New South Wales

Poisons and Therapeutic Goods Amendment (Cosmetic Use) Regulation 2021

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*.

BRAD HAZZARD, MP
Minister for Health and Medical Research

Explanatory note

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

The Regulation makes other law revision amendments.

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under the

Poisons and Therapeutic Goods Act 1966

1 Name of Regulation

This Regulation is the *Poisons and Therapeutic Goods Amendment (Cosmetic Use) Regulation 2021*.

2 Commencement

This Regulation commences on 1 September 2021 and is required to be published on the NSW legislation website.

Schedule 1 Amendment of Poisons and Therapeutic Goods Regulation 2008

[1] Whole Regulation

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

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

[2] Clause 3 Definitions

Omit "and Ageing" from the definition of ***Commonwealth Department of Health*** in clause 3(1).

[3] Clause 3(1), definition of "current Poisons Standard"

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

Insert instead "Commonwealth Act".

[4] Clause 3(1), definition of "Therapeutic Goods Order No. 80"

Omit the definition. Insert instead—

> ***Therapeutic Goods Order No. 95*** means the *Therapeutic Goods Order No. 95 Child-resistant packaging requirements for medicines 2017*, as in force from time to time under the Commonwealth Act.

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

Omit "*Therapeutic Goods Order No. 80*" wherever occurring.

Insert instead "*Therapeutic Goods Order No. 95*".

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

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

[7] Part 3A

Insert after Part 3—

Part 3A Restricted substances used for cosmetic and other purposes—the Act, Part 3, Div 1A

Division 1 Preliminary

68A Definitions

In this Part—

direction means a direction to a nurse to administer a relevant substance given by a medical practitioner or nurse practitioner in accordance with Division 2.

relevant substance—see clause 68B(1).

responsible provider, in relation to a relevant substance, means a person carrying on a business of administration of the relevant substance to which this Part applies, for fee or reward and whether or not for profit, but does not include an individual who is an employee or contractor of the business.

68B Application of Part

(1) This Part applies to the administration of the following substances (***relevant substances***) to a patient—

(a) a substance specified in the Act, section 18C(a) or (b),

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

(i) calcium hydroxylapatite in preparations for injection or implantation for tissue augmentation or cosmetic use,

(ii) collagen in preparations for injection or implantation for tissue augmentation or cosmetic use,

(iii) deoxycholic acid,

(iv) polyacrylamide in preparations for injection or implantation for tissue augmentation or cosmetic use,

(v) polycaprolactone in preparations for injection or implantation for tissue augmentation or cosmetic use,

(vi) polylactic acid in preparations for injection or implantation for tissue augmentation or cosmetic use.

(2) This Part does not apply to the administration of a relevant substance to a patient by—

(a) an authorised practitioner administering the relevant substance in the lawful practice of the practitioner's profession, or

(b) a person employed at the hospital administering the relevant substance to a patient in a hospital on the direction of an authorised practitioner, other than a veterinary practitioner.

(3) This Part does not apply to the administration of a relevant substance to an animal by—

(a) a veterinary practitioner in the lawful practice of the practitioner's profession, or

(b) another person on the direction of a veterinary practitioner.

Division 2 Administration

68C Nurse may administer relevant substance on direction of medical practitioner or nurse practitioner

(1) A person must not administer a relevant substance to a patient unless the person—

(a) is a nurse, and

(b) is acting in accordance with a direction of a medical practitioner or nurse practitioner.

(2) A nurse must not administer a relevant substance unless satisfied there is appropriate equipment available for use in a patient medical emergency.

(3) A nurse who administers a relevant substance in accordance with a direction must record the following information for each administration—

(a) the nurse's name,

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

(c) the batch number of the relevant substance,

(d) the information specified in clause 68E(1)(a)–(e) and (i).

(4) A nurse must give a copy of the record to the responsible provider.

68D Direction by medical practitioner or nurse practitioner

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

(2) A direction must be written, signed by the medical practitioner or nurse practitioner and given to the nurse in person or by facsimile, email or other electronic means.

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

(4) A direction has effect—

(a) for a written direction—for the period specified in the direction, not exceeding 6 months from the date on which the medical practitioner or nurse practitioner personally reviewed the patient under subclause (1), and

(b) for an oral direction—for the particular administration of the relevant substance to which the direction applies.

68E Content of direction

(1) A direction must include the following information—

(a) the patient's name,

(b) the patient's address,

(c) the name and telephone number of the medical practitioner or nurse practitioner giving the direction,

(d) the address of the principal place of practice, within the meaning of the *Health Practitioner Regulation National Law (NSW)*, of the medical practitioner or nurse practitioner giving the direction,

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

(f) the responsible provider's name,

(g) the date on which the medical practitioner or nurse practitioner personally reviewed the patient under clause 68D(1),

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

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

(j) for 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.

(2) If a direction is given orally, it is not required to include the information specified in subclause (1)(b)–(i).

68F Records of directions

(1) A medical practitioner or nurse practitioner who gives a written direction must—

(a) keep a copy of the direction, and

(b) provide a copy of the direction to the responsible provider.

(2) A medical practitioner or nurse practitioner who gives an oral direction must—

(a) make and keep a record of the direction, which must also include the address of the patient, and

(b) provide a copy of the record to the responsible provider.

Division 3 Miscellaneous

68G Storage

The person who occupies or has control of premises at which the administration of a relevant substance to which this Part applies occurs 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 a way that, if its container breaks or leaks, the substance cannot mix with or contaminate food intended for consumption by humans or animals, and

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

68H Duties of responsible providers

(1) A responsible provider must ensure the administration of a relevant substance to which this Part applies that occurs as part of the responsible provider's business is carried out in accordance with this Part.

(2) A responsible provider must ensure—

(a) there are appropriate risk management policies and procedures in place to protect the health and safety of patients, and

(b) there is appropriate equipment available for use in a patient medical emergency, and

(c) each nurse administering a relevant substance is adequately trained for a patient medical emergency.

(3) A responsible provider must ensure that a relevant substance is administered in the form of a therapeutic good that may, under the Commonwealth Act, be lawfully manufactured for use in Australia.

(4) A responsible provider must keep a copy of—

(a) each direction given by a medical practitioner or nurse practitioner for the administration of a relevant substance by a nurse under this Part, and

(b) each record made by a nurse under clause 68C that relates to the direction.

68I Category 1 and category 2 requirements—the Act, s 18D(2)

Note. The Act, section 18D(2) provides that a person who contravenes 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 for a corporation and 200 penalty units or imprisonment for 6 months, or both, for an individual. The maximum penalty for a category 2 requirement is 250 penalty units for a corporation and 50 penalty units for an individual.

(1) The following provisions are category 1 requirements—

(a) clause 68C(1) and (2),

(b) clause 68D(1),

(c) clause 68H(1)–(3).

(2) The following provisions are category 2 requirements—

(a) clause 68C(3) and (4),

(b) clause 68D(2),

(c) clause 68E(1),

(d) clause 68F,

(e) clause 68G,

(f) clause 68H(4).