

South Australia

# **Controlled Substances (Poisons) (Miscellaneous) Variation Regulations 2021**

under the *Controlled Substances Act 1984*

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## **Part 1—Preliminary**

### **1—Short title**

These regulations may be cited as the *Controlled Substances (Poisons) (Miscellaneous) Variation Regulations 2021*.

### **2—Commencement**

These regulations come into operation on 1 April 2022.

### **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

Regulation 3(1)—after the definition of *Commonwealth Regulations* insert:

*correctional institution* has the same meaning as in the *Correctional Services Act 1982*;

### 5—Variation of regulation 22—Exemptions from section 18A of Act

Regulation 22(3), definition of *correctional institution*—delete the definition

### 6—Variation of regulation 33—How prescriptions are to be given

- (1) Regulation 33(6)(b)—delete "the Chief Executive so that it is received no later than the 7th day of the month following the month in which the drug was dispensed (or such later day as the Chief Executive may, on the application of the prescriber, authorise)" and substitute:

a data source entity at, or immediately following, the time the record is created (unless subregulation (6a) applies)

- (2) Regulation 33(6a)—delete subregulation (6a) and substitute:

- (6a) If a prescriber is unable to transmit a record relating to a prescription in accordance with subregulation (6)(b) because the electronic system used to keep the record is not compatible with the electronic system of a data source entity, the prescriber must transmit the record electronically to the Chief Executive so that it is received no later than—

- (a) if the prescription is prepared on a day falling within the first 14 days of a month—the 21st day of that month; or
- (b) if the prescription is prepared on any other day—the 7th day of the month following the month in which the prescription was prepared; or
- (c) in any case, such later day as the Chief Executive may, on application, authorise.

Maximum penalty: \$5 000.

Expiation fee: \$1 250.

- (6b) The Minister may exempt a prescriber or class of prescribers from the operation of subregulation (6)(b) or (6a) (or both) if satisfied that proper cause exists for the exemption.

**7—Variation of regulation 34—Written prescriptions**

- (1) Regulation 34(1a)(b)—delete "the Chief Executive so that it is received no later than the 7th day of the month following the month in which the drug was dispensed (or such later day as the Chief Executive may, on the application of the prescriber, authorise)" and substitute:

a data source entity at, or immediately following, the time the record is created (unless subregulation (1b) applies)
- (2) Regulation 34(1b)—delete subregulation (1b) and substitute:
  - (1b) If a prescriber is unable to transmit a record relating to a prescription in accordance with subregulation (1a)(b) because the electronic system used to keep the record is not compatible with the electronic system of a data source entity, the prescriber must transmit the record electronically to the Chief Executive so that it is received no later than—
    - (a) if the prescription is written on a day falling within the first 14 days of a month—the 21st day of that month; or
    - (b) if the prescription is written on any other day—the 7th day of the month following the month in which the prescription was prepared; or
    - (c) in any case, such later day as the Chief Executive may, on application, authorise.

Maximum penalty: \$ 5 000.  
Expiation fee: \$1 250.
- (3) Regulation 34(1c)—after "subregulation (1a)(b)" insert:

or (1b) (or both)

**8—Insertion of regulation 34A**

After regulation 34 insert:

**34A—Giving prescriptions for drugs of dependence—special provisions**

- (1) Before a prescriber gives a prescription for the supply of a drug of dependence for human use (whether the prescription is given in writing, in an approved electronic form, by telephone, by fax or by an approved electronic communication), the prescriber must take all reasonable steps to access the information held in the monitored drugs database relating to the person for whom the drug is to be prescribed.

Maximum penalty: \$5 000.
- (2) Subregulation (1) does not apply if—
  - (a) the drug (not being dextromoramide or pethidine) is for use by a person aged 70 years or more; or

- (b) the drug (not being dextromoramide or pethidine) is for use by a person whose life expectancy is reasonably believed by the registered health practitioner principally responsible for treatment of the person, to be less than 12 months and—
  - (i) the prescriber has informed the Minister of the person's name and address, date of birth and the nature of the condition for which the drug is prescribed; and
  - (ii) the prescription for the drug is endorsed either "Notified Palliative Care Patient" or "NPCP"; or
- (c) the drug is for use by a person who is receiving treatment in a hospital or a correctional institution and the duration of treatment of the person with the drug while the person is in the hospital or correctional institution does not exceed 14 days; or
- (d) the drug is for use by a person who is being discharged from a hospital following treatment in the hospital and the duration of treatment of the person with the drug after discharge does not exceed 14 days.

### **9—Variation of regulation 35A—Dispensing prescriptions for drugs of dependence and other monitored drugs—special provisions**

- (1) Regulation 35A(1)(b)—delete " the Chief Executive so that it is received no later than the 7th day of the month following the month in which the drug was dispensed (or such later day as the Chief Executive may, on the application of the pharmacist, authorise)" and substitute:
  - a data source entity at, or immediately following, the time the record is created (unless subregulation (2) applies)
- (2) Regulation 35A(1)—after the penalty provision insert:
  - Expiation fee: \$1 250.
- (3) Regulation 35A(1a) and (2)—delete subregulations (1a) and (2) and substitute:
  - (2) If a pharmacist is unable to transmit a record relating to a prescription in accordance with subregulation (1)(b) because the electronic system used to make the record is not compatible with the electronic system of a data source entity, the pharmacist must transmit the record electronically to the Chief Executive so that it is received no later than—
    - (a) if the drug is dispensed on a day falling within the first 14 days of a month—the 21st day of that month; or
    - (b) if the drug is dispensed on any other day—the 7th day of the month following the month in which the drug was dispensed; or

- (c) in any case, such later day as the Chief Executive may, on application, authorise.  
Maximum penalty: \$ 5 000.  
Expiation fee: \$1 250.
- (4) Regulation 35A(4)—before paragraph (a) insert:
  - (aa) dispense a drug of dependence unless the pharmacist or practitioner has taken all reasonable steps to access the information held in the monitored drugs database relating to the person for whom the drug is to be dispensed; or
- (5) Regulation 35A—after subregulation (5) insert:
  - (6) Subregulation (4)(aa) does not apply if—
    - (a) the drug (not being dextromoramide or pethidine) is for use by a person aged 70 years or more; or
    - (b) the prescription for the drug (not being dextromoramide or pethidine) is endorsed either "Notified Palliative Care Patient" or "NPCP"; or
    - (c) the drug is for use by a person who is receiving treatment in a hospital or a correctional institution and the duration of treatment of the person with the drug while the person is in the hospital or correctional institution does not exceed 14 days; or
    - (d) the drug is for use by a person who is being discharged from a hospital following treatment in the hospital and the duration of treatment of the person with the drug after discharge does not exceed 14 days.

**10—Variation of regulation 45A—Restrictions on manufacture, sale, supply and use of certain paints and tinters**

- (1) Regulation 45A(1)(b)—delete paragraph (b) and substitute:
  - (b) an anti-fouling or anti-corrosive paint containing more than 0.1% Lead; or
  - (ba) a paint (other than an anti-fouling or anti-corrosive paint) or tinter containing more than 0.009% Lead; or
- (2) Regulation 45A—after subregulation (2) insert:
  - (2a) For the purposes of this regulation, the proportion of Lead contained in a paint is calculated as a percentage of the element present in the non-volatile content of the paint.

**11—Variation of regulation 53A—Disclosure of confidential information contained in monitored drugs database (section 60A(1)(e) of Act)**

Regulation 53A—after subregulation (3) insert:

- (4) Information contained in the monitored drugs database may be disclosed in accordance with an authorisation given by the Minister.

**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

No            of 2021