

Opioid Prescribing Legislation and Regulation

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This article first appeared in GP Update in 2014 and has been updated this year to reflect changes in Western Australian legislation.

Despite the introduction of a National Registration Scheme on 1 July 2010, drug prescribing regulation has remained fragmented and is based on inconsistent individual state/territory legislation. There have been many concerns expressed, by coroners as well as others, about the inappropriate prescribing of drugs capable of inducing dependence, particularly benzodiazepines and opioids. These highlight the need for doctors to be aware of and understand the requirements imposed on them by the respective state/territory laws.

The purpose of this article is to demonstrate common themes and pitfalls across the various State/Territory regulatory requirements.

Drug Scheduling:

A Therapeutic Goods Administration committee¹ categorises drugs into one of eight schedules as part of the Poisons Standard (SUSMP)^{2,3}, which is amended several times per year. They then pass these recommendations over to each State/Territory to incorporate into their legislation.

Schedule 8 [S8] controlled drugs are considered to have a high potential for abuse and addiction. They include a broad range of drugs – e.g. amphetamines, barbiturates, opioids, and benzodiazepines (flunitrazepam and alprazolam are S8 drugs) – although not all of the drugs in these classes are Schedule 8 drugs.

This article does not discuss S8 stimulant regulation (e.g. dexamphetamine and methylphenidate), nor cannabinoids, which are subject to differing requirements.

Commonwealth requirements:

To prescribe under the Pharmaceutical Benefits Scheme (PBS), a doctor may need to obtain federal government authority from Medicare Australia to satisfy certain conditions. Commonwealth PBS authority is different to and **does not** address state/territory legislative and regulatory requirements, which are separate (and generally more restrictive).

State/territory requirements⁴

The definitions, terms, relevant drugs and requirements vary between states/territories (see the table below).

In general terms, before prescribing you need to consider:

1. Is the patient drug dependent?

If a patient presents and requires the prescription of S8 drugs and your assessment is that the patient is drug dependent (or equivalent term used), then you will need to consider the additional

patient is drug dependent (or equivalent term used), then you will need to consider the additional and stringent requirements about obtaining an Authority (or equivalent) **before you prescribe**. Note that in some states (QLD, VIC, TAS,), drug addicted patients seeking S4 drugs of dependency (particularly benzodiazepines) may also require consideration.

2. Does the patient need to be reported as drug dependent to the authorities?

Some jurisdictions (NT, TAS , VIC, WA,) separately require that a drug dependent patient be reported under certain conditions.

3. Does the length of anticipated treatment of a non-drug dependent patient with S8 drugs require approval?

If the patient is not deemed to be drug dependent, then there are strict time limits that S8 drugs can be prescribed before approval is required, likely including the time other doctors have been prescribing the same medication(s).

Note that in NSW an Authority is required for only a very limited list of S8 drugs if the patient is not drug dependent. In WA, some patients being treated with S8 opioids for pain do not require authority, but need to be on a treatment contract at 30 days.

In NT and TAS, out of state prescribers are not able to prescribe S8 drugs.

Given the complex and varying requirements, if you deal with S8 prescribing, it is imperative that you familiarise yourself with the relevant regulations.

References

1. National Drugs and Poisons Scheduling Committee
2. Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP)
Poisons Standard February 2017 (SUSMP No 16)
3. Due to the disparity of terms and definitions between the various jurisdictions, the following abbreviations have been used (the table uses the specific legislative terms):
4. Drug addicted/dependent/seeking patients are collectively referred to in this article as "drug dependent" patients
5. Authority/Permit /Approval are collectively referred to in this article as an "approval"

State and Territory Opioid Prescribing Legislation and Requirements

State/Territory	Definitions	Lenth of Treatment before authority required if not drug dependant
ACT	Drug dependent - a person with a condition who, as a result of the administration of a controlled medicine [S8 drugs] or prohibited substance, demonstrates, in relation to the person's use of the medicine or substance, impaired control or drug-seeking behaviour that suggests impaired control and who, as a result of the cessation of the administration of the medicine or substance, is likely to experience symptoms of mental or physical distress or disorder	Approval: Treatment > 2 months (includes treatment by other prescriber)
NSW	Drug dependent person – means a person who has acquired an overpowering desire for the continued administration of such a drug, as a result of repeated administration of: (a) a drug of addiction [Schedule 8], or (b) a prohibited drug within the meaning of the <i>Drug Misuse and Trafficking Act 1985</i> [contains illicit drugs, and many others]	Authority: continuous therapeutic use > 2 months

NT	<p>Addiction – means a state of physiological or psychological dependence on, or increased tolerance to, the habitual and excessive use of the substance, and includes pain and other symptomatic indications arising specifically from withdrawal of the substance</p>	<p>Notification: treatment > 8 weeks in aggregate in preceding 12 months; specific initial and maximal dosing limits also apply; > 30% dosing increases or dosing increases within 2 weeks</p> <p>Authority: if prescribing S8 drug for > 15 patients</p>
QLD	<p>Drug dependent person – means a person:</p> <p>(a) who, as a result of repeated administration to the person of controlled or restricted drugs or poisons</p> <ul style="list-style-type: none"> • demonstrates impaired control; or • exhibits drug-seeking behaviour that suggests impaired control over the person's continued use of controlled or restricted drugs or poisons; and <p>(b) who, when the administration to the person of controlled or restricted drugs or poisons ceases, suffers or is likely to suffer mental or physical distress or disorder.</p>	<p>Approval: Treatment > 2 months (includes prior treatment)</p>
SA	<p>Dependent on drugs – means the person has:</p> <p>(a) acquired, as a result of the repeated administration of prescription drugs or controlled drugs, an overpowering desire for the continued administration of such drugs; and</p> <ul style="list-style-type: none"> • is likely to suffer mental or physical distress or disorder on cessation of the administration of such drugs; OR <p>(b) a history of consuming or using prescription drugs or controlled drugs in a quantity or manner that:</p> <ul style="list-style-type: none"> • in the case of drugs lawfully supplied to the person—is contrary to the prescribing practitioner's instructions relating to consumption or use of the drug; and, in any case—presents a risk to the person's health. 	<p>Authority: Treatment > 2 months (includes prior treatment)</p>
TAS	<p>Drug seeking behaviour – means a person is taken to exhibit drug-seeking behaviour in respect of a drug of dependence if there is reason to believe that:</p> <p>(a) he or she is seeking to obtain a drug of dependence for the purpose of selling or supplying it to another person; or</p> <p>(b) he or she is seeking to obtain a drug of dependence for a non-medical purpose; or</p> <p>(c) as a result of the administration to him or her of the drug, he or she exhibits:</p> <ul style="list-style-type: none"> (i) impaired ability to manage properly the use of any such drug; or (ii) behaviour which suggests such impaired ability; or 	<p>Authority: Treatment > 60 days</p>

	<p>(d) failure to obtain drugs of dependence for a non-medical purpose is likely to cause the person to exhibit signs of mental/physical distress/disorder.</p> <p>Drug dependent person – means a person who:</p> <ul style="list-style-type: none"> • has acquired, as a result of the repeated administration of drugs of dependence, an overpowering desire for their continued administration; or • has a condition such that the cessation of the administration of a drug of dependence, or on inability to obtain such a drug, is likely to cause then to exhibit signs of mental or physical distress or disorder; or • exhibits drug-seeking behaviour that suggests impaired control as a result of the person's continued use of drugs of dependence; or • consumes or uses a drug of dependence contrary to the prescribing practitioner's instructions. 	
VIC	<p>Drug dependence – NO CURRENT DEFINITION</p> <p>Drugs and Posions Regulation (DPR) suggests intention is clinical drug dependence (drug seeking, addiction, escalating doses) rather than pharmacological tolerance).</p> <p>Drug-dependent person – (repealed definition) means a person who habitually uses drugs of addiction to such an extent that he has lost the power of self-control with respect to the use of drugs of addiction</p>	Permit Treatment > 8 continuous weeks, includes treatment by other doctors
WA	<p>Drug dependent person – a person who has acquired, as a result of repeated administration of drugs of addiction or Schedule 9 poisons, an overpowering desire for the continued administration of a drug of addiction or a Schedule 9 poison</p> <p>Oversupplied person – a person who has over a period of time obtained, or obtained prescriptions for, quantities of drugs of addiction that are greater than is reasonably necessary for therapeutic use.</p>	<p>Authority: No time requirement.</p> <p>S8 treatment contract should be in place at 30 days</p> <p>Maximal dosing limits apply</p> <p>Prescribing methadone/alprazolam /flunitrazepam</p>

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