



# Poisons and Therapeutic Goods Amendment (Miscellaneous) Regulation 2011

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*.

JILLIAN SKINNER, MP  
Minister for Health

## Explanatory note

The objects of this Regulation are as follows:

- (a) to allow the Director-General to authorise the director of nursing of a private health facility or nursing home to possess a quantity of certain drugs of addiction (such as morphine) exceeding the usual limit,
- (b) to authorise the destruction of unusable or unwanted drugs of addiction at public hospitals in certain circumstances,
- (c) to require the name of the supplier of regulated goods and the premises from which such goods are supplied to be shown on the invoices that are required to be issued and kept by the supplier,
- (d) to make minor amendments consequential on the commencement of the *Health Practitioner Regulation Amendment Act 2010*, the commencement of the *Therapeutic Goods Order No. 80* of the Commonwealth and the repeal of the *Private Hospitals and Day Procedure Centres Act 1988*.

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

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Clause 1 Poisons and Therapeutic Goods Amendment (Miscellaneous) Regulation  
2011

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**Poisons and Therapeutic Goods Amendment  
(Miscellaneous) Regulation 2011**

under the

Poisons and Therapeutic Goods Act 1966

**1 Name of Regulation**

This Regulation is the *Poisons and Therapeutic Goods Amendment  
(Miscellaneous) Regulation 2011*.

**2 Commencement**

This Regulation commences on the day on which it is published on the  
NSW legislation website.

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## Schedule 1      Amendment of Poisons and Therapeutic Goods Regulation 2008

**[1] Clause 3 Definitions**

Insert “podiatrist,” after “Act,” in paragraph (b) of the definition of *authorised practitioner* in clause 3 (1).

**[2] Clause 3 (1), definition of “private health facility”**

Omit “or premises licensed as a private hospital under the *Private Hospitals and Day Procedure Centres Act 1988*”.

**[3] Clause 3 (1)**

Omit the definition of *Therapeutic Goods Order No. 65*. Insert instead:

*Therapeutic Goods Order No. 80* means the order of that number called *Child-Resistant Packaging Requirements for Medicines*, as in force from time to time under section 10 of the *Therapeutic Goods Act 1989* of the Commonwealth.

**[4] Clauses 7 (1) (b), 26 (1) (b) and 69 (1) (b)**

Omit “*Therapeutic Goods Order No. 65*” wherever occurring.

Insert instead “*Therapeutic Goods Order No. 80*”.

**[5] Clause 7 Packaging and labelling generally**

Insert after clause 7 (3):

- (4) Despite subclause (1), an authorised practitioner or pharmacist who supplies a poison to a person who, in the opinion of the authorised practitioner or pharmacist, would suffer undue hardship through difficulty in opening a container that is packaged in accordance with *Therapeutic Goods Order No. 80*, is not required to package the poison in accordance with that Order.

**[6] Clause 18 Schedule 3 substances to be supplied personally by pharmacists**

Insert “podiatrist,” after “nurse practitioner,” in clause 18 (4).

**[7] Clause 26 Packaging and labelling generally**

Insert after clause 26 (3):

- (4) Despite subclause (1), an authorised practitioner or pharmacist who supplies a restricted substance to a person who, in the opinion of the authorised practitioner or pharmacist, would suffer

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undue hardship through difficulty in opening a container that is packaged in accordance with *Therapeutic Goods Order No. 80*, is not required to package the substance in accordance with that Order.

**[8] Clause 33 Prescriptions may be issued only for certain purposes**

Insert after clause 33 (6):

- (7) A podiatrist must not issue a prescription for a restricted substance otherwise than in the course of practising as a podiatrist, and must endorse any such prescription with the words “FOR PODIATRY TREATMENT ONLY”.

**[9] Clause 39 Prescriptions may be filled only if in proper form**

Omit “an authorised practitioner” from clause 39 (2) (c).

Insert instead “a veterinary practitioner”.

**[10] Clause 43 Supply by certain health practitioners**

Insert after clause 43 (6):

- (7) A podiatrist must not supply a restricted substance to any person otherwise than in the course of practising as a podiatrist.

**[11] Clause 47 Supply by pharmacists to nursing homes of stock for emergency use**

Insert “podiatrist,” after “nurse practitioner,” in clause 47 (3) (b).

**[12] Clause 59 Administration of prescribed restricted substances**

Insert at the end of clause 59 (1) (c) (iii):

, or

- (iv) a podiatrist in the course of practising as a podiatrist.

**[13] Clause 69 Packaging and labelling generally**

Insert after clause 69 (3):

- (4) Despite subclause (1), an authorised practitioner or pharmacist who supplies a drug of addiction to a person who, in the opinion of the authorised practitioner or pharmacist, would suffer undue hardship through difficulty in opening a container that is packaged in accordance with *Therapeutic Goods Order No. 80*, is not required to package the drug in accordance with that Order.

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**[14] Clause 103 Possession of drugs of addiction by directors of nursing of private health facilities and nursing homes**

Insert after clause 103 (1):

- (1A) The Director-General may, by order in writing, authorise the possession of a drug of addiction specified in subclause (1), by the director of nursing of a specified private health facility or nursing home, in a quantity that exceeds the limit specified in subclause (1).
- (1B) The Director-General may, by order published in the Gazette, authorise the possession of a drug of addiction specified in subclause (1), by a director of nursing of a specified class of private health facilities or nursing homes, in a quantity that exceeds the limit specified in subclause (1).

**[15] Clause 103 (3)**

Omit “subclause (1)”. Insert instead “this clause”.

**[16] Clause 126A**

Insert after clause 126:

**126A Destruction of unusable or unwanted drugs of addiction in public hospitals**

- (1) The authorised director of a public hospital may destroy any unusable or unwanted drug of addiction at the hospital but only in the presence of:
  - (a) a pharmacist, or
  - (b) a registered medical practitioner, or
  - (c) an authorised midwife, or
  - (d) an authorised nurse, or
  - (e) a registered dentist.
- (2) A person who destroys a drug of addiction in accordance with this clause:
  - (a) must record the fact of the destruction of the drug by an entry in the drug register maintained by the hospital, and
  - (b) must ensure that the entry includes the relevant date and the name, professional registration number and signature of that person and the person who witnessed the destruction of the drug.

Maximum penalty: 20 penalty units.

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(3) In this clause:

*authorised director*, in relation to a public hospital, means:

- (a) the director of pharmacy at that hospital, or
- (b) if no such position exists at that hospital, the person responsible for controlling drugs of addiction at that hospital, or
- (c) a pharmacist authorised in writing for the purposes of this clause by the director of pharmacy or the person responsible for controlling drugs of addiction at the hospital.

*authorised midwife* means a registered midwife who is in charge of a ward at a hospital or who is authorised by the director of nursing of a hospital to oversee the destruction of drugs at the hospital for the purposes of this clause.

*authorised nurse* means a registered nurse who is in charge of a ward at the hospital or who is authorised by the director of nursing of a hospital to oversee the destruction of drugs at the hospital for the purposes of this clause.

**[17] Clause 128 Destruction of unwanted drugs of addiction in a private health facility or nursing home**

Omit clause 128 (4).

**[18] Clause 131 Records of supply by wholesale**

Insert at the end of clause 131 (2) (c):

, and

- (d) the name of the supplier and the address of the premises from which the goods were supplied.