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MINISTER PC

South Australia

Controlled Substances (Poisons) (Real Time Prescription Monitoring) Variation Regulations 2020

under the *Controlled Substances Act 1984*

Contents

Part 1—Preliminary

1—Short title

These regulations may be cited as the *Controlled Substances (Poisons) (Real Time Prescription Monitoring) Variation Regulations 2020*.

2—Commencement

These regulations come into operation on 1 November 2020.

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)—after the definition of ***APVMA*** insert:

Australian jurisdiction means the Commonwealth or a State or Territory of the Commonwealth;

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

data source entity means any of the following:

(a) eRx Script Exchange Pty Ltd;

(b) MediSecure Pty Ltd;

(c) Medication Knowledge Pty Ltd;

(d) a prescription exchange service operating in an Australian jurisdiction;

(3) Regulation 3(1), definition of ***Metropolitan Adelaide***—delete the definition and substitute:

Metropolitan Adelaide means Metropolitan Adelaide as defined by the *Development Act 1993* immediately before 1 July 2019;

monitored drug means any of the following:

(a) any S8 poison;

(b) any S4 poison that is a benzodiazepine;

(c) any S4 poison that contains Codeine;

(d) any of the following S4 poisons:

(i) Gabapentin;

(ii) Pregabalin;

(iii) Quetiapine;

(iv) Tramadol;

(v) Zolpidem;

(vi) Zopiclone;

monitored drugs database means an electronic database kept by the Department that contains information relating to the sale, supply, prescription, administration and use of monitored drugs;

(4) Regulation 3—after subregulation (3) insert:

(4) For the purposes of these regulations—

(a) an electronic prescription for a drug is ***presented*** when it is accessed electronically for the purpose of dispensing the drug; and

(b) a prescription for a drug given to a pharmacist by fax is ***presented*** when a faxed copy of the prescription is transmitted to the pharmacy at which the drug is to be dispensed.

5—Variation of regulation 33—How prescriptions are to be given

Regulation 33(6)—delete subregulation (6) and substitute:

(6) If a prescription for a monitored drug for human use is prepared in an approved electronic form, the prescriber must—

(a) keep a record of—

(i) the details required by subregulation (5) to be included in the prescription; and

(ii) the date of birth of the person for whom the prescription has been prepared; and

(b) transmit that record electronically to 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).

Maximum penalty: $5 000.

Expiation fee: $1 250.

(6a) A prescriber will be taken to have complied with subregulation (6)(b) in relation to a record made by the prescriber if the information contained in the record is collected electronically by a data source entity and is transmitted electronically to the monitored drugs database by the data source entity.

6—Variation of regulation 34—Written prescriptions

(1) Regulation 34(1)(d)(iii)—delete subparagraph (iii)

(2) Regulation 34—after subregulation (1) insert:

(1a) A prescriber who writes a prescription for the supply of a monitored drug for human use—

(a) must keep a record of—

(i) the details required to be included and specified under subregulation (1); and

(ii) the date of birth of the person for whom the prescription has been written; and

(b) if the record is kept in electronic form—must transmit that record electronically to 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).

Maximum penalty: $5 000.

Expiation fee: $1 250.

(1b) A prescriber will be taken to have complied with subregulation (1a)(b) in relation to a record made by the prescriber if the information contained in the record is collected electronically by a data source entity and is transmitted electronically to the monitored drugs database by the data source entity.

(1c) The Minister may exempt a prescriber or class of prescribers from the operation of subregulation (1a)(b) if satisfied that proper cause exists for the exemption.

7—Variation of regulation 35—Dispensing prescriptions

(1) Regulation 35(2)(e)(ii)—delete "drug of dependence" and substitute:

monitored drug

(2) Regulation 35(16)—delete subregulation (16) and substitute:

(16) For the purposes of this regulation, a prescription for a drug is ***fully dispensed*** if—

(a) in the case of a prescription authorising dispensing of the drug once only—the drug has been dispensed on 1 occasion; or

(b) in the case of a prescription authorising dispensing of the drug more than once—the drug has been dispensed for the last time.

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

(1) Regulation 35A(1)—delete "drug of dependence" and substitute:

monitored drug

(2) Regulation 35A—after subregulation (1) insert:

(1a) A pharmacist will be taken to have complied with subregulation (1)(b) in relation to a record made by the pharmacist if the information contained in the record is collected electronically by a data source entity and is transmitted electronically to the monitored drugs database by the data source entity.

(3) Regulation 35A(3)—after the penalty provision insert:

Expiation fee: $1 250.

(4) Regulation 35A(5)—delete "drug of dependence" and substitute:

monitored drug

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

(1) Regulation 37(1)—after the penalty provision insert:

Expiation fee: $1 250.

(2) Regulation 37(2)—after the penalty provision insert:

Expiation fee: $1 250.

10—Insertion of regulation 53A

After regulation 53 insert:

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

(1) Information contained in the monitored drugs database relating to a particular person may be disclosed to a prescriber involved in the medical treatment or care of that person to enable that prescriber to access that information and disclose that information to—

(a) any registered health practitioner involved in the medical treatment or care of that person; and

(b) any pharmacist to whom a prescription for a monitored drug for that person has been presented.

(2) Information contained in the monitored drugs database relating to a particular person may be disclosed to a pharmacist to whom a prescription for a monitored drug for that person has been presented to enable that pharmacist to access that information and disclose that information to—

(a) any other pharmacist to whom a prescription for a monitored drug for that person has been presented; and

(b) any registered health practitioner involved in the medical treatment or care of that person.

(3) Information contained in the monitored drugs database may be disclosed to a health authority of an Australian jurisdiction responsible for the administration or enforcement of a law that regulates the sale, supply, prescription, administration and use of monitored drugs.

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

No of 2020