Monitored Medicines Standard Companion Document

Version 1, September 2021

Queensland Government

Contents

Preface

The *Medicines and Poisons Act 2019* and subordinate Medicines and Poisons (Medicines) Regulation 2021 require health practitioners in Queensland to comply with Departmental Standard: Monitored Medicines (the Standard) if prescribing a monitored medicine for dispensing or giving a treatment dose for a patient, or if dispensing a monitored medicine for a patient.

The object of this document—the Monitored Medicines Standard Companion Document—is to assist health practitioners in complying with the Standard by:

- providing general information and guidance aligning directly with each minimum requirement articulated in the Standard
- providing examples of how compliance with each minimum requirement could potentially be demonstrated.

This document (Monitored Medicines Standard Companion Document), version 1, 16 September 2021 has been approved by Acting Deputy Director-General and Chief Medical Officer, Prevention Division, Queensland Health.

Using this document

This document should be read in conjunction with Departmental Standard: Monitored Medicines (the Standard).

References to 'compliance' in this document relate only to compliance with the Standard. Health practitioners must also comply with any relevant requirements in the *Medicines and Poisons Act 2019* and its subordinate regulations and associated instruments, and any other relevant legislation.

The general guidance in this document aligns with contemporary best practice approaches, however guidance is not exhaustive and may not be suitable for all patients.

- Health practitioners must apply their professional judgement to determine the most appropriate strategies to use for each patient.
- This document contains general guidance. Health practitioners should consider current professional practice standards and evidence in interpreting and applying guidance in this document.

The following terminology is used in this document:

- Must / must not - These terms indicate mandatory requirements.
- Should / should not - These terms indicate recommendations.
- May / may not - These terms indicate optional actions.

Different terms can be used to describe persons who receive and access healthcare, including 'patient', 'consumer' and 'client'. In this document, the term 'patient' is used.

The term 'dispenser' (rather than 'pharmacist') is generally used in this document. This is because any person authorised to dispense monitored medicines must comply with the Standard when dispensing monitored medicines, and this may include persons other than pharmacists e.g. medical practitioners.

Background

What are monitored medicines?

'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 specified in Schedule 2, Part 4 of the Medicines and Poisons (Medicines) Regulation 2021 (the MPMR).

What is the Monitored Medicines Standard?

The Monitored Medicines Standard (the Standard) is a departmental standard made by the chief executive of Queensland Health, under the *Medicines and Poisons Act 2019*. It sets out mandatory minimum requirements Queensland prescribers and dispensers must comply with if prescribing a monitored medicine for dispensing or giving a treatment dose for a patient, or if dispensing a monitored medicine for a patient.

The object of the 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.

Who must comply with the Standard?

All persons authorised to prescribe or dispense a monitored medicine for a patient must comply with the Standard.

Where there are multiple dispensers involved in dispensing a monitored medicine for a patient, the dispenser who makes the dispensing record must comply with the Standard.

When does the Standard apply?

Pursuant to sections 93 and 126 of the MPMR, health practitioners must comply with the Standard in the following circumstances. Failure to comply with relevant minimum requirements when required may result in regulatory action being taken by Queensland Health.

Application of Part 1 of the Standard: Prescribing monitored medicines

	Application	Examples
When is compliance with Part 1 required?	Compliance with Part 1 is required 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. Part 1 applies: • irrespective of whether the patient ordinarily resides in Queensland or another jurisdiction • irrespective of the treatment setting e.g. community, hospital, residential aged care facility.	Compliance with Part 1 would be required if: • A general practitioner writes a prescription for a monitored medicine that is to be dispensed by a pharmacist. • A medical practitioner in a hospital writes a post-operative discharge prescription for three days' supply of a monitored medicine to be dispensed by a pharmacist. • A nurse practitioner in a prison setting directs a registered nurse to provide a patient with five days' worth of a monitored medicine on their discharge from prison.
When is compliance with Part 1 **not** required?	Compliance with Part 1 is **not** required if a person prescribes a monitored medicine: • to be administered to a patient; or • for an animal.	Compliance with Part 1 would **not** be required if: • An orthopaedic surgeon writes up an order in a hospital medical chart for a monitored medicine to be administered to a patient. • An endorsed midwife orally directs a nurse to administer a monitored medicine to a patient.

Application of Part 2 of the Standard: Dispensing monitored medicines

	Application	Examples
When is compliance with Part 2 required?	Compliance with Part 2 is required if a dispenser dispenses a monitored medicine for a patient. Part 2 applies: • irrespective of whether the prescription for the monitored medicine was an oral or written prescription • irrespective of whether the monitored medicine was prescribed in Queensland or another jurisdiction • for each occasion a monitored medicine is dispensed (including each individual repeat prescription that is dispensed).	Compliance with Part 2 would be required if: • A pharmacist receives an oral or written prescription, processes it, and supplies a medicine to a patient. • A pharmacist dispenses a monitored medicine on a repeat prescription. • A medical practitioner dispenses a monitored medicine on prescription from another medical practitioner.
When is compliance with Part 2 **not** required?	Compliance with Part 2 is **not** required if a person: • gives a dispensed monitored medicine to a patient under staged supply arrangements (i.e. provides dispensed medicines to a patient in instalments as per the prescriber's instructions). • dispenses a monitored medicine for an animal.	Compliance with Part 2 would **not** be required if after initially dispensing a monitored medicine, a pharmacist provides the medicine to the patient in instalments as instructed by the prescriber e.g. • The patient collects the medicine once a week. • The patient attends the pharmacy for daily supervised dosing. Note, however, that in the above examples, compliance with Part 2 would be required when the medicine is initially dispensed.

Guidance: general

Prioritising patient safety

- At all times, prescribers and dispensers must make the health, safety and wellbeing of the patient their priority.
- Prescribers and dispensers should:
  - demonstrate responsibility and accountability for all decisions made and actions taken
  - apply professional judgement to the quality use of monitored medicines and management of associated risks.

Avoiding patient harm

- Prescribers and dispensers should be cognisant of the potential for inadvertently causing patient harm through:
  - the 'squeezed balloon' or 'substitution' effect: health practitioners inadvertently shifting the burden of harm in relation to a monitored medicine to other licit or illicit substances e.g. as a result of refusing to prescribe or dispense a monitored medicine
  - the 'chilling effect': health practitioners becoming reluctant to appropriately provide monitored medicines to patients, potentially resulting in patients receiving sub-optimal care, reduced access to treatment and/or poorer health outcomes [1, 2].
- Abruptly ceasing or decreasing a patient's monitored medicine treatment may cause serious patient harm, including seizures and death.
  - Health practitioners should make reasonable attempts to engage with patients before deciding to end a therapeutic relationship or to refuse monitored medicine treatment.
  - If a health practitioner is ending the therapeutic relationship, they should (where possible) ensure the patient is adequately informed of the decision, and facilitate arrangements for the patient's continuing care [3, 4].

Delivering patient-centred care

- At all times, prescribers and dispensers of monitored medicines should provide patient-centred care: healthcare that is respectful of, and responsive to, the preferences, needs and values of patients [5, 6].
- Providing patient-centred care is particularly important for patients from vulnerable, marginalised or disadvantaged groups [5]. Such groups may include, but are not limited to:
  - First Nations peoples
  - patients from rural and remote areas
  - patients from culturally and linguistically diverse backgrounds
  - patients with substance use disorders
  - patients with disabilities, mental health conditions or impaired decision-making capacity

- lesbian, gay, bisexual, transgender, intersex or queer (LGBTIQ+) patients
- patients in contact with the criminal justice system
- other patients vulnerable to (or with lived experience of) stigma and discrimination [5, 7].

Providing collaborative care

- Prescribers and dispensers share responsibility for:
  - identifying and managing monitored medicine-related patient risks
  - explaining the risks and benefits of monitored medicines prescribed to patients.
- Collaboration does not alter a health practitioner's accountability for the care they provide to patients.

Using QScript

- The *Medicines and Poisons Act 2019* provides for the establishment of the 'monitored medicines database', allowing for the implementation of real-time prescription monitoring in Queensland. The database—named 'QScript'—is a read-only real-time prescription monitoring system which allows authorised health practitioners to review a patient's monitored medicine prescription history at the point of care.
- Although the information in QScript is expected to assist health practitioners in complying with the Standard, they must not rely solely on QScript to identify high-risk clinical scenarios or patients at risk of harm, as:
  - QScript does not contain all relevant clinical information about patients
  - risks of harm or drug-seeking behaviours may arise before a patient reaches the level of triggering an alert in QScript.
- Use of QScript is not a substitute for obtaining clinical history or undertaking clinical assessments of patients.

Record-keeping

- Health practitioners should maintain clear, accurate and contemporaneous records of the care they provide.
- Access to clinical records may be granted to other persons/entities (e.g. the patient, Queensland Health, other government entities etc.) under privacy laws and other legislation.
- Aside from the automated upload of prescribing and dispensing data:
  - QScript is a read-only system **for health practitioners.**
  - Health practitioners cannot record information in QScript.
- In accordance with section 224 of the MPMR, health practitioners keeping a record to comply with the Standard (either manually or electronically), must, during the period for which the record must be kept, take all reasonable steps to ensure the record is:
  - kept in a retrievable form; and
  - kept securely to ensure it can not be altered, obscured, deleted or removed without detection.

If the record is kept electronically, the record must be preserved in a retrievable form in the event of equipment failure or other catastrophes. It is an essential activity of health practitioners to have back-up procedures in place.

- The documentation requirements articulated in the Standard reflect minimum expectations in relation to record-keeping. Health practitioners may need to document additional information beyond what the Standard requires in order to make an appropriate record of the care they have provided and/or to meet relevant professional standards, codes and expectations in relation to record-keeping practices.

'High-risk clinical scenarios'

- The six 'high-risk clinical scenarios' articulated in the Standard identify circumstances where patients may be at risk of serious harms associated with the use of monitored medicines.
  - The identification of the scenarios should prompt prescribers and dispensers to consider implementing appropriate strategies to reduce any risks. This should be done in consultation with the patient.
  - Health practitioners should familiarise themselves with the scenarios and their obligations under the Standard, to improve patient safety and to ensure they are compliant with the Standard.
- Where possible, the presence of high-risk clinical scenarios for individual patients will be highlighted in QScript by an alert. However, prescribers and dispensers should not rely entirely on QScript to identify patients at risk of harm.
- It is important to recognise and address high-risk clinical scenarios early, as early identification can lead to improved treatment outcomes [8, 9].
- For guidance on each of the six high-risk clinical scenarios in the Standard, please see **Appendix A.**

Guidance: minimum requirements

Part 1: Prescribing monitored medicines

Outcome Measure P1

Prescribers must take reasonable steps to confirm the patient's identity.

Minimum Requirement 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.

General guidance

- It is not necessary for the prescriber themselves to confirm the patient's identity to be compliant with this minimum requirement; confirmation can be undertaken by another person (a delegate) e.g. another prescriber, a practice manager, reception staff, clinic nurse. However, prior to writing a prescription for a monitored medicine, the prescriber must be satisfied:
  - that reasonable steps have been taken to confirm the patient's identity; and
  - that they are able to produce documentation evidencing those reasonable steps.
- Where possible, it is recommended that photographic identification (ID) is sighted by the prescriber/their delegate to confirm the patient's identity e.g.
  - current Australian photographic driver licence, Adult Proof of Age or Photo Identification Card
  - other current photographic licence cards issued by a government agency e.g. Marine Licence Indicator, Industry Authority, firearms licence etc.
  - current school or university student ID card
  - current Australian or international passport or Australian ImmiCard
  - current Defence Force or Police Service photographic ID card
  - prisoner identification card certified by a corrective services officer.
- Medicare cards/numbers may assist in confirming a patient's identity, but they should not be relied upon as the sole evidence of identity as:
  - Medicare cards do not have photographs, making it possible for a person to fraudulently present another person's Medicare card as their own.
  - A person may have more than one Medicare number.
  - Some patients will not have a Medicare number e.g. international visitors [10, 11].
- Where possible, it is preferable that the patient's legal name (as opposed to nicknames) and Individual Healthcare Identifier is recorded in clinical software and on prescriptions, as this will

promote data integrity within QScript, which will help ensure health practitioners using QScript have access to high quality information to inform their clinical decision-making.

Drug-seeking behaviour and patient identity

- Some patients may attempt to obscure their identity in an attempt to obtain monitored medicines, by:
  - using an alias
  - presenting with false/another person's ID
  - refusing to provide ID on request
  - falsely claiming they have no ID or other documents to confirm their identity e.g. claiming they lost or forgot their wallet or that their ID has been stolen
  - producing fraudulent documents [12, 13, 14].
- Prescribers (and their delegates) should be alert to these possibilities when attempting to confirm the identity of patients, particularly if other potential indicators of drug-seeking behaviour and/or monitored medicine misuse are evident (see Appendix B).

Using QScript to verify a patient's monitored medicine history

- QScript information may assist prescribers in verifying a patient's reported monitored medicines history. This may help prescribers confirm a patient's identity.
- When searching for or viewing a patient's record in QScript, prescribers should consider whether the information they find (including a finding of 'no matching record found') is consistent with the patient's known or reported clinical history. If this is not the case, prescribers should consider the possibility that:
  - the patient may have a QScript record under another name e.g. an alias, pseudonym, maiden name
  - duplicate and/or erroneous QScript records may have been created in the past, resulting in the prescriber seeing an incomplete patient record
  - incorrect patient details have been used to search for the patient e.g. as a result of typos, incorrect date of birth, alternative spellings of names
  - the information provided by the patient was inaccurate
  - the patient has not been correctly identified.

Patients with no documentation to confirm their identity

- Some patients will genuinely have no documents to assist in confirming their identity.
- If a patient is unable to present ID, the prescriber should attempt to cross-reference available information with information from other sources to confirm the patient's identity—see Compliance guidance, below.

Special considerations for technology-based consultations [15, 16, 17]

Prescribers undertaking technology-based consultations should attempt to verify the patient's identity by using at least three patient identifiers e.g. by asking the patient to provide their:

- full name;
- address; and
- date of birth.

Compliance guidance

For a prescriber to have met **Minimum Requirement P1-1:**

One or more of the following should be evident:		
☐	Documented evidence that photographic identification (ID) has been sighted by the prescriber or their delegate.	For example: • a notation has been made indicating the patient's photographic ID has been sighted by the prescriber or their delegate; or • the patient's photographic ID details have been recorded e.g. ID type, ID number, expiry date; or • the patient's photographic ID has been scanned or photocopied.
☐	Documented evidence: • that the patient was unable to present photographic ID; and • that reasonable attempts were made to confirm the patient's identity by cross-referencing information from different sources.	For example, a notation has been made indicating the patient was unable to present photographic ID and the prescriber has documented they have cross-referenced the clinical history provided by the patient with information obtained from collateral sources e.g. • information held in QScript, My Health Record, The Viewer, CIMHA; or • information from a previous prescriber or other treating health practitioner.
☐	For technology-based consultations—documented evidence that reasonable steps were taken to confirm the patient's identity.	For example, a notation has been made indicating the patient correctly provided their full name, address and date of birth.
☐	Documented evidence from the prescriber's place of practice that written policies, procedures and/or protocols designed to ensure consistent and correct identification of patients are in place and are adhered to.	

Outcome Measure 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.

Minimum Requirement 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.

General guidance

- Prescribers must document their clinical assessments:
  - regardless of whether the patient is new, inherited or a regular/returning patient
  - regardless of whether the prescriber is consulting the patient face-to-face or via a technology-based consultation.
- Monitoring and assessment of a patient's clinical presentation and treatment progress should be an ongoing process.

Identification of health risks

- Identification of risks does not necessarily warrant cessation of prescribing, but it does provide an opportunity for the prescriber and patient to engage in an open and honest discussion and to work together to minimise risks and prevent harm.
- Risks should be re-assessed at each review to determine if there has been any change in the patient's risk profile.
- When assessing for health risks, prescribers should be alert to potential indicators of drug-seeking behaviour and/or monitored medicine misuse (see Appendix B).

Special considerations for technology-based consultations [16, 18]

- Prescribers undertaking technology-based consultations should consider whether the setting sufficiently allows them to undertake comprehensive assessments of the patient and identify health risks.
- If in doubt about whether a technology-based consultation is clinically appropriate, prescribers should attempt to organise a face-to-face consultation, to ensure appropriate assessments and direct physical examinations (if required) can occur.
- Prescribers conducting technology-based consultations with a patient should document (in addition to standard record-keeping requirements):
  - their rationale for undertaking a technology-based consultation
  - any concerns regarding the clinical appropriateness of doing so
  - any issues during the consultation that may have compromised their ability to assess the patient e.g. poor-quality image or sound.

Compliance guidance

For a prescriber to have met Minimum Requirement P2-1:

One or more of the following should be evident:		
☐	The prescriber has documented their initial and ongoing identification of the patient's concerns, needs, priorities and/or goals.	
☐	The prescriber has documented their Initial and ongoing biopsychosocial patient assessments.	For example: • biomedical e.g. underlying conditions, medical history and pharmacotherapy • psychological e.g. beliefs, mood, sleep, attitudes • social e.g. role of relationships, work, other life events.
☐	The prescriber has documented their initial and ongoing assessments of the patient's risk profile.	For example: • overdose risks (including accidental and intentional overdoses) • substance use disorder risks • drug-seeking behaviour and/or monitored medicine misuse (see Appendix B). • age-related risks • medicine-related risks • risks associated with co-morbid health conditions e.g. hepatic or renal impairment, mental health issues or other relevant medical conditions.
☐	The prescriber has used validated clinical tools to establish baseline levels of functioning and/or to assess the patient's progress to determine ongoing effectiveness of the monitored medicine.	For example: • Opioid Risk Tool • Routine Opioid Outcome Monitoring (ROOM) tool • Alcohol, Smoking and Substance Involvement Screening Test (ASSIST) • Indigenous Risk Impact Screen (IRIS) • Mental State Examination (MSE) • 5 As of analgesia therapy • Depression, Anxiety Stress Scale (DASS) • Pain, Enjoyment of Life and General Activity Scale (PEG Scale) • Epworth Sleepiness Scale (ESS)

☐	The prescriber has documented the patient's diagnosis.	For example: • a definitive diagnosis • differential diagnoses • confirmation of a diagnosis previously made by another practitioner.
☐	The prescriber has obtained collateral information from relevant sources.	For example: • information from other/previous treating health practitioners, including pharmacists • results of diagnostic investigations (e.g. imaging results, blood tests) • information contained in QScript, My Health Record, The Viewer, CIMHA etc.
☐	The prescriber has documented details of previous and/or additional treatment strategies used.	For example: • physical therapies e.g. physiotherapy, occupational therapy • psychological therapies e.g. cognitive behavioural therapy (CBT) or other psychological therapies, sleep hygiene education, relaxation and/or mindfulness techniques • other medications e.g. trialling the patient with non-opioid medications e.g. paracetamol or non-steroidal anti-inflammatory drugs (NSAIDS).
☐	The prescriber has documented details of the diagnostic investigations they have undertaken or organised.	
☐	The prescriber has documented their assessment of the patient's experience of and compliance/engagement with the monitored medicines treatment regimen.	

Minimum Requirement 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:

a. the clinical justification for treatment with the monitored medicine; and
b. the clinical justification for the prescribed dose of the monitored medicine; and
c. when the next review of the patient is planned to be undertaken.

General guidance

- A treatment plan must be documented for all patients being prescribed a monitored medicine:
  - regardless of whether the patient is new, inherited or a regular/returning patient
  - regardless of whether the prescriber is consulting the patient face-to-face or via a technology-based consultation.
- Treatment plans should contain an exit strategy so both prescriber and patient are clear about what is intended if the monitored medicine does not achieve agreed treatment goals and/or improve patient outcomes.
- Prescribers treating patients who have been on long-term monitored medicine treatment should regularly re-evaluate the continued use of the medicine in the context of the patient's clinical condition, treatment goals, and the risks and benefits of ongoing use.

Compliance guidance

For a prescriber to have met Minimum Requirement P2-2, they must have documented the following information:

Their clinical justification for treatment with the monitored medicine. One or more of the following should be evident:		
☐	The prescriber has documented details of the clinical condition being treated with the monitored medicine.	For example: • the diagnosis for which the monitored medicine is being prescribed; or • the clinical symptoms which it is hoped the monitored medicine will alleviate.
☐	The prescriber has documented the goals of treatment with the monitored medicine.	For example: • the specific functional goals it is hoped the monitored medicine will help the patient achieve; or • the level of pain reduction it is hoped the monitored medicine will achieve.

☐	The prescriber has documented why commencement of / continued treatment with the monitored medicine is justified.	For example: • alternative pharmacological and non-pharmacological treatment options have been explored and have failed, are contraindicated, not tolerated or are otherwise inappropriate; or • the prescriber and patient have agreed to a monitored medicine trial, and the prescriber has documented the trial length, goals of treatment and exit plan; or • the decision to prescribe the monitored medicine was made following consideration of recommendations / input from relevant specialists or clinical guidelines; or • continued / long-term monitored medicine prescribing is justified based on the patient's response to treatment e.g. functional improvements.

Their clinical justification for the prescribed dose of the monitored medicine.
One or more of the following should be evident:

☐	The prescriber has documented why the particular dose was chosen.	For example: • the decision to prescribe a particular dose was made following consideration of recommendations / input from relevant specialists or clinical guidelines; or • objective clinical assessments supported the use of the dose to maintain or promote patient function.
☐	The prescriber has documented why the patient's dose is increasing / decreasing / staying the same.	For example: • the dose is increasing/decreasing/staying the same due the patient's response to treatment e.g. functional improvements, side effects etc.; or • the patient is being maintained on the same dose at this time pending the results of diagnostic investigations; or • the patient's dose has been temporarily increased due to an acute flare-up of symptoms.
☐	The prescriber has documented the specific plan for the patient's dose.	For example: • slow tapering by [x}% per month; or • increase by [x] mg every [x] weeks until symptoms resolve; or • time-limited trial at a specific dose.

When the next review of the patient is planned to be undertaken.
One or more of the following should be evident:

☐	The prescriber has documented the specific date on which they intend to review the patient.	
☐	The prescriber has documented the approximate timeframe within which they intend to review the patient.	For example: • see pt in 1/52; or • review in 4 weeks to assess impact on function.
☐	The prescriber has documented the specific triggers which would warrant review of the patient.	For example: • patient to be reviewed after report received from [other health practitioner]; or • patient to contact prescriber for review if pain has not reduced by [date].
☐	The prescriber has documented that they do not intend to undertake further reviews of the patient.	For example, because: • no further review of the patient is required in relation to their monitored medicine treatment; or • the prescriber-patient therapeutic relationship has been terminated.

Outcome Measure 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.

Minimum Requirement 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:

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

b. the prescriber and QOTP service provider establish a Joint Prescribing Plan (JPP); and

   i. the prescriber documents the terms of the JPP including (at a minimum) the following information:

      A. the monitored medicine(s) to be prescribed by the prescriber; and

      B. the formulation and maximum daily dose of the monitored medicine(s) to be prescribed by the prescriber; and

      C. the risk mitigation strategies implemented to address the risk of monitored medicine-related patient harm; and

      D. the date on which the JPP will cease or be reviewed by the prescriber and QOTP service provider; and

   ii. the prescriber prescribes in accordance with the JPP; or

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:

   i. the prescriber prescribes in a manner reasonable in the urgent circumstance; and

   ii. the prescriber documents:

      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

      B. why they believed it was urgent and essential to prescribe the monitored medicine(s); and

      C. the risk mitigation strategies implemented to address the risk of monitored medicine-related patient harm.

General guidance

- To promote continuity of care, prescribers establishing JPPs are strongly encouraged to proactively communicate the details of the JPP to the pharmacy where the patient is being / will be dispensed their OTP approved opioids and/or additional monitored medicines (if known).
- If a JPP is established, it is recommended that:
  - the prescription(s) for the additional monitored medicine(s) are sent to the same pharmacy where the patient collects their OTP approved opioids
  - the dispensing arrangements for the additional monitored medicine(s) align with the dispensing arrangements for the OTP approved opioids e.g. the patient's benzodiazepines are supplied on the same days as the patient presents to their pharmacy to receive their OTP approved opioids
  - the prescriber and QOTP service provider regularly communicate to ensure that ongoing prescribing of monitored medicines is safe and in the best interests of the patient.
- Examples of risk mitigation strategies can be found on pages 25–27 of this document.

Difficulties contacting the QOTP service provider

- There may be circumstances where the prescriber is unable to reach a patient's QOTP service provider to establish a JPP or vary the terms of an existing JPP.
- In such circumstances the prescriber should determine the clinical need for the additional monitored medicine(s)—is it urgent and essential to prescribe the monitored medicine(s) for the patient's wellbeing? If the prescriber believes a monitored medicine prescription is clinically necessary such that they choose to prescribe, they:
  - must document the information specified in part (c)(ii) of this minimum requirement
  - should consider:
    - contacting the patient's QOTP pharmacy to attempt to confirm the date the patient obtained their last QOTP dose (to help inform clinical decision-making regarding appropriate medicine/dose to prescribe)
    - prescribing the minimum quantity that is clinically necessary
    - proactively advising the QOTP service provider and/or the patient's pharmacy (if known) of the actions they took at the earliest opportunity, to help maintain patient safety and to promote continuity of care for the patient.
- The prescriber may wish to telephone the Alcohol and Drug Clinical Advisory Service (ADCAS - 1800 290 928) or the local Alcohol and Other Drugs Service (AODS) for clinical advice, if required.

Patients receiving QOTP treatment under 'shared care' arrangements

- In some circumstances a patient may be registered on the QOTP under a 'shared care' arrangement: arrangements made between a Queensland Health AODS and another prescriber (typically a general practitioner) for the co-management of a patient whose treatment under the QOTP is stable.
  - The patient remains registered on the QOTP with the AODS, but the ongoing QOTP treatment is provided by the shared care prescriber.
  - Should the patient's QOTP treatment de-stabilise, the AODS resumes management of the patient's QOTP treatment.

- Shared care arrangements:
  - are established voluntarily by the relevant AODS and shared care prescriber on a case-by-case basis
  - require Departmental approval—shared care arrangements can only be established if the Department of Health has issued a prescribing approval to the shared care prescriber (see section 67 of the *Medicines and Poisons Act 2019*) authorising the arrangements.
- If a patient is subject to QOTP shared care arrangements:
  - QScript will display the name/details of the AODS prescriber as the patient's QOTP service provider—not the shared care prescriber (although the patient's medication history may show that the shared care prescriber has prescribed the patient OTP approved opioids)
  - a prescriber wishing to establish a JPP with the QOTP service provider must do so with the AODS—not the shared care prescriber.

Patients commencing on the QOTP who are currently receiving monitored medicines treatment

- Patients being admitted onto the QOTP may already be receiving ongoing monitored medicine treatment at the time of their QOTP admission. Prescription information in QScript may help QOTP service providers identify this.
- Where this is the case, to maintain patient safety it is strongly recommended that the QOTP service provider admitting the patient onto the QOTP proactively contacts the patient's prescriber(s) of monitored medicines, to co-ordinate the patient's monitored medicines treatment and/or establish JPPs.
- If one or more JPPs are established, it is strongly recommended that the QOTP service provider or other prescribers proactively communicate the details of the JPPs to the pharmacy where the patient is being dispensed their OTP approved opioids and/or additional monitored medicines (if known).

Patients receiving hospital care

Hospital prescribers providing a current QOTP patient with a monitored medicine prescription for dispensing must comply with this minimum requirement by attempting to contact the patient's QOTP service provider to establish a JPP—even though the monitored medicine prescription may be a one-off event.

Compliance guidance

For a prescriber to have met Minimum Requirement P3-1:

One of the following must be evident:	
☐	A completed QOTP admission form exists (signed on or prior to the date the monitored medicine(s) were prescribed) which confirms that the prescriber (or the Queensland Health AODS for which the prescriber worked at the time) was the patient's QOTP service provider at the time the monitored medicine was prescribed.
☐	The prescriber established a JPP with the QOTP service provider, and: a. documented the terms of the JPP, including: i. the monitored medicine(s) to be prescribed by the prescriber; and ii. the formulation and maximum daily dose of the monitored medicine(s) to be prescribed by the prescriber; and iii. the risk mitigation strategies implemented to address the risk of monitored medicine-related patient harm; and iv. the date on which the JPP will cease or be reviewed by the prescriber and QOTP service provider; and b. prescribed in accordance with the JPP.
☐	If the prescriber has prescribed a monitored medicine in the absence of a JPP or in a manner inconsistent with the terms of an established JPP—the prescriber has: a. prescribed in a manner reasonable in the urgent circumstance; and b. documented: i. details of their attempt(s) to contact the QOTP service provider to establish a JPP or vary the terms of the established JPP; and ii. why they believed it was urgent and essential to prescribe the monitored medicine(s); and iii. the risk mitigation strategies implemented to address the risk of monitored medicine-related patient harm.

Outcome Measure P4

Prescribers must be able to demonstrate the steps they have taken to reduce the risk of monitored medicine-related patient harm.

Minimum Requirement 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:

- *Scenario B: Patient previously registered on the Queensland Opioid Treatment Program*
- *Scenario C: Patient receiving monitored medicines from multiple prescribers*
- *Scenario D: Increased patient overdose risk—average total daily opioids of 100mg OME or greater*
- *Scenario E: Increased patient overdose risk—opioid and benzodiazepine/z-drug combination*
- *Scenario F: Patient receiving an opioid or benzodiazepine/z-drug for the first time in 90 days*

General guidance

- Risk mitigation strategies should be:
  - implemented as part of a shared decision-making process with the patient
  - appropriate for the specific risk(s) identified and the patient's circumstances
  - proportionate to the size and type of risk(s) identified.
- Prescribers seeking guidance on appropriate risk mitigation strategies may wish to contact ADCAS (1800 290 928) for advice or the Alcohol and Drug Information Service (1800 177 833) for contacts for local AOD services.
- Abruptly ceasing or decreasing a patient's monitored medicine treatment without appropriate ongoing support/treatment may cause serious patient harm [19, 20, 21, 22]. See **'Avoiding patient harm'**, earlier, for other risks prescribers should be alert to.

If the prescriber is satisfied that no risk mitigation strategies are required

If after assessment of the patient the prescriber is satisfied no risk mitigation strategies are required, the prescriber should document this.

Compliance guidance

For a prescriber to have met Minimum Requirement P4-1, the prescriber must have documented the risk mitigation strategies implemented to address the risk of monitored medicine-related harm.

Risk mitigation strategies must be evident, for example:

General strategies		
☐	There is a treatment contract/agreement (signed by the patient) in place which describes expectations, responsibilities and/or conditions in relation to the patient's monitored medicines treatment.	
☐	The prescriber has provided patient education regarding the identification and management of monitored medicine-related risks.	For example: education regarding the identification/management of overdose, driving risks, interactions with alcohol, other central nervous system depressants or other medicines.
☐	The prescriber has implemented a gradual de-prescribing plan (with patient engagement).	
☐	The prescriber has rationalised / is rationalising the patient's monitored medicine regimen (if the patient is prescribed multiple monitored medicines concurrently).	
☐	The prescriber has provided the patient with support options (particularly if de-prescribing has commenced).	
☐	The prescriber has increased the frequency of reviews of the patient.	
☐	The prescriber has documented their agreement with the patient as to who will be the patient's sole/primary prescriber of monitored medicines.	
☐	The prescriber has conducted random urine drug screens to confirm presence/absence of prescribed medication or illicit drug use.	

Supply-related strategies		
☐	The prescriber has requested staged supply as part of the dispensing instructions on monitored medicines prescriptions.	For example: supervised daily dosing, daily pick-up from the pharmacy, pick-up 2–3 times per week or weekly.
☐	The prescriber has prescribed only enough monitored medicine(s) until the patient is scheduled to return for review or until their next appointment with their specialist.	
☐	The prescriber has recommended or organised the use of a Dose Administration Aid.	

Choice of monitored medicine		
☐	The prescriber has explicitly documented their decision not to prescribe monitored medicines that are more likely to be misused.	For example: high-potency opioids, parenteral and liquid formulations.
☐	The prescriber has explicitly documented their decision not to prescribe a monitored medicine which the patient is (or has been) dependent on, has misused, or has injected.	

Clinical collaboration		
☐	The prescriber has sought advice on treatment options and/or risk mitigation strategies.	For example, from: ADCAS (1800 290 928) or local AODS.
☐	The prescriber has referred the patient for review by relevant treatment services.	For example: pain management service, AODS or addiction specialist, allied health service, mental health service provider, Home Medicines Review, MedsCheck.

Opioid-specific strategies		
☐	The prescriber has implemented opioid rotation.	
☐	The prescriber has provided or prescribed take-home naloxone.	
☐	If commencing the patient on an opioid; the prescriber has prescribed a short-acting formulation for the initial opioid dose.	
☐	The prescriber has commenced/recommenced the patient on the Queensland Opioid Treatment Program (QOTP), if authorised, or referred the patient to a QOTP service provider for commencement on medication-assisted treatment of opioid dependence.	

Outcome Measure P5

Patients must be provided with information about the risks and benefits of monitored medicine use.

Minimum Requirement 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.

General guidance

- Patients should be part of the decision-making process when being prescribed a monitored medicine and should be fully informed of the risks and benefits so they can provide informed consent about the proposed treatment. This should be a two-way conversation which takes into account the patient's level of health literacy [6].
- Prescribers should actively seek to identify and address the risks/benefits that are important to the patient (in addition to those which are important to the prescriber). Care should be taken to avoid assumptions being made about:
  - the information a patient might want or need
  - the clinical or other factors a patient might find significant
  - the patient's level of knowledge or understanding of what is proposed [6].
- Prescribers should not assume previous prescribers or other health practitioners have informed the patient about the risks/benefits of their prescribed monitored medicine.
- Prescribers may wish to consider:
  - applying the 'BRAN' model i.e. discussing with the patient the Benefits, Risks and Alternatives of using the monitored medicine, and the likely impacts/outcomes of doing Nothing
  - asking a patient to sign a treatment/care plan so that there is a clear record, for both patient and prescriber, of the planned treatment and the risks/benefits discussed.
- Where patients are given information in writing (or via other media), prescribers should still discuss the significant or material risks/benefits with the patient and provide the patient with an opportunity to have any questions answered [6].

Compliance guidance

For a prescriber to have met Minimum Requirement P5-1:

One or more of the following should be evident:		
☐	The prescriber has documented: • the **key points from their discussion with the patient** about risks and benefits relevant to the patient; and • confirmation of the patient's understanding.	
☐	The prescriber has documented: • they are satisfied that that **the patient has been informed** about risks and benefits relevant to them; and • confirmation of the patient's understanding.	For example: • Pt has previously discussed risk of overdose with [health practitioner] and is aware of signs/symptoms. • [Patient name] has researched [monitored medicine] – understands risk of dependence.
☐	The prescriber has documented: • that **the patient has been provided written information** regarding risks and benefits relevant to the patient; and • confirmation that the patient understands same.	For example: Gave [patient name] 'Opioids and you' fact-sheet – discussed key risks, likely benefits and timeframes. [Patient name] confirms she understands risks of [X].
☐	The patient's clinical record includes **a copy of a document signed by the patient** which: • outlines risks and benefits relevant to the patient; and • includes confirmation from the patient that they understand same.	For example: A treatment/care plan, treatment contract or consent form.

Outcome Measure P6

Prescribers must document circumstances where they have prescribed a monitored medicine under duress.

Minimum Requirement P6-1

If a prescriber prescribes a monitored medicine under duress, the prescriber must document:

a. details of the duress experienced; and
b. details of the actions they took in response to the duress.

General guidance

- If a prescriber feels unsafe when a patient is requesting a monitored medicine:
  - they should not put themselves, staff members or other patients in danger
  - the safest response may be to provide the patient with a prescription and request them to leave the premises
  - depending on the circumstances it may be necessary to call the Queensland Police Service (QPS), security services or another person/entity for assistance (either during or after the event).
- Documentation of duress events (as with all clinical documentation) should be objective and factual; access to clinical records may granted to other persons/entities under privacy laws and other legislation. Prescribers should document details of duress events as soon as possible, so the record is contemporaneous.
- If the prescriber-patient therapeutic relationship is compromised as a result of duress, the prescriber may wish to discontinue the care of the patient. If this is the case, the prescriber should (where possible and depending on safety considerations) ensure the patient is adequately informed of the decision and facilitate arrangements for the patient's continuing care [3, 10].

Compliance guidance

For a prescriber to have met Minimum Requirement P6-1, they must have documented the following if they have prescribed a monitored medicine under duress:

Each of the following should be evident:		
☐	Details of the duress experienced.	For example: • the nature of the duress—e.g. verbal threat, physical intimidation, blackmail/extortion attempt; and/or • specific threats made by the patient (verbal, physical or otherwise); and/or • what the patient said and did during their presentation (to the prescriber, other staff, other patients etc.); and/or • what medicine was requested and dose (if relevant); and/or • specific concerns held by the prescriber (or staff)—e.g. fear of being physically harmed or stalked, retaliatory behaviour, harm to family members, damage to physical property etc.; and/or • names of any witnesses to the incident; and/or • CCTV footage of the incident, witness statements etc.
☐	Details of the actions the prescriber took in response to the duress.	For example: • prescribed the smallest amount possible in the lowest dose; and/or • supplied additional (non-prescribed) medication to the patient; and/or • reported the incident to QPS (with Queensland Police report number documented); and/or • enlisted assistance of other persons e.g. QPS, local security, other staff; and/or • banned patient from the practice in the future; and/or • 'high-risk patient' flag placed in the clinical software system or on patient's clinical record; and/or • communicated concerns to other health practitioners known to be involved in the patient's care e.g. the patient's QOTP service provider, the patient's usual pharmacy (if known).

Part 2: Dispensing monitored medicines

Outcome Measure D1

Dispensers must be able to demonstrate the steps they have taken to reduce the risk of monitored medicine-related patient harm.

Minimum Requirement D1-1

In relation to a monitored medicine proposed to be dispensed for a patient, the dispenser must document details of:

a. any medicine-related problem identified; and

b. any clinical intervention performed.

General guidance

- Irrespective of whether a patient is being initiated on a monitored medicine or has been taking a monitored medicine long-term, when dispensing a monitored medicine dispensers should:
  - verify the prescription is valid and that therapy is indicated and safe—Is the patient willing to use/adhere to therapy?
  - undertake a salient medication history
  - assess for medicine-related problems (including assessing for potential indicators of drug-seeking behaviour and/or monitored medicine misuse—see Appendix B)
  - provide information to the patient to ensure safe and effective use of the medicine
  - perform clinical interventions and/or discuss risk mitigation strategies with the patient and/or prescriber, where necessary [23, 24].
- Early identification of clinically significant risks should be a priority and risk mitigation strategies should be discussed with the patient and/or prescriber as early as possible.

If an agent is collecting the monitored medicine on behalf of the patient

- Care should be taken to maintain patient confidentiality—patient consent is required before patient information is disclosed to a carer, agent or authorised representative collecting a medicine on behalf of the patient [23].
- Agents should be counselled sufficiently (whilst maintaining appropriate patient confidentiality) to allow a proper understanding of all the information required by the patient to use the monitored medicine safely and effectively and to motivate the patient to comply with that advice [25].
- Where clarification regarding a monitored medicine prescription is required, the patient or their agent should be consulted and if necessary, the prescriber contacted [25].

Quick reference: risk mitigation strategies in relation to monitored medicines

A comprehensive range of risk mitigation strategies is available to dispensers (see Compliance guidance in relation to clinical interventions, below). However, some risk mitigation strategies that may be specifically relevant to monitored medicines are listed below for quick reference:

- recommending (with patient and prescriber engagement):
  - a formal medication review (e.g. MedsCheck or Home Medicines Review)
  - the use of take-home naloxone (supported with education on how to recognise and respond to opioid overdoses and how to administer naloxone as part of an overdose response plan) [26].
  - the use of a Dose Administration Aid
  - the implementation of staged supply arrangements e.g. supervised daily dosing, daily pick-up from the pharmacy, pick-up 2–3 times per week or weekly.
- providing the patient with:
  - education regarding the identification and management of monitored medicine-related risks e.g. education regarding the identification/management of overdose, driving risks, interactions with alcohol, other central nervous system depressants or other medicines
  - education about the benefits of having one prescriber and one pharmacy (e.g. improved continuity of care)
  - support options (particularly if de-prescribing has commenced)
- confirming the treatment plan with the prescriber e.g. confirming the indication, dose, expected length of time prescribing will occur
- advising the prescriber of concerns identified in relation to potential indicators of drug-seeking behaviour and/or monitored medicine misuse (see Appendix B) e.g. self-escalation of doses, demanding specific formulations or specific medicines by name, frequent requests for early refills of prescriptions.

Compliance guidance

For a dispenser to have met Minimum Requirement D1-1, they must have documented each of the following:

If the dispenser has identified any medicine-related problem in relation to the monitored medicine proposed to be dispensed—the dispenser has documented the details of the identified problem(s).

This includes [27]:

☐ **Problems relating to the choice of monitored medicine prescribed or taken.**

For example:

- duplication of medicines—e.g. the concurrent use of the medicines is either inappropriate or unusual because they are from the same therapeutic class, or a patient is taking multiple forms of the same generic medicine
- medicine interaction—e.g. interaction between a monitored medicine and another prescribed or non-prescription medicine
- wrong medicine— e.g. the patient is taking a monitored medicine that has been incorrectly prescribed or incorrectly dispensed
- incorrect strength—e.g. monitored medicine prescriptions lacking clear/sufficient information about the medicine strength or which show a strength which appears to be incorrect
- inappropriate dosage form—e.g. inappropriate or incorrect formulation in terms of the intended use of the product, including incorrect route of administration
- contraindication or precaution apparent—e.g. there is a contraindication or precautions to the medicine being used due to the patient's medical conditions, or a monitored medicine / monitored medicine class has been prescribed to a patient who has previously had a major adverse event
- no indication apparent—e.g. there is no clear reason apparent for the monitored medicine to be used
- other drug selection problem—e.g. monitored medicine being used is out-of-date or has deteriorated, monitored medicine is discontinued or out of stock on a long-term basis, the pharmacist believes a more effective and/or safer medicine is available

☐ **Problems relating to the prescribed dose or dosing schedule of a monitored medicine.**

For example:

- prescribed dose too high—e.g. based on either previous therapy or reference dose ranges, through error, or because of a particular patient parameter e.g. renal function, weight, age
- prescribed dose too low—e.g. based on either previous therapy or reference dose ranges, or through error
- incorrect or unclear dosing instructions—e.g. specified dosing time is sub-optimal, duration of medicine use is too short/long (including incorrect dose titrations), frequency or dosage schedule is inappropriate
- other dose problem—e.g. patient is opioid naïve and prescribed a potent opioid such as fentanyl or hydromorphone, problems relating to repeat intervals.

☐	**Problems relating to the way the patient takes the monitored medicine.** For example: • under-use by patient—e.g. patient uses too little of a monitored medicine as a result of forgetfulness or lack of understanding of the prescribed dosage regimen, patient takes the monitored medicine when necessary instead of on a regular basis (if so prescribed), patient chooses to discontinue the monitored medicine • over-use by patient—e.g. patient uses too much of a monitored medicine as a result of forgetfulness or lack of understanding of the prescribed dosage regimen, challenges managing health condition • erratic use of the monitored medicine—e.g. patient is taking the monitored medicine on an erratic basis • intentional monitored medicine misuse or other medicine/drug misuse—e.g. suspected intentional over-use of a potentially misused product, including non-prescription items, situations where the prescription appears to be a forgery (refer to Appendix B for a list of potential indicators of drug-seeking behaviour and/or monitored medicine misuse). • difficulty using dosage form—e.g. patient lacks understanding of how to use the dosage form or has a physical problem with the administration of the dosage form/device as it is intended to be used, or brand needs to be substituted to improve the patient's ability to use the medicine • other compliance problem—e.g. patient wishes to collect a prescription for a monitored medicine which has been ceased or replaced by another medicine, patient is stockpiling monitored medicines.
☐	**Problems relating to actual or potential conditions that require management or prevention.** For example: • condition undertreated—e.g. patient has a symptom or disease that is not being treated adequately • condition untreated—e.g. patient has a symptom or medical condition that is not currently being treated • preventive therapy required—e.g. patient requires additional therapy to prevent a likely adverse event as a result of their therapy, coexisting disease or risk factors • other undertreated indication problem
☐	**Problems relating to monitoring the efficacy or adverse effects of a medicine.** For example: • pathology monitoring—e.g. it appears that a pathology test is required • non-pathology monitoring—e.g. it appears that non-pathology monitoring is required, such as falls risk assessment, cognition ability test, sleep study • other monitoring problem—e.g. patient has another problem relating to monitoring of their medicine or medical conditions for either efficacy or adverse effects, patient should have monitoring but has problems attending the laboratory or paying for the test/equipment needed.
☐	**Problems relating to the presence of signs or symptoms that may be attributed to a monitored medicine.** For example: toxicity, allergic reaction, withdrawal symptoms or adverse effect present—e.g. including situations where compliance issues have led to symptoms of toxicity.

☐	**Other monitored-medicine related problem** For example: patient has presented with signs of intoxication.

If the dispenser has performed any clinical intervention in relation to the monitored medicine being dispensed—the dispenser has documented the details of the intervention(s) performed.

This includes [27]:

☐	Recommendations for a change in therapy. For example: • dose increase • dose decrease • medicine change • medicine formulation change • medicine brand change (outside of routine brand substitution)—e.g. pharmacist recommends brand change (same medicine, same dose) due to patient difficulty using a particular brand, such as changing from a brand that comes in blister packs to one that comes in a bottle because the patient finds blister packs difficult to open • dose frequency/schedule change—e.g. total daily dose remains the same, but the pharmacist suggests a change in the number of times a day or the timing of doses each day • prescription not dispensed—Note: If the dispenser decides not to dispense a prescribed monitored medicine because they determine it is clinically inappropriate to do so, they must comply with Minimum Requirement D2-1. • other changes to therapy
☐	**Recommendations for referral.**[1] For example: • refer to prescriber—e.g. problem is of sufficient seriousness for the patient to see the prescriber again to resolve the problem • refer to hospital—e.g. problem is of sufficient seriousness for the patient to go to hospital to resolve the problem • refer for medication review—e.g. pharmacist initiates the process for a Home Medicines Review or MedsCheck • recommend other referral to prescriber—e.g. to dentist, podiatrist etc.

[1] Unless it is an emergency situation, attempts should be made to contact the prescriber before referring the patient to other health service providers.

☐	**Provision of information.** For example: • education or counselling session—e.g. dispenser conducts a detailed counselling or education session with the patient/carer, specifically targeted at resolving the identified problem • written summary of medicine—e.g. dispenser provides the patient with a detailed list/profile of their medicines • recommend Dose Administration Aid—e.g. dispenser suggests the use of a Dose Administration Aid or spacer device • other written information
☐	**Recommendations for monitoring.** For example: • pathology monitoring—e.g. dispenser suggests to the prescriber that they undertake pathology monitoring for efficacy or adverse effects of the monitored medicine • non-pathology monitoring—e.g. dispenser suggests that the patient undertake non-pathology monitoring for efficacy or adverse effects of the medicine, such as falls risk assessment, cognition ability test, sleep study
☐	**No recommendations necessary.** For example: problem has been investigated and does not need to be addressed with any changes or monitoring.

Minimum Requirement D1-2

If any of the following high-risk clinical scenarios apply:

- *Scenario A: Patient currently registered on the Queensland Opioid Treatment Program*
- *Scenario B: Patient previously registered on the Queensland Opioid Treatment Program*
- *Scenario C: Patient receiving monitored medicines from multiple prescribers*
- *Scenario D: Increased patient overdose risk—average total daily opioids of 100mg OME or greater*
- *Scenario E: Increased patient overdose risk—opioid and benzodiazepine/z-drug combination*
- *Scenario F: Patient receiving an opioid or benzodiazepine/z-drug for the first time in 90 days*

and the dispenser holds significant concerns about the clinical appropriateness of dispensing the monitored medicine, the dispenser:

a. must attempt to communicate with the prescriber regarding their concerns prior to deciding whether to dispense the monitored medicine; and

b. must document the details and outcome of their attempt(s) to communicate with the prescriber.

General guidance

- The identification of high-risk clinical scenarios should prompt dispensers to individually assess the level of risk of harm to the patient and implement appropriate strategies to reduce any risks identified.
- Communication with patients is an important element of identifying and attempting to resolve medicine-related problems. Patients should be part of the decision-making process and should be fully informed of the risks and benefits of treatment [23].

Difficulties contacting the prescriber or differences of opinion regarding the clinical appropriateness of dispensing the monitored medicine

- There may be circumstances where the dispenser holds significant concerns about the clinical appropriateness of dispensing a monitored medicine, but:
  - the dispenser is unable to reach the prescriber; or
  - on consultation with the prescriber there is a difference of opinion regarding the clinical appropriateness of dispensing.
- In such circumstances:
  - professional judgement should be exercised by the dispenser in determining the appropriate action to take, noting that dispensers have the right to decline to supply medicines if they believe supply is unsafe or inappropriate, even if the prescriber is not in agreement [23, 25].
  - dispensers may wish to consider:
    - whether it is essential that the medicine is supplied immediately, or whether it is appropriate to delay supply until further information can be gathered e.g. further clinical

guidance from current and credible references, or a more appropriate time to discuss therapy with the prescriber

- whether it is appropriate to supply a minimal amount of the prescribed medicine to allow the patient to receive the proposed treatment while potentially minimising risks of harm
- seeking further advice or information from reputable sources (e.g. ADCAS ph: 1800 290 928, QScript, professional indemnity insurer).

- If the dispenser decides not to dispense a monitored medicine for a patient because the dispenser determines it is clinically inappropriate to do so, the dispenser must comply with Minimum Requirement D2-1.

Compliance guidance

For a dispenser to have met Minimum Requirement D1-2, they must have documented the following information if a high-risk clinical scenario applies and the dispenser holds significant concerns about the clinical appropriateness of dispensing the monitored medicine:

One of the following should be evident:		
☐	The details and outcome of the dispenser's successful attempt to communicate with the prescriber.	For example, the dispenser has documented the key points of their conversation with the prescriber and the outcome of the conversation e.g. agreed plan for treatment.
☐	The details and outcome of the dispenser's unsuccessful attempt(s) to communicate with the prescriber	For example, the dispenser has documented the date, time and means of their unsuccessful attempt(s) e.g. • 'Called [prescriber] at [practice name] at [time] but practice was closed.' • 'Rang [prescriber] on [phone number] at [time] to discuss concerns about [clinical concerns]. No answer. Left message to call back.'

Outcome Measure D2

Decisions not to dispense a monitored medicine due to safety concerns must be documented.

Minimum Requirement 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):

a. their clinical justification for the decision not to dispense; and

b. the information they provided to the patient regarding the decision not to dispense; and

c. the information they provided to the prescriber regarding the decision not to dispense.

General guidance

If a dispenser decides not to dispense a monitored medicine due to their belief it is clinically inappropriate to do so, the dispenser should support the patient in receiving appropriate management and treatment. This may involve explaining to the patient:

- information about the medicine-related problem(s) that has/have been identified
- the reason(s) for not dispensing the medicine
- any recommended actions to be taken by the patient to maintain their safety [23].

Compliance guidance

For the dispenser to have met Minimum Requirement D2-1, they must have documented the following information if they decide not to dispense a monitored medicine because they determine it is clinically inappropriate to do so:

Each of the following should be evident:		
☐	The dispenser's clinical justification for the decision not to dispense.	For example, the dispenser has documented the medicine-related problem(s) they identified (see Minimum requirement D1-1).
☐	The information provided to the patient regarding the decision not to dispense.	For example, the dispenser has documented: • what they discussed with the patient regarding their clinical concerns; and/or • any advice or recommendations they provided to the patient e.g. recommendation to present to hospital or to return to their general practitioner for review; and/or • information given to the patient regarding alternative treatment options.
☐	The information they provided to the prescriber regarding the decision not to dispense.	For example: • the dispenser has documented what information the dispenser communicated to the prescriber about their decision, and when this communication occurred; and/or • the dispenser has a copy of a letter or email they sent to the prescriber which discusses their decision not to dispense.

Outcome Measure D3

Dispensers must document circumstances where they have dispensed a monitored medicine under duress.

Minimum Requirement D3-1

If a dispenser dispenses a monitored medicine under duress, the dispenser must:

a. document details of the duress experienced; and
b. advise the prescriber of the duress; and
c. document details of the actions they took in response to the duress.

General guidance

- If a dispenser feels unsafe when a patient is requesting a monitored medicine:
  - they should not put themselves, staff members or other patients in danger
  - the safest response may be to provide the patient with the monitored medicine and request them to leave the premises
  - depending on the circumstances it may be necessary to call the Queensland Police Service (QPS), security services or another person/entity for assistance (either during or after the event)
  - the prescriber should be informed of the patient's behaviour in either verbal or written form as soon as possible after the event—in doing so, the dispenser should inform the prescriber of any action they took or intend to take in relation to the patient e.g. reporting the incident to the police, banning the patient from the pharmacy.
- Documentation of duress events (as with all clinical documentation) should be objective and factual; access to clinical records may granted to other persons/entities under privacy laws and other legislation. Dispensers should document details of duress events as soon as possible, so the record is contemporaneous.
- If the dispenser-patient therapeutic relationship is compromised as a result of duress, the dispenser may wish to discontinue the care of the patient. If this is the case, the dispenser should (where possible and depending on safety considerations) ensure the patient is adequately informed of the decision and facilitate arrangements for the patient's continuing care [4].

Compliance guidance

For a dispenser to have met Minimum Requirement D3-1, they must have documented the following information if they have dispensed a monitored medicine under duress:

Each of the following should be evident:		
☐	Details of the duress experienced.	For example: • the nature of the duress—e.g. verbal threat, physical intimidation, blackmail/extortion attempt; and/or • specific threats made by the patient (verbal, physical or otherwise); and/or • what the patient said and did during their presentation (to the dispenser, other staff, other patients etc.); and/or • what medicine was requested and dose (if relevant); and/or • specific concerns held by the dispenser (or staff)—e.g. fear of being physically harmed or stalked, retaliatory behaviour, harm to family members, damage to physical property etc.; and/or • names of any witnesses to the incident; and/or • CCTV footage of the incident, witness statements etc.
☐	Details of the actions they took in response to the duress.	For example: • called the prescriber to advise of the duress; and/or • dispensed only a small amount of the medicine (instead of full prescribed amount); and/or • supplied additional (non-prescribed) medication to the patient; and/or • reported the incident to QPS (with Queensland Police report number documented); and/or • enlisted assistance of other persons e.g. QPS, local security, other staff; and/or • banned patient from the pharmacy in the future; and/or • 'high-risk patient' flag placed in the clinical software system or on patient's clinical record; and/or • communicated concerns to other health practitioners known to be involved in the patient's care e.g. the patient's QOTP service provider

Glossary

Term	Meaning
abuse	Deliberate use of a monitored medicine for non-therapeutic purposes.
ADCAS	'Alcohol and Drug Clinical Advisory Service' A specialist telephone support service for health professionals in Queensland (phone: 1800 290 928), providing clinical advice regarding the management of patients with alcohol and other drug concerns [28].
administer	As defined in section 26 of the *Medicines and Poisons Act 2019.*
AODS	'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 [29].
benzodiazepines	Includes all benzodiazepines.
CIMHA	'Consumer Integrated Mental Health and Addiction' application. CIMHA is a state-wide consumer-centric clinical information system designed to support clinicians in the provision of mental health services within Queensland. CIMHA is used by authorised employees from Hospital and Health Services, the Department of Health and non-government organisations, and authorised private hospital staff [30].
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.[2]
deprescribing	The systematic process of identifying and discontinuing drugs in instances in which existing or potential harms outweigh existing or potential benefits within the context of an individual patient's care goals, current level of functioning, life expectancy, values, and preferences [31].

[2] 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
dispense	As defined in section 25(2) of the *Medicines and Poisons Act 2019.*
dispenser	A person authorised to dispense a monitored medicine.
dispensing record	As defined in section 124(2) of the Medicines and Poisons (Medicines) Regulation 2021.
diversion	Unlawful transfer of prescribed medication from legal sources to individuals it was not prescribed for.
Dose Administration Aid	As defined in Schedule 22, Dictionary of the Medicines and Poisons (Medicines) Regulation 2021.
drug-seeking behaviour	Drug-seeking behaviour is a poorly defined term that describes a range of activities directed towards attainment of sought-after medications [32]. See Appendix B for potential indicators of drug-seeking behaviour and/or monitored medicine misuse.
duress	A circumstance: (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 (b) where— (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 (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 (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.*

Term	Meaning
harm minimisation	A policy approach which aims to reduce the harms of substance use through coordinated, multi-agency responses that address the three pillars of: • demand reduction—strategies to delay, prevent or reduce use • supply reduction—strategies to restrict availability and access to substances • harm reduction—strategies to encourage safer behaviours, reduce preventable risk factors, and reduce health and social inequalities among specific population groups [33].
health literacy	Degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions [6].
health practitioner	As defined in Schedule 1, Dictionary of the *Medicines and Poisons Act 2019.*
high-risk clinical scenario	As defined in Appendix A.
Home Medicines Review	A Home Medicines Review (HMR) is a clinical process that considers the patient's medicines and health in order to enhance the Quality Use of Medicines and reduce the number of adverse medicines events. An HMR is a collaborative process between the referring medical practitioner ('referrer'), the general practitioner (if this is not the referrer), other members of the patient's healthcare team (including the patient's usual community pharmacy if they have one), accredited pharmacist, patient, and where appropriate, a carer [34].
Individual Healthcare Identifier	A unique number used to identify an individual for health care purposes [35].
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'.
medication assisted treatment of opioid dependence	The use of medication (opioid agonists and antagonists) and psychosocial support in combination for treatment of people who are opioid dependent [26].
medicine	As defined in section 11 of the *Medicines and Poisons Act 2019.*

Term	Meaning
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. [3]
MedsCheck	A MedsCheck service is provided within a community pharmacy and consists of a review of a patient's medicines to improve the patient's understanding of their medicines and ultimately, patient outcomes. The service aims to support self-management by evaluating a patient's knowledge about their medicines, addressing any problems the patient has identified with their medicines, and advising the patient about the best way to utilise and store their medicines [36].
misuse	Includes the use of monitored medicines: (a) for non-therapeutic purposes; or (b) without a valid prescription; or (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.
My Health Record	My Health Record is a secure, online summary of an individual's health information, available to all Australians. Healthcare providers authorised by their healthcare organisation can access My Health Record to view and add to their patients' health information [37].
OME	Oral morphine equivalent—an approximate equivalent dose of oral morphine.
opioid rotation	Opioid rotation is a strategy applied during opioid therapy for pain that refers to a switch from one opioid to another in an effort to improve clinical outcomes (benefits or harms) [38].
opioid use disorder	As defined in the American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders (DSM-5).
OTP approved opioid	A medicine approved for treating patients under an opioid treatment program.

[3] 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
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.
prescribe	As defined in Schedule 1, Dictionary of the *Medicines and Poisons Act 2019.*
prescriber	A person authorised to prescribe a monitored medicine.
prescribing approval	As defined in section 67 of the *Medicines and Poisons Act 2019.*
prescription	As defined in Schedule 1, Dictionary of the *Medicines and Poisons Act 2019.*
Prescription Exchange Service	An electronic system for recording or transferring prescriptions, or information in prescriptions, between prescribers and dispensers.
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).
QScript	Queensland's real-time prescription monitoring solution. QScript is a database containing real-time monitored medicines prescription information which can be viewed by prescribers and dispensers to support them in making better-informed and safer clinical decisions for patients.
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.
rationalise	Rationalising medicines is the complex individualised process of balancing the potential risks and benefits of reducing or withdrawing medicines [39].
shared care arrangement	An arrangement, authorised by a prescribing approval issued by the Department of Health, in which a patient's treatment under the Queensland Opioid Treatment Program is co-managed by a Queensland Health Alcohol and Drug Service and another prescriber.
shared care prescriber	A prescriber who has been authorised by a prescribing approval issued by the Department of Health to enter into a shared care arrangement for the treatment of a particular patient under the Queensland Opioid Treatment Program.

Term	Meaning
staged supply	Provide dispensed medicines to a patient in instalments as per the prescriber's instructions.
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.*
technology-based consultation	Patient consultations that use any form of technology, including but not restricted to videoconferencing, internet and telephone, as an alternative to face-to-face consultations [16].
The Viewer	The Viewer is a web-based application which collates data from multiple Queensland Health systems, ensuring healthcare professionals can access patients' information quickly, without having to log in to different systems. The Viewer is used by Hospital and Health Service staff, Mater Health clinicians, Queensland general practitioners (via the Health Provider Portal) and other service providers [40].
treatment contract / agreement	A formal contract or plan established by a health practitioner and a patient, specifying the manner in which certain forms of care will be delivered [41].
treatment plan	Documentation that sets out the proposed treatment regimen for an individual patient.
z-drug(s)	Zolpidem and zopiclone.

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Appendix A

Scenario A: Patient currently registered on the Queensland Opioid Treatment Program

Definition

A patient currently registered on the Queensland Opioid Treatment Program (irrespective of whether the patient has been 'picking up' their doses).

General guidance

- The Queensland Opioid Treatment Program (QOTP) is a program administered in Queensland for the treatment of persons dependent on opioids. The QOTP functions within a harm minimisation framework with the broad goal of reducing health, social and economic harms to individuals and the community arising from unsanctioned opioid use [26], through the delivery of medication-assisted treatment of opioid dependence (sometimes referred to as 'opioid replacement therapy' or 'opioid substitution therapy').
- Patients registered on the QOTP have a diagnosed substance use disorder (opioid use disorder) and may be prescribed the following medicines—referred to as 'OTP approved opioids'—to eliminate withdrawal, control or eliminate cravings and attenuate or block the euphoric effect of further opioid use [26]:
  - methadone liquid/syrup
  - sublingual buprenorphine
  - sublingual buprenorphine/naloxone
  - long-acting injection buprenorphine [26, 42].
- As patients registered on the QOTP have a current substance use disorder diagnosis, they may be particularly at risk of harms arising from the use of monitored medicines.
- To support safer, coordinated care and to minimise burdens on patients, it is recommended QOTP patients have one prescriber (and preferably one dispensing point) for all monitored medicines they are being dispensed, including OTP approved opioids.
- If it is not possible/appropriate for a patient's QOTP service provider to be their sole prescriber of monitored medicines, a Joint Prescribing Plan (JPP) must be established between the QOTP service provider and any other health practitioner prescribing monitored medicines for supply to the patient (except in limited circumstances), as per Minimum Requirement P3-1.
- Prescribers and dispensers treating a patient currently registered on the QOTP may wish to consider prescribing/supplying take home naloxone as a harm reduction strategy, supported with education on how to recognise and respond to opioid overdoses and how to administer naloxone as part of an overdose response plan [26].

Scenario B: Patient previously registered on the Queensland Opioid Treatment Program

Definition

A patient who has previously been registered on the Queensland Opioid Treatment Program.

General guidance

- Patients previously registered on the Queensland Opioid Treatment Program (QOTP) have been diagnosed with a substance use disorder (opioid use disorder) in the past and may be at risk of harm as a result of relapse to opioid use disorder or drug-seeking behaviours.
- To help inform clinical decision-making for prescribers and dispensers, key Information about a patient's previous QOTP treatment episodes **(extending back to 1 January 2015 only)** is displayed in QScript, including:
  - treatment episode start and end date
  - the OTP approved opioid (e.g. methadone, buprenorphine) the patient was prescribed on commencement of the treatment episode—this medicine may have changed during the episode
  - the reason for discharge
  - the QOTP service provider's name, telephone number and address.
- Prescribers and dispensers treating a patient previously registered on the QOTP:
  - may wish to consider prescribing/supplying take home naloxone as a harm reduction strategy if the patient is being prescribed an opioid, supported with education on how to recognise and respond to opioid overdoses and how to administer naloxone as part of an overdose response plan [26]
  - may wish to consider discussing with the patient any concerns the patient may have regarding relapse to opioid use disorder
  - may wish to telephone the Alcohol and Drug Clinical Advisory Service (ADCAS - 1800 290 928) or their local AODS if they are seeking clinical advice on the management of patients previously registered on the QOTP.

Scenario C: Patient receiving monitored medicines from multiple prescribers

Definition

A patient who in the previous 90 days has been dispensed monitored medicine prescriptions written by four (4) or more prescribers.

General guidance

- Patients receiving monitored medicines from multiple prescribers may be at risk of being provided fragmented or poorly coordinated healthcare, which in turn may increase their risk of overdose or other harms as they may:
  - receive sub-optimal treatment for their clinical condition(s); and/or
  - gain access to excessive quantities and/or high-risk combinations of monitored medicines.
- Where a patient is receiving monitored medicines from multiple prescribers, prescribers and dispensers should carefully consider whether the patient is 'oversupplied' or otherwise at risk of monitored medicine-related harm.
  - 'Oversupplied' patients can be identified as having received overlapping prescriptions that enable(d) them to obtain more medication than would reasonably be required for a specific time period e.g. the patient has obtained a prescription from a different prescriber every 2–3 days and has been dispensed a months' worth of medicine on each prescription.
  - An oversupplied patient may have undiagnosed substance use disorder, be at risk of overdose, be misusing or diverting their medication or may have a medical condition that is not being appropriately managed.
  - Information in QScript may assist prescribers/dispensers in identifying oversupplied patients. For example, review of a patient's monitored medicine prescribing and dispensing dates may reflect that the patient has received overlapping prescriptions that would provide them access to excessive quantities of monitored medicines.
- Some patients may be consulting multiple prescribers but are receiving quantities of monitored medicines appropriate for their clinical condition i.e. they are not oversupplied.
  - For example, a patient may consult different prescribers (at different practices or at the one practice) depending on their availability at the time a new prescription is required or may be prescribed monitored medicines from a range of multidisciplinary health practitioners concurrently involved in their care e.g. a dentist, general practitioner, orthopaedic surgeon and psychiatrist.
  - As prescription records in QScript contain information about the prescriber, reviewing a patient's prescription history in QScript may assist in identifying if the monitored medicine prescriptions provided to a patient were generated from prescribers practising from the same or different locations.
- Prescribers and dispensers treating a patient receiving monitored medicines from multiple prescribers:

- may wish to consider providing the patient with education about the benefits of having one prescriber and one dispenser (e.g. improved continuity of care) and/or may wish to work with the patient to nominate/establish a primary prescriber
- may wish to consider prescribing/supplying take home naloxone as a harm reduction strategy if the patient is being prescribed an opioid, supported with education on how to recognise and respond to opioid overdoses and how to administer naloxone as part of an overdose response plan [26].

Scenario D: Increased patient overdose risk—average total daily opioids of 100mg oral morphine equivalent (OME) or greater

Definition

A patient whose average total daily opioid dose:

- is currently 100mg OME or greater—based on the amount of opioids dispensed over the previous 90 days; or
- 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.

General guidance

- Patients consuming high doses of opioids, whether as a single opioid or combination of different opioids, are at increased risk of accidental overdose [43, 44, 45].
- Although Queensland Health has identified a daily dose of 100mg OME daily as being a high-risk clinical scenario, prescribing opioids at any dose carries some risks.
  - Health practitioners should not assume that a patient receiving a daily dose of less than 100mg OME is not at risk of harm.
  - As a patient's opioid dose increases, so does their risk of harm.
- Abrupt cessation or rapid de-prescribing of opioids without the provision of appropriate ongoing supports may result in serious patient harm [19, 20], and is strongly discouraged.
  - While it may be desirable for patients who require opioids to be prescribed lower doses, many patients have been on daily opioid doses of over 100mg OME for a long time. Such patients should be managed carefully and provided appropriate therapeutic support to minimise the risk of patient harm.
  - De-prescribing of a patient's opioids should only occur if it is clinically appropriate, safe to do so and undertaken with patient consent.
  - Where de-prescribing is clinically indicated, prescribers and patients should collaboratively develop a gradual de-prescribing plan, incorporating gradual dose reductions, regular reviews and appropriate supports (e.g. non-pharmacological interventions, psychological and social support).
  - Where a patient is being de-prescribed opioids, care should be taken to avoid the 'squeezed balloon effect' and 'chilling effect' (see 'Avoiding patient harm', earlier).
- Note that due to the complexities associated with accurately estimating OME in relation to OTP approved opioids, QScript does not take into account OTP approved opioids when calculating whether a patient's average total daily opioid dose is above or below 100mg OME.
- Prescribers and dispensers treating a patient on a daily opioid dose of 100mg OME or greater:
  - should consider the risk of harm to the patient in the context of the patient's use of other prescribed medicines, alcohol or illicit substances

- may wish to consider prescribing/supplying take home naloxone as a harm reduction strategy, supported with education on how to recognise and respond to opioid overdoses and how to administer naloxone as part of an overdose response plan [26].

Scenario E: Increased patient overdose risk—opioid and benzodiazepine/z-drug combination

Definition

A patient who in the previous 90 days has been dispensed:

- an opioid and a benzodiazepine/z-drug; or
- an opioid—and it is proposed they are prescribed or dispensed a benzodiazepine/z-drug; or
- a benzodiazepine/z-drug—and it is proposed they are prescribed or dispensed an opioid.

General guidance

- Patients concurrently consuming opioids and benzodiazepines/z-drugs are at increased risk of accidental overdose [43].
- Although Queensland Health has identified the combination of opioids and benzodiazepines/z-drugs as being a high-risk clinical scenario, combinations of other prescribed medicines, alcohol and illicit substances can also pose a risk of harm.
- Abrupt cessation or rapid de-prescribing of opioids or benzodiazepines/z-drugs without the provision of appropriate ongoing supports may result in serious patient harm [19, 20, 21, 22], and is strongly discouraged.
  - While it may be desirable to avoid co-prescribing opioids and benzodiazepines/z-drugs, many patients have complex care needs for which such combinations may be an appropriate medicine intervention. These patients should be managed carefully and provided appropriate therapeutic support to minimise the risk of patient harm.
  - De-prescribing of a patient's opioids or benzodiazepines/z-drugs should only occur if it is clinically appropriate, safe to do so and undertaken with patient consent.
  - Where de-prescribing is clinically indicated, prescribers and patients should collaboratively develop a gradual de-prescribing plan, incorporating gradual dose reductions, regular reviews and appropriate supports (e.g. non-pharmacological interventions, psychological and social support).
  - Where a patient is being de-prescribed opioids or benzodiazepines/z-drugs, care should be taken to avoid the 'squeezed balloon effect' and 'chilling effect' (see 'Avoiding patient harm', earlier).
- Prescribers and dispensers treating a patient who is concurrently receiving an opioid and benzodiazepine/z-drug:
  - should consider the risk of harm to the patient in the context of the patient's use of other prescribed medicines, alcohol or illicit substances
  - may wish to consider prescribing/supplying take home naloxone as a harm reduction strategy, supported with education on how to recognise and respond to opioid overdoses and how to administer naloxone as part of an overdose response plan [26].

Scenario F: Patient receiving an opioid or benzodiazepine/z-drug for the first time in 90 days

Definition

A patient who in the previous 90 days has **not** been dispensed:

- an opioid (including tramadol and codeine-containing medicines)—and it is proposed they are prescribed or dispensed an opioid; or
- a benzodiazepine/z-drug—and it is proposed they are prescribed or dispensed a benzodiazepine/z-drug.

General guidance

- Careful consideration should be given to commencing (or recommencing) a patient on opioids, benzodiazepines or z-drugs.
  - Use of these medicines for acute conditions is associated with increased risk of long-term use, which in turn is associated with increased risk of patient harms, including overdose [46, 47, 48, 49].
  - Patients who have not recently consumed an opioid or benzodiazepine/z-drug may not be tolerant to these medicines, and therefore may be at risk of overdose if commenced at too high a dose.
  - Patients prescribed these medicines in the past may have experienced loss of tolerance and may be at risk of overdose if recommenced at the dose they were previously prescribed.
- Prior to commencing/recommencing a patient on opioids, benzodiazepines or z-drugs, the prescriber and patient should agree to a monitored medicine trial which should specify the trial length, goals of treatment and exit strategy.
- Careful consideration should be given to the prescribed dose and quantity and whether repeat prescriptions are required.
  - The higher the initial dosage, the larger the quantity and whether the patient fills a second prescription are key factors which increase the risk of a patient continuing chronic opioid, benzodiazepine or z-drug therapy.
  - When prescribing or dispensing these medicines, health practitioners should start with the end in mind, by beginning with short-duration prescriptions at the lowest effective dose and engaging patients in discussions of when to re-evaluate their symptoms and begin tapering [46, 47, 48, 49].
- Prescribers and dispensers treating a patient receiving an opioid or benzodiazepine/z-drug for the first time in 90 days may wish to consider prescribing/supplying take home naloxone as a harm reduction strategy if the patient is being prescribed an opioid, supported with education on how to recognise and respond to opioid overdoses and how to administer naloxone as part of an overdose response plan [26].

Appendix B

Potential indicators of drug-seeking behaviour and/or monitored medicine misuse [12, 13, 14]

Drug-seeking behaviour is not limited to users of illicit drugs or patients seeking to use their medicine for non-therapeutic purposes or divert their medicine to others. Patients displaying drug-seeking behaviour may have legitimate medical conditions but have, or are developing, a substance use disorder. Others may have undiagnosed or under-treated medical conditions.

The table below provides examples of potential indicators of drug-seeking behaviour but it is important to consider these in the context of other circumstances surrounding the patient and the consultation. Where there is a concern that a patient may be displaying drug-seeking behaviour or misusing their monitored medicine(s), it is important for prescribers and dispensers to:

- assess the level of risk of harm to the patient (and others)
- implement risk mitigation strategies proportionate to the risks identified
- avoid making assumptions about or stigmatising the patient.

Type of indicator	Examples
Requests and claims	• Demanding or aggressively complaining about the need for a medicine. • Requesting specific medicines by name. • Claiming multiple pain medicine allergies or previous adverse drug reactions. • Requesting private (non-PBS/RPBS) prescriptions. • Presenting with a vague complaint (e.g. lower back pain). • Frequently requesting early refills of prescriptions. • Claiming to be on the waiting list for surgery or unable to afford dental work and needing to manage dental pain. • Patterns of reporting lost, stolen, misplaced, damaged or destroyed prescriptions or medicines. • Claiming they are unable to provide identification (on request) e.g. claiming they lost or forgot their wallet.
Inconsistencies	• Unable to provide a consistent and/or credible history. • Examinations and investigation findings are inconsistent with reported symptoms e.g. claims of pain are disproportionate to apparent cause/mechanism of injury. • Providing old medical history documentation/reports for current conditions. • Providing reports and referrals from overseas practices that cannot be verified.

Misuse of medicines	• Taking extra, unauthorised doses of monitored medicines. • Hoarding medicines. • Using prescribed medicine for non-therapeutic purposes (e.g. for euphoria). • Injecting an oral formulation of prescribed medicine. • Unsanctioned use of prescribed medicine to treat other conditions/symptoms. • Obtaining (or attempting to obtain) monitored medicines from multiple prescribers for quantities beyond therapeutic need. • Self-escalating doses of prescribed medicine. • Using supplemental monitored medicines obtained from other sources e.g. emergency departments. • Using prescribed medicines in any way other than as directed by the prescriber i.e. dose, route, duration. • Using medicines obtained from family, friends or illicitly.
Physical signs	• Prescribed medicine is not present in random urine drug screens (may indicate the patient is diverting their medication). • Presenting intoxicated or in withdrawal. • Physical examination reveals old or recent evidence of injecting drug use. • Deterioration at home or work or reduction in social activities because of medicine side effects.
Manipulative behaviour	• Consistently disruptive when arriving at the practice/clinic. • Frequently calling outside of clinic hours or when a particular prescriber (who prescribed monitored medicines) is on call. • Displaying threatening or coercive behaviour or applying emotional pressure to obtain prescriptions. • Offering bribes. • Failing to truthfully disclose relevant information regarding history or prescription medicine or substance use. • Fraudulently claiming to be an interstate visitor. • Inappropriate use of primary care services.
Resistant behaviour	• Anger or irritability when questioned closely about pain or other symptoms. • Being more concerned about the medicine than the medical problem. • Unwilling to consider other medicines or non-pharmacological treatments. • Frequent unauthorised dose escalations after being told that it is inappropriate. • Unwilling to sign a treatment plan, contract or agreement. • Refusing diagnostic workups, consultations and/or clinical investigations. • Refusing to attend specialist appointments when referred. • Non-compliant with instructions regarding monitored medicine use. • Repeated failure to comply with practice/clinic policies. • Refusing to provide identification on request.

Illegal activity	• Obtaining, stealing or 'borrowing' medicines prescribed to family members or friends. • Using aliases and/or presenting with false/another person's ID to obtain monitored medicines. • Forging prescriptions (including altering genuine prescriptions). • Producing fraudulent documents e.g. forged letter from an alleged 'previous doctor' or forged specialist report. • Selling or giving away prescribed medicines to others (diversion). • Obtaining monitored medicines from illicit sources e.g. buying off the street.