# Rules & Regulations for Prescribing Pain Relief in Australia

**Australian Pain Management Association - Health Literacy Fact Sheet Series**

In Australia, medicines defined as Schedule 8 (S8) under the Standard for the Uniform Scheduling of Medicines and Poisons are strictly regulated because of the high risk of misuse and/or physical and psychological dependence associated with them. They have to be prescribed, dispensed, documented and destroyed in specific ways that are in compliance with each state and territory's different drug regulations. S8 medicines are under stricter control than Schedule 4 (S4) medicines (Prescription Only Medicine). The requirements for Prescription Only Medicines (S4) have been standardised between states and territories. This is not the case for Schedule 8 (S8) medicines, also called Controlled Drugs.

Australia has no central body to regulate the handling of S8 drugs. Although the Therapeutic Goods Administration (TGA) is the national body for the regulation of medicines, each state and territory self-regulate under the general principles established by the TGA and has their own interpretation and legislation regarding S8 drugs, which results in varied prescribing requirements.

In 2020 changes were made to the approved indications of immediate and modified release opioids as part of opioid reforms by the Therapeutic Goods Administration (TGA) to help address opioid misuse and abuse.

Immediate release opioid products should only be used for the management of severe acute pain, where patients must be unresponsive or intolerant, or have achieved inadequate relief of their acute pain to maximum tolerated doses on non-opioid treatments. Immediate release opioids play an important role in the short-term management of severe acute pain, such as post-operative pain.

Modified-release products should only be used for the management of severe pain where other treatment options have failed, are contraindicated, not tolerated or are otherwise inappropriate to provide sufficient management of pain and the patient requires daily, continuous, long-term treatment.

Modified-release opioids are not indicated to treat chronic non-cancer pain (other than in exceptional circumstances), or to be used for 'as-needed' (PRN) pain relief. In addition, hydromorphone and fentanyl modified release products should not be used in opioid naïve patients. The TGA has deliberately not defined 'exceptional circumstances' as it is acknowledged there may be a range of potential situations where they might apply to an individual patient, subject to the clinical judgment of the prescriber.

However, the overall outcome of the indication change is to narrow the circumstances in which opioids are prescribed for chronic non-cancer pain and for prescribers to rule out other potential treatment modalities before determining 'exceptional circumstances' apply.

---

**The legal requirements for obtaining authority and writing prescriptions for S8 medicines are complex, so this fact sheet will focus on the requirements for doctors.**

---

## Why are S8 medicines called 'drugs of dependence'?

Drugs of dependence are defined as prescription medicines that have a recognised therapeutic need but also a higher potential for misuse, abuse and dependence, can make a valuable contribution to patient care. However, problematic or risky use of these medicines might occur, along with harmful outcomes.

The drugs of dependence that are associated with the most problematic use include opioids, benzodiazepines and steroids.

---

## What are doctors required to do?

Generally, prescribing doctors need 2 separate approvals for the prescription of Controlled Drugs.

The first approval is from the PBS. The Controlled Drug needs to be prescribed using an authority PBS/RPBS prescription and the prescriber must have the prescription approved by Services Australia or the DVA. Without this approval, a pharmacist must not supply the medicine as a PBS/RPBS benefit.

The second approval is from the state Department of Health. S8 medications (and in some states and territories some benzodiazepines) cannot be prescribed without a permit or an appropriate approval from the relevant state or territory health department's pharmaceutical services unit (PSU) to patients who are known or suspected to be drug dependent.

For non-drug-dependent persons, S8 medications cannot be prescribed for a period greater than 2 months without an appropriate approval in some states or territories.

Permits or approvals are generally obtained by completing an application form and forwarding it to the relevant state or territory authority. The application form usually requests clinical information about the patient's condition. In some states (e.g. WA) a report from a specialist is required.

Only one valid permit will be issued at a time. If the doctor is taking over the care of a patient previously on a drug of dependence from a prescriber who has a valid permit, the previous prescriber must cancel that permit before a new one can be issued to the new doctor.

Only one doctor in the practice needs to hold a valid permit. However, if another doctor in that practice sees the patient and wishes to prescribe they must check the details of the permit (to determine if it is current) and they cannot prescribe more than the permit indicates. It is wise to endorse the prescription "deputy to Dr X the permit holder".

## How does the law define 'drug dependent'?

Legislation in most jurisdictions includes a definition of a "drug dependent person".

The definitions differ between the states and territories, however generally a "drug-dependent person" is a person who:

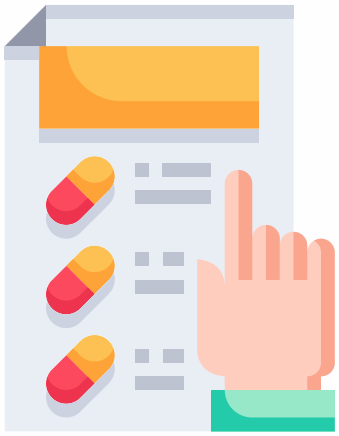
- exhibits impaired control or drug-seeking behaviour
- is likely to experience withdrawal symptoms of a mental and/or physical nature as a result of cessation of the medication (withdrawal)
- has consumed prescribed medications contrary to, or in excess of, prescribed instructions.

# Why is the government so concerned about pain management drugs like opioids ?

There was some research published by the University of Queensland last year: Adewumi AD, et.al. Opioid medication prescribing in Queensland, 1997–2018: a population study. Med J Aust 2021; 215 (3): 137-138.

In this research, they analysed Monitoring of Drugs of Dependence System (MODDS) data for adult Queensland residents (18 years or older) for whom opioids were dispensed during 1 January 1997 – 31 December 2018.

The number of patients for whom opioids were dispensed increased from 28,299 in 1997 to 322,307 in 2018; the number of Queensland medical practitioners who prescribed opioids increased from 4,537 to 20,226 over the same time period. Over two thirds of the prescriptions were for low doses of opioids.



This study showed findings indicate that most Queensland medical practitioners prescribe lower opioid doses, and that the proportion prescribing lower doses has increased since 2004. The proportion of people dispensed doses of opioids associated with increased risk of accidental overdose was small and has declined over time.

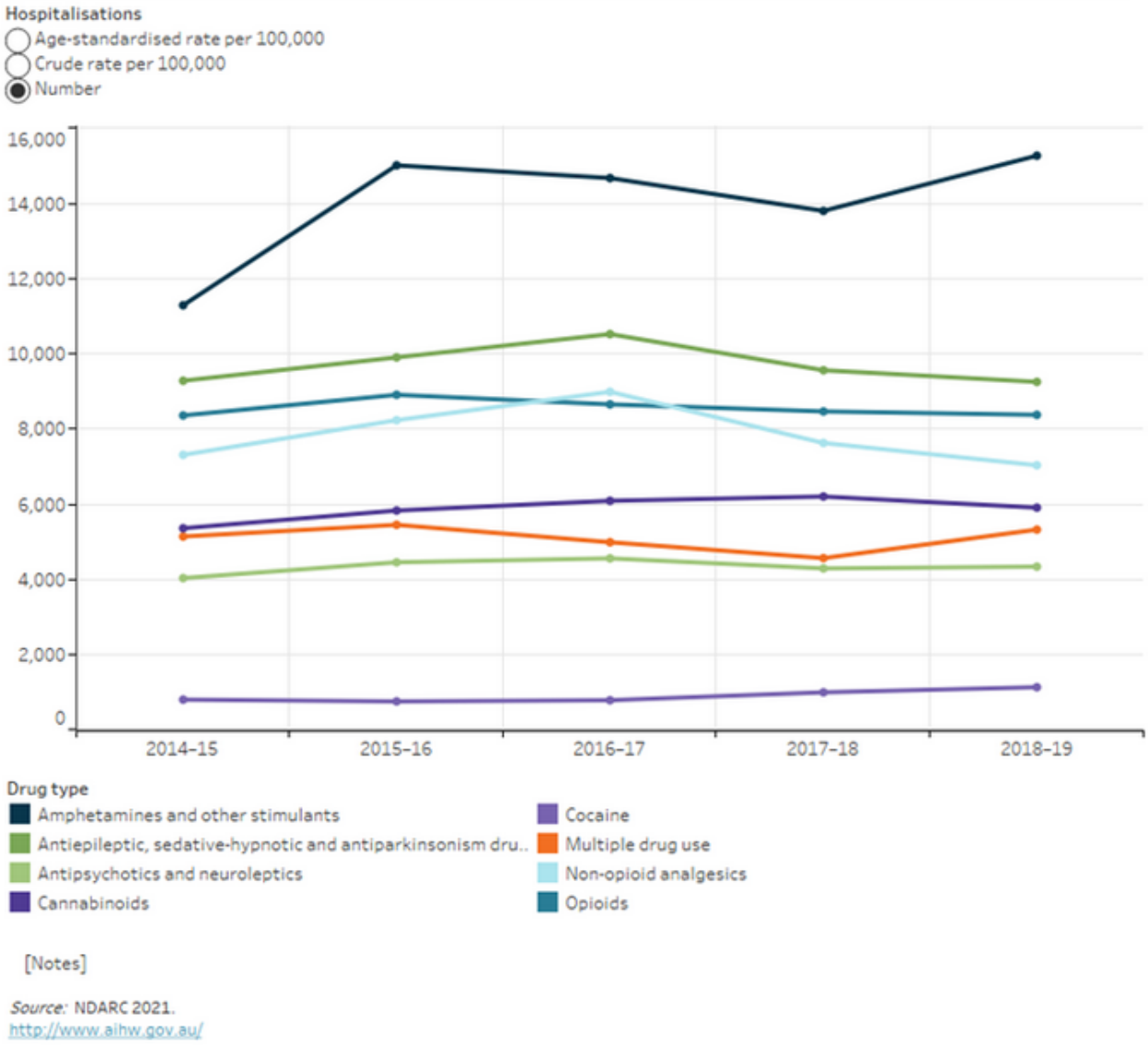
## So why worry?

Legal or pharmaceutical opioids (including medicines such as codeine and oxycodone) are responsible for far more deaths and poisoning hospitalisations than illegal opioids (such as heroin). Data from the AIHW (Australian Institute of Health and Welfare) published in 2018 reported:

Every day in Australia, nearly 150 hospitalisations and 14 emergency department (ED) presentations involve opioid harm, and 3 people die from drug-induced deaths involving opioid use. This may be from opioid misuse or accidental overdose.

Opioid pain relief treatments are not alone in causing hospitalisations. The National Hospital Morbidity Database contains information on drug-related hospitalisations. In 2018–19, 61,780 of the 11.5 million hospitalisations in Australia's public and private hospitals had a drug-related (excluding alcohol) principal diagnosis, which equates to 0.5% of all hospitalisations.

The total number and rate of drug-related (excluding alcohol) hospitalisations rose from 56,578 in 2014–15 to 61,780 in 2018–19 (from 244.3 to 250.6 per 100,000 population). The rise in drug-related hospitalisations has largely been driven by increases associated with amphetamines and other stimulants.




[Notes]

*Source:* NDARC 2021.
http://www.aihw.gov.au/

## Summary

It is widely recognised opioids pain relieving medicines are extremely valuable agents in the management of acute pain (including post-operative pain), in palliative care, in chronic cancer pain and in a small number of people with persistent non-malignant pain. The government wants GPs and all doctors to reflect carefully on each and every prescription of opioids for chronic non-malignant pain, other than in a palliative setting.

To keep track of prescribing practices, there are strict legal requirements around the prescription of drugs of addiction or controlled drugs, known as Schedule 8 (S8) medicines. The Australian Health Practitioner Regulation Agency (AHPRA) and the associated state or territory medical boards have the power to take disciplinary action, including immediate suspension of a doctor's registration or impose conditions, in the case of inappropriate S8 prescribing.

Inappropriate opioid prescribing can lead to patient harm as well as a medicolegal risk to prescribers so it is important that doctors find the balance between following the rules and helping their patients.