



New South Wales

Poisons and Therapeutic Goods Amendment Regulation 1997

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*.

ANDREW REFSHAUGE, M.P.,
Deputy Premier and Minister for Health

Explanatory note

Amendments relating to treatment of cancer-related pain

Section 28 of the *Poisons and Therapeutic Goods Act 1966* prohibits, among other things, a medical practitioner from prescribing or supplying certain drugs of addiction to a person for continuous therapeutic use by the person for more than 2 months unless the prior written approval of the Director-General of the Department of Health has been obtained. Exceptions to this prohibition may be authorised by the regulations.

The objects of Schedule 1 [1], [4] and [5] to this Regulation are to authorise a medical practitioner to prescribe or supply such a drug for continuous therapeutic use by a person for up to 12 months if

- (a) the medical practitioner is of the opinion that the person requires the drug for the relief of pain associated with cancer, and
- (b) an appropriate medical practitioner has made the diagnosis of cancer and has estimated the person's life expectancy to be 12 months or less.

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The authorisation will not however apply to certain specified drugs of addiction.

Schedule 1 [2] and [3] make amendments by way of law revision.

Amendment relating to mines

Nitrous oxide when used for therapeutic purposes is a restricted substance included in Schedule 4 to the Poisons List. However, under the *Poisons and Therapeutic Goods Regulation 1994*, nitrous oxide can be supplied (without prescription) for use in connection with first aid in coal or shale mines.

The object of Schedule 1 [6] to this Regulation is to enable nitrous oxide to be supplied (without prescription) for such use in other mines.

This Regulation is made under the *Poisons and Therapeutic Goods Act 1966*, including section 4 (1) (definition of *supply by wholesale*), section 28 and section 45C (the general regulation making power).

Poisons and Therapeutic Goods Amendment Regulation 1997

1 Name of Regulation

This Regulation is the *Poisons and Therapeutic Goods Amendment Regulation 1997*.

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.

Schedule 1 Amendments

(Clause 2)

[1] **Clauses 86 and 94**

Omit “person referred” wherever occurring.
Insert instead “person as referred”.

[2] **Clauses 86 and 94**

Omit “section 29 of the Act” wherever occurring.
Insert instead “section 29 of the Act if”.

[3] **Clauses 86 (a) and (b) and 94 (a) and (b)**

Omit “if” wherever occurring.

[4] **Clause 86 (2)**

Insert at the end of clause 86:

- (2) A medical practitioner is authorised to issue a prescription for a drug of addiction for a person as referred to in section 28 (a) or (b) of the Act for continuous therapeutic use by that person for a period of up to 12 months without an authority under section 29 of the Act if
 - (a) the medical practitioner is of the opinion that the person requires the drug for the relief of pain associated with cancer, and
 - (b) a medical practitioner (whether or not the medical practitioner referred to in paragraph (a)) whose qualifications in the diagnosis and treatment of cancer are recognised by the National Specialist Qualification Advisory Committee of Australia or who is approved by the Director-General for the purposes of this paragraph:
 - (i) has made the diagnosis of cancer, and
 - (ii) has estimated the person’s life expectancy to be 12 months or less.

(3) Subclause (2) does not authorise a medical Practitioner to prescribe the following drugs of addiction in the circumstances referred to in that subclause:

dextromoramide(all forms)

fentanyl (all forms)

pethidine (parenteral forms only)

[5] Clause 94 (2)

Insert at the end of clause 94:

(2) A medical practitioner is authorised to supply a drug of addiction to a person as referred to in section 28 (a) or (b) of the Act for continuous therapeutic use by that person for a period of up to 12 months without an authority under section 29 of the Act if

(a) the medical practitioner is of the opinion that the person requires the drug for the relief of pain associated with cancer, and

(b) a medical practitioner (whether or not the medical practitioner referred to in paragraph (a)) whose qualifications in the diagnosis and treatment of cancer are recognised by the National Specialist Qualification Advisory Committee of Australia or who is approved by the Director-General for the purposes of this paragraph:

(i) has made the diagnosis of cancer, and

(ii) has estimated the person's life expectancy to be 12 months or less.

(3) Subclause (2) does not authorise a medical practitioner to supply the following drugs of addiction in the circumstances referred to in that subclause:

dextromoramide (all forms)

fentanyl (all forms)

pethidine (parenteral forms only)

[6] Appendix E Supply by wholesale

Omit item 16. Insert instead:

16 First aid in mines

A person is authorised to be in possession of nitrous oxide for use in connection with the carrying out of first aid at a mine if:

- (a) in the case of a coal or shale mine, the person is appointed in accordance with the regulations under the *Coal Mines Regulation Act 1982* to be in charge of a first aid room at the mine or as a first aid attendant at the mine, or
- (b) in the case of any other mine, the person is employed in accordance with clause 57 of the *Mines Inspection General Rule 1994* to provide first aid treatment at the mine.