# Queensland Health Departmental Standard

## Monitored medicines – version 1

27 September 2021

Queensland Government

## Queensland Health Departmental Standard: Monitored medicines
## Version 1

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### For more information contact:

Chief Medical Officer and Healthcare Regulation Branch, Prevention Division, Department of Health, GPO Box 48, Brisbane QLD 4001, email HLIU@health.qld.gov.au.

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# Contents

# 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 as a result of misuse, abuse, diversion, substance use disorder and/or overdose. 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 harms arising from the use of monitored medicines, by encouraging early identification and appropriate management of monitored medicine-related health risks.

This Standard aims to achieve this object by requiring prescribers and dispensers to document evidence of the steps they have taken to:

- ensure the prescribing and dispensing of monitored medicines for patients is clinically justified, safe and appropriate
- identify and mitigate the risks of monitored medicine-related patient harm, including (but not limited to) the risks of misuse, abuse, diversion, substance use disorder and/or overdose
- ensure patients are informed of the risks and benefits associated with the use of monitored medicines.

# 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**<br>Prescribing monitored medicines | Part 1 applies if a prescriber prescribes a monitored medicine for dispensing or giving a treatment dose for a patient i.e. if a prescriber directs a person, orally or in writing, to:<br>• dispense a monitored medicine for the treatment of a person<br>• give a treatment dose of a monitored medicine for the treatment of a person. |
| **Part 2**<br>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:<br>• was an oral or written prescription<br>• was prescribed in Queensland or another jurisdiction. |

## In this Standard, 'high-risk clinical scenarios' for patients are defined as follows:

| Scenario | Meaning |
|---|---|
| **Scenario A**<br>Patient currently registered on the Queensland Opioid Treatment Program | A patient currently registered on the Queensland Opioid Treatment Program (irrespective of whether the patient has been 'picking up' their doses). |
| **Scenario B**<br>Patient previously registered on the Queensland Opioid Treatment Program | A patient who has previously been registered on the Queensland Opioid Treatment Program. |
| **Scenario C**<br>Patient receiving monitored medicines from multiple prescribers | A patient who in the previous 90 days has been dispensed monitored medicine prescriptions written by four (4) or more prescribers. |
| **Scenario D**<br>Increased patient overdose risk—average total daily opioids of 100mg OME or greater | A patient whose average total daily opioid dose:<br>• is currently 100mg OME or greater—based on the amount of opioids dispensed over the previous 90 days; or<br>• will be 100mg OME or greater—based on the amount of opioids dispensed over the previous 90 days (if any) and the amount of opioids proposed to be prescribed or dispensed. |
| **Scenario E**<br>Increased patient overdose risk—opioid and benzodiazepine/z-drug combination | A patient who in the previous 90 days has been dispensed:<br>• an opioid and a benzodiazepine/z-drug; or<br>• an opioid—and it is proposed they are prescribed or dispensed a benzodiazepine/z-drug; or<br>• a benzodiazepine/z-drug—and it is proposed they are prescribed or dispensed an opioid. |
| **Scenario F**<br>Patient receiving an opioid or benzodiazepine/z-drug for the first time in 90 days | A patient who in the previous 90 days has **not** been dispensed:<br>• an opioid (including tramadol and codeine-containing medicines)—and it is proposed they are prescribed or dispensed an opioid; or<br>• a benzodiazepine/z-drug—and it is proposed they are prescribed or dispensed a benzodiazepine/z-drug. |

# Regulatory requirements

## Part 1 - Prescribing monitored medicines

Part 1 applies if a prescriber prescribes a monitored medicine for dispensing or 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 | |
|---|---|---|---|
| **P1** | Prescribers must take reasonable steps to confirm the patient's identity. | P1-1 | A prescriber who prescribes a monitored medicine for a patient must be able to produce documentation evidencing the reasonable steps that were taken, prior to writing the prescription, to confirm the patient's identity. |
| **P2** | Prescribers must be able to justify their decision(s) to prescribe a monitored medicine for a patient—including when accepting the transfer of care from another prescriber. | P2-1 | A prescriber who prescribes a monitored medicine for a patient must document their initial and ongoing clinical assessments of the patient, including the identification of health risks. |
| | | P2-2 | A prescriber who prescribes a monitored medicine for a patient must document their initial and updated treatment plan(s) for prescribing the monitored medicine, including (at a minimum) the following information:<br>a. the clinical justification for treatment with the monitored medicine; and<br>b. the clinical justification for the prescribed dose of the monitored medicine; and<br>c. when the next review of the patient is planned to be undertaken. |

| Outcome measure | Minimum requirements |
|---|---|
| **P3** Except for limited circumstances, prescribers must not prescribe a monitored medicine to a patient currently registered on the Queensland Opioid Treatment Program (QOTP) unless they have explicit agreement from the QOTP service provider to do so. | P3-1 If high-risk clinical scenario ***Scenario A:*** *Patient currently registered on the Queensland Opioid Treatment Program* applies, the prescriber must not prescribe a monitored medicine to the patient unless:<br>a. the prescriber (or the Queensland Health Alcohol and Other Drug Service for which the prescriber works) is the patient's QOTP service provider; or<br>b. the prescriber and QOTP service provider establish a Joint Prescribing Plan (JPP); and<br>i. the prescriber documents the terms of the JPP including (at a minimum) the following information:<br>A. the monitored medicine(s) to be prescribed by the prescriber; and<br>B. the formulation and maximum daily dose of the monitored medicine(s) to be prescribed by the prescriber; and<br>C. the risk mitigation strategies implemented to address the risk of monitored medicine-related patient harm; and<br>D. the date on which the JPP will cease or be reviewed by the prescriber and QOTP service provider; and<br>ii. the prescriber prescribes in accordance with the JPP; or<br>c. if the prescriber is unable to contact the QOTP service provider to establish a JPP or vary the terms of an established JPP—the prescriber reasonably believes it is urgent and essential to prescribe the monitored medicine(s) for the patient's wellbeing, and:<br>i. the prescriber prescribes in a manner reasonable in the urgent circumstance; and<br>ii. the prescriber documents:<br>A. the details of their attempt(s) to contact the QOTP service provider to establish a JPP or vary the terms of the established JPP; and<br>B. why they believed it was urgent and essential to prescribe the monitored medicine(s); and<br>C. the risk mitigation strategies implemented to address the risk of monitored medicine-related patient harm. |

| Outcome measure | | Minimum requirements | |
|---|---|---|---|
| **P4** | Prescribers must be able to demonstrate the steps they have taken to reduce the risk of monitored medicine-related patient harm. | P4-1 | A prescriber who prescribes a monitored medicine for a patient must document the risk mitigation strategies implemented to address the risk of monitored medicine-related patient harm if any of the following high-risk clinical scenarios apply:<br>• ***Scenario B:*** *Patient previously registered on the Queensland Opioid Treatment Program*<br>• ***Scenario C:*** *Patient receiving monitored medicines from multiple prescribers*<br>• ***Scenario D:*** *Increased patient overdose risk—average total daily opioids of 100mg OME or greater*<br>• ***Scenario E:*** *Increased patient overdose risk—opioid and benzodiazepine/z-drug combination*<br>• ***Scenario F:*** *Patient receiving an opioid or benzodiazepine/z-drug for the first time in 90 days* |
| **P5** | Patients must be provided with information about the risks and benefits of monitored medicine use. | P5-1 | A prescriber who prescribes a monitored medicine for a patient must document evidence that the patient has been informed—in a way that the patient understands—about the risks and benefits of the monitored medicine being prescribed. |
| **P6** | Prescribers must document circumstances where they have prescribed a monitored medicine under duress. | P6-1 | If a prescriber prescribes a monitored medicine under duress, the prescriber must document:<br>a. details of the duress experienced; and<br>b. details of the actions they took in response to the duress. |

# 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:

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

| Outcome measure | | Minimum requirements | |
|---|---|---|---|
| **D1** | Dispensers must be able to demonstrate the steps they have taken to reduce the risk of monitored medicine-related patient harm. | D1-1 | In relation to a monitored medicine proposed to be dispensed for a patient, the dispenser must document details of:<br>a. any medicine-related problem identified; and<br>b. any clinical intervention performed. |
| | | D1-2 | If any of the following high-risk clinical scenarios apply:<br>• ***Scenario A:*** *Patient currently registered on the Queensland Opioid Treatment Program*<br>• ***Scenario B:*** *Patient previously registered on the Queensland Opioid Treatment Program*<br>• ***Scenario C:*** *Patient receiving monitored medicines from multiple prescribers*<br>• ***Scenario D:*** *Increased patient overdose risk—average total daily opioids of 100mg OME or greater*<br>• ***Scenario E:*** *Increased patient overdose risk—opioid and benzodiazepine/z-drug combination*<br>• ***Scenario F:*** *Patient receiving an opioid or benzodiazepine/z-drug for the first time in 90 days*<br>and the dispenser holds significant concerns about the clinical appropriateness of dispensing the monitored medicine, the dispenser:<br>a. must attempt to communicate with the prescriber regarding their concerns prior to deciding whether to dispense the monitored medicine; and<br>b. must document the details and outcome of their attempt(s) to communicate with the prescriber. |

| Outcome measure | | Minimum requirements | |
|---|---|---|---|
| **D2** | Decisions not to dispense a monitored medicine due to safety concerns must be documented. | D2-1 | If a dispenser decides not to dispense a monitored medicine for a patient because they determine it is clinically inappropriate to do so, the dispenser must document the following information (if they have not already):<br>a. their clinical justification for the decision not to dispense; and<br>b. the information they provided to the patient regarding the decision not to dispense; and<br>c. the information they provided to the prescriber regarding the decision not to dispense. |
| **D3** | Dispensers must document circumstances where they have dispensed a monitored medicine under duress. | D3-1 | If a dispenser dispenses a monitored medicine under duress, the dispenser must:<br>a. document details of the duress experienced; and<br>b. advise the prescriber of the duress; and<br>c. document details of the actions they took in response to the duress. |

# Glossary

| Term | Meaning |
|---|---|
| abuse | Deliberate use of a monitored medicine for non-therapeutic purposes. |
| administer | As defined in section 26 of the *Medicines and Poisons Act 2019*. |
| Alcohol and Other Drugs Service | Services, provided by Queensland Health, which provide people with a range of interventions that influence and support the decision to reduce or cease harmful substance use. |
| benzodiazepines | Includes all benzodiazepines. |
| clinical intervention | In relation to **Minimum Requirement D1-1**—means any professional activity by the dispenser directed towards improving the quality use of medicines and resulting in a recommendation for a change in the patient's medication therapy, means of administration or medication-taking behaviour.[1] |
| dispense | As defined in section 25(2) of the *Medicines and Poisons Act 2019*. |
| dispenser | A person authorised to dispense a monitored medicine. |
| diversion | Unlawful transfer of prescribed medication from legal sources to individuals it was not prescribed for. |

[1] Adapted with permission from the Pharmaceutical Society of Australia, from: Pharmaceutical Society of Australia. Guidelines for pharmacists performing clinical interventions. A.C.T.: PSA; 2018.

| Term | Meaning |
|---|---|
| duress | A circumstance:<br>(a) where an act is reasonably necessary in order to resist actual and unlawful violence threatened to a person, or to another person in the person's presence; or<br>(b) where—<br>(i) a person does or omits to do an act in order to save himself or herself or another person, or his or her property or the property of another person, from serious harm or detriment threatened to be inflicted by some person in a position to carry out the threat; and<br>(ii) the person doing the act or making the omission reasonably believes he or she or the other person is unable otherwise to escape the carrying out of the threat; and<br>(iii) doing the act or making the omission is reasonably proportionate to the harm or detriment threatened. |
| give a treatment dose | As defined in section 25(3) of the *Medicines and Poisons Act 2019.* |
| health practitioner | As defined in Schedule 1, Dictionary of the *Medicines and Poisons Act 2019.* |
| high-risk clinical scenario | As defined in the 'Scope' of this Standard. |
| Joint Prescribing Plan | A plan, formulated and agreed upon jointly by a prescriber and a Queensland Opioid Treatment Program (QOTP) service provider, for how the prescriber will manage the prescribing of monitored medicines (other than QOTP medicines) to a specific patient. |
| JPP | See 'Joint Prescribing Plan'. |
| medicine | As defined in section 11 of the *Medicines and Poisons Act 2019.* |
| medicine-related problem | In relation to **Minimum Requirement D1-1**—means an event or circumstance involving monitored medicine treatment that actually or potentially interferes with the patient experiencing an optimum outcome of medical care.[1] |
| misuse | Includes the use of monitored medicines:<br>(a) for non-therapeutic purposes; or<br>(b) without a valid prescription; or<br>(c) 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. |

| Term | Meaning |
|---|---|
| OME | Oral morphine equivalent—an approximate equivalent dose of oral morphine. |
| 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 | Means a person seeking or receiving therapeutic treatment or the supply or administration of a medicine. |
| prescribe | As defined in Schedule 1, Dictionary of the *Medicines and Poisons Act 2019*. |
| prescriber | A person authorised to prescribe a monitored medicine. |
| prescription | As defined in Schedule 1, Dictionary of the *Medicines and Poisons Act 2019*. |
| QOTP | See 'Queensland Opioid Treatment Program'. |
| QOTP service provider | A prescriber or Queensland Health Alcohol and Other Drugs Service with whom a patient is registered on the Queensland Opioid Treatment Program (QOTP). |
| Queensland Opioid Treatment Program | The Queensland Opioid Treatment Program (QOTP) is a program administered in Queensland for the treatment of persons dependent on opioids. It aims to reduce health, social and economic harms to individuals and the community. Queensland's Department of Health has clinical and regulatory oversight of the QOTP. |
| substance use disorder | As defined in the American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders (DSM-5). |
| supply | As defined in Schedule 1, Dictionary of the *Medicines and Poisons Act 2019*. |
| treatment plan | Documentation that sets out the proposed treatment regimen for an individual patient. |
| z-drug | Zolpidem and zopiclone. |

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.