



New South Wales

Poisons and Therapeutic Goods Amendment (Residential Care Facilities) Regulation 2018

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*.

BRAD HAZZARD, MP
Minister for Health

Explanatory note

The objects of this Regulation are to amend the *Poisons and Therapeutic Goods Regulation 2008*:

- (a) to insert certain new definitions, including a definition of **responsible person**, being the director of nursing of a residential care facility or a residential care facility manager, and
- (b) to enable pharmacists to supply substances specified in Schedule Three of the Poisons List (such as paracetamol and pseudoephedrine) to responsible persons if the substance has been approved by the Secretary of the Ministry of Health for urgent use in the residential care facility, and
- (c) to allow responsible persons for residential care facilities to have possession of restricted substances for urgent use in the residential care facility, and
- (d) to expand the list of persons authorised to obtain possession of prescribed restricted substances to include certain persons in residential care facilities, and
- (e) to expand the list of persons authorised to possess morphine sulphate to include responsible persons for residential care facilities (and registered nurses at residential care facilities in certain circumstances) and to increase the amount of morphine sulphate that authorised persons may possess, and
- (f) to only allow private health facilities to keep supplies of pethidine hydrochloride, and
- (g) to require responsible persons for residential care facilities that are not nursing homes to keep registers of the residential care facility's stocks of morphine sulphate, and
- (h) to enable residential care facilities that are not nursing homes to have any unwanted stocks of morphine sulphate destroyed by a retail pharmacist on the premises of the residential care facility.

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

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Poisons and Therapeutic Goods Act 1966

1 Name of Regulation

This Regulation is the *Poisons and Therapeutic Goods Amendment (Residential Care Facilities) Regulation 2018*.

2 Commencement

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

Schedule 1 Amendment of Poisons and Therapeutic Goods Regulation 2008

[1] Clause 3 Definitions

Insert in alphabetical order in clause 3 (1):

director of nursing means, in relation to a residential care facility, a registered nurse who is responsible for the care of the residents of the residential care facility.

residential care facility manager means the person (not being the director of nursing) employed at the residential care facility who is responsible for the management of that facility.

responsible person, in relation to a residential care facility, means:

- (a) the director of nursing of the residential care facility, or
- (b) in the case of a residential care facility for which there is no director of nursing—the residential care facility manager.

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

Omit clause 18 (4). Insert instead:

- (4) This clause does not apply to the supply to the responsible person for a residential care facility of any substance that is:
 - (a) in the manufacturer's original pack, and
 - (b) approved by the Secretary for urgent use in a residential care facility, and
 - (c) supplied in accordance with:
 - (i) any conditions of the approval, and
 - (ii) a written order signed by the responsible person.

[3] Clause 47

Omit the clause. Insert instead:

47 Supply by pharmacists to residential care facilities of stock for urgent use

- (1) The responsible person for a residential care facility is authorised to have possession of a restricted substance (including a prescribed restricted substance) that is approved by the Secretary for urgent use in a residential care facility.
- (2) A retail pharmacist is authorised to supply a restricted substance (including a prescribed restricted substance) in the manufacturer's original pack to the responsible person for a residential care facility, but only if the substance is supplied:
 - (a) at the premises of, and in the course of carrying on the business of, the pharmacy, and
 - (b) in accordance with a written order signed by the responsible person.
- (3) The responsible person for a residential care facility must not:
 - (a) sign an order under this clause for a restricted substance unless the substance is approved by the Secretary for urgent use in that residential care facility, or

- (b) allow any restricted substance in his or her possession to be used otherwise than for administration to a resident of the residential care facility by a registered nurse in accordance with the direction of an authorised practitioner (other than a veterinary practitioner) or by an authorised practitioner (other than a veterinary practitioner).

Maximum penalty: 15 penalty units.

- (4) An approval under this clause:
 - (a) is to be by order in writing, and
 - (b) may apply generally or may be limited to a particular residential care facility or class of residential care facilities, and
 - (c) may apply generally or may be limited to a particular substance or class of substance, and
 - (d) may be given unconditionally or subject to conditions.

[4] Clause 62 Authorised persons

Insert after clause 62 (b):

- (b1) the responsible person for a residential care facility,
- (b2) a registered nurse at a residential care facility that is not a nursing home, but for the purpose only of administering doses of such substances to individual residents of the residential care facility,

[5] Clause 103

Omit the clause. Insert instead:

103 Possession of drugs of addiction at private health facilities and residential care facilities

- (1) The following persons are authorised to have possession of ampoules of morphine sulphate in a quantity not exceeding 30 ampoules, each of 1 millilitre or less, at a concentration of 30 milligrams or less of morphine sulfate per millilitre:
 - (a) the director of nursing of a private health facility,
 - (b) the responsible person for a residential care facility,
 - (c) a registered nurse at a residential care facility, but for the purpose only of administering doses of such drugs to individual residents of the residential care facility.
- (2) The director of nursing of a private health facility is authorised to have possession of 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.
- (3) **Order of Secretary—specified facilities**

The Secretary may, by order in writing, authorise the possession of a drug of addiction specified in subclause (1) or (2), in a quantity that exceeds the limit specified in subclause (1) or (2), by the following persons:

 - (a) in the case of morphine sulphate:
 - (i) the director of nursing of a specified private health facility, or
 - (ii) the responsible person for a specified residential care facility,
 - (b) in the case of pethidine hydrochloride—the director of nursing of a specified private health facility.

(4) **Order of Secretary—specified classes of facilities**

The Secretary may, by order published in the Gazette, authorise the possession of a drug of addiction specified in subclause (1) or (2), in a quantity that exceeds the limit specified in subclause (1) or (2), by the following persons:

- (a) in the case of morphine sulphate:
 - (i) the director of nursing of a specified class of private health facilities, or
 - (ii) the responsible person for a specified class of residential care facilities,
- (b) in the case of pethidine hydrochloride—the director of nursing of a specified class of private health facilities.

(5) A retail pharmacist is authorised to supply a drug of addiction to the director of nursing of a private health facility or residential care facility, or the residential care facility manager of a residential care facility, but only if the drug is supplied:

- (a) at the premises of, and in the course of carrying on the business of, the pharmacy, and
- (b) in accordance with a written order signed by the director of nursing or the residential care facility manager.

(6) The director of nursing or the residential care facility manager must not sign an order for any quantity of a drug of addiction if the quantity of that drug that will be in the possession of the director of nursing or the residential care facility manager as a result of the order being filled will be in excess of the maximum quantity allowed by this clause.

Maximum penalty: 20 penalty units.

(7) The director of nursing of a private health facility must not allow any drug of addiction in his or her possession under subclause (1) or (2) to be used otherwise than for administration to a patient in accordance with the directions of an authorised practitioner (other than a veterinary practitioner) or by an authorised practitioner (other than a veterinary practitioner).

Maximum penalty: 20 penalty units.

(8) The responsible person for a residential care facility must not allow any drug of addiction in his or her possession under subclause (1) to be used otherwise than for administration to a resident of the facility by a registered nurse in accordance with the directions of an authorised practitioner (other than a veterinary practitioner) or by an authorised practitioner (other than a veterinary practitioner).

Maximum penalty: 20 penalty units.

(9) This clause does not limit the power of a director of nursing or a residential care facility manager to have possession of drugs of addiction, or to supply drugs of addiction to patients or residents, in accordance with the Act or this Regulation.

(10) A person does not commit an offence under this clause in relation to any pethidine hydrochloride that was lawfully in the person's possession before the commencement of this clause.

[6] Clause 110

Omit the clause. Insert instead:

110 Application of Subdivision

- (1) Except as provided by subclause (2), this Subdivision applies to drugs of addiction that are kept at any place (including the pharmacy of a hospital) for the purposes of manufacture, supply, research or testing.
- (2) This Subdivision does not apply to drugs of addiction that are:
 - (a) kept in a hospital ward, or
 - (b) kept in a residential care facility, or
 - (c) in the possession of a carrier for the purpose of those drugs of addiction being delivered to the persons to whom they are addressed.

[7] Clause 114, heading

Omit “nursing home”. Insert instead “residential care facility”.

[8] Part 4, Division 5, Subdivision 2, heading

Insert “and residential care facilities” after “wards”.

[9] Clause 115

Omit the clause. Insert instead:

115 Application of Subdivision

This Subdivision applies to the following:

- (a) drugs of addiction that are kept in a hospital ward other than drugs of addiction that are kept in a pharmacy at the hospital,
- (b) drugs of addiction that are kept in a residential care facility that is a nursing home,
- (c) drugs of addiction that are kept in a residential care facility that is not a nursing home and are possessed in accordance with clause 103.

[10] Clause 116

Omit the clause. Insert instead:

116 Registers to be kept

- (1) The nurse or midwife in charge of a hospital ward must keep a register of drugs of addiction (a *ward register*) in that ward.
- (2) The responsible person for a residential care facility must keep a register of drugs of addiction (a *residential care facility register*) in that residential care facility.
- (3) A ward register or a residential care facility register is to be in the form of a book that:
 - (a) contains consecutively numbered pages, and
 - (b) is so bound that the pages cannot be removed or replaced without trace, and

- (c) contains provision on each page for the inclusion of the particulars required to be entered in the book.
- (4) Separate pages of the ward register or residential care facility register must be used for each drug of addiction and for each form and strength of the drug.
- (5) The Secretary may from time to time approve the keeping of a ward register or a residential care facility register in any other form.
Maximum penalty: 20 penalty units.

[11] Clause 117 Entries in registers

Insert “or residential care facility” after “any ward” in clause 117 (1).

[12] Clause 117 (1)

Insert “or residential care facility register” after “ward register”.

[13] Clause 117 (1) (d)

Insert “or residential care facility” after “ward”.

[14] Clauses 118 (1) and 119

Omit “(including a ward register)” wherever occurring.

[15] Clause 128

Omit the clause. Insert instead:

128 Destruction of unwanted drugs of addiction in private health facilities or residential care facilities

- (1) A retail pharmacist who is engaged in the supply of restricted substances or drugs of addiction to any of the following:
 - (a) a private health facility,
 - (b) a residential care facility,
 - (c) a patient in a private health facility,
 - (d) a patient in a residential care facility that is a nursing home,is, subject to subclauses (2) and (3), authorised to destroy any unwanted drug of addiction on the premises of that private health facility or residential care facility.
- (2) A retail pharmacist is only authorised to destroy an unwanted drug of addiction on the premises of a residential care facility that is not a nursing home if that drug of addiction was supplied in accordance with clause 103.
- (3) Subclause (1) applies only where the drug is destroyed in the presence of:
 - (a) if the private health facility or residential care facility is the holder of a licence under Division 2 of Part 8—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 director of nursing of the private health facility or residential care facility or the residential care facility manager.
- (4) A pharmacist 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 private health facility or residential care facility, and

- (b) must ensure that the entry in the drug register includes the date and the name, professional registration number and signature of the pharmacist and the name and signature of person who witnessed the destruction of the drug.

Maximum penalty: 20 penalty units.