Application for prescribing approval for QOTP approved opioids (QOTP – Patient Class) Medicines and Poisons Act 2019

MPA-75,78&82: PCTA-Version 3:10/2024

Information about this application form

This application form is to be used to apply for a **prescribing approval** under the *Medicines and Poisons Act 2019* (**MPA**).

'Prescribing approvals' are defined in section 67 of the MPA as follows:

A **prescribing approval** is an approval that authorises a person to carry out any of the following regulated activities with a medicine stated in the approval—

a) prescribing the medicine for a person, or a class of persons, stated in the approval in the stated circumstances;

b) buying, possessing, administering, dispensing and giving a treatment dose of the medicine in the stated circumstances.

Under the MPA, medicines approved for treating patients under the Queensland Opioid Treatment Program (**QOTP**) are '**approved opioids**'. Approved opioids are those medicines listed on the Pharmaceutical Benefits Scheme Opiate Dependence Treatment Program Section 100 Item list.

This form is to be used to apply for an initial prescribing approval or renewal or amendment of an existing prescribing approval authorising the treatment of persons with approved opioids under the QOTP.

This form is to be used for applications for **patient class** QOTP prescribing approvals only. To apply for a QOTP **shared - care** prescribing approval, please use the Application for a prescribing approval (QOTP - Shared Care) form.

The types of applications that can be made using this form are:

- an initial application for the following types of patient class QOTP prescribing approval (section 75 of the MPA)
    - a Level 1 (Full) QOTP prescriber approval for all approved opioids; or
    - a Level 2 QOTP prescriber approval for buprenorphine-naloxone and long-acting injection buprenorphine only, or
    - a Level 2 Interim supervised QOTP prescriber approval for all approved opioids, under the supervision of a Level 1 (Full) QOTP prescriber
    - a Level 3 Temporary alternate prescribing (hospital inpatient) approval to continue treatment for a QOTP registered patient while in hospital
    - a Level 3 Temporary alternate prescribing (backfill) approval to continue treatment in the absence of the patient's current QOTP prescriber
- an amendment of a patient class QOTP prescribing approval (section 78 of the MPA); or
- a renewal of a patient class QOTP prescribing approval (section 82 of the MPA).

For information about types of patient class QOTP prescribing approvals, see fact sheet on QOTP Prescriber types and training pathways.

Your application WILL NOT be considered, or may be returned to you for completion, unless:

1. ALL parts of this application form are completed accurately;

2. ALL the relevant attachments are included; and
3. the Consent and Declaration is completed and signed.

Scope of a prescribing approval

Patient class QOTP prescribing approvals authorise the treatment of particular patients with approved opioids under the QOTP and are limited to registered medical practitioners and nurse practitioners.

A *prescribing approval* is a type of substance authority that may be granted under the MPA, that authorises a person to carry out the regulated activities stated in the approval, with the medicines stated and in the stated circumstances. The holder of a substance authority, including a person acting under a substance authority, is authorised to carry out a regulated activity with a regulated substance in the authorised way (section 31 of the MPA).

Requirements and conditions

Requirements and standard conditions for prescribing approvals

Unless stated otherwise in the approval, the requirements and standard conditions described in sections 70 and 91 of the MPA and prescribed in the following chapters of the Medicines and Poisons (Medicines) Regulation 2021 (**MPMR**), apply to the prescribing approval:

- chapter 3 'Standard conditions for substance authorities', part 4 'Prescribing approvals for approved opioids';
- chapter 4 'General requirements for dealings', part 6 'Prescribing medicines'; and
- chapter 8 'Offences'.

The approval holder must notify the chief executive of Queensland Health (chief executive) or delegate in the approved form, as soon as practicable but no later than 5 business days, if the approval holder's circumstances change in a way that substantially affects:

a) a dealing the approval holder is authorised to carry out under the approval; or

b) the ability of the approval holder to comply with the conditions of the approval.

A prescriber holding a prescribing approval for approved opioids under the QOTP must comply with **section 31 of the MPMR**:

- If **starting treatment** of a patient under the QOTP — by giving notice to the chief executive (or delegate) in the approved form as soon as practicable, and **no later than the end of the next business day**;
- If **stopping treatment** of a patient under the QOTP — by giving notice to the chief executive (or delegate) in the approved form as soon as practicable, and **no later than 3 business days after treatment stops**.

Applying for an initial prescribing approval

In determining an application for a prescribing approval, the factors in section 76 of the MPA may be taken into consideration.

Queensland Health assesses all information provided with an application including:

- background, skills and qualifications of persons who will be responsible for overseeing activities to be carried out or will have access to medicines;
- which regulated substances are to be included in the substance authority.

Applying for amendment of a prescribing approval

In determining an application for amendment, the factors in section 79 of the MPA may be taken into consideration. Queensland Health assesses all information provided with an application to amend a prescribing approval including:

- the conditions of the substance authority; and
- any changes to the matters considered by the chief executive (or delegate) when the substance authority was granted.

Applying for renewal of a prescribing approval

In determining an application for renewal, the factors in section 83 of the MPA may be taken into consideration. Queensland Health assesses all information provided with an application to renew a prescribing approval including:

- the conditions of the substance authority; and
- any changes to the matters considered by the chief executive (or delegate) when the substance authority was granted.

If the chief executive (or delegate) decides to grant the renewal of the prescribing approval, the chief executive (or delegate) may also decide to take either of the following actions if the chief executive (or delegate) is satisfied the action is reasonably necessary:

- impose additional conditions on the substance authority (section 70(1)(b) of the MPA);
- change a condition of the substance authority, including a standard condition (section 70(2) of the MPA).

Deciding applications for prescribing approval

All applications are assessed individually, and there is no guarantee that a prescribing approval, or an amendment or renewal of a prescribing approval will be granted to any applicant.

Under Chapter 3, Part 3, Division 4 of the MPA, unless a later day is agreed to under section 88 of the MPA, applications must be decided on or before the day that is 90 days after:

a) the day the chief executive (or delegate) receives the application; or

b) if one of more notices under section 87(1) have been given to the applicant — the day the chief executive (or delegate) receives the further information stated in the last notice.

Applications not decided by this time are taken to have been refused (section 89(4) of the MPA).

To apply, submit via email the **attached** application form, accompanied by all supporting documents to:

The Chief Executive, Queensland Health
c/o Medicines Approvals and Regulation Unit (MARU)
QOTP@health.qld.gov.au

Queensland Government

Queensland Health

Medicines and Poisons Act 2019

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APPLICATION FOR A PRESCRIBING APPROVAL
Approved opioids – QOTP patient class approval

Privacy statement – please read carefully

Personal information collected by Queensland Health is handled in accordance with the *Information Privacy Act 2009*. Queensland Health is collecting your personal information on this form under authority of the *Medicines and Poisons Act 2019*. The information is being collected to ensure that health risks arising from the use of regulated substances are appropriately managed. All personal information will be securely stored and only accessible by Queensland Health. Your personal information will not be disclosed to any other third parties without consent unless the disclosure is authorised or required by law. For information about how Queensland Health protects your personal information, or to learn about your right to access your own personal information, please see our website at www.health.qld.gov.au/global/privacy.

Application type

Initial application for QOTP prescribing approval **Level 1 (full):** Prescribe all QOTP approved opioids **(buprenorphine-naloxone, long-acting injection buprenorphine, buprenorphine-mono and methadone)**	☐
Initial application for QOTP prescribing approval **Level 2:** Approval to treat patients with **buprenorphine-naloxone and long-acting injection buprenorphine only**	☐
Initial application for **Interim supervised** QOTP prescribing approval **Level 2:** Approval to treat patients with **buprenorphine-naloxone, long-acting injection buprenorphine, buprenorphine-mono and methadone**	☐
Initial application for **Temporary alternate prescribing Level 3 (hospital inpatient):** Approval to continue treatment for a QOTP registered patient while in hospital	☐
Initial application for **Temporary alternate prescribing Level 3 (backfill):** Approval to backfill a patient's current QOTP prescriber (limited to maintaining current dose and takeaway arrangements) Name of the patient's current QOTP prescriber	☐
Application to **amend** an approval to treat patients with approved opioids under the QOTP (Patient Class Approval) Approval number	☐
Application to **renew** an approval to treat patients with approved opioids under the QOTP (Patient Class Approval) Approval number	☐

Section 1 – Applicant details (s76 MPA)

Provide details of the prescriber seeking the approval

☐ Medical practitioner	☐ Nurse practitioner	Ahpra Registration No
Title	Surname	Given name/s
Do you prescribe for QOTP patients from more than one location? **If yes, please list additional locations in Section 7 of this form.**	☐ **Yes**	☐ **No**
Clinic/Practice name		
Clinic/Practice address		
Town/Suburb	State	P/C
Work phone	Mobile phone	
Work email address		

Section 1 (continued) – Applicant details (s76 MPA)

Do you have any restrictions on your professional registration (e.g. conditions or undertakings) that prevent you from prescribing the medicines you are applying for approval to prescribe?	☐ Yes	☐ No
If yes, provide further details:		

Section 2 – Prescriber Training (for initial applications only)

For Full (Level 1) QOTP prescriber or (Level 2) buprenorphine-naloxone and long acting injection buprenorphine prescriber approval applications only. Please provide evidence of completion of prescriber training. Not required for interim alternative prescribers.

Level 1 (Full) QOTP prescriber	☐ Completion of **relevant brief eLearning packages** (Insight's online QOTP prescriber course)
	☐ Clinical placement with a Level 1 (Full) QOTP prescriber
Level 2 QOTP prescriber Buprenorphine-naloxone and long acting injection buprenorphine only	☐ Completion of **relevant brief eLearning packages** (Insight's online QOTP prescriber course)
Level 3 Temporary alternate prescriber (backfill or continuing treatment of hospital inpatient)	☐ No compulsory training but recommend completion of **relevant brief eLearning packages** (Insight's online QOTP prescriber course)

Section 3 – Interim supervised QOTP prescribing approval Level 2 only

Nominate your supervising QOTP Level 1 (full) prescriber here

Title		Surname		Given name/s	
QOTP Prescriber Approval No					
Clinic/Practice name					
Clinic/Practice address					
Town/Suburb		State		P/C	
Work phone		Mobile phone			
Work email address					

Section 4 – Approved opioid(s) proposed to be prescribed under this approval (s67 MPA)

☐ Buprenorphine-mono sublingual tablets	☐ Long-acting injection buprenorphine (LAI-BPN)
☐ Buprenorphine/naloxone sublingual film	☐ Methadone syrup/liquid (Level 1 prescribers only)

Section 5 – Duration of the prescribing approval (s69 MPA)

Please specify the desired term for the prescribing approval. Applicants should note that typically prescribing approvals will not be issued for more than 2 years.

Please specify the term of approval sought:

☐ 3 months	☐ 2 years	☐ Another term or end date, please specify

Dates for Level 3 temporary alternative prescribing approval – backfill only (s.69 MPA)				
Please specify backfill period	Start date		End date	

Section 6 – Additional information and attachments

Provide any additional information to support your application (e.g. if an amendment application, what you are seeking to have amended).

Section 7 – Additional workplaces

Please provide details of additional workplaces you propose to provide QOTP treatment from

Clinic name	**Clinic address**

Section 8 – Consent and Declaration

By making this application:

- ☐ I consent to Queensland Health collecting, using and disclosing my personal information for the purpose of determining this application and any matters relevant to this prescribing approval
- ☐ I consent to Queensland Health making enquiries of, and exchanging information with, the authorities of any Australian state or territory, or of the Commonwealth, regarding any matters relevant to this application (which may include a criminal history check). If relevant information cannot be obtained from other entities, Queensland Health will determine the application on the information available.
- ☐ I declare that, to the best of my knowledge, all information provided in and with this application form is true and correct in every detail.
- ☐ I understand that if anything has been stated in this application form,or in an attachment provided with this application, that is false or misleading, any substance authority granted may be suspended or cancelled.

Signature	Full name	Date
		(DD/MM/YYYY)

Clear form