



New South Wales

Poisons and Therapeutic Goods Amendment (Methadone) Regulation 2000

under the

Poisons and Therapeutic Goods Act 1966

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

CRAIG KNOWLES, M.P.,

Minister for Health

Explanatory note

The object of this Regulation is to amend the *Poisons and Therapeutic Goods Regulation 1994*:

- (a) to require a pharmacist supplying methadone syrup on prescription at a retail pharmacy to keep certain records of that supply, and
- (b) to make it an offence for a pharmacist at a retail pharmacy to supply more than 50 people a day with doses of methadone syrup unless the pharmacist is acting in accordance with an exemption referred to in paragraph (c) or a licence issued under Division 2 of Part 7 of that Regulation (relating to licences to manufacture or supply drugs of addiction), and
- (c) to enable the owner of a pharmacy that was supplying daily doses of methadone syrup to more than 50 persons at the commencement of the Regulation to apply for an exemption from the offence referred to in paragraph (b) in relation to the pharmacy, and
- (d) to provide for certain transitional provisions in relation to the above amendments.

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Explanatory note

This Regulation is made under the *Poisons and Therapeutic Goods Act 1966*, including section 45C (the general regulation-making power).

Poisons and Therapeutic Goods Amendment (Methadone) Regulation 2000

1 Name of Regulation

This Regulation is the *Poisons and Therapeutic Goods Amendment (Methadone) Regulation 2000*.

2 Amendment of Poisons and Therapeutic Goods Regulation 1994

The *Poisons and Therapeutic Goods Regulation 1994* is amended as set out in Schedule 1.

3 Notes

The explanatory note does not form part of this Regulation.

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Schedule 1 Amendments

Schedule 1 Amendments

(Clause 2)

[1] **Clauses 93A–93C**

Insert after clause 93:

93A Records to be kept by pharmacists of methadone prescriptions

- (1) A pharmacist who supplies methadone syrup on prescription at a retail pharmacy must keep a record of the supply in accordance with this clause.

Maximum penalty: 20 penalty units.

- (2) A record under this clause must contain the following particulars:
- (a) the name of the person to whom the supply was made,
 - (b) the number of the prescription on which the supply was made,
 - (c) the person who gave the prescription,
 - (d) the amount of methadone syrup supplied,
 - (e) the day on which the supply occurred,
 - (f) if the whole or part of the methadone syrup was supplied for consumption on a different day to that on which it was supplied, the day or days on which it is to be consumed and the amount to be consumed on that day or on each of those days.
- (3) Records made under this clause in relation to a particular pharmacy are to be made in writing in a book in which all such records for the pharmacy are kept.
- (4) The Director-General may from time to time approve the keeping of records under this clause in any other form.
- (5) A record made under this clause must be kept for at least 2 years from the date on which it is made.

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- (6) This clause does not take effect until 1 month after the publication in the Gazette of the *Poisons and Therapeutic Goods Amendment (Methadone) Regulation 2000*.

93B Supply by pharmacists of methadone syrup

- (1) A pharmacist must not, on any particular day, supply methadone syrup on prescription at a retail pharmacy to a person if that supply would result in more than 50 persons having been supplied with methadone syrup on prescription at that pharmacy on that day.

Maximum penalty: 20 penalty units.

- (2) For the purposes of subclause (1), if an amount of methadone syrup is supplied for consumption on a day other than the day on which it is supplied, the supply of that amount is taken to have occurred on the day on which the amount is to be consumed.
- (3) Subclause (1) does not apply to the supply of methadone syrup at a pharmacy in accordance with:
- (a) an exemption granted under clause 93C, or
 - (b) a licence issued under Division 2 of Part 7.

93C Exemptions relating to methadone supply at pharmacies

- (1) The owner of a pharmacy may apply in writing to the Director-General for an exemption from clause 93B (1) in relation to the pharmacy.
- (2) The Director-General may require the owner of the pharmacy to furnish such information as is necessary to enable the Director-General to determine the application.
- (3) The Director-General may, by notice in writing served on the owner of the pharmacy, grant the exemption or refuse to grant the exemption.
- (4) The Director-General may only grant an exemption if satisfied that, immediately before the commencement of clause 93B, more than 50 persons were receiving amounts of methadone syrup for consumption on a daily basis from the pharmacy concerned.

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- (5) An exemption is subject to such conditions as may be specified in the notice referred to in subclause (3) and to such further conditions as the Director-General may from time to time notify in writing to the holder of the exemption.
- (6) The Director-General may from time to time vary or revoke any condition of an exemption by notice in writing served on the holder of the exemption.
- (7) An exemption remains in force until:
 - (a) the expiry date (if any) specified in the exemption, or
 - (b) it is surrendered or cancelled,whichever occurs first.
- (8) The Director-General may, if the Director-General sees fit, suspend or cancel an exemption by notice in writing served on the holder of the exemption.
- (9) An exemption has no effect during any period of suspension.
- (10) For the removal of doubt, an exemption is not a licence or authority for the purposes of this Regulation.

[2] Clause 161

Insert after clause 160:

161 Transitional provisions relating to supply of methadone at pharmacies

Until 3 months after the commencement of clause 93B, a pharmacist does not commit an offence under that clause by supplying methadone syrup on prescription at a retail pharmacy to not more than the number of persons who were, immediately before that commencement, being supplied on prescription at that pharmacy with methadone syrup for consumption on a daily basis.

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Amendments

Schedule 1

[3] Dictionary

Insert in alphabetical order:

retail pharmacy means premises approved under section 24A
of the *Pharmacy Act 1964*.