Drugs, Poisons and Controlled Substances Amendment (Real-time Prescription Monitoring) Regulations

Exposure Draft

TABLE OF PROPOSALS

Victoria

Drugs, Poisons and Controlled Substances Amendment (Real-time Prescription Monitoring) Regulations

Exposure Draft

1 Objective

The objective of these Regulations is to amend the Drugs, Poisons and Controlled Substances Regulations 2017 to—

(a) prescribe entities required to provide information to the monitored poisons database; and

(b) prescribe poisons which are to be monitored on the monitored poisons database; and

(c) prescribe exceptions to the requirement to check the monitored poisons database; and

(d) prescribe the content of records to be provided to the monitored poisons database; and

(e) make consequential amendments.

2 Authorising provisions

These Regulations are made under sections 129(1) and 132 of the **Drugs, Poisons and Controlled Substances Act 1981**.

3 Commencement

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

4 Principal Regulations

In these Regulations, the Drugs, Poisons and Controlled Substances Regulations 2017[1] are called the Principal Regulations.

5 Definitions

In regulation 5 of the Principal Regulations **insert** the following definition—

"***prescription exchange service*** means a system that provides for the electronic transfer of prescription information between a person who issues a prescription and a pharmacist;".

6 Required form for issuing prescriptions

For regulation 24(3)(g) of the Principal Regulations **substitute**—

"(g) in the case of a Schedule 8 poison, a monitored poison or a Schedule 9 poison if the prescription is for a person and not an animal, that person's date of birth;

(ga) in the case of a Schedule 8 poison or a Schedule 9 poison—

(i) if the poison may be supplied only once, a statement, using words and not just figures, that there is to be no repeat supply; and

(ii) a statement of quantity to be supplied, written in both words and figures;".

7 Details to be contained in records

(1) In regulation 108(1)(m) of the Principal Regulations, for "authorisation." **substitute** "authorisation; and".

(2) After regulation 108(1)(m) of the Principal Regulations **insert**—

"(n) in the case of a transaction involving the supply of a monitored poison by a pharmacist to or for a person in circumstances specified in regulation 47(1)(a), (b), (c), (d), or (e) or regulation 48(1)(a),(b) or (c), the date of birth of that person.".

8 Form of notification of a drug-dependent person

Regulation 127 of the Principal Regulations is **revoked**.

9 New Part 20 of Chapter 2 inserted

After Part 19 of Chapter 2 of the Principal Regulations **insert**—

"Part 20—Monitored poisons database

132A Data source entity

For the purposes of the definition of ***data source entity*** in section 4(1) of the Act an entity specified in Schedule 4 is prescribed to be a data source entity.

132B Monitored poison

For the purposes of paragraphs (c) and (d) of the definition of ***monitored poison*** in section 4(1) of the Act a poison or class of

poison specified in Schedule 5 is prescribed to be a monitored poison.

132C Monitored supply poison

On and after 1 April 2020, for the purposes of paragraph (a) and (b) of the definition of ***monitored supply poison*** in section 4(1) of the Act a poison or class of poison specified in Schedule 6 is prescribed to be a monitored supply poison.

132D Pharmacist to provide certain supply information to prescription exchange service

A pharmacist who has created a record of supply of a monitored poison using an electronic system that is compatible with a prescription exchange service—

(a) must register with the prescription exchange service and;

(b) must provide the record of supply to the prescription exchange service at the time the record of supply is created.

Note

For the purposes of management of information by a prescription exchange service, the **Health Records Act 2001** contains provisions relating to the collection, use, disclosure, retention and security of health information, in particular see Schedule 1 Health Privacy Principles 1.1, 1.2, 2, 3 and 4.

132E Records and information to be provided to the monitored poisons database

(1) For the purposes of section 30B(2)(b) of the Act, a data source entity must provide information, including records, in accordance with subregulation (2) to the monitored poisons database at the

time the records are collected by the data source entity, if available.

(2) For the purposes of section 30B(2)(c) of the Act the prescribed records are—

(a) records of the prescription of a monitored poison, including where the prescription has been issued—

(i) to a person in Victoria; or

(ii) to a person ordinarily resident in Victoria, where the supply has occurred in another State or a Territory; or

(iii) in another State or a Territory but the monitored poison has been supplied in Victoria;

(b) records of the supply of a monitored poison, including where the supply has occurred—

(i) to a person in Victoria; or

(ii) in another State or a Territory to a person ordinarily resident in Victoria; or

(iii) to a person in another State or a Territory on the basis of a prescription or instruction written in Victoria; and

(3) For the purposes of section 30B(2)(c) of the Act the prescribed information is—

(a) in relation to a record referred to in subregulation (2)(a)—

(i) the date of prescribing; and

(ii) the name and address of the person; and

(iii) the date of birth of the person; and

(iv) the name, form, strength and quantity of the monitored poison; and

(v) the number of repeats; and

(vi) the directions for use; and

(vii) the name, address and the phone number of the person who writes the prescription; and

(b) in relation to a record referred to in subregulation (2)(b)—

(i) the date of supply; and

(ii) the name and address of the person; and

(iii) the date of birth of the person; and

(iv) the name, form, strength and quantity of the monitored poison; and

(v) the directions for use; and

(vi) the name, address and the phone number of the person authorising the supply; and

(vii) the name, address and the phone number of the pharmacy or pharmacy department.

132F Circumstances where it is not mandatory for pharmacist to check monitored poisons database—certain classes of person

(1) For the purposes of section 30E of the Act, a pharmacist is not required to comply with that section in relation to a person for whom a monitored supply poison may be supplied

before supplying the monitored supply poison for that person if the person is—

(a) an in-patient being treated in hospital; or

(b) a patient being treated in an emergency department of a hospital; or

(c) a prisoner being treated in a prison; or

(d) a person being treated in a police gaol; or

(e) a resident being treated in an aged care service.

(2) Subregulation (1) does not apply if patient referred to in subregulation (1)(a) or (b) is supplied a monitored supply poison on discharge.

132G Circumstances where it is not mandatory to check monitored poisons database—certain classes of person

(1) For the purposes of sections 30F, 30G and 30H of the Act, a registered medical practitioner, a nurse practitioner or an authorised supplier (as the case requires) is not required to comply with the relevant section in relation to a person for whom a monitored supply poison may be prescribed or supplied before prescribing or supplying the monitored supply poison for that person if the person is—

(a) an in-patient being treated in hospital; or

(b) a patient being treated in an emergency department of a hospital; or

(c) a prisoner being treated in a prison; or

(d) a person being treated in a police gaol; or

(e) a resident being treated in an aged care service.

(2) Subregulation (1) does not apply if patient referred to in subregulation (1)(a) or (b) is prescribed or supplied a monitored supply poison on discharge.

132H Circumstances where it is not mandatory to check monitored poisons database—incurable medical condition

(1) For the purposes of section 30E of the Act, a pharmacist is not required to comply with that section in relation to a person for whom a monitored supply poison may be supplied before supplying the monitored supply poison for that person if the following applies—

(a) the person is suffering an incurable, progressive, far-advanced disease or medical condition; and

(b) the prognosis is of a limited life expectancy due to the disease or medical condition; and

(c) the supply of the monitored supply poison is intended to provide palliative treatment; and

(d) the person is not a drug-dependent person.

(2) For the purposes of sections 30F, 30G and 30H of the Act, a registered medical practitioner, a nurse practitioner or an authorised supplier (as the case requires) is not required to comply with the relevant section in relation to a person for whom a

monitored supply poison may be prescribed or supplied before prescribing or supplying the monitored supply poison for that person if the following applies—

(a) the person is suffering an incurable, progressive, far-advanced disease or medical condition; and

(b) the prognosis is of limited life expectancy due to the disease or medical condition; and

(c) the prescribing or supply of the monitored supply poison is intended to provide palliative treatment; and

(d) the person is not a drug-dependent person.".

10 Form 1 revoked

Form 1 of Schedule 2 to the Principal Regulations is **revoked**.

11 Schedules 4, 5 and 6 inserted

After Schedule 3 to the Principal Regulations **insert**—

"Schedule 4—Data source entities

Regulation 132A

1 eRx Script Exchange Pty Ltd

2 MediSecure Pty Ltd

3 Any prescription exchange service operating in the Commonwealth, another State or a Territory

4 Medication Knowledge Pty Ltd

Schedule 5—Monitored poisons

Regulation 132B

1 All benzodiazepines that are Schedule 4 poisons

2 Quetiapine

3 Zolpidem

4 Zopiclone

Schedule 6—Monitored supply poisons on and after 1 April 2020

Regulation 132C

1 All Schedule 8 poisons

2 All benzodiazepines that are Schedule 4 poisons

3 Quetiapine

4 Zolpidem

5 Zopiclone".

Endnotes

[1] Reg. 4: S.R. No. 29/2017.