

# Key legislative requirements – medical practitioners

*Medicines and Poisons Act 2019*

## Introduction

The *Medicines and Poisons Act 2019* (MPA) and the Medicines and Poisons (Medicines) Regulation 2021 (MPMR) commenced on 27 September 2021.

The MPA and MPMR define the lawful actions in relation to medicines (schedule 2 (S2), 3 (S3), 4 (S4) and 8 (S8)) of the Poisons Standard<sup>1</sup>) for therapeutic use in Queensland.

The legislation and associated legislative instruments (including departmental standards and extended practice authorities) can be accessed from the Queensland Health site [Legislation, standards and extended practice authorities](#).

## Commonly used terms and phrases

The MPA introduces new terminology and modifies terms previously used in the repealed *Health Act 1937* and repealed Health (Drugs and Poisons) Regulation 1996 (HDPR). **Appendix 1** in this fact sheet contains definitions for some of the commonly used terms. Other definitions can be found in the dictionaries of both the MPA and the MPMR.

## Authority to deal with medicines

The MPMR has thirteen Schedules that contain the authorisations for people to carry out certain activities (or ‘dealings’) with medicines. People who have an authorisation to deal with a medicine in a Schedule are termed *approved persons*.

Schedule 6 of the MPMR sets out the types of activities (dealings), the medicines and the scope for dealing with the medicines (as-of-right authorisation) that may be carried out by approved persons who are:

- Medical practitioners - generally (Part 1)
- Specialist medical practitioners, including Registrars (Part 2)
- Physician assistants (Part 3).

The MPA also enables the making of **Emergency Orders** in particular circumstances such as a declared public health emergency or a disaster situation. Emergency orders are an alternative authorisation for *approved persons* specified in the Emergency Order; the order may temporarily extend or restrict an *approved person's* primary authorisation. Active Emergency Orders are published on the [Updates and alerts](#) web page.

<sup>1</sup>The Standard for Uniform Scheduling of Medicines and Poisons that details the schedules for medicines and poisons and packaging and labelling requirements - [The Poisons Standard \(the SUSMP\) | Therapeutic Goods Administration \(TGA\)](#).

## Prescribing medicines

Medical practitioners may prescribe medicines for the treatment of patients under their care where the medical practitioner has assessed the medicines to be reasonably necessary for the therapeutic treatment of the patient.

A prescription is a direction that may be given orally or in writing, and may authorise:

- The dispensing of a medicine by a pharmacist or the giving of a treatment dose, for example, by nurses in rural hospitals (a prescription for supply); or
- The administration of a medicine (e.g. an entry on a medication chart).

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*. This applies to both prescriptions for supply and prescriptions for administration.

A quick reference guide on the requirements for writing prescriptions can be found in [Writing lawful prescriptions](#).

Some **important changes** to the requirements applying to medical practitioners issuing written prescriptions are highlighted below. This list does not include all the changes. Practitioners should also read Chapter 4 and Schedule 6 of the MPMR.

- There is a new requirement that all prescriptions for monitored medicines include the date of birth of the patient.
- A prescription for supply for an S8 medicine must still include the quantity to be supplied in words and numbers, however a paper prescription for an S8 medicine that has been generated on a computer no longer needs to have the particulars handwritten on the prescription other than a hand-written signature.
- A paper prescription for supply that has been generated on a computer may not be amended once it has been printed. If an error is identified after a prescription has been printed, the error must be corrected in the prescribing software and a new prescription generated.
- Prescribers must not self-prescribe or self-administer a high-risk medicine. High risk medicines include all S8 medicines, benzodiazepines, S4 codeine-containing medicines, gabapentin, pregabalin, quetiapine, tramadol, zolpidem and zopiclone. These medicines are also monitored medicines whose dispensing is recorded in the monitored medicines database, QScript.

## Monitored medicines

Monitored medicines are medicines potentially presenting a high risk of harm to patients as a result of misuse, abuse, diversion, substance use disorder and/or overdose.

Before prescribing, dispensing or giving a treatment dose of a monitored medicine for a patient, a medical practitioner is required to check QScript, the real-time prescription monitoring system. QScript provides information about a patient's pattern of use of monitored medicines to alert a prescriber about circumstances where a patient may be at

risk of serious harms associated with the use of monitored medicines. See further details about QScript here: [www.health.qld.gov.au/qscript](http://www.health.qld.gov.au/qscript).

When prescribing a monitored medicine for supply, it is a requirement for the medical practitioner to comply with the provisions of the [Departmental Standard: Monitored Medicines](#). This is a separate requirement to accessing QScript, however, the information in QScript may prompt the prescriber to implement appropriate strategies to reduce the risk of harm for a patient they are treating. The standard sets out mandatory minimum requirements.

The [Monitored Medicines Standard Checklist for prescribers](#) summarises the key obligations and the [Monitored Medicines Standard Companion Document](#) provides guidance and examples for each requirement in the standard.

If a medical practitioner is dispensing a monitored medicine on a prescription, they must comply with the **Departmental Standard: Monitored Medicines** for dispensing.

The fact sheet [Compliance, monitoring and enforcement \(health.qld.gov.au\)](#) describes the approach to compliance, monitoring and enforcement for the requirement to access QScript under section 41 of the MPA as well as other provisions in the medicines and poisons regulatory scheme.

## Restricted medicines

The authorities to deal with restricted medicines<sup>2</sup> are limited to certain types of prescribers. Medical practitioners should refer to Schedule 6 of the MPMR to determine if the prescription falls within the limits of the medical practitioner's *approved persons* authority in the schedule.

Prescribers who are not automatically authorised as an *approved person* to prescribe a restricted medicine under the MPMR may apply for a prescribing approval from Queensland Health.

Restricted medicines include *approved opioids* under the Queensland Opioid Treatment Program. All prescribers of *approved opioids* require a prescribing approval.

Note 1: A Queensland Health issued prescribing approval is separate to the approval to prescribe an authority PBS prescription item given by a delegate of the Commonwealth Department of Health.

Note 2: For patients who are being treated with a restricted medicine at the time they are admitted to a hospital, prison, watch-house or detention centre, a medical practitioner may prescribe the restricted medicine for the continuing treatment of the patient during their admission.

## Prescribing approvals

A prescriber whose authorisation to prescribe a restricted medicine is because they hold a prescribing approval issued by Queensland Health must include the **prescribing approval number** on all prescriptions for the restricted medicine. The inclusion of the prescribing

<sup>2</sup> Restricted medicines are listed in Part 1 of Schedule 2 of the MPMR

approval number is important because it enables the person acting on the prescription, such as the dispensing pharmacist, to be sure that the prescription is from a legitimate prescriber.

Note 3: A prescribing approval number is given by Queensland Health and is distinct from the approval numbers issued by the Commonwealth Department of Health, such as a PBS prescriber number or an MBS provider number.

Information about prescribing approvals including application forms and guidelines are available for *approved opioids*, psychostimulants and other restricted medicines at <https://www.health.qld.gov.au/system-governance/licences/medicines-poisons/medicines/prescribing-approvals>.

## Standing orders

Medical practitioners may make a standing order for the treatment of patients at an aged care facility, hospital, prison or detention centre, or at a place used to provide an Aboriginal or Torres Strait Islander health service. Standing orders may not be made for use at any other place, including medical practices and clinics, unless Queensland Health has approved the use of standing orders at that place.

A standing order must be approved by a medicines committee for the place where it is to be implemented. The informational elements that must be included in a standing order are now specified in the Regulation. See Part 7 of Chapter 4 of the Regulation for further information.

### Clinical protocols

Clinical protocols are a special type of standing order, made by a medical practitioner, that applies in relation to a procedure or diagnostic test performed by a clinical perfusionist, respiratory scientists, nuclear medicine technologist, speech pathologist or orthoptist.

Further information about clinical protocols is available at:

[https://www.health.qld.gov.au/data/assets/pdf\\_file/0017/1110761/fs-clinicians-working-under-clinical-protocol.pdf](https://www.health.qld.gov.au/data/assets/pdf_file/0017/1110761/fs-clinicians-working-under-clinical-protocol.pdf).

## Supplying medicines to patients

A medical practitioner who supplies a S4 or S8 medicine to a patient must **attach a label to the medicine** and **make a record of the supply**. The requirements for labelling medicines that are supplied to patients (given as a treatment dose) are contained in section 134 of the MPMR while section 136 contains the information that must be in a record about the supply.

## Substance management plans

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

is accountable for ensuring all employed or contracted staff are aware of and have access to the plan as a resource.

All medical practitioners who are employed or contracted at a place at which a substance management plan applies (a *regulated place*) must comply with the requirements for dealing with medicines specified in the substance management plan for that place. Places required to have a substance management plan are listed in Schedule 17 of the MPMR and include public and private hospitals, aged care facilities and pharmacies.

For more information on the content of a Substance Management Plan see the [guidance document](#).

#### **Transition arrangements for substance management plans**

A regulated place will have a 12-month transition period from the commencement date of the MPA (27 September 2021) to develop a plan.

## Other requirements

### **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 in Part 2 of Chapter 8 of the Regulation and in the [Departmental Standard: Secure Storage of S8 Medicines](#).

### **Disposal of medicine waste (including S8 medicines)**

Part 11 of Chapter 4 of the MPMR contains the requirements for disposing of medicines, including S8 medicines and other diversion-risk medicines. To prevent environmental contamination, medicines must not be disposed of as general waste. They may not be poured down a sink, flushed down a toilet, or sent to landfill. Medicine waste must be destroyed by high temperature incineration by an approved waste management contractor.

Rather than sending S8 medicine waste to Forensic and Scientific Services for destruction (as was previously required under the HDPR), S8 medicine waste that has been **rendered unusable and unidentifiable** may now be included with other scheduled medicine waste that is sent away for incineration.

S8 medicine waste may also be transferred to another health practitioner (such as a pharmacist) for destruction if the person transferring the waste is satisfied that the person to whom they are transferring the waste is authorised to destroy the S8 medicine waste. A person receiving S8 medicine waste must acknowledge receipt of the waste by either:

- a) signing an entry for the transfer in the medicine register for the S8 safe in which the waste was kept; or
- b) signing a separate notice acknowledging the receipt.

Ambulance officers, dentists, medical practitioners, pharmacists, nurses, midwives, podiatrists, and veterinary surgeons are authorised to destroy S8 medicine waste if the

destruction is witnessed by another person who is also authorised to destroy S8 medicines and who is not related, or in a de facto relationship with the person destroying the waste.

The requirement to have the destruction of S8 medicine waste witnessed does not apply to waste that is:

- a) residue from a medicine in the form of—
  - (i) an unused portion of a tablet;
  - (ii) the unused partial contents of a previously sterile ampoule or container;
  - (iii) a used transdermal patch; and
- b) destroyed immediately after the medicine is no longer required for administration.

Further detailed instructions for destroying S8 medicine waste are contained in the fact sheet [Disposal of S8 medicine waste](#).

### **Reporting matters to the chief executive**

There are reporting obligations for health practitioners under the MPA. The notification requirements are contained in Chapter 8 of the MPMR and include the requirement to notify lost or stolen S8 medicines, and for a pharmacist to notify non-receipt of a paper copy of a prescription that was sent to a pharmacy by digital communication (fax/email).

There are specific forms that must be used when notifying Queensland Health. These can be found on the Qld Health website at: <https://www.health.qld.gov.au/clinical-practice/guidelines-procedures/medicines/reporting-medicines-matters>.

## **For further information**

Contact Healthcare Approvals and Regulation Unit

HARU@health.qld.gov.au

## Appendix 1 – Commonly used terms

Term	Meaning
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.
Dispense	Dispense means to sell the medicine to a person on prescription i.e. on the authority of a prescriber.
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.
High-risk medicine	The term used to collectively describe the group of medicines which may not be self-prescribed or self-administered (other than pursuant to lawful prescribing or supply). High-risk medicines are all S8 medicines, all benzodiazepines, codeine, gabapentin, pregabalin, quetiapine, tramadol, zolpidem and zopiclone
Monitored medicines	The term used to collectively describe the group of medicines (listed in Part 4 of Schedule 2 of the MPMR) whose use is monitored via real-time prescription monitoring (QScript).
Prescribe	A term that relates to the action of a practitioner authorising treatment with a medicine, either administration or supply, to be carried out by another person.
Regulated place	A place, listed in Schedule 17 of the MPMR, where a substance management plan applies.
Restricted medicine	The term used to collectively describe medicines that have additional restrictions on who can prescribe them. A medicine may be restricted because, for example, it is teratogenic or is in short supply. Restricted medicines are listed in Part 1 of Schedule 2 of the MPMR.
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.