Queensland Health

Key legislative requirements: registered nurses and enrolled nurses

Medicines and Poisons Act 2019

Introduction

From 27 September 2021, the *Medicines and Poisons Act 2019* (MPA) and the Medicines and Poisons (Medicines) Regulation 2021 (MPMR) and associated legislative instruments define the lawful actions in relation to medicines[1] (schedule 2 (S2), 3 (S3), 4 (S4) and 8 (S8)) of the Poisons Standard[2]) for therapeutic use in Queensland.

The MPA and MPMR can be accessed from the Queensland Legislation website via *In force legislation*– www.legislation.qld.gov.au.

The legislative instruments that have been approved by the chief executive[3] (Director General) to support the MPMR include departmental standards and extended practice authorities. These legislative instruments can be accessed from the Queensland Health website - Legislation, departmental standards and extended practice authorities.

This information sheet has been prepared to provide an overview of the fundamental legislative requirements as it relates to the majority of registered nurses and enrolled nurses (nurses), as approved persons[4], to deal[5] (undertake regulated activities) with medicines.

Many of the requirements under the new Medicines and Poisons legislative scheme are similar to requirements under the repealed Health (Drugs and Poisons) Regulation 1996 (HDPR), however, the structure and the terminology of the new legislation have been modernised.

Terminology

The MPA introduces new terminology and modifies terms previously used in the repealed *Health Act 1937* and repealed Health (Drugs and Poisons) Regulation 1996 (HDPR). Refer to the full list of terms and associated definitions listed in the Dictionary in Schedule 1 of the MPA, and Schedule 22 of the MPMR for the full range of definitions.

Appendix 1 details some of the terms commonly used including the meaning of 'the authorised way'. The 'authorised way' is a key concept in the MPA - it links a person's authorisation to perform particular regulated activities (dealings) with the specified conditions or requirements for performing the activity lawfully.

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[1] Section 11, *Medicines and Poisons Act 2019*.

[2] The legal title of the Standard for Uniform Scheduling of Medicines and Poisons (SUSMP) that details the schedules for medicines and poisons and packaging and labelling requirements - The Poisons Standard (the SUSMP) | Therapeutic Goods Administration (TGA).

[3] The Director General, as chief executive of Queensland Health (section 10, *Public Services Act 2008)*, is responsible for administering the legislation portfolio set out under the Queensland Government's Administrative Arrangements Order.

[4] Section 13, MPMR.

[5] Section 18, *Medicines and Poisons Act 2019*.

Authorisation to deal with medicines

Schedule 7 of the MPMR, sets out the types of activities (dealings), the medicines and the scope[6] for dealing with the medicines that may be carried out by 'approved persons' who are:

- registered nurses (Part 3, Division 2),
- registered nurses who are nurse managers at a relevant institution[7] (Part 3, Division 3),
- registered nurses who are nurse managers at a rural hospital or a hospital in an isolated are (Part 3, Division 4),
- registered nurses who are employed at a prison (Part 3, Division 5)
- enrolled nurses (part 4), and
- enrolled nurses with a medicines notation on their Nursing and Midwifery Board of Australia registration (Part 5).

The MPMR specifies the circumstances, scope and supervision arrangements for when students may possess and administer medicines while training to obtain a qualification as an enrolled nurse[8] or as a registered nurse[9].

Extended practice authority – registered nurses

The new scheme introduces an authority known as an 'Extended Practice Authority' (EPA). The MPA (section 232(4)) enables the Director General to make EPAs to state the places or contexts an approved person may undertake additional regulated activities with medicines. EPAs impose conditions on dealings with the medicines specified and may require a person to hold particular qualifications or training. In making an EPA, consideration has been given to a range of factors such as community need, any risks associated with the proposed dealing with the medicines, and the governance capability of the entity the approved person works for (see MPMR Chapter 9, Part 1).

The term EPA has a discrete meaning within the legislative scheme. EPAs allow authorisation to be provided to deal with particular medicines for particular circumstances within conditions such as administering specified prescription-only (S4) medicines to a patient without a prescription when the general requirement is that administration of an S4 medicine is only on a prescription. The name 'extended practice' refers to the authority, it does not define the professional practice of the approved person authorized under the EPA as 'extended practice'.

Schedule 7, Part 3 of the MPMR establishes the Extended Practice Authority - registered nurses (EPA-RN). The EPA-RN replaces the 'Drug Therapy Protocol – Rural and Isolated Practice Area Endorsed Nurse', the 'Drug Therapy Protocol – Sexual Health Program Nurse (including Reproductive Health)' and the 'Drug Therapy Protocol – Immunisation Program Nurse' made under the repealed HDPR.

[6] *Scope of dealing* may include the circumstance, purpose, extended practice authority or other matter for dealing with medicines.

[7] means an aged care facility, hospital, prison or detention centre (refer to Schedule 22 of MPMR).

[8] Schedule 7, Part 6 of the MPMR.

[9] Schedule 13, Part 7 (trainee health practitioner) of the MPMR.

The EPA-RN has four parts. A new Part A provides authority for a registered nurse to administer or give a treatment dose of specified medicines if the registered nurse is working for a Hospital and Health Service (HHS) and when the registered nurse is credentialed to work under a health management protocol specified for the registered nurse.

Parts B, C and D of the EPA-RN transition the former drug therapy protocols with Part B providing an alternative authorisation in response to the Nursing and Midwifery Board of Australia's discontinuation of the RIPEN endorsement. On commencement of the MPA, registered nurses who were acting under the drug therapy protocols of the repealed HDPR will continue to have the same authorisation to administer or give a treatment doses of medicines as they did under the repealed HDPR.

Under Parts B, C and D, registered nurses who hold the specified qualification or who have successfully completed the required training are authorized to practice under the relevant part of the EPA-RN without a legislative requirement to be credentialed for their practice (although some employers may choose to extend organisational credentialing to these registered nurses). Parts B, C and D are not limited to registered nurses working in HHSs.

What is the difference between a prescription, a standing order and a clinical protocol?

A *prescription*[10] is instruction provided by a person who is authorised to prescribe, orally or in writing, including electronic prescriptions[11] and medication charts, to administer, dispense or give a treatment dose of medicine for the treatment of a person or animal. The MPMR includes requirements for a lawful prescription to administer a medicine such as a medication chart prescription (see Chapter 4 Part 6, Division 4). Like the HDPR, a prescriber who gives an oral prescription (e.g. a telephone order) for an S8 medicine must confirm that prescription in writing no later than the next business day (see section 100).

A *standing order* is a document authorising a medicine to be administered or given as a treatment dose to a patient at a relevant institution[12] (aged care facility, hospital, prison or detention centre), *or* in stated circumstances at a particular services or places[13] (making other standing orders) that are not a relevant institution. An approved person who administers a medicine on a standing order must make and keep a record of the administration (see section 141 of the MMMR). For more information on making a standing order, see Chapter 4, Part 7, Division 2 of the MPMR.

A *clinical protocol*[14] is a type of standing order applying in relation to a specified class of approved persons e.g. a nuclear medicine technologist, performing a procedure or diagnostic test at a place.

[10] Part 6 of the MPMR.

[11] Section 83 of the MPMR.

[12] Chapter 4, Part 7, Division 2 of the MPMR.

[13] Section 104 of the MPMR.

[14] Section 101 of the MPMR.

Giving a treatment dose

Registered nurses who are authorised to give a treatment dose of medicines must comply with the requirements specified in Chapter 4, Part 9 of the MPMR to ensure the activity is conducted in the 'authorised way'. 'Giving a treatment dose' allows one or more doses to be given, for example, as a course of treatment.

A registered nurse who is authorised to give a treatment dose of a S4 or S8 medicine to a patient must *attach a label to the medicine*[15] and *make a record of the supply*[16].

Can a registered nurse repackage medicines?

A registered nurse who gives a treatment dose to fill a prescription for an S4 or S8 medicine may supply the quantity prescribed even if less than a manufacturer's standard pack. In order to fill the prescription, the quantity of medicine may be packaged into another container. See also the document *Supply, labelling and recording of medicines by registered nurses in rural hospitals or isolated practice areas* on the Queensland Health intranet site.

Registered nurses, referred to in Schedule 7, Part 3, Division 4 and 5, may repackage a medicine into a dose administration aid (DAA) only if given for a treatment dose[17] on a prescription in rural discharge circumstances, or for a prison patient on a prescription from a prescriber employed at the prison and in accordance with the Repackaging medicines into a dose administration aid: Guidelines for registered nurses.

S2 and S3 medicines are to be supplied to patients in the manufacturers packaging, which contains the information about how to safely administer and store the medicine.

Expired prescriptions and medications

Nurses must not give a treatment dose or administer a medicine on a prescription that has expired[18]. From the date written, prescriptions for S2, S3 and S4 medicines are valid for *12 months*, while S8 medicine prescriptions are valid for *six months*.

Expired medicines - A treatment dose of a medicine must not be given if the date on the container or label indicates the medicine is beyond its expiry date.

What is a substance management plan?

A substance management plan sets out how known and foreseeable risks associated with any dealing with a regulated substance are to be managed at the regulated place. A responsible person at a regulated place (Schedule 17, MPMR) must make a substance management plan that complies with the Department Standard – Substance Management Plans for medicines.

Nurses who are employed or contracted at a regulated place must comply with the requirements of the substance management plan made for that place.

[15] Section 134 of the MPMR.

[16] Section 136 of the MPMR

[17] Chapter 4, Part 9 of the MPMR

[18] Section 142 of the MPMR.

Other requirements

Registered nurses and enrolled nurses must comply with the storage, record-keeping, disposal and notification requirements (reporting to the chief executive) specified in the MPMR.

Storage and record-keeping

Medicines must be stored to maintain their integrity and limit the opportunity for diversion or unintended poisoning. The requirements for storing medicines are contained in Chapter 8 Part 2 of the MPMR and in the Departmental Standard: Secure Storage of S8 Medicines

Disposal of medicine waste (including S8 medicine waste)

There are new arrangements for the destruction of S8 medicines in the MPMR. Unwanted or expired S8 medicines should not be sent to Forensic and Scientific Services, Queensland Health.

The MPMR stipulates the requirements for disposing of waste from diversion-risk medicines[19], including S8 medicines. Most medicine waste may be sent to an approved waste management contractor for high temperature incineration.

If the waste is from an S8 medicine, it must first be destroyed[20] (rendered unusable and unidentifiable) before being sent away for disposal. The specific requirements for destroying S8 medicines are detailed in the information sheet - *Disposal of S8 medicine waste.*

Reporting matters to the chief executive

There are a number of reporting obligations for health practitioners to notify the chief executive[21] under the MPMR, including the requirement to notify lost or stolen S8 medicines.

The Queensland Health web page Reporting medicines matters to the chief executive contains the suite of notification forms.

Additional resources

In addition to the linked resources referred to in this factsheet, other relevant documents, resources and information sheets may be accessed from Factsheets and supporting documents.

For further information contact

Healthcare and Regulatory Approvals Unit - HARU@health.qld.gov.au

[19] Chapter 4, Part 11 of the MPMR.

[20] by an approved person and witnessed by another approved person, who are both authorised to dispose of diversion-risk medicines and destroy S8 medicines.

[21] The Director General, as chief executive of Queensland Health.

Appendix 1 – Commonly used terms

Term	Meaning
Authorised way	The 'authorised way' is a central tenet of the MPA and supporting regulations. A person carries out a regulated activity in the 'authorised way' if they are authorised to deal with medicines (regulated substances), they are authorised to deal with, and if they comply with the requirements to carry out the activity as specified under the MPA and MPMR. This includes compliance with Departmental Standards and Extended Practice Authorities, as legislative instruments, and if working at a regulated place, the Substance Management Plan.
Deals	A person deals or is dealing with a medicines as a regulated substance, if the person carries out any of the following - manufacture; buy; possess; supply (includes sell, dispense or give a treatment dose); administer, prescribe or make a standing order for medicines; apply a poison; and dispose of waste or otherwise use a prohibited substance.
Give a treatment dose	Distinct from 'dispense', to give a treatment dose of a medicine means to supply one or more doses of the medicine to a person to be taken by a particular person, or administered to an animal, at a later time.
Monitored medicines	Is the term used to describe a group of medicines (listed in Part 4 of Schedule 2 of the MPMR). The use of these medicines is monitored via real-time prescription monitoring (QScript).
Dispense	The term used in relation to a person selling a medicine to a patient on the authority of a prescriber.
Supply	Supply is an umbrella term that includes to 'sell', 'dispense' and 'give a treatment dose' as particular types of supply but does not include to administer or to dispose of waste. The term 'issue' as defined in the repealed HDPR will not be used in the MPA framework.

A term used in this fact sheet that is defined in the MPA or the MPMR has the meaning as stated in the MPA or MPMR.