



New South Wales

Poisons and Therapeutic Goods Amendment Regulation 2022

under the

Poisons and Therapeutic Goods Act 1966

Her Excellency the Governor, with the advice of the Executive Council, has made the following Regulation under the *Poisons and Therapeutic Goods Act 1966*.

BRAD HAZZARD, MP
Minister for Health

Explanatory note

This Regulation amends the *Poisons and Therapeutic Goods Regulation 2008* for the following purposes—

- (a) to permit the supply of a restricted substance or drug of addiction to be directed orally, including by telephone, or by email or fax, in urgent circumstances in addition to in an emergency,
- (b) to make permanent certain arrangements for the issue of prescriptions for restricted substances and drugs of addiction by email or fax in public health organisations,
- (c) to continue, for a limited period, certain arrangements for the issue of prescriptions for restricted substances by email or fax in private health facilities,
- (d) to extend the number of days' treatment that may be supplied by a pharmacist in an emergency and without the direction of a health practitioner from 3 days to 7 days,
- (e) to clarify the circumstances under which prescriptions for type C unregistered drugs of addiction may be issued for the purposes of clinical trials,
- (f) to update provisions relating to synthetic local anaesthetics,
- (g) to make other minor amendments.

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1 Name of Regulation

This Regulation is the *Poisons and Therapeutic Goods Amendment Regulation 2022*.

2 Commencement

This Regulation commences on 30 September 2022.

Schedule 1 Amendment of Poisons and Therapeutic Goods Regulation 2008

[1] **Clause 3 Definitions**

Insert in alphabetical order in clause 3(1)—

public health organisation has the same meaning as in the *Health Services Act 1997*, section 7.

[2] **Clause 35 Form of prescription**

Omit “subclause (1) or (1A)(a) or (c)–(i)” from clause 35(2A).

Insert instead “subclause (1)(a)–(f) and (1A)(a) and (c)–(i)”.

[3] **Clause 36 Emergency prescriptions may be given by telephone or otherwise**

Insert “or other urgent circumstances” after “emergency” in clause 36(1).

[4] **Clause 36(1)**

Insert “including” before “by telephone” in clause 36(1).

[5] **Clause 36A, heading**

Omit “during COVID-19 pandemic”. Insert instead “—public health organisations”.

[6] **Clause 36A(1)**

Omit “During the prescribed period, a”. Insert instead “A”.

[7] **Clause 36A(1)**

Insert “employed in or engaged by a public health organisation in relation to carrying out functions in the course of that employment or engagement” after “pharmacist”.

[8] **Clause 36A(6)**

Omit the subclause. Insert instead—

(6) In this clause—

restricted substance includes a prescribed restricted substance and a special restricted substance.

[9] **Clause 36B**

Insert after clause 36A—

36B Special provisions for prescribing restricted substances—private health facilities

(1) This clause applies to a medical practitioner or nurse practitioner and a pharmacist—

(a) employed in or engaged by the same private health facility, and

(b) in relation to carrying out functions in the course of that employment or engagement.

(2) During the prescribed period, a medical practitioner or nurse practitioner may issue a prescription for a restricted substance by sending a prescription to a pharmacist by email or facsimile.

(3) A medical practitioner or nurse practitioner who issues a prescription for a restricted substance in accordance with this clause must keep the prescription.

- (4) A pharmacist to whom a prescription is sent under this clause must—
 - (a) print a copy of the prescription, and
 - (b) keep a printed copy.
- (5) The copy of the prescription printed by the pharmacist is taken to be a prescription for the purposes of Division 4 of this Part.
- (6) This clause does not apply to a medication chart prescription.
- (7) In this clause—
 - prescribed period* means the period commencing on the commencement of this clause and ending at the end of 31 March 2023.
 - private health facility* has the same meaning as in the *Private Health Facilities Act 2007*, section 4.
 - restricted substance* does not include a prescribed restricted substance or a special restricted substance.

[10] Clause 45 Emergency supply by pharmacists otherwise than on direction of health practitioner

Omit “3 days” from clause 45(2)(a). Insert instead “7 days”.

[11] Clause 45A Supply by pharmacists in accordance with determination under National Health Act 1953 of Commonwealth

Omit “issued by the Pharmaceutical Society of Australia and as in force on 1 July 2012” from clause 45A(1)(b).

Insert instead “published by the Pharmaceutical Society of Australia in 2018 and as in force from time to time”.

[12] Clause 45A(2)

Omit “*National Health (Continued Dispensing) Determination 2012*”.

Insert instead “*National Health (Continued Dispensing) Determination 2022*”.

[13] Clause 45A(2)

Omit “on the commencement of the *Poisons and Therapeutic Goods Amendment (Continued Dispensing) Regulation 2013*”.

Insert instead “from time to time”.

[14] Clause 58 Administration by persons employed at hospitals and managed correctional centres

Omit clause 58(3)(b). Insert instead—

- (b) orally, including by telephone, or
- (c) in another way approved by the Secretary.

[15] Clause 81 Emergency prescriptions may be given by telephone or otherwise

Insert “or other urgent circumstances” after “emergency” in clause 81(1).

[16] Clause 81(1)

Insert “including” before “by telephone”.

[17] Clause 81A

Insert after clause 81—

81A Special provisions for prescribing drugs of addiction—public health organisations

- (1) This clause applies to a medical practitioner or nurse practitioner and a pharmacist—
 - (a) employed in or engaged by the same public health organisation, and
 - (b) in relation to carrying out functions in the course of that employment or engagement.
- (2) A medical practitioner or nurse practitioner may issue a prescription for a drug of addiction by sending a prescription to a pharmacist by email or facsimile.
- (3) A medical practitioner or nurse practitioner who issues a prescription for a drug of addiction in accordance with this clause must keep the prescription.
- (4) A pharmacist to whom a prescription is sent under this clause must—
 - (a) print a copy of the prescription, and
 - (b) keep a printed copy.
- (5) The copy of the prescription printed by the pharmacist is taken to be a prescription for the purposes of Division 4 of this Part.
- (6) This clause does not apply to a medication chart prescription.

[18] Clause 84A Authority required for prescriptions for clinical trials

Insert “for the purposes of a clinical trial” before “unless”.

[19] Clause 84A

Omit paragraph (aa).

[20] Clause 120 Administration by persons employed at hospitals and managed correctional centres

Omit clause 120(3)(b). Insert instead—

- (b) orally, including by telephone, or
- (c) in another way approved by the Secretary.

[21] Appendix C Persons authorised to possess and use substances

Omit “synthetic cocaine substitutes (prepared for parenteral use)” from clause 3.

Insert instead “a Schedule 2, 3 or 4 substance that is a synthetic local anaesthetic”.

[22] Appendix C, clause 5

Insert after clause 5(1)(e)—

- (f) a Schedule 2, 3 or 4 substance that is a synthetic local anaesthetic.