New South Wales

Poisons and Therapeutic Goods Amendment Regulation 2020

under the

Poisons and Therapeutic Goods Act 1966

[*The following enacting formula will be included if the Regulation is made:*]
Her Excellency the Governor, with the advice of the Executive Council, has made the following Regulation under the *Poisons and Therapeutic Goods Act 1966*.

Minister for Health and Medical Research

Explanatory note

The object of this Regulation is to prescribe requirements for the storage and administration of the following substances used for cosmetic purposes—

(a) botulinum toxins for human use,

(b) hyaluronic acid and its polymers in preparations for injection or implantation,

(c) deoxycholic acid,

(d) polyacrylamide,

(e) polylactic acid.

This Regulation is made under the *Poisons and Therapeutic Goods Act 1966*, including sections 18D 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 Regulation 2020*.

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 before paragraph (a) of the definition of ***authorised practitioner*** in clause 3(1)—

(a1) in Part 3A, a medical practitioner, dentist, nurse authorised under section 17A of the Act, optometrist authorised under section 17B of the Act or podiatrist authorised under section 17C of the Act, and

[2] Clause 3(1), paragraph (a) of definition of "authorised practitioner"

Omit "(Drugs of addiction)".

[3] Clause 3(1), paragraph (b) of definition of "authorised practitioner"

Omit "in a Part other than Part 4". Insert instead "in any other Part".

[4] Clause 3(1), definitions of "current Poisons Standard" and "Therapeutic Goods Order No. 80"

Omit "*Therapeutic Goods Act 1989* of the Commonwealth" wherever occurring.

Insert instead "Commonwealth Act".

[5] Clause 24 Supply of certain Schedule 2 or 3 substances to be recorded

Omit the definition of ***Secretary*** from clause 24(5).

[6] Part 3A

Insert after Part 3—

Part 3A Restricted substances used for cosmetic and other purposes

68A Substances to which Division 1A of Part 3 of Act applies

For the purposes of section 18C(c) of the Act, the following substances specified in Schedule 4 of the Poisons List are prescribed—

(a) deoxycholic acid,

(b) polyacrylamide,

(c) polylactic acid.

68B Definitions

In this Part—

direction means a direction given by an authorised practitioner to a nurse to administer a relevant substance for the purposes of clause 68D.

patient means a person to whom a relevant substance is, or is proposed to be, administered.

relevant substance means the following substances to which Division 1A of Part 3 of the Act applies—

(a) botulinum toxins for human use,

(b) hyaluronic acid and its polymers in preparations for injection or implantation,

(c) deoxycholic acid,

(d) polyacrylamide,

(e) polylactic acid

responsible provider, in relation to a relevant substance, means the person who provides the service of administration of the relevant substance for fee or reward or in the course of a business (whether or not for profit), but does not include an individual who is involved in providing that service under contract or in the course of the individual's employment.

Note. Section 18D of the Act provides that a person who contravenes a requirement identified in the regulations as a category 1 or category 2 requirement is guilty of an offence. The maximum penalty for a category 1 requirement is 1,000 penalty units in the case of a body corporate or 200 penalty units or imprisonment for 6 months (or both) in the case of an individual. The maximum penalty for a category 2 requirement is 250 penalty units in the case of a body corporate or 50 penalty units in any other case.

68C Application of Part

This Part does not apply to the following—

(a) the administration of a relevant substance in any of the following circumstances—

(i) to a patient by an authorised practitioner in the lawful practice of the practitioner's profession,

(ii) to a patient in a hospital by a person employed at the hospital on the direction of an authorised practitioner,

(iii) to an animal by a veterinary practitioner in the lawful practice of the practitioner's profession or by another person on the direction of a veterinary practitioner,

(b) the storage of a relevant substance for the purposes of administration as referred to in paragraph (a),

(c) the storage of a relevant substance at a pharmacy.

68D Administration by nurse on direction of authorised practitioner only

(1) A person must not administer a relevant substance to a patient unless the person is a nurse acting on the direction of an authorised practitioner.

(2) A nurse must not administer a relevant substance to a patient unless it is administered in accordance with a direction that—

(a) is given in accordance with clause 68E, and

(b) has not ceased to have effect.

(3) Subclauses (1) and (2) are category 1 requirements.

68E Directions by authorised practitioners

(1) An authorised practitioner may give a direction to a nurse only if the authorised practitioner has personally reviewed the patient in person or by audiovisual link.

(2) An authorised practitioner must include the following information in a direction—

(a) the name of the patient,

(b) the address of the patient,

(c) the name and telephone number of the authorised practitioner and the address of the authorised practitioner's principal place of practice

(within the meaning of the *Health Practitioner Regulation National Law (NSW)*),

(d) the address of the premises at which the relevant substance is to be administered,

(e) the name of the responsible provider,

(f) the date on which the authorised practitioner personally reviewed the patient under subclause (1),

(g) the period for which the direction has effect,

(h) the number of times, and the intervals at which, the relevant substance is to be administered,

(i) in relation to each administration of the relevant substance—

(i) the name and form of the relevant substance, and

(ii) the part of the patient's face or body to which the relevant substance is to be administered, and

(iii) the route of administration (if not readily apparent), and

(iv) the quantity of the relevant substance to be administered.

(3) An authorised practitioner must give a direction to a nurse in writing, by facsimile or email or by other electronic means, and must sign the direction (including by electronic signature).

(4) However, if the authorised practitioner is present when the relevant substance is administered by the nurse to whom the direction is given, the direction may be given orally.

(5) If a direction is given orally, it is not required to contain the information specified in subclause (2)(b)–(h).

(6) A direction has effect—

(a) in the case of a direction given in writing—for the period specified in the direction, not exceeding 6 months from the date on which the authorised practitioner personally reviewed the patient under subclause (1), and

(b) in the case of a direction given orally—for the particular administration of the relevant substance to which the direction applies only.

(7) An authorised practitioner who gives a direction in writing must keep a copy of the direction and provide a copy of the direction to the responsible provider.

(8) An authorised practitioner who gives a direction orally must make and keep a record of the direction (which must also include the address of the patient) and provide a copy of the record to the responsible provider.

(9) Subclause (1) is a category 1 requirement and subclauses (2)–(5), (7) and (8) are category 2 requirements.

68F Nurses to keep records

(1) A nurse who administers a relevant substance acting on a direction of an authorised practitioner must record the following information in relation to each administration—

(a) the name of the nurse,

(b) the date on which the relevant substance was administered,

(c) the information specified in clause 68E(2)(a)–(e) and (i) in respect of the administration of the relevant substance.

(2) A nurse must give a copy of the information recorded under this clause to the responsible provider.

(3) Subclauses (1) and (2) are category 2 requirements.

68G Storage

(1) The person in occupation or control of premises at which a relevant substance is stored must ensure that the relevant substance is kept—

(a) in a room or enclosure to which the public does not have access, and

(b) apart from food intended for consumption by humans or animals, and

(c) in such a way that, if its container breaks or leaks, the substance cannot mix with or contaminate any food intended for consumption by humans or animals, and

(d) in accordance with any conditions for storage specified on the label of the substance.

(2) Subclause (1) is a category 2 requirement.

68H Duties of responsible providers

(1) The responsible provider of a relevant substance must—

(a) ensure the administration of any relevant substance as part of the service or business provided by the provider complies with this Part, and

(b) ensure there are appropriate risk management policies and procedures to protect the health and safety of patients, and

(c) ensure that any relevant substance administered as part of the service or business provided by the provider is administered in the form of therapeutic goods that may, under the Commonwealth Act, be lawfully manufactured in, or imported into, Australia for use in Australia, and

(d) keep a copy of any direction given by an authorised practitioner for the administration of a relevant substance by a nurse together with any record made by a nurse under clause 68F that relates to the direction.

(2) Subclause (1)(a)–(c) are category 1 requirements and subclause (1)(d) is a category 2 requirement.

[7] Whole Regulation

Omit "Director-General" and "Director-General's" wherever occurring.

Insert instead "Secretary" and "Secretary's", respectively.