

Health practitioners working under a clinical protocol

Medicines and Poisons Act 2019

Audience

Clinical perfusionists, respiratory scientists, nuclear medicine technologists, speech pathologists, orthoptists

Introduction

From 27 September 2021, the legislation that defines the lawful way to deal with scheduled medicines in Queensland will be contained in the *Medicines and Poisons Act 2019* (the MP Act), the Medicines and Poisons (Medicines) Regulation 2021 (the Medicines Regulation) and associated legislative instruments. This new suite of legislation will replace the Health Act 1937, the Health (Drugs and Poisons) Regulation 1996 and the Health Regulation 1996.

The current versions of the MP Act and the Medicines Regulation can be found on the Queensland Legislation website at [In force legislation - Queensland Legislation - Queensland Government](https://www.legislation.qld.gov.au/).

The legislative instruments under the MP Act including Departmental Standards can be found at <https://www.health.qld.gov.au/system-governance/licences/medicines-poisons/medicines-poisons-act/legislation-standards>.

Substance management plans

There is a new requirement in the MP Act for certain places to have a Substance Management Plan (SMP) that articulates the local policies and procedures for dealing with medicines. The places required to have a SMP are listed in Schedule 17 of the Regulation and include hospitals, aged care facilities and pharmacies. Practitioners must be aware of, and abide by, all relevant requirements in a SMP applying at their place of practice.

Authorisation to administer medicines

The Medicines Regulation has 13 Schedules that contain the authorisations for people to carry out certain activities (or 'dealings') with medicines. Those people who have an authorisation to deal with a medicine in a Schedule in the Medicines Regulation are termed *approved persons*.

One way of dealing with a medicine is to **administer** the medicine to another person. Several classes of approved persons have an authorisation, in the Schedules in the Medicines Regulation, to administer medicines. Each approved person's schedule specifies the types of medicines that the person may administer, and the scope of the administration. For example, the administering of a medicine may be self-directed (because the person is an authorised prescriber of the medicine), in accordance with a prescription given by an authorised prescriber, or in accordance with a standing order for the medicine.

The authorities for **clinical perfusionists, respiratory scientists, nuclear medicine technologists, speech pathologists** to administer medicines are contained in Schedule 12 of the Medicines Regulation. The authority for **orthoptists** is in Schedule 8.

These schedules also include the authorities to **possess** and **dispose** of the specified medicines if applicable. Information about the new requirements for disposing of S8 medicine waste can be found at [Disposal of S8 medicine waste](#).

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

A **prescription** is a direction, given orally or in writing, to administer, dispense or give a treatment dose of a medicine for the treatment of a person or animal.

A **standing order** is a document authorising a medicine to be administered or given as a treatment dose at a stated place or in stated circumstances.

A **clinical protocol** is a type of standing order applying in relation to an approved person performing a procedure or diagnostic test at a place for practising any of the following professions:

- clinical perfusion
- orthoptics
- nuclear medicine technology
- respiratory science
- speech pathology.

Who can make a clinical protocol and what information must be in a protocol?

A medical practitioner, as an approved person (Schedule 6, Division 1) to make a standing order for a non-restricted medicine (which includes a clinical protocol). If the clinical protocol is for an orthoptist it may only be made an ophthalmologist (see Schedule 8, Part 4, Column 3).

A clinical protocol must be in writing and state the following information:

- a) the name of the prescriber;
- b) the place to which it relates;
- c) the class of persons who may administer a medicine under the protocol;
- d) the circumstances in which the protocol applies;
- e) 1 or more medicines to which the protocol applies;
- f) the way each medicine may be administered; and
- g) the day, no later than 2 years after the protocol is made, by which the protocol must be reviewed.

What transitional arrangements are in place for clinical protocols that were made under the Health (Drugs and Poisons) Regulation 1996 (HDPR)?

Section 253 of the Regulation provides for an existing clinical protocol that was made under the HDPR to be taken to be a clinical protocol under the MP Act until such time as the existing clinical protocol is revoked or expires.

What will happen in relation to orthoptist health management protocols that were made under the HDPR?

Under the HDPR, orthoptists were required to practice in accordance with a health management protocol. Under the Medicines Regulation, orthoptists who administer medicines to patients as part of their practice are required to have an ophthalmologist made clinical protocol that authorises the medicines they may administer. The Medicines Regulation includes transitional arrangements (in section 254) so that an existing health management protocol for an orthoptist that was made under the HDPR is taken to be a lawful clinical protocol applying to the orthoptist until the existing health management protocol is revoked or expires.

Additional documents which may be of interest:

- [Writing lawful prescriptions](#)
- [Departmental Standard Secure Storage of S8 Medicines](#)
- [Guide to Substance Management Plans.](#)

For further information

Queensland Health

Healthcare and Regulatory Approvals Unit

Email: HARU@health.qld.gov.au