOXY-1-NAPHTHOYL)INDOLE (JWH-081)
(1-PENTYLINDOL-3-YL)-(2,2,3,3-TETRAMETHYLCYCLOPROPYL) METHANONE (UR144)
PRAVADOLINE (WIN 48098)
1-PROPYL-2-METHYL-3-(1-NAPHTHOYL)INDOLE (JWH-015)
2,3,5-TRIMETHOXYAMPHETAMINE (TMA-4)

[Schedule 2 amended: SL 2020/214 r. 7.]

Schedule 3 — Requirements for safes

[r. 94]

1. Requirements for small safe

The requirements for a small safe are set out in the Table.

Table

	Requirements
Cabinet/body	Must be made from solid steel plate at least 10 mm thick or a steel skin with concrete fill at least 50 mm thick All joints must be continuously welded
Door	Must be made from solid steel plate at least 10 mm thick or a steel skin with concrete fill at least 50 mm thick Must be fitted flush to the cabinet/body with a maximum clearance of 1.5 mm when closed Hinge system must be a system that does not allow the door to be opened if the hinge is removed
Lock	Must be a 6 lever key lock or a 4 wheel combination lock or a digital lock that provides security that is equivalent to a 6 lever key lock or 4 wheel combination lock
Mounting	Must be mounted on a concrete floor or a brick or concrete wall with at least 4 expanding bolts of at least 12 mm in diameter If mounting on a concrete floor or a brick or concrete wall is not possible must be securely mounted on structural elements of the building such as studs or floor joists

2. Requirements for large safe

The requirements for a large safe are set out in the Table.

Table

	Requirements
Cabinet/body	Must be made from solid steel plate at least 10 mm thick or a steel skin with concrete fill at least 50 mm thick All joints must be continuously welded
Door	Must be made from solid steel plate at least 10 mm thick or a steel skin with concrete fill at least 50 mm thick Must be fitted flush to the cabinet/body with a maximum clearance of 1.5 mm when closed Hinge system must be a system that does not allow the door to be opened if the hinge is removed Must be secured with at least 2 locking bolts of at least 32 mm diameter
Lock	Must be a 6 lever key lock or a 4 wheel combination lock or a digital lock that provides security that is equivalent to a 6 lever key lock or 4 wheel combination lock
Mounting	Must be mounted on a concrete floor with an expanding bolt with a diameter of at least 16 mm unless the safe weighs more than 1 tonne
Installation	Must be installed by a person licensed under the *Security and Related Activities (Control) Act 1996* to install safes
Weight	Must have a minimum weight of 250 kg

Schedule 4 — Prescribed offences and modified penalties

[r. 148A]

[Heading inserted: SL 2024/224 r. 5.]

Offences under *Medicines and Poisons Act 2014*		**Modified penalty**
s. 15(1)	Supplying Schedule 6 nitrous oxide	$6 000
s. 15(2)	Supplying Schedule 6 nitrous oxide where likely to pose a serious threat to health, safety and welfare	$6 000
Offence under *Medicines and Poisons Regulations 2016*		**Modified penalty**
r. 148F(1)	Failing to record supply of Schedule 6 nitrous oxide	$1 000

[Schedule 4 inserted: SL 2024/224 r. 5.]

Schedule 5 — Infringement notice forms

[r. 148C]

[Heading inserted: SL 2024/224 r. 5.]

Form 1 — Infringement notice

<table>
<tr><td colspan="2">Medicines and Poisons Act 2014
INFRINGEMENT NOTICE</td><td>Infringement notice no.</td></tr>
<tr><td rowspan="4">Alleged offender</td><td rowspan="2">Name</td><td></td></tr>
<tr><td></td></tr>
<tr><td rowspan="2">Address</td><td></td></tr>
<tr><td></td></tr>
<tr><td rowspan="4">Details of alleged offence</td><td>Date or period</td><td></td></tr>
<tr><td>Place</td><td></td></tr>
<tr><td>Written law contravened</td><td></td></tr>
<tr><td>Details of offence</td><td></td></tr>
<tr><td>Date</td><td>Date of notice</td><td></td></tr>
<tr><td rowspan="2">Authorised officer</td><td>Name</td><td></td></tr>
<tr><td>Signature</td><td></td></tr>
<tr><td>Modified penalty</td><td colspan="2">$_____</td></tr>
<tr><td>Due date for payment of modified penalty</td><td colspan="2">/ /
(Within 28 days after the date of this notice)</td></tr>
</table>

Form 1

TAKE NOTICE	It is alleged that you have committed the above offence. **If you do not want to be prosecuted in court for the offence**, pay the modified penalty to the Approved Officer within 28 days after the date of this notice. **If you do not pay** the modified penalty within 28 days, you may be prosecuted or enforcement action may be taken under the *Fines, Penalties and Infringement Notices Enforcement Act 1994*. Under that Act, some or all of the following action may be taken — your driver's licence may be suspended, your vehicle licence may be suspended or cancelled, you may be disqualified from holding or obtaining a driver's licence or vehicle licence, your vehicle may be immobilised or have its number plates removed, your details may be published on a website, your earnings or bank accounts may be garnished, and your property may be seized and sold. **If you need more time** to pay the modified penalty, you should contact the Approved Officer at the address below. Paying the modified penalty will not be regarded as an admission for the purposes of any civil or criminal court case. **If you want this matter to be dealt with by prosecution in court**, sign and date here: _____ / / and send this notice to the Approved Officer at the address below within 28 days after the date of this notice. If you consider that you have good reason to have this notice withdrawn, you can write to the Approved Officer at the address below requesting that this notice be withdrawn and setting out the reasons why you consider that this notice should be withdrawn. Your letter must be received not later than 28 days after the date of this notice.

How to pay	By post	[*Insert details for paying by post*]		
	Online	[*Insert details for paying online*]		
	By telephone	[*Insert details for paying by telephone*]		
Method of service			**Date of service**	

[Form 1 inserted: SL 2024/224 r. 5.]

Form 2 — Withdrawal of infringement notice

Medicines and Poisons Act 2014 **WITHDRAWAL OF INFRINGEMENT NOTICE**			**Withdrawal no.**
Alleged offender	Name		
	Address		
Details of infringement notice	Infringement notice no.		
	Date of issue		
Details of alleged offence	Date or period		
	Place		
	Written law contravened		
	Details of offence		
Approved Officer withdrawing notice	Name		
	Signature		

Form 2

<table>
<tr><td>Date</td><td>Date of withdrawal</td><td colspan="2"></td></tr>
<tr><td>Withdrawal of infringement notice

[*Delete whichever is not applicable]</td><td colspan="3">The above infringement notice issued against you for the above alleged offence has been withdrawn.

If you have already paid the modified penalty for the alleged offence, you are entitled to a refund.

* Your refund is enclosed.

or

* You may claim your refund by signing and dating this notice and sending it to:

Approved Officer — Medicines and Poisons Act 2014

[Insert postal and email address]</td></tr>
<tr><td>Your signature</td><td></td><td>Date</td><td></td></tr>
</table>

[Form 2 inserted: SL 2024/224 r. 5.]

Notes

This is a compilation of the *Medicines and Poisons Regulations 2016* and includes amendments made by other written laws. For provisions that have come into operation see the compilation table.

Compilation table

Citation	Published	Commencement
Medicines and Poisons Regulations 2016	17 Jan 2017 p. 443-586	30 Jan 2017 (see r. 2 and *Gazette* 17 Jan 2017 p. 403)
Health Regulations Amendment Regulations 2018 Pt. 3	13 Nov 2018 p. 4428-31	1 Dec 2018 (see r. 2(b))
Medicines and Poisons Amendment Regulations 2019	15 Mar 2019 p. 786-92	r. 1 and 2: 15 Mar 2019 (see r. 2(a)); Regulations other than r. 1 and 2: 16 Mar 2019 (see r. 2(b))
Health Regulations Amendment (Fees and Charges) Regulations 2019 Pt. 8	14 Jun 2019 p. 1883-94	1 Jul 2019 (see r. 2(b))
Medicines and Poisons Amendment Regulations (No. 2) 2019	19 Nov 2019 p. 4051-2	r. 1 and 2: 19 Nov 2019 (see r. 2(a)); Regulations other than r. 1 and 2: 20 Nov 2019 (see r. 2(b))
Medicines and Poisons Amendment Regulations 2020	SL 2020/214 6 Nov 2020	r. 1 and 2: 6 Nov 2020 (see r. 2(a)); Regulations other than r. 1 and 2: 7 Nov 2020 (see r. 2(b))
Health Regulations Amendment (Veterinary Practice) Regulations 2022 Pt. 2	SL 2022/93 17 Jun 2022	18 Jun 2022 (see r. 2(b) and SL 2022/81 cl. 2)
Health Regulations Amendment (Fees and Charges) Regulations 2022 Pt. 6	SL 2022/136 15 Jul 2022	16 Jul 2022 (see r. 2(b))
Medicines and Poisons Amendment Regulations 2023	SL 2023/3 27 Jan 2023	r. 1 and 2: 27 Jan 2023 (see r. 2(a)); Regulations other than r. 1 and 2: 1 Feb 2023 (see r. 2(b))
Health Regulations Amendment (Fees and Charges) Regulations 2023 Pt. 7	SL 2023/96 30 Jun 2023	1 Jul 2023 (see r. 2(b))
Health Regulations Amendment (Fees and Charges) Regulations 2024 Pt. 7	SL 2024/91 12 Jun 2024	1 Jul 2024 (see r. 2(b))

Citation	Published	Commencement
Medicines and Poisons Amendment Regulations (No. 3) 2024	SL 2024/218 30 Oct 2024	r. 1 and 2: 30 Oct 2024 (see r. 2(a)); Regulations other than r. 1 and 2: 31 Oct 2024 (see r. 2(b))
Medicines and Poisons Amendment Regulations (No. 2) 2024	SL 2024/224 30 Oct 2024	r. 1 and 2: 30 Oct 2024 (see r. 2(a)); Regulations other than r. 1 and 2: 31 Oct 2024 (see r. 2(b))

Defined terms

[This is a list of terms defined and the provisions where they are defined. The list is not part of the law.]

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