



New South Wales

Poisons and Therapeutic Goods Amendment (Miscellaneous) Regulation 2001

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*.

CRAIG KNOWLES, M.P.,
Minister for Health

Explanatory note

The objects of this Regulation are:

- (a) to make certain pharmaceutical supplies available for emergency use in nursing homes, and
- (b) to provide for the storage of prescribed restricted substances in certain hospital areas, and
- (c) to provide for the destruction of drugs of addiction and the drug pentazocine in private health facilities, and
- (d) to alter the strengths of drugs of addiction for emergency use that are permitted to be stored and used in nursing homes and private hospitals, and
- (e) to provide for the supply of emergency asthma management drugs, and
- (f) to update the definitions of “child-resistant closure” and “hallucinogen”, and
- (g) to update a reference to a Department and to the Act, and
- (h) to update the lists of special restricted substances and prescribed restricted substances.

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Explanatory note

This Regulation is made under the *Poisons and Therapeutic Goods Act 1966*, including sections 17, 24 and 45C (the general regulation-making power).

Poisons and Therapeutic Goods Amendment (Miscellaneous) Regulation 2001

1 Name of Regulation

This Regulation is the *Poisons and Therapeutic Goods Amendment (Miscellaneous) Regulation 2001*.

2 Commencement

- (1) Except as provided by subclause (2), this Regulation commences on 2 November 2001.
- (2) Schedule 2 commences on 1 March 2002.

3 Amendment of Poisons and Therapeutic Goods Regulation 1994

The *Poisons and Therapeutic Goods Regulation 1994* is amended as set out in Schedules 1 and 2.

4 Notes

The explanatory note does not form part of this Regulation.

Schedule 1 Amendments

(Clause 2)

[1] Clause 17 Schedule 3 substances to be supplied personally by pharmacists

Insert after clause 17 (2):

- (3) This clause does not apply to the supply of salbutamol or terbutaline in metered aerosols for first aid purposes to a person who holds a current emergency asthma management certificate issued by an organisation approved by the Director-General for the purposes of this subclause.
- (4) This clause does not apply to the supply to the chief nurse of a nursing home of any substance in a manufacturer's original pack, in accordance with a written order signed by the chief nurse, if the Director-General has determined that the substance may be supplied for emergency use at the nursing home in accordance with the authorisation of a medical practitioner, dentist or nurse practitioner who prescribes substances to the nursing home's residents.

[2] Clause 32 Storage of prescribed restricted substances (including pentazocine) in hospital wards

Insert at the end of clause 32:

- (2) This clause does not apply to the storage of prescribed restricted substances (including pentazocine) on an emergency trolley, anaesthetic trolley or operating theatre trolley.

[3] Clause 47A

Insert after clause 47:

47A Supply by pharmacists to nursing homes of stock for emergency use

- (1) A retail pharmacist may supply the chief nurse of a nursing home with a manufacturer's original pack of a relevant prescribed substance for emergency use at the nursing home in

accordance with an authorisation by a medical practitioner, dentist or nurse practitioner who prescribes substances to the nursing home's residents.

(2) A relevant prescribed substance may not be supplied under this clause unless it is supplied in accordance with a written order signed by the chief nurse.

Maximum penalty: 15 penalty units.

(3) In this clause:

relevant prescribed substance means a restricted substance (including a prescribed restricted substance), included in a list of substances as determined, from time to time, by the Director-General for the purposes of this section.

[4] Clause 69 Destruction of pentazocine

Omit "and 124". Insert instead "and either clause 124 or 124A".

[5] Clause 105 Possession of drugs of addiction by chief nurses of private hospitals

Omit clause 105 (1) (a) and (b). Insert instead:

(a) no more than 5 ampoules, each of 1 millilitre or less, of morphine sulfate, at a concentration of 30 milligrams or less of morphine sulfate per millilitre,

(b) no more than 5 ampoules, each of 2 millilitres or less, of pethidine hydrochloride, at a concentration of 50 milligrams or less of pethidine hydrochloride per millilitre.

[6] Clause 123 Drugs of addiction not to be destroyed

Insert "or by or under the direct personal supervision of a person authorised, whether generally or in a particular case, by an authority under Part 7 held by the person" after "inspector" in clause 123 (2) (a).

[7] Clause 123 (2) (d)

Insert "or 124A" after "124".

[8] Clause 124A

Insert after clause 124:

124A Destruction of unwanted drugs of addiction in a private hospital, nursing home or day procedure centre

- (1) A retail pharmacist who is engaged in the supply of drugs of addiction to a private hospital, nursing home or day procedure centre is authorised to destroy any unwanted drug of addiction on the premises of that private hospital, nursing home or day procedure centre.
- (2) Subclause (1) applies only where the drug is destroyed in the presence of:
 - (a) where the private hospital, nursing home or day procedure centre is the holder of a licence under Division 2 of Part 7—the person who is named on the licence as being responsible for the storage of drugs of addiction, or
 - (b) in any other case—the chief nurse of the private hospital, nursing home or day procedure centre.
- (3) A pharmacist who destroys a drug of addiction in accordance with this clause must record the fact of the destruction of the drug by an entry in the drug register maintained by the private hospital, nursing home or day procedure centre. The entry must be dated and signed by the pharmacist and countersigned by a person who witnessed the destruction of the drug.

Maximum penalty: 20 penalty units.

[9] Appendix E Supply by wholesale

Insert after clause 17:

18 Asthma first aid

A person who holds a current emergency asthma management certificate issued by an organisation approved by the Director-General for the purposes of clause 17 (3) is authorised to be in possession of salbutamol or terbutaline in metered aerosols in connection with the carrying out of first aid.

[10] Dictionary

Omit the definition of ***child-resistant closure***. Insert instead:

child-resistant closure means:

- (a) in the case of a can fitted with a press-on lid—a lid of the design known as “double tight” or “triple tight”, or
- (b) in any other case—a closure that is resistant to opening by children and that complies with:
 - (i) section 2 (Requirements for Reclosable Packages) of AS 1928–2001, Child Resistant Packages, or
 - (ii) a design approved by any order made under section 10 of the *Therapeutic Goods Act 1989* of the Commonwealth, or
 - (iii) a design approved for the time being by the Director-General.

[11] Dictionary, definition of “Commonwealth Department of Health”

Omit “Human Services and Health”. Insert instead “Health and Aged Care”.

[12] Dictionary, definition of “the Act”

Insert “and Therapeutic Goods” after “Poisons”.

Schedule 2 Amendments

(Clause 2)

[1] Appendix B Special restricted substances

Insert “when included in Schedule 4 of the Poisons List” after “Amylobarbitone” and “Pentobarbitone”.

[2] Appendix B

Omit “Butobarbitone”, “Quinalbarbitone” and “Secbutobarbitone”.

[3] Appendix D Prescribed restricted substances

Omit the matter relating to the following substances:

Amylobarbitone

Barbituric acid derivatives not otherwise specified in this Appendix

Benzodiazepine derivatives not otherwise specified in this Appendix

Butobarbitone

Cyclobarbitone

Pentobarbitone

Quinalbarbitone

Secbutobarbitone

[4] Appendix D

Insert in alphabetical order:

Amylobarbitone when included in 50.0 grams
Schedule 4 of the Poisons List

Barbiturates except when separately 50.0 grams
specified in the Poisons List

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Schedule 2

Benzodiazepine derivatives except when separately specified in the Poisons List	0.5 gram
Pentobarbitone when included in Schedule 4 of the Poisons List	50.0 grams

[5] Dictionary, definition of "hallucinogen"

Omit paragraphs (b)–(e) of the definition. Insert instead:

(b) tetrahydrocannabinol and its alkyl homologues where Schedule 8 of the Poisons List applies.

BY AUTHORITY