Application for a prescribing approval for approved opioids (QOTP - Shared Care) - Medicines and Poisons Act 2019

MPA-75,78,&82:IPTA Version 1:09/22



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.

This form is to be used to apply for:

- an initial application for a prescribing approval (section 75 of the MPA);
- an amendment of a prescribing approval (section 78 of the MPA); or
- a renewal of a prescribing approval (section 82 of the MPA)

for the treatment of a person with approved opioids under a shared care arrangement under the Queensland Opioid Treatment Program (QOTP).

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
- the Declaration is signed.

Scope of a prescribing approval

Prescribing approvals treat a particular patient with approved opioids under the QOTP are limited to registered medical practitioners and nurse practitioners.

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). 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.

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 approval 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 (section 42 of the MPMR):

- 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 sections 30 and 31 of the MPMR by:

- Giving notice to the chief executive (or delegate) when starting treatment of a person in the approved form as soon as practicable, and no later than the end of the next business day;
- Giving notice to the chief executive (or delegate) when stopping treatment of a person in the approved form as soon as practicable, and no later than 3 business day after treatment stops.

Applying for a initial prescribing approval

In determining the application for a prescribing approval, the matters 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 the 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 the application for renewal, the factors in section 82 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 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).

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, division 4 of the MPA, applications are decided within 90 days of the application (final consideration day – section 86 of the MPA), or the latest day the chief executive (or delegate) receives information from the applicant (section 89 of the MPA), unless a later date is agreed (section 88 of the MPA). 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 Healthcare Approvals and Regulation Unit (HARU) QOTP@health.gld.gov.au



Queensland Health

Medicines and Poisons Act 2019

MPA-75,78&82:IPTA

Version 1; 09/2022

APPLICATION FOR A PRESCRIBING APPROVAL Approved opioids – QOTP - shared care 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. Failure to provide information may render the form incomplete, which may constitute an offence under the *Medicines and Poisons Act 2019*. 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.gld.gov.au/global/privacy.

Application type									
Initial application for approval to treat a patient with approved opioids (methadone or buprenorphine) under the Queensland Opioid Treatment Program (Shared Care Approval)									
Application to amend an approval to treat patients with approved opioids under the QOTP (Shared Care Approval)									
Approval number									
Application to renew an approval to treat patients with approved opioids under the QOTP (Shared Care Approval)									
Approval number									
Section 1 — Applicant details (s76 MPA)									
Provide details of the medical practitioner or nurse practitioner seeking the approval									
Title	Surname				Given names				
AHPRA registration No									
Street address					Town/ Suburb		P/C		
Postal address					- Guburb		P/C		
Work phone		Mobile			Email				
Do you have any restrictions on your registration (e.g. conditions or undertakings) that would prevent you from prescribing the medicines you are applying for approval for?							No		
If yes, provide further details of the restrictions on your registration									
Section 2 — Patient details									
Provide details of	of the patient this	application for a	pproval relates	s to	1				
Title	Surname				Given names				
Gender	Male	Female	Other			Date of birth			
Street address				Town/ Suburb	P/C				
Section 3 — Approved opioid(s) proposed to be prescribed under this approval (s68 MPA)									
Buprenorphine sublingual tablets Long-acting injection (SEE QUESTION BELOW)									
Buprenorphine/naloxone sublingual film Methadone syrup/liquid									
If you intend to prescribe a long-acting injection, have you watched the required training video? https://insight.qld.edu.au/training/admininisterlai-bpn/detail Yes									



Section 4 — S	hared care - Alcohol and	Other Drugs Service	(AODS) QOTP prescriber			
	I have an agreement from the following QOTP approved prescriber of a Hospital and Health Service Mental Health (Alcohol and Other Drugs) Service to treat the above-named patient under the QOTP with the approved opioid(s) specified in Section 3.					
Title	Surname		Given names			
Clinic name						
Work phone		Email				
Street address			Town/ Suburb	P/C		
Section 5 — D	uration of the prescribing	approval (s69 MPA)				
	e desired term or end date for t be issued for more than two (. Applicants should note that typ	ically prescribing		
Please specify	the term of approval sought	:				
2 years	Another term or end	date, please specify				
Section 6 — A	dditional information and	attachments				
Section 7 — C	onsent and declaration					
			osing my personal informatio s prescribing approval	n for the purpose of		
Australia (which m	n state or territory, or of the	Commonwealth, regay check). If relevant inf	exchanging information with, rding any matters relevant to ormation cannot be obtained formation available.	this application		
	that, to the best of my knowect in every detail.	vledge, all information	provided in and with this app	lication form is true		
			ation form, or in an attachmer ority granted may be suspen			
Full name of ap	plicant	Design	ation (position) of applicant			
Signature of ap	plicant	1		Date (DD/MM/YYYY)		

Please email the completed form to:

QOTP@health.qld.gov.au