



New South Wales

Poisons and Therapeutic Goods Amendment (Real Time Prescription Monitoring) 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 objects of this Regulation are—

- (a) to establish a system, including a database, for the real time monitoring of the prescribing and supply of certain medicines that may be subject to abuse, and
- (b) to authorise prescribers, suppliers and entities using electronic prescribing or dispensing systems to provide information for inclusion in the database, and
- (c) to allow for the use and disclosure of information in the database for prescribed purposes, including monitoring the prescribing and supply of monitored medicines, whether in New South Wales or elsewhere in Australia, and
- (d) to allow the Secretary of the Ministry of Health to exempt a person or class of persons from the obligations imposed by this Regulation.

This Regulation is made under the *Poisons and Therapeutic Goods Act 1966*, including sections 17, 24 and 45C (the general regulation-making power).

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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 (Real Time Prescription Monitoring) Regulation 2021*.

2 Commencement

This Regulation commences on the day on which it is published on the NSW legislation website.

Schedule 1 Amendment of Poisons and Therapeutic Goods Regulation 2008

[1] Part 8A

Insert after Part 8—

Part 8A Real time prescription monitoring

174A Interpretation

In this Part—

data source entity means—

- (a) the Australian Health Practitioner Regulation Agency established by section 23 of the *Health Practitioner Regulation National Law (NSW)*, or
- (b) eRx Script Exchange Pty Ltd, or
- (c) Fred IT Group Pty Ltd, or
- (d) Medication Knowledge Pty Ltd, or
- (e) MediSecure Ltd, or
- (f) any prescription exchange service prescribed by, or otherwise recognised for the purposes of, a law of the Commonwealth or another State or Territory.

database means the monitored medicines database established under clause 174C.

healthcare identifier means the healthcare identifier assigned to a person or an organisation under the *Healthcare Identifiers Act 2010* of the Commonwealth.

monitored medicine means a substance listed in Appendix E.

prescriber means an authorised practitioner, other than a veterinary practitioner.

regulatory authority means an entity—

- (a) with functions that include the regulation of monitored medicines or the regulation of health practitioners, and
- (b) that is established under a law of—
 - (i) New South Wales, or
 - (ii) another State or Territory, or
 - (iii) the Commonwealth.

174B Objects

The objects of this Part are to—

- (a) establish a system for the real time monitoring of the prescribing and supply of monitored medicines, and
- (b) require the establishment of a database of information about the prescribing and supply of monitored medicines, and
- (c) authorise prescribers, pharmacists and data source entities to provide information for inclusion in the database, and

- (d) allow for the use and disclosure of information in the database for purposes that include monitoring the prescribing and supply of monitored medicines.

174C Establishment and purpose of database

- (1) The Secretary is to establish and maintain a monitored medicines database to record data about the prescribing and supply of monitored medicines.
- (2) The Secretary may enter into an agreement with a person (the *database operator*) to operate and maintain the database.
- (3) The database operator may, subject to the terms of the agreement, carry out any of the Secretary's functions under this Part other than the power to give an exemption under clause 174J.

174D Recording of information by prescribers

- (1) This clause applies to a prescriber who uses an electronic prescribing system that is connected to a prescription exchange service operated by a data source entity.
- (2) A prescriber who issues a prescription for a monitored medicine may, for the purposes of the database, record the following information about the person who is prescribed the monitored medicine—
 - (a) full name,
 - (b) date of birth,
 - (c) gender,
 - (d) street address,
 - (e) other relevant information approved by the Secretary, including healthcare identifier, if available.
- (3) A prescriber who issues a prescription for a monitored medicine is to record, for the purposes of the database, the following information—
 - (a) the following information about the prescriber—
 - (i) full name,
 - (ii) registration number or code recorded in the national register under section 225(c) of the *Health Practitioner Regulation National Law (NSW)*,
 - (iii) healthcare identifier, if available,
 - (iv) other relevant contact information, including telephone number and email address,
 - (b) the following additional information—
 - (i) for a monitored medicine that is included in Schedule 4 of the Poisons List—the information required by clause 35(1)(a)–(f),
 - (ii) for a monitored medicine that is included in Schedule 8 of the Poisons List—the information required by clause 80(1)(a)–(f),
 - (iii) other relevant practice information approved by the Secretary, including practice name and address and healthcare identifier, if available.

174E Recording of information by pharmacists

- (1) This clause applies to a pharmacist who uses an electronic dispensing system that is connected to a prescription exchange service operated by a data source entity.
- (2) A pharmacist who supplies a monitored medicine may, for the purposes of the database, record—
 - (a) the following information about the person who is supplied a monitored medicine—
 - (i) full name,
 - (ii) date of birth,
 - (iii) gender,
 - (iv) street address,
 - (v) other relevant information approved by the Secretary, including healthcare identifier, if available,
 - (b) the following information about the pharmacist—
 - (i) full name,
 - (ii) registration number or code recorded in the national register under section 225(c) of the *Health Practitioner Regulation National Law (NSW)*,
 - (iii) healthcare identifier, if available,
 - (iv) other relevant contact information, including telephone number and email address,
 - (c) the following additional information—
 - (i) the date on which the monitored medicine was supplied,
 - (ii) other relevant information approved by the Secretary about the business from which the monitored medicine was supplied, including the business name, address and healthcare identifier, if available,
 - (iii) the prescription reference number for the prescription under which the monitored medicine was supplied.

174F Authority to transfer information

A data source entity is authorised to transfer the following information for inclusion in the database—

- (a) information the entity receives from a prescriber—
 - (i) under clause 174D, or
 - (ii) who is in another State or Territory when the prescriber issues a prescription for a monitored medicine to a person ordinarily resident in New South Wales,
- (b) information the entity receives from a pharmacist—
 - (i) under clause 174E, or
 - (ii) who is in another State or Territory if the pharmacist supplies a monitored medicine to a person ordinarily resident in New South Wales,
- (c) any other information received from a prescriber or pharmacist if that information is reasonably required for the operation of the database.

174G Use and disclosure of information by Secretary

Information in the database may be used or disclosed by the Secretary for the purposes of—

- (a) operating, maintaining or improving the database, and
- (b) monitoring the prescribing and supply of monitored medicines—
 - (i) by individual prescribers and pharmacists, or
 - (ii) on a more general, including State-wide, basis, and
- (c) providing that information, whether directly or via a data source entity, to another State or Territory for inclusion in a database established under a law of that State or Territory and serving substantially the same purpose as the database, and
- (d) providing information to a regulatory authority where that information is reasonably required by the authority for the purpose of regulating the prescribing, supply or use of monitored medicines, and
- (e) providing information to a data source entity for purposes connected to monitoring the prescribing or supply of monitored medicines, and
- (f) for any other lawful purpose.

174H Use of information by certain prescribers and by pharmacists

Information in the database may be used by a dentist, a medical practitioner, a nurse practitioner or a pharmacist for the purposes of—

- (a) providing treatment to an individual patient by—
 - (i) reviewing the prescribing of monitored medicines to the patient by other prescribers, and
 - (ii) reviewing the supply of monitored medicines to the patient by pharmacists, and
- (b) providing advice to a prescriber or a pharmacist on the treatment of an individual patient.

174I Unauthorised access to database

A person must not without lawful authority knowingly access, use or disclose information held in the database.

Maximum penalty—20 penalty units.

174J Exemption

- (1) The Secretary may, by written order, exempt any person, or any class of persons, from the requirements of this Part.
- (2) An exemption may be given unconditionally or subject to conditions.

[2] Appendix E

Insert after Appendix D—

Appendix E Monitored medicines

Clause 174A

Substance

All substances included in Schedule 8 of the Poisons List

Any benzodiazepine derivative included in Schedule 4 of the Poisons List

Bromazepam

Chlordiazepoxide

Clobazam

Clonazepam

Clorazepate

Codeine when included in Schedule 4 of the Poisons List

Diazepam

Flurazepam

Lorazepam

Medazepam

Midazolam

Nitrazepam

Oxazepam

Prazepam

Pregabalin

Quetiapine

Temazepam

Tramadol

Triazolam

Zolazepam

Zolpidem

Zopiclone
