

Queensland Health Departmental Standard

Monitored medicines – version 2

1 July 2024



Queensland
Government

Queensland Health Departmental Standard: Monitored medicines Version 2

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Version control

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Preface

The *Medicines and Poisons Act 2019* (the Act) establishes a contemporary framework for the regulation of medicines, poisons, pesticides and other prohibited substances in Queensland. This framework will impact a broad range of persons.

This framework includes three regulations (the Regulations):

- Medicines and Poisons (Medicines) Regulation 2021;
- Medicines and Poisons (Poisons and Prohibited Substances) Regulation 2021; and
- Medicines and Poisons (Pest Management Activities) Regulation 2021.

The Act authorises the chief executive of Queensland Health to make departmental standards in relation to matters regulated under the Act (section 233, Part 4, Chapter 7 of the Act).

A departmental standard outlines for professions and industries the mandatory expectations and specific requirements needed to ensure regulatory compliance with the Act and Regulations.

This Standard (Monitored Medicines Standard) has been made by the Director-General, Queensland Health in accordance with section 233 of the Act.

Object

'Monitored medicines' are medicines identified by Queensland Health as potentially presenting a high risk of harm to patients and the community as a result of overdose, dependence, misuse, and/or diversion. The list of monitored medicines is prescribed in Schedule 2, Part 4 of the Medicines and Poisons (Medicines) Regulation 2021 (Medicines Regulation).

The object of this Standard—the Monitored Medicines Standard—is to protect and improve patient health and wellbeing and reduce patient and community harms arising from the use of monitored medicines, by:

- promoting clinical collaboration between health practitioners treating patients with monitored medicines
- encouraging the delivery of safe, coordinated monitored medicine treatment.

Scope

Pursuant to sections 93 and 126 of the Medicines Regulation, this Standard applies to all health practitioners authorised to prescribe or dispense monitored medicines in Queensland.

Part	Application
Part 1 Prescribing monitored medicines	Part 1 applies if a prescriber prescribes a monitored medicine for dispensing or for giving a treatment dose for a patient i.e. if a prescriber directs a person, orally or in writing, to: <ul style="list-style-type: none">• dispense a monitored medicine for the treatment of a person• give a treatment dose of a monitored medicine for the treatment of a person.
Part 2 Dispensing monitored medicines	Part 2 applies if a dispenser dispenses a monitored medicine for a patient, irrespective of whether the prescription for the monitored medicine: <ul style="list-style-type: none">• was an oral or written prescription• was prescribed in Queensland or another jurisdiction.

Regulatory requirements

Part 1 - Prescribing monitored medicines

Part 1 applies if a prescriber prescribes a monitored medicine for dispensing or for giving a treatment dose for a patient i.e. if a prescriber directs a person, orally or in writing, to:

- dispense a monitored medicine for the treatment of a person
- give a treatment dose of a monitored medicine for the treatment of a person.

Outcome measure	Minimum requirements
<p>Outcome measure P1</p> <p>A patient who is currently registered on the Queensland Opioid Treatment Program (QOTP) is not prescribed a monitored medicine by a prescriber who is not the patient's QOTP service provider, unless the prescriber has explicit agreement from the QOTP service provider to prescribe the monitored medicine.</p>	<p>Minimum requirement P1-1</p> <p>A prescriber must not prescribe a monitored medicine for a patient currently registered on the QOTP unless:</p> <ol style="list-style-type: none">1. the prescriber is the patient's QOTP service provider; or2. the prescriber:<ol style="list-style-type: none">2.1. has agreement from the patient's QOTP service provider to prescribe the monitored medicine for the patient; and2.2. documents the details of that agreement; or3. if the prescriber reasonably believes it is urgent and essential to prescribe the monitored medicine for the patient's wellbeing, but is unable to contact the patient's QOTP service provider to obtain their agreement to do so—the prescriber:<ol style="list-style-type: none">3.1. prescribes an amount of the monitored medicine that is not more than 3 days' supply of the medicine or the smallest available size of a manufacturer's pack of the medicine (whichever is smallest); and3.2. documents:<ol style="list-style-type: none">3.2.1. the details of their attempt(s) to contact the QOTP service provider; and3.2.2. why they believed it was urgent and essential to prescribe the monitored medicine for the patient.

Part 2 - Dispensing monitored medicines

Part 2 applies if a dispenser dispenses a monitored medicine for a patient, irrespective of whether the prescription for the monitored medicine:

- is an oral or written prescription
- was prescribed in Queensland or another jurisdiction.

Outcome measure	Minimum requirements
<p>Outcome measure D1</p> <p>Dispensers are able to demonstrate the steps they have taken to reduce the risk of monitored medicine-related patient harm.</p>	<p>Minimum requirement D1-1</p> <p>A dispenser who holds significant concerns about the clinical appropriateness of dispensing a monitored medicine for a patient currently registered on the QOTP, must:</p> <ol style="list-style-type: none">1. attempt to communicate with the prescriber regarding their concerns prior to deciding whether to dispense the monitored medicine; and2. document:<ol style="list-style-type: none">2.1. the details of their concerns2.2. the details and outcome of their attempt(s) to communicate with the prescriber.

Glossary

Term	Meaning
dependence	As described, for each relevant substance, in the International Classification of Diseases, 11 th Revision (World Health Organization).
dispense	As defined in section 25(2) of the <i>Medicines and Poisons Act 2019</i> .
dispenser	A person authorised to dispense a monitored medicine.
diversion	Unlawful transfer of prescribed medication from legal sources to an individual it was not prescribed for.
give a treatment dose	As defined in section 25(3) of the <i>Medicines and Poisons Act 2019</i> .
health practitioner	As defined in Schedule 1, Dictionary of the <i>Medicines and Poisons Act 2019</i> .
misuse	The use of a monitored medicine: <ul style="list-style-type: none"> • for non-therapeutic purposes; or • without a valid prescription; or • in a way that is not consistent with the prescriber's instructions (whether inadvertently or deliberately).
monitored medicine	A medicine prescribed in Schedule 2, Part 4 of the Medicines and Poisons (Medicines) Regulation 2021.
overdose	When too much of a monitored medicine is taken, resulting in a toxic effect on the body. Can be fatal, non-fatal, intentional and/or accidental.
patient	A person seeking or receiving therapeutic treatment or the supply or administration of a medicine.
prescriber	A person authorised to prescribe a monitored medicine.
prescription	As defined in Schedule 1, Dictionary of the <i>Medicines and Poisons Act 2019</i> .
QOTP / Queensland Opioid Treatment Program	The Queensland Opioid Treatment Program (QOTP) is a program administered in Queensland for the treatment of persons with opioid dependence. It aims to reduce health, social and economic harms to individuals and the community. Queensland's Department of Health has regulatory oversight of the QOTP.

Term	Meaning
QOTP service provider	<p>A patient's 'QOTP service provider' includes both:</p> <ul style="list-style-type: none"> • the prescriber with whom the patient is registered on the QOTP; and • any other health practitioner who both: <ul style="list-style-type: none"> – works within the same clinic/service/practice as that prescriber; and – is authorised to prescribe approved opioids for the patient on the QOTP.

A term used in this Standard that is defined in the Act or the Medicines Regulation, and is not referred to in this glossary, has the meaning stated in the Act or Medicines Regulation.