Western Australia

Pharmacy Act 2010

Pharmacy Regulations 2010

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Defined terms

Western Australia

Pharmacy Act 2010

Pharmacy Regulations 2010

Part 1 — Preliminary

1. Citation

These regulations are the *Pharmacy Regulations 2010*.

2. Commencement

These regulations come into operation as follows —

(a) regulations 1 and 2 — on the day on which these regulations are published in the *Gazette*;

(b) the rest of the regulations — on the day on which the *Pharmacy Act 2010* section 3 comes into operation.

3. Pharmacy business (s. 3(1))

For the purposes of paragraph (d) of the definition of ***pharmacy business*** in section 3(1) of the Act —

(a) the following types of permit referred to in the *Medicines and Poisons Regulations 2016* in the Table to regulation 79(2) are prescribed —

(i) a Health service permit;

(ii) a Health service permit — Department/ hospital;

(iii) a Health service permit — Public sector agency;

(iv) a Government permit;

(v) a Research/Education permit;

and

(b) the type of licence that is a Schedule 2 retail licence referred to in the *Medicines and Poisons Regulations 2016* in the Table to regulation 74(2) is prescribed.

[Regulation 3 inserted: Gazette 17 Jan 2017 p. 411.]

Part 2 — Registration of pharmacies and certificates of registration

4. Application for registration of premises as a pharmacy (s. 42)

An application for the registration of premises as a pharmacy must be accompanied by the following —

(a) plans, and specifications, of the premises that are sufficiently detailed to show that the premises meet the requirements for the minimum standards of fitness for the competent and safe practice of pharmacy prescribed under regulation 13;

(b) unless the premises comprise the whole of a building, plans of the building where the premises are situated that show the location of the premises within the building;

(c) the relevant application fee specified in Schedule 2;

(d) the following information in respect of each person who owns, or hold a proprietary interest in, the pharmacy business that is, or is to be, carried on at the premises —

(i) the nature of the interest held by the person;

(ii) the name and address of the person;

(iii) a telephone number and email address for the person;

(e) the following information in respect of the premises, or the pharmacy business that is, or is to be, carried on at the premises —

(i) a copy of any bill of sale over any fittings or equipment in the premises, or to be used in the premises, or for the purposes of the pharmacy business;

(ii) a copy of any sale agreement for the premises or the pharmacy business;

(iii) a copy of any partnership agreement for the pharmacy business;

(iv) a copy of any lease for the premises;

(v) a copy of any agreement under which any person has, or will have, a proprietary interest in the pharmacy business;

(vi) a copy of any agreement between persons who hold a proprietary interest in the pharmacy business, that makes provision for any rights the persons possess by virtue of having the proprietary interests;

(vii) a copy of any agreement for the provision of management services to the pharmacy business or to any pharmacist controlled company that holds a proprietary interest in the pharmacy business;

(viii) a copy of any agreement (except a contract of employment) between any person and any entity in respect of the provision of accounting, information technology, human resources or other support services to the pharmacy business;

(ix) if a pharmacist controlled company is acting as a trustee (whether of a fixed trust, unit trust, discretionary trust or other kind of trust), a copy of the relevant trust deed (if any exists);

(x) a copy of any security interest in respect of the pharmacy business.

5. Duration of registration of premises as a pharmacy (s. 45)

(1) Registration of premises as a pharmacy has effect for a period beginning from the day on which the premises are registered as a pharmacy and ending on the 30 June next following that day.

(2) Registration that is renewed has effect for a period of 12 months from the expiration of the previous registration.

6. Renewal of registration

An application for the renewal of the registration of premises as a pharmacy must be —

(a) made in the approved manner and form; and

(b) accompanied by the relevant application fee specified in Schedule 2.

7. Replacement of certificate of registration of premises as a pharmacy

If the Board is satisfied that a certificate of registration has been lost or destroyed it may issue a replacement certificate on payment of the relevant fee specified in Schedule 2.

Part 3 — The register

8. Register: additional information to be recorded (s. 49(2)(d))

For the purposes of section 49(2)(d) of the Act, the following information is prescribed as information to be included in the register in respect of a registered pharmacy —

(a) the name and business address of each person who owns, or holds a proprietary interest in, the pharmacy business carried on at the premises;

(b) the nature of the interest held by each person referred to in paragraph (a);

(c) the name and business address of the pharmacist who has overall responsibility for the pharmacy business carried on at the pharmacy under section 56 or 58(2) of the Act.

9. Change to information recorded in the register

(1) If there is any change to the information recorded in the register in respect of a pharmacy, the person in whose name the pharmacy is registered under section 39 of the Act must, within 14 days of the change, give notice of the change in writing to the Board.

Penalty: a fine of $500.

(2) A person giving notice to the Board of a change to the information recorded in the register in respect of a pharmacy is to pay to the Board the relevant fee specified in Schedule 2.

10. Fee to obtaining a certified copy of the register or a particular entry in the register (s. 50(4))

The fee payable to obtain a certified copy of the register or a particular entry in the register is the relevant fee specified in Schedule 2.

Part 4 — Pharmacies

11. Terms used

In this Part —

pharmacy registered under the old Act means premises taken, under section 83 of the Act, to be registered as a pharmacy under Part 4 Division 1 of the Act;

pharmacist with overall responsibility, in relation to a pharmacy, means the pharmacist who has overall responsibility for the pharmacy business carried on at the pharmacy under section 56 or 58(2) of the Act;

prescription has the meaning given in the *Medicines and Poisons Act 2014* section 3;

significant alteration is an alteration to the pharmacy that affects the construction, structure, layout or floor area of the pharmacy;

tobacco product has the meaning given in the *Tobacco and Other Products Control Act 2006* Glossary.

[Regulation 11 amended: Gazette 17 Jan 2017 p. 411.]

12. Tobacco products not to be sold or supplied at pharmacies

A person must not sell or supply a tobacco product at a registered pharmacy.

Penalty: a fine of $5 000.

13. Minimum standards of fitness for the competent and safe practice of pharmacy — Schedule 1

(1) The requirements listed in Schedule 1 are prescribed as the minimum standards of fitness for the competent and safe practice of pharmacy for the purposes of the Act.

(2) If, immediately before the day on which the *Pharmacy Act 2010* section 3 came into operation, a pharmacy registered under the

old Act was not in compliance with the requirement for the minimum standard of fitness for the competent and safe practice of pharmacy set out in Schedule 1 —

(a) item 6(1); or

(b) item 7,

then that requirement applies in respect of such a pharmacy only after significant alterations to that pharmacy are next completed.

14. Significant alteration to a pharmacy

(1) The pharmacist with overall responsibility for a pharmacy must not cause or permit any significant alteration to be made to the pharmacy without the prior written approval of the Board.

Penalty: a fine of $1 000.

(2) The pharmacist with overall responsibility for a pharmacy must make application to the Board for approval to make significant alterations to that pharmacy at least 2 months before the commencement of the alterations.

Penalty: a fine of $ 500.

(3) An application under subregulation (2) must be accompanied by —

(a) all relevant plans and specifications relating to the proposed significant alterations; and

(b) the relevant application fee specified in Schedule 2.

(4) The Board may, by notice in writing given to an applicant, request that the applicant provide to the Board such further information as the Board reasonably requires to decide the application.

(5) The Board must not withhold approval under this regulation unless it is satisfied that if the alterations were carried out in accordance with the plans and specifications given to the Board the pharmacy would cease to meet the requirements for the

minimum standards of fitness for the competent and safe practice of pharmacy prescribed under regulation 13.

15. Pharmacy to be well lit, air conditioned and kept clean and in good repair

The pharmacist with overall responsibility for a pharmacy is to ensure that —

(a) the pharmacy is well lit, adequately ventilated and is air conditioned; and

(b) the pharmacy and all fixtures and fittings in the pharmacy are maintained in a safe, clean and hygienic condition and in good repair.

Penalty: a fine of $1 000.

16. Record keeping

(1) The pharmacist with overall responsibility for a pharmacy is to ensure that a record is made of all prescriptions dispensed at, or from, the pharmacy.

Penalty: a fine of $1 000.

(2) The pharmacist with overall responsibility for a pharmacy is to ensure that a record made under this regulation —

(a) is kept at the pharmacy in a safe and secure location and dealt with in a confidential manner; and

(b) is retained at the pharmacy for 24 months after the prescription is dispensed.

Penalty: a fine of $1 000.

(3) This regulation is in addition to and not in derogation of any other law relating to the duty of a person to make and keep records.

Part 5 — Other matters

17. Person ceasing to be a close family member of a pharmacist (s. 58(4)(a))

For the purposes of section 58(4)(a) of the Act, a proprietary interest that is an interest in a partnership or a pharmacist controlled company held by a person who has ceased to be a close family member of a pharmacist due to death, divorce or separation is to be dealt with as follows —

(a) the person who holds the proprietary interest is to divest himself or herself of the interest before the end of the period approved by the Board under section 58(4)(b);

(b) if the person has ceased to be a close family member of the pharmacist due to divorce or separation, then the interest is to be redeemed by the company or partnership, in accordance, where relevant, with any provisions of the constitution of the company or rules of the partnership.

18. Fee to obtain copy of minutes of Board (s. 33(4))

The fee payable to obtain a copy of any minutes of the Board available for inspection under section 33(3) of the Act is the relevant fee specified in Schedule 2.

Schedule 1 — Minimum standards of fitness for the competent and safe practice of pharmacy

[r. 13]

1. Premises generally

The premises are to —

(a) have at least one door allowing direct access to members of the public from a street or thoroughfare; and

(b) have no direct access to any adjoining premises.

2. Premises, fixtures and fittings to be clean etc.

(1) The premises and all fixtures and fittings at the premises are to be in a safe, clean and hygienic condition and in good repair.

(2) The premises are to have such devices and systems provided and maintained in good working order as is necessary to ensure that the premises are reasonably secure against burglary, robbery, theft and unexplained loss.

3. Equipment on premises

The premises are to be equipped with the equipment referred to in the Table.

Table

Item	Equipment	Number required
1.	Bar code scanner	one at each dispensing station
2.	Beakers: 100 ml 250 ml	one of each
3.	Appropriate heating device (e.g. gas, microwave or electric hotplate)	one

Item	Equipment	Number required
4.	Funnel (glass or plastic)	one
5.	Measures graduated (dispensing glass): 10 ml 25 ml 50 ml 100 ml 250 ml	one of each
6.	Mortars and Pestles: Glass 75 mm Ceramic	one of each
7.	Refrigerator	one
8.	Scales Either: Dispensing Beam type to weigh to 50 g Counter Beam type to weigh to 1 kg with metric weights 5 mgm to 500 gm inclusive OR Electronic balance to weigh to at least 200 gm, with a readability of not less than 0.01 gm and standard deviation $\leq \pm 0.01$ gm	one set of each
9.	Slabs-ointment: 250 mm x 250 mm (minimum size)	one

Item	Equipment	Number required
10.	Spatulas: Stainless Steel	at least 2 different sizes
11.	Stirring Rods: Glass	one

4. Access to reference documents

The premises are to have a copy of, or immediate electronic access to, the latest editions, and all published amendments or supplements to those editions, of each of the following documents —

(a) the Australian Medicines Handbook (also known as *AMH*);

(b) the Australian Pharmaceutical Formulary and Handbook;

(c) the MIMS annual or eMIMS or AusDI;

(d) the Therapeutic Guidelines (complete series);

(e) the *Pharmacy Act 2010* and the *Pharmacy Regulations 2010*;

(f) the *Medicines and Poisons Act 2014* and the *Medicines and Poisons Regulations 2016*.

[Clause 4 amended: Gazette 17 Jan 2017 p. 411.]

5. Records

The premises are to have a safe and secure location for the keeping of records made under regulation 16.

6. Dispensary

(1) The premises are to have an area for the dispensing of medicines or drugs that has a minimum floor area of 10 square metres (the ***dispensary***).

(2) The dispensary is to have a suitable sink that has hot and cold running water connected.

7. Area for private consultation

The premises are to have an area in which a consultation conducted by a pharmacist is not reasonably likely to be overheard by a person not a party to the consultation.

Schedule 2 — Fees

[r. 4, 6, 7, 9, 10, 14, 18]

[Heading inserted: SL 2024/110 r. 4.]

Provision	Subject matter	Fee
Application fees		
r. 4	Grant of registration of premises as a pharmacy	$1 150
r. 6	Renewal of registration of premises as a pharmacy	$950
r. 14	Significant alteration to a pharmacy	$750
Other fees		
r. 7	Replacement of certificate of registration	$55
r. 9	Change to information recorded in the register	$55
r. 10	Certified copy of the register or a particular entry in the register	$55
r. 18	Copy of minutes of the Board	$55

[Schedule 2 inserted: SL 2024/110 r. 4.]

Notes

This is a compilation of the *Pharmacy Regulations 2010* and includes amendments made by other written laws. For provisions that have come into operation, or versions that include editorial changes made under the *Legislation Act 2021* Part 3, see the compilation table. For provisions affected by editorial changes see the editorial changes table.

Compilation table

Citation	Published	Commencement
Pharmacy Regulations 2010	1 Oct 2010 p. 5093-110	r. 1 and 2: 1 Oct 2010 (see r. 2(a)); Regulations other than r. 1 and 2: 18 Oct 2010 (see r. 2(b) and *Gazette* 1 Oct 2010 p. 5076)
Pharmacy Amendment Regulations 2012	1 Jun 2012 p. 2280-1	r. 1 and 2: 1 Jun 2012 (see r. 2(a)); Regulations other than r. 1 and 2: 1 Jul 2012 (see r. 2(b))
Health Regulations Amendment (Poisons) Regulations 2016 Pt. 4	17 Jan 2017 p. 409-11	30 Jan 2017 (see r. 2(b) and *Gazette* 17 Jan 2017 p. 403)
Pharmacy Amendment Regulations 2019	24 Dec 2019 p. 4429-30	r. 1 and 2: 24 Dec 2019 (see r. 2(a)); Regulations other than r. 1 and 2: 25 Dec 2019 (see r. 2(b))
Pharmacy Amendment Regulations 2024	SL 2024/110 26 Jun 2024	r. 1 and 2: 26 Jun 2024 (see r. 2(a)); Regulations other than r. 1 and 2: 1 Jul 2024 (see r. 2(b))
***Pharmacy Regulations 2010* with editorial changes as at 15 May 2026**		

Editorial changes table

The *Legislation Act 2021* Part 3 authorises the Parliamentary Counsel to make editorial changes to laws. This power cannot be used to change the effect of a law. If an editorial change is made to a law, the law has effect as if the change had been made by another law that amended the law and commenced on the day on which the change is made.

To see the editorial changes included in a version of a law, see the compare document for that version on the WA legislation website.

Provision/s affected	**Authorising provision of *Legislation Act 2021* Part 3**	**Effective date of change**
r. 11	s. 25(2)	15 May 2026

Defined terms

[This is a list of terms defined and the provisions where they are defined. The list is not part of the law.]

Defined term	Provision(s)
dispensary	Sch. 1 cl. 6(1)
pharmacist with overall responsibility,	11
pharmacy registered under the old Act	11
prescription	11
significant alteration	11
tobacco product	11

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