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South Australia

Controlled Substances (Poisons) Variation Regulations 2013

under the *Controlled Substances Act 1984*

Contents

Part 1—Preliminary

1—Short title

These regulations may be cited as the *Controlled Substances (Poisons) Variation Regulations 2013*.

2—Commencement

These regulations come into operation on the day on which they are made.

3—Variation provisions

In these regulations, a provision under a heading referring to the variation of specified regulations varies the regulations so specified.

Part 2—Variation of *Controlled Substances (Poisons) Regulations 2011*

4—Variation of regulation 3—Interpretation

(1) Regulation 3(1), definition of ***CE***—delete "***CE***" and substitute:

Chief Executive

(2) Regulation 3(1)—after the definition of ***council*** insert:

council subsidiary means a subsidiary of a council established under the *Local Government Act 1999*;

(3) Regulation 3(1)—after the definition of ***liquified petroleum gas*** insert:

medication chart prescription has the same meaning as in the *National Health (Pharmaceutical Benefits) Regulations 1960* of the Commonwealth;

(4) Regulation 3(1)—after the definition of ***motor spirit*** insert:

National Health Act means the *National Health Act 1953* of the Commonwealth;

National Health (Continued Dispensing) Determination means the determination of that name, as in force from time to time, made under section 89A(3) of the National Health Act;

National Health (Residential Medication Chart) Determination means the determination of that name, as in force from time to time, made under section 93A(2) of the National Health Act;

(5) Regulation 3(1)—after the definition of ***petroleum product*** insert:

pharmaceutical benefit has the same meaning as in Part VII of the National Health Act;

(6) Regulation 3(1)—after the definition of ***poison*** insert:

prescribed (continued dispensing) pharmaceutical benefit means a pharmaceutical benefit listed in the National Health (Continued Dispensing) Determination as a pharmaceutical benefit that may be supplied under section 89A of the National Health Act by approved pharmacists without a prescription;

prescribed (residential medication chart) pharmaceutical benefit means a pharmaceutical benefit that is an applicable pharmaceutical benefit for the purposes of the National Health (Residential Medication Chart) Determination;

(7) Regulation 3(1)—after the definition of ***Uniform Poisons Standard*** insert:

Vaccine Administration Code means the document of that name published by the Department as in force from time to time.

(8) Regulation 3—after subregulation (2) insert:

(3) In these regulations, ***incorporated hospital*** and ***SAAS*** have the same respective meanings as in the *Health Care Act 2008*.

5—Variation of regulation 12—Sale or supply to end user (section 15 of Act)

Regulation 12—after its present contents (now to be designated as subregulation (1)) insert:

(2) A council, council subsidiary or health service facility is exempt from section 15 of the Act in respect of the supply by the council, council subsidiary or health service facility of adrenaline for administration to a person as part of an immunisation program delivered by the council, council subsidiary or health service facility.

6—Variation of regulation 14—Special provisions relating to sale or supply of pseudoephedrine

Regulation 14(4)—delete "CE" and substitute:

Chief Executive

7—Variation of regulation 18—Regulation of prescription drugs—administration of certain S4 drugs (section 18(1d)(a)(iii) of Act)

(1) Regulation 18(1)—before "Benzocaine" insert:

Articaine

(2) Regulation 18—after subregulation (2) insert:

(3) For the purposes of section 18(1d)(a)(iii) of the Act, a registered health practitioner of a class determined by the Minister may administer a prescription drug (not being a drug of dependence) to a person if—

(a) the registered health practitioner has, not more than 3 years before the administration of the drug, successfully completed a training program approved by the Minister from time to time for the purposes of this subregulation; and

(b) the drug is listed in the Vaccine Administration Code or is a drug approved by the Minister from time to time for the purposes of this subregulation; and

(c) the drug is administered as part of—

(i) an immunisation program delivered by—

(A) an incorporated hospital; or

(B) SAAS; or

(C) a council or council subsidiary; or

(ii) an immunisation program delivered by an organisation approved by the Minister for the purposes of this subregulation; and

(d) the drug is administered in accordance with—

(i) the Vaccine Administration Code; and

(ii) —

(A) in the case of a drug administered as part of the *National Immunisation Program—the National Immunisation Program Schedule* and the *Australian Immunisation Handbook*; or

(B) in any other case—requirements specified by the Minister.

(4) In this regulation—

Australian Immunisation Handbook means *The Australian Immunisation Handbook* published by the Commonwealth Department of Health and Ageing, as in force from time to time;

National Immunisation Program Schedule means the *National Immunisation Program Schedule* published by the Commonwealth Department of Health and Ageing, as in force from time to time.

8—Revocation of regulation 20

Regulation 20—delete the regulation

9—Variation of regulation 21—Exemptions from section 18 of Act

(1) Regulation 21(1)—delete subregulation (1) and substitute:

(1) A council, council subsidiary or health service facility is exempt from section 18(1c)(d) of the Act in respect of the supply of an S4 drug under an immunisation program run by the council, council subsidiary or health service facility.

(2) Regulation 21(2)—delete "supplies an S4 drug without dispensing a prescription is exempt from section 18(1c)(a) of the Act in relation to that supply" and substitute:

sells or supplies an S4 drug without dispensing a prescription is exempt from section 18(1b)(a) and (1c)(a) of the Act in relation to that sale or supply

(3) Regulation 21(2)(a)—delete paragraph (a) and substitute:

(a) the drug is sold or supplied to a council, council subsidiary or health service facility for use in an immunisation program delivered by the council, council subsidiary or health service facility and the pharmacist has received a written order for the drug from the council, council subsidiary or health service facility; or

(4) Regulation 21(2)(b)—before "supply" insert:

sell,

(5) Regulation 21(2)(c)—before "supplied" insert:

sold or

(6) Regulation 21(2)(d)—delete paragraph (d) and substitute:

(d) the drug is sold or supplied to a registered health practitioner or veterinary surgeon authorised to sell, supply or administer S4 drugs and the pharmacist has received a written order for the drug from that practitioner or veterinary surgeon; or

(7) Regulation 21(2)(f)(i)(A)—before "supplied" insert:

sold or

(8) Regulation 21(2)(f)(i)(B)—before "supply" insert:

sale or

(9) Regulation 21(2)(f)(ii)—before "supplies" insert:

sells or

(10) Regulation 21(2)(f)(iii)—before "supplied" first occurring insert:

sold or

(11) Regulation 21(2)(f)(iii)(A)—before "supplier" insert:

seller or

(12) Regulation 21(2)(f)(iii)(D)—before "supplied" insert:

sold or

(13) Regulation 21(2)—after paragraph (f) insert:

or

(g) the drug is a prescribed (continued dispensing) pharmaceutical benefit and the sale or supply is made in accordance with the conditions specified in the National Health (Continued Dispensing) Determination.

10—Variation of regulation 26—Packaging and labelling of poisons (section 24 of Act)

(1) Regulation 26(6)—after "practitioner" wherever occurring insert:

or veterinary surgeon

(2) Regulation 26(6)—after "prescribe" insert:

, sell

(3) Regulation 26(6)—before "supply" second occurring insert:

sale or

(4) Regulation 26(7)—delete "the" second occurring and substitute:

specified

11—Variation of regulation 27—Storage of poisons (section 25 of Act)

Regulation 27(b)(ii)(B) and (C)—delete subsubparagraphs (B) and (C) and substitute:

(B) is enclosed in—

- a child-resistant package; or
- a blister pack; or
- a container approved by the Minister; or

12—Variation of regulation 33—How prescription to be given

Regulation 33—after subregulation (6) insert:

(7) This regulation does not apply to a prescriber who gives a medication chart prescription for a prescribed (residential medication chart) pharmaceutical benefit in accordance with the conditions specified in the National Health (Residential Medication Chart) Determination.

13—Variation of regulation 34—Written prescriptions

Regulation 34—after subregulation (3) insert:

(4) This regulation does not apply to a person who writes a medication chart prescription for a prescribed (residential medication chart) pharmaceutical benefit.

14—Variation of regulation 35—Dispensing prescriptions

(1) Regulation 35—delete "CE" wherever occurring and substitute in each case:

Chief Executive

(2) Regulation 35—after subregulation (11) insert:

(12) This regulation (other than subregulations (1)(b) and (7)(a) and (b)) does not apply to a pharmacist or medical practitioner who dispenses a drug on a medication chart prescription for a prescribed (residential medication chart) pharmaceutical benefit that is sold or supplied in accordance with the conditions specified in the National Health (Residential Medication Chart) Determination.

15—Variation of regulation 37—Special restrictions on prescription or supply of drugs of dependence by registered health practitioners and veterinary surgeons

Regulation 37(2), (3) and (4)—delete subregulations (2), (3) and (4) and substitute:

(2) A registered health practitioner must not prescribe or supply a drug of dependence for use by himself or herself unless the prescription or supply is in circumstances of a verifiable emergency.

Maximum penalty: $5 000.

(3) Subregulation (1) does not apply to the supply of a drug of dependence by a pharmacist if the pharmacist is dispensing a prescription for the drug.

(4) A veterinary surgeon must not prescribe, sell or supply a drug of dependence for an animal without having first examined the animal unless the prescription, sale or supply is in circumstances of a verifiable emergency.

Maximum penalty: $5 000.

16—Substitution of regulation 38

Regulation 38—delete the regulation and substitute:

38—Restriction on prescribing or supplying S2, S3 or S4 poisons containing S8 poisons

A prescriber must not prescribe or supply for use by a person who the prescriber knows or has reasonable cause to believe is dependent on drugs—

(a) an S2 poison or S3 poison that contains a poison listed in Schedule 8 of the Uniform Poisons Standard; or

(b) an S4 poison that contains a poison listed in Schedule 8 of the Uniform Poisons Standard,

for the purpose of maintaining or treating the person's dependence unless the prescriber prescribes or supplies the drug in accordance with an authority granted by the Minister.

Maximum penalty: $5 000.

17—Substitution of regulation 39

Regulation 39—delete the regulation and substitute:

39—Records to be kept by manufacturers of drugs of dependence

A person who manufactures a drug of dependence must—

(a) record the following details immediately after the drug is manufactured:

(i) the date of manufacture;

(ii) the trade name or the approved name of the drug or, if it does not have either a trade or approved name, its ingredients;

(iii) the amount and, if applicable, the strength of the drug manufactured;

(iv) the total amount of the drug now on the premises on which the drug was manufactured; and

(b) sign and date the record immediately after the record is made.

Maximum penalty: $5 000.

18—Variation of regulation 40—Records to be kept by sellers and suppliers of drugs of dependence

(1) Regulation 40(1) and (2)—delete "CE" wherever occurring and substitute in each case:

Chief Executive

(2) Regulation 40(1)—delete "A supplier who supplies" and substitute:

A supplier who sells or supplies

(3) Regulation 40(1)(a)—after ", immediately after" insert:

selling or

(4) Regulation 40(1)(a)(ii), (iii), (vi) and (vii)—before "supplied" wherever occurring insert:

sold or

(5) Regulation 40(1)(a)(vi)—before "supply" insert:

sale or

(6) Regulation 40(1)(b)—after ", if the drug is" insert:

sold or

(7) Regulation 40(1)(b)(i)—before "supplying" insert:

selling or

(8) Regulation 40(1)(b)(i)—before "supply" insert:

sell or

(9) Regulation 40(1)(b)(ii)—before "supplied" insert:

sold or

19—Variation of regulation 42—Supply or administration of drugs of dependence by registered health practitioner

(1) Regulation 42(1)—delete "(other than by dispensing a prescription)"

(2) Regulation 42(1)(h)—delete paragraph (h) and substitute:

(h) the amount of the drug (if any) now remaining—

(i) in stock on the premises at which the drug is supplied or administered; or

(ii) otherwise in the possession of the practitioner.

20—Variation of regulation 43—Sale, supply or administration of drugs of dependence by veterinary surgeon

(1) Regulation 43—delete "supplies (other than by dispensing a prescription)" and substitute:

sells or supplies

(2) Regulation 43—before "supplied" first occurring insert:

sold,

(3) Regulation 43(b)—before "supplied" insert:

sold,

(4) Regulation 43(d)—delete "administered or supplied" and substitute:

sold, supplied or administered

(5) Regulation 43(f)—before "supplied" wherever occurring insert:

sold,

(6) Regulation 43(g)—delete paragraph (g) and substitute:

(g) the amount of the drug (if any) now remaining—

(i) in stock on the premises at which the drug is sold, supplied or administered; or

(ii) otherwise in the possession of the veterinary surgeon.

21—Variation of regulation 44—Additional requirements for administration of drugs of dependence in health service facility

Regulation 44(1)(a)(ii)—after "signature" insert:

and the date of the making of the entries

22—Variation of regulation 45—Destruction of drugs of dependence

Regulation 45(1)(a)—delete paragraph (a) and substitute:

(a) the destruction is witnessed by another person, being—

(i) an authorised officer; or

(ii) a police officer; or

(iii) a registered health practitioner; or

(iv) a veterinary surgeon; or

(v) a person who has been authorised in writing by the Chief Executive of the SA Ambulance Service to administer drugs of dependence; and

23—Insertion of regulation 56

After regulation 55 insert:

56—Ministerial approvals, determinations and exemptions

The Minister may at any time, as he or she thinks fit—

(a) revoke an approval, determination or exemption granted by the Minister under regulation 18(3), 24(1)(c), 26(7), 27(b)(ii), 44(1)(a) or 49(3); or

(b) impose any conditions on such an approval, determination or exemption, or vary or revoke any conditions imposed on such an approval, determination or exemption.

Note—

As required by section 10AA(2) of the *Subordinate Legislation Act 1978*, the Minister has certified that, in the Minister's opinion, it is necessary or appropriate that these regulations come into operation as set out in these regulations.

Made by the Governor

after consultation by the Minister with the Controlled Substances Advisory Council and with the advice and consent of the Executive Council
on 11 July 2013

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