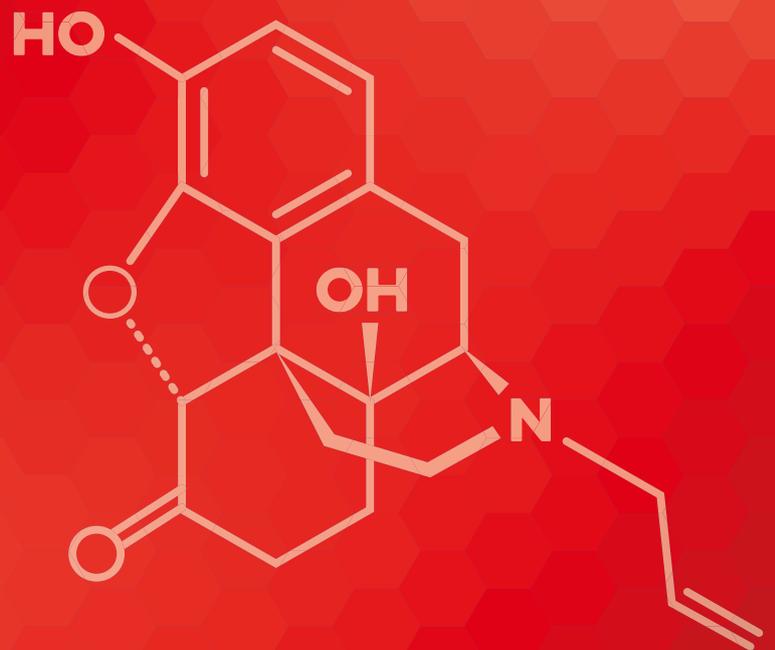
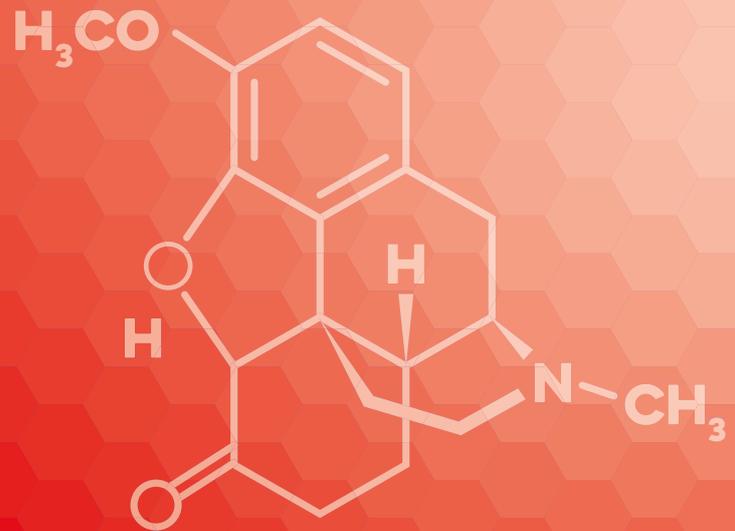
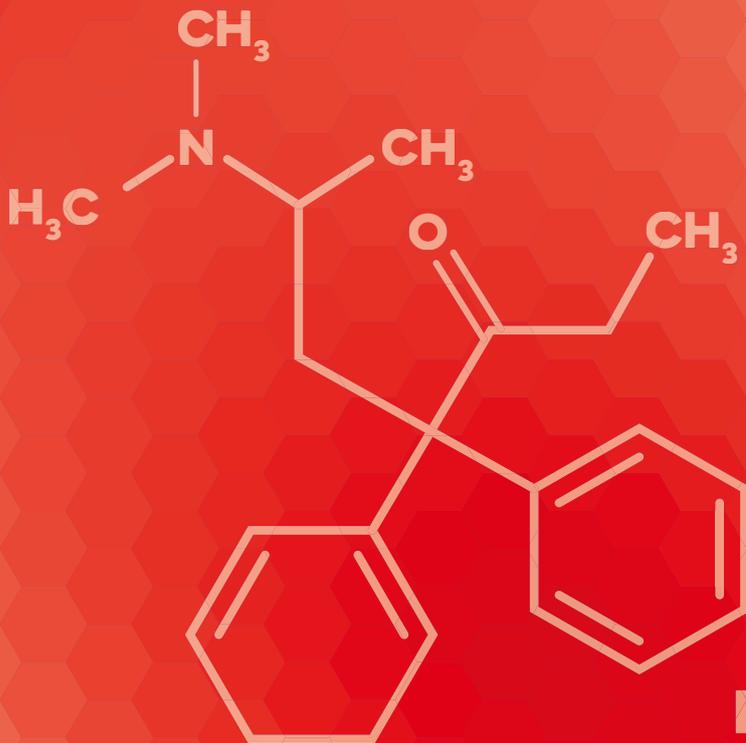




RACGP

*Prescribing drugs of dependence  
in general practice, Part A*

**Clinical governance framework**



## **Prescribing drugs of dependence in general practice, Part A – Clinical governance framework**

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## *Foreword*

Witnessing the growing problem of prescription drug deaths in Australia is confronting for those of us dedicated to good health outcomes for our patients. The Royal Australian College of General Practitioners (RACGP) is determined to take a proactive role in addressing this problem.

Our concerns about mortality and morbidity in this area are echoed by the broader health sector, health authorities and consumer groups. Prescription drug harms and deaths touch the lives of men and women of all ages and all demographics. Unfortunately, appropriate primary and secondary services to address problematic drug use are often not given high priority by society or governments.

This problem does not have a quick solution. The issues are complex and will require a coordinated effort to resolve effectively. General practice is not solely responsible for managing this problem, but it is an issue in our consulting rooms that we need to address.

This guide on clinical governance is a starting place for general practice to be a solution to problematic prescription drug use. The guide is a living document and will be regularly updated.

The RACGP would like to thank the key advisers, reviewers and the many state- and territory-based organisations and individuals who have provided thoughtful and constructive feedback in the development of this guide. Coordination with other services is essential to effect a constructive solution.

The RACGP welcomes feedback on this guide to continually improve services at the general practice level, and looks forward to ongoing collaboration with key agencies to improve care in this sector. Please use the feedback section on our website to help co-create this guide.

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## Acronyms

<b>ACSQHC</b>	Australian Commission on Safety and Quality in Health Care
<b>ADIS</b>	Alcohol and Drug Information Service
<b>AHPRA</b>	Australian Health Practitioner Regulation Agency
<b>AMA</b>	Australian Medical Association
<b>CBT</b>	Cognitive behaviour therapy
<b>CPD</b>	Continuing professional development
<b>CRAM</b>	Clinical risk assessment and management
<b>DACAS</b>	Drug and Alcohol Clinical Advisory Service
<b>DASAS</b>	Drug and alcohol Specialist Advisory Service
<b>DHS</b>	Department of Human Services
<b>DSM-5</b>	Diagnostic and Statistical Manual of Mental Disorders (5th edition)
<b>GC-MS</b>	Gas chromatography–mass spectrometry
<b>GP</b>	General practitioner
<b>ICD-10</b>	International Statistical Classification of Diseases and Related Health Problems, 10th revision
<b>MDMA</b>	3,4-methylenedioxy-N-methylamphetamine
<b>MED</b>	Morphine equivalent dose
<b>NOUGG</b>	National Opioid Use Guideline Group
<b>PBS</b>	Pharmaceutical Benefits Scheme
<b>PDIS</b>	Parent Drug Information Service
<b>PSIS</b>	Prescription Shopping Information Service
<b>PSU</b>	Pharmaceutical services unit
<b>RACGP</b>	The Royal Australian College of General Practitioners
<b>RPBS</b>	Repatriation Pharmaceutical Benefits Scheme
<b>S4</b>	Schedule 4
<b>S8</b>	Schedule 8
<b>SUD</b>	Substance use disorder
<b>SUSMP</b>	Standard for the Uniform Scheduling of Medicines and Poisons
<b>TGA</b>	Therapeutic Goods Administration
<b>UDT</b>	Urine drug test
<b>WHO</b>	World Health Organization
<b>YoDAA</b>	Youth Drug and Alcohol Advice

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## Summary

Clinical governance should ensure that patient care is accessible, appropriate and responsible. Drugs of dependence have important therapeutic uses and are highly beneficial to many individuals and the clinically appropriate supply of these medicines needs to be maintained. To ensure this, measures are required to minimise harm from inappropriate and unsanctioned use.

General practice needs to be an integral part of the solution to problematic prescription drug use in Australia.

The quality and safety of care could also be improved on a national level through:

- consistent laws and regulatory definitions of drugs of dependence across all jurisdictions
- an effective, real-time national prescription monitoring or surveillance program
- state and territory health systems that support continual and coordinated care for patients with complex and/or multiple problems (eg combined substance use disorders [SUDs], chronic pain and mental illness) in conjunction with general practice
- national support for the 'medical home' concept, ie, a patient having one general practice and preferably one general practitioner (GP) to provide ongoing care and accountable prescribing of drugs of dependence
- adequate resourcing of systems of care within general practice for patients with SUDs.

The following sections contain summaries of the recommendations from the rest of the guide. Note that '**should**' refers to a recommendation, '**must**' to an obligation, '**must not**' to a prohibition and '**may**' for a discretionary action. General practices need to consider the recommendations in the context of their local circumstances. Implementation of recommendations should be based on relevancy and appropriateness on a practice-by-practice basis.

For definitions of key terms such as dependence and tolerance, refer to [Appendix A](#).

## General practice systems of care

The quality and safety of patient care is no longer confined to the individual practitioner.

General practices have responsibilities to work collaboratively with practitioners to continuously improve care for their patients and improve quality and safety concerning prescription drugs. With respect to drugs of dependence:

- General practices should undergo and attain **accreditation** according to the RACGP's *Standards for general practices* (4th edition) (the Standards) and have **clinical leaders** with designated areas of responsibility regarding safety and quality improvement systems. Practices should:
  - support and facilitate ongoing **quality assurance arrangements**
  - consider appropriate monitoring systems to ensure early alert and **sentinel systems** are in place.
- General practices should assist GPs in preventing prescription drug misuse by:
  - promoting and supporting GPs in using **non-pharmacological** interventions
  - promoting the development of **competency in prescribing** drugs of dependence – this may have particular relevance to registrars.

- General practices should have **systems of care** that seek to maximise health outcomes and social functioning for all patients prescribed drugs of dependence while minimising drug and alcohol misuse, abuse, diversion and crime. Practices should:
  - implement strategies to ensure the occupational health and **safety of GPs** and other members of the practice team
  - promote multidisciplinary care for patients who use drugs of dependence
  - have agreed **clinical policies** regarding prescribing drugs of dependence
  - have an effective **handover system** that ensures safe and continuing healthcare delivery for patients
  - insist on timely, **high-standard referral letters** for clinical handover or shared-care arrangements from secondary care
  - consider having policies regarding **risk stratification of patients** to reduce clinical and occupational risks.
- General practices should consider secondary prevention strategies that attempt to manage problematic drug use in its early stages of development before it results in significant morbidity. Practices should:
  - consider **letters to the practice population** to reduce benzodiazepine use
  - have agreed **clinical policies** regarding a standard approach/management to patients displaying drug-seeking behaviour
  - facilitate GP access to **information management** data designed to monitor potential prescription drug abuse (eg state and territory health ministries' drug units and Prescription Shopping Information Service [PSIS])
  - consider policies on simple benzodiazepine and **opiate withdrawal regimes**.
- Selected general practices should support the organisation and coordination of services for patients with substance use disorder. These practices should:
  - support **GP-based dependency programs** with suitably qualified staff, organised support and ongoing quality assurance arrangements (where possible)
  - consider tertiary prevention to limit existing disease and its effects through appropriate treatment (eg opioid substitution therapy for opioid-dependent patients).

## Accountable prescribing

Accountable prescribing is a commitment to evidence-based practice, the use of medicines with proven effectiveness and avoidance of medicines when they do not help or when they cause harm. Prescribing must be based on a comprehensive medical assessment, a diagnosis, thoughtful consideration of the likely risks and benefits of any medication as well as alternative interventions, and a management plan derived through shared decision making.

- GPs must prescribe within **legislative frameworks** and should comply with **professional standards** and approved clinical guidelines.
- GPs must maintain **professional boundaries** when prescribing drugs of dependence.
- GPs should maintain or improve their skills in relevant areas such as chronic pain, mental health or drugs of dependence.
- GPs should optimise **non-pharmacological interventions**.
- GPs should use **universal precautions** in guiding their approach to patients who require drugs of dependence.
- GPs should inform patients that drugs of dependence should be prescribed from only one practice and preferably by only one GP, and drugs should be dispensed from one pharmacy.

- GPs must ensure that **patient records** are clear, up-to-date and contain sufficient information for another practitioner to take over care.
- GPs have the right to discontinue care of a patient who has behaved in a violent or threatening manner.
- GPs should be prepared to utilise **specialist support** to manage problematic drug use in complex patients with significant issues or if the clinical situation deteriorates.
- In the context of drug dependent patients:
  - prescribing must be based on a **comprehensive medical assessment**
  - GPs **must seek a permit or an authority** from the relevant state or territory health department when prescribing an S8 drug to a patient who is drug dependent.

## Patient focus

Patients have the right to respectful care that promotes their dignity, privacy and safety. Patients with problematic use of prescription drugs and those who use illicit drugs have the same entitlement to respectful care.

The decision to prescribe drugs of dependence, like other aspects of clinical practice, should be made with the patient. Shared decision making brings together the GP's clinical expertise and judgement and the patient's values and preferences (which are informed by their beliefs and their personal circumstances such as their age, family and social relationships). Patient-focused care is not equivalent to care dictated by the patient – boundaries and clinical judgement are key components of high-quality care.

To facilitate patients (and their carers) to participate in **shared decision making**:

- General practices and GPs should provide patients with information (at the appropriate level and manner) about the purpose, realistic expectations, options, and benefits and risks of any treatments.
- GPs may wish to consider using patient information resources to help patients understand their options and the consequences of their decisions.
- GPs should develop respectful, non-judgemental and clear responses to inappropriate requests for drugs of dependence.



# 1. Introduction

Prescription medication misuse is a worldwide problem. In Australia, there are growing concerns about the increasing misuse and associated harms of a range of pharmaceuticals.<sup>1</sup> Many types of medications are misused,<sup>2</sup> particularly drugs of dependence. Of particular concern is the problematic use of benzodiazepines and prescription opioids.<sup>1,3</sup>

Reducing misuse of pharmaceutical drugs and associated harms is a national priority.<sup>4</sup> The Royal Australian College of General Practitioners (RACGP) has developed a series of guides on drugs of dependence to help GPs play an important role in tackling the problem.

Part A – Clinical governance framework, describes the overarching principles and strategies for use with the individual drugs of dependence guides.

## 1.1 Aims

This guide aims to improve the quality and safety of prescribing of drugs of dependence in general practice by:

- helping practices develop a clinical governance framework for prescribing drugs of dependence that complements the Australian regulatory framework
- supporting practices and GPs in the development of an environment of quality improvement and best practice with regard to drugs of dependence
- promoting safer prescribing and non-prescribing within general practices
- enabling the recognition of higher risk situations and offering solutions to manage these appropriately
- bringing together tools and evaluation processes for patients with more complex problems
- providing solutions to enable general practice to prevent and manage prescription drug misuse.

The intended impact is a reduction in adverse events associated with prescribing drugs of dependence.

## 1.2 How to use this guide

This guide is designed to assist GPs in the management of drugs of dependence. It is not a set of mandatory rules. General practice has varying degrees of exposure to issues surrounding drugs of addiction. Each practice needs to determine which features of this guide are relevant for their circumstances.

General practices need to consider the recommendations and implement these according to their local circumstances.

The appendices contain examples of some practice policies. These examples are not individually approved or endorsed by the RACGP Council, or by the Standards. They are based on policies and practices from national and international sources. If practices wish to adopt any of these policies, they should be adapted or modified for relevance and applicability to the local context.

### 1.2.1 Who will use this guide and why?

This guide may be used by practice owners, managers and support staff who:

- are concerned about prescription drug abuse in their practice area and want to prevent a mishap

- service a population with a high prevalence of mental illness, pain and/or addiction problems and want to ensure they provide the best possible care
- have had an adverse event associated with prescription drug abuse and want to know how to prevent a recurrence
- have doctors who have expressed concerns about what is happening regarding drugs of dependence
- want to contribute toward reducing prescription drug abuse in their community.

This guide may be used by GPs who:

- rarely sees patients who abuse prescription medication, but want to know more about the proper management and treatment of these patients
- occasionally sees patients who abuse prescription medication, but uncertain of their legal responsibilities
- felt unsafe during a consult with a patient with drug-seeking behaviour, and would like to take something to their practice manager to address this
- saw an adverse event with a colleague, and would like to know how their practice and colleagues can manage this problem better
- is starting in a new practice and would like a way of talking about the issues of prescribing drugs of dependence at the next practice meeting
- works with other GPs who frequently prescribe drugs of dependence for conditions where other (safer/more effective) evidence-based therapies exist (eg insomnia), and is concerned about this practice and the risks associated with it, and would like some guidelines to discuss with them and implement in their practice
- would like the support of professional colleagues and the RACGP in advising patients on the risks and benefits of use of prescribed opioids and be able to make an assessment that weighs the risks versus the benefits of continued prescribing and the skills to taper and terminate opioids when appropriate.

This guide may be used by medical students who:

- were taught the harms associated with the use of benzodiazepines and opioids, yet have seen this in some practices.

This guide may be used by general practice registrars who:

- are starting in a practice in their first GP rotation and want advice on how to prescribe safely
- want assistance in implementing a policy of one prescriber for any drug of dependence
- want to feel confident and supported in advising senior colleagues that they will not provide ongoing prescriptions for drugs of dependence to patients they do not know.

This guide may be used by a psychiatrist, alcohol and drug addiction specialist, chronic pain specialist, other medical practitioner, practice nurse, nurse practitioner, credentialed mental health nurse, psychologist, social worker, or allied health professional who:

- is concerned about the prescribing habits of the doctors they work with and would like some guidelines to discuss with them.

## 1.3 Why do we need this guide?

Drugs of dependence have an important and valuable role in patient care. In recent years, the number of psychoactive drugs and formulations available in Australia has increased substantially.<sup>3</sup> Many of these drugs have provided significant benefits to patients. However, the evidence demonstrates that pharmaceutical misuse is rapidly emerging as a drug problem.<sup>5</sup>

GPs need to be aware of the extent of the problem of pharmaceutical drug misuse, the factors involved and the role of general practice in potential solutions.

### 1.3.1 The extent of the problem

#### 1.3.1.1 How Australia compares

The US<sup>6</sup> and Canada<sup>7</sup> acknowledge there is a serious problem with the misuse of prescription opioids.<sup>3</sup> Prescriptions in the US account for 99% of the worldwide consumption of oxycodone, while it only comprises 4.7% of the world's population.<sup>5</sup> This may make Australia's issues seem minor in comparison, however, Australian data shows a high prevalence of misuse of prescriptions opioids.<sup>2</sup> According to the 2014 World Drug Report, the annual prevalence of misuse of prescription opioids is:<sup>2</sup>

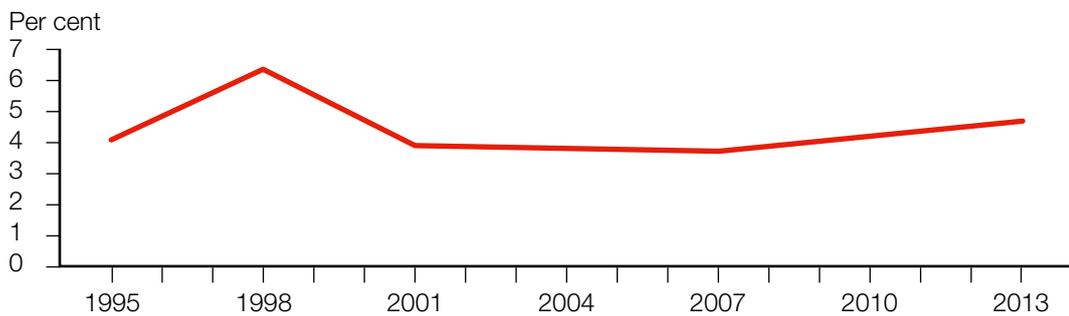
- Australia 3.1%
- Canada 1%
- Nigeria 3.6 %
- Pakistan 1.5%
- US 5.2 %.

While benzodiazepine prescribing has remained reasonably steady (approximately 7 million prescriptions per year<sup>8</sup>), there has been a dramatic change in the profile of the benzodiazepines prescribed and alprazolam use has increased by one-third.<sup>4</sup>

There is an understanding that the pattern of substance misuse changes over time as the types and availability of illicit and pharmaceutical drugs change.<sup>3</sup> However, there are still a number of gaps in our understanding of problematic use of prescribed drugs of dependence in Australia.<sup>9</sup> Research in this area continues.

Key findings of the *National Drug Strategy Household Survey 2013*<sup>10</sup> indicate:

- the number of people participating in any illicit use of drugs, including pharmaceutical misuse, in Australia is increasing
- the proportion of people using most illegal drugs has remained relatively stable and the use of some illegal drugs has even slightly decreased over the last three years
- in 2013, nearly 8 million (42%) people in Australia aged 14 years or older had ever illicitly used drugs, including misuse of pharmaceuticals; almost 3 million (15.0%) had done so in the last 12 months, compared to approximately 2.7 million (14.7%) in 2010
- non-medical use of pharmaceuticals in the previous 12 months had increased overall since 2007 and was at the highest level of use since 1998 (from 3.7% in 2007 to 4.7% in 2013) (*Figure 1*)
- the increase in pharmaceutical misuse in 2013 was mainly due to significant increases in recent use by men aged 30–39 (from 4.5% to 6.9%) and women aged 40–49 (from 3.1% to 4.5%)
- among people who reported recent misuse of any kind of painkiller/analgesic (3.3%), about three-quarters had misused over-the-counter pain killers and half had misused prescription pain killers.

**Figure 1. Misuse of pharmaceuticals by people aged 14 and over, 1995–2013**

Source: Australian Institute of Health and Welfare.

### 1.3.1.2 The harms

Drug-related harm is experienced by both sexes and across all ages and levels of use (experimental, recreational, dependent) and with therapeutic use. Harms includes loss of life through overdose and accidents, negative mental and physical health effects, family and social problems, psychological and emotional difficulties, and legal and financial problems.<sup>11</sup>

## 1.3.2 The factors involved

### 1.3.2.1 Problematic use is widespread

Pharmaceutical drug misuse problems exist on a spectrum ranging from inadvertent misuse associated with inappropriate prescribing practices through to deliberate misuse.<sup>5</sup> There are numerous reasons people deliberately misuse prescription medications. Self-medication (pain, anxiety, insomnia), drug substitution, enhancement of other drugs and enjoyment are common examples. Vulnerable individuals may use substances including psychoactive prescription drugs to make themselves feel better.<sup>12</sup> This new, hidden population<sup>13</sup> may differ from the usual drug user stereotypes as they may be more highly functioning and may have higher socioeconomic status, better education and more social support.<sup>3</sup>

### 1.3.2.2 More drugs are being prescribed (and diverted)

Prescription rates of opioids have substantially increased: between 1997 and 2012, oxycodone and fentanyl supply increased 22-fold and 46-fold respectively.<sup>3</sup> Oxycodone is now the seventh leading drug prescribed in Australian general practice.<sup>3</sup> The number of opioid prescriptions subsidised by the Pharmaceutical Benefits Scheme (PBS) increased from 2.4 million in 1992 to seven million in 2007.<sup>3</sup>

Not all prescriptions will lead to improved patient outcomes.

### 1.3.2.3 Sources of drugs

In a 2012 study of participants in an Australian methadone and buprenorphine treatment program (ie people representing the more 'severe' end of the spectrum of problematic pharmaceutical drug users), most regular prescription opioid users reported buying their opioids from others. In contrast, a medical practitioner was the main source of benzodiazepines (*Table 1*).<sup>14</sup>

**Table 1. Self-reported sources of pharmaceuticals used by study participants in the 28 days before treatment entry\***

	A source	Usual source	Source for most recent unsanctioned use
<b>Benzodiazepines</b>			
n	144	123	139
Doctor – real symptom	104 (72%)	79 (64%)	–
Doctor – fake symptom	32 (22%)	9 (7%)	–
• Any prescribed source	113 (78%)	88 (72%)	62 (45%)
Gift	63 (44%)	10 (8%)	50 (36%)
Swap	22 (15%)	1 (1%)	2 (1%)
Stolen	9 (6%)	3 (2%)	5 (4%)
Forged prescription	5 (3%)	0	2 (1%)
Bought from friend	28 (19%)	12 (10%)	11 (8%)
Buy from dealer	25 (17%)	9 (7%)	7 (5%)
• Any non-prescribed source	80 (56%)	35 (28%)	77 (55%)
• Both prescribed and non-prescribed	80 (56%)	–	–

\* Data are number (%) unless otherwise specified  
Source: Nielsen S, Bruno R, et al. The sources of pharmaceuticals for problematic users of benzodiazepines and prescription opioids. *Med J Aust* 2013; 199(10):696–9 © Copyright 2013 *The Medical Journal of Australia*.

### 1.3.3 Being part of the solution

General practice prescribing practices are a key to minimising the harms from drugs of dependence.

If prescribers do not rise to the challenge of appropriate and accountable prescribing, there is a risk Australia will experience the high rates of the prescription drug abuse of other countries or face oppressive regulatory responses.

This guide encourages general practices and GPs to be part of the solution by reducing prescription drug abuse through clinical governance at a practice level and accountable prescribing at the GP level. Both levels are supported by formal and informal controls around drugs of dependence.

Good clinical governance in prescribing drugs of dependence is supported by a comprehensive practice policy and a unified approach to drugs of dependence, and these, in turn, support individual GPs to prescribe these drugs safely and appropriately.

## 1.4 Developing an environment for quality improvement in prescribing of drugs of dependence

The health sector is characterised by complexity, multiple stakeholders (national and state/territory governments, public and private providers, professions and consumer groups) and numerous regulatory agencies and regulatory standards.<sup>15</sup> Policy makers, regulators and professional bodies all have roles to play in developing an environment for quality improvement that supports general practice in its quest for quality.

Multiple levels of regulation surround the prescription of drugs of dependence. The overarching control mechanisms are legislation and regulation. Legislation focuses on the drug, who can prescribe it, which patient is eligible and the legal penalties for non-compliance. Regulators license prescribers and can apply penalties. They provide an important level of protection for patient safety. However, legislation offers limited scope for ensuring patient-centred care or clinical effectiveness, and has little ability to drive quality improvement.

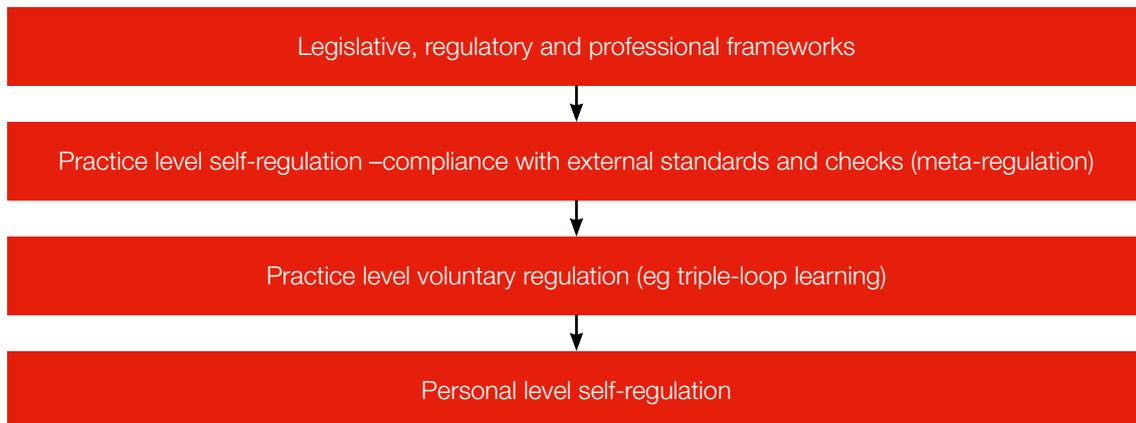
Self-regulation by GPs around quality and safety has improved.<sup>15</sup> Although important for quality improvement within individual general practices, self-regulation is not sufficient to realise improvements across the whole of primary care.<sup>15</sup> Media scrutiny and scandals in healthcare settings mean the public no longer accept doctors' self-regulation of safety and quality.<sup>15</sup>

Between overarching frameworks and practitioner self-regulation is regulation at the practice level. Meta-regulation is a reasonably recent level, which evolved in response to regulatory failures (not necessarily within the health sector, although they have occurred here). Clinical governance falls within the level of meta-regulation.

Meta-regulation is enforced self-regulation.<sup>15</sup> It enhances the self-regulatory capacity of general practices by requiring risk management and quality improvement strategies, which achieve more than legally required.<sup>16</sup> That is, external standards are used to drive internal quality improvement.

Meta-regulation brings together general practice's understanding of the issues and its capacity to manage them with demands and expectations of government agencies and professional bodies such as the RACGP.

**Figure 2. Levels of practice regulation**



Adapted from Healy J, Braithwaite J. Designing safer health care through responsive regulation. *MJA* 2006;184:S56–S59.

A 'softer' version of practice regulation involves learning models such as triple-loop learning<sup>17</sup> in which practitioners evaluate their outcomes (first loop) and feed this learning into the practice (second loop).<sup>15</sup> The third loop occurs when a regulator, such as an accreditation agency or a health department, learns from monitoring the practice's double-loop learning and revises its regulatory goals for the whole field.<sup>15</sup>

## 1.4.1 Clinical governance

Clinical governance should ensure patient care is accessible, approachable and responsible, and a practice environment is developed that provides quality improvement in prescribing of drugs dependence.

### 1.4.1.1 What is clinical governance?

Clinical governance is a 'system through which organisations are responsible for continuously improving the quality of their services and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish'.<sup>18</sup> It involves a number of interlinked structures and activities designed to ensure that managers, clinicians, pharmacists and those who govern health services are aware of their roles and responsibilities, and have the appropriate arrangements and processes in place to effect robust governance.<sup>19</sup> For the system to work effectively, each level of service must properly take on their responsibilities

Clinical governance is a framework for quality improvement that coordinates interactions between patients, healthcare providers and the healthcare system. Each practice has tailored policies and procedures that coordinate with other healthcare services (eg pharmacies, alcohol and drug services) and align with local and national health policy (eg National Drug Strategy 2010–2015).

Clinical governance is a process made up of a large number of elements. In the context of drugs of dependence, elements of clinical governance include:<sup>20,21</sup>

- lines of responsibility and accountability (clinical leaders)
- risk management – practice policies and general standards to support patient safety and clinical effectiveness
- education on clinical effectiveness – evidence-based practice
- clinical audit – important for identifying patients at risk of dependence
- research and development.

For many of these elements there is a range of criteria or recognised standards of good practice that can be used in audit and benchmarking.

While GPs have direct accountability for prescribing drugs of dependence, the whole practice team has a responsibility to engage in activities to improve patient safety and reduce problematic use of prescription medication in the community.

### 1.4.1.2 Clinical governance within a general practice

Clinical governance is achieved through effective leadership and commitment to excellence within general practice and across the healthcare sector.

Full implementation of clinical governance in any general practice may take time as policies and procedures are developed and partnerships with other providers are formed.

There are considerable gaps in available services, such as pain medicine and dependence treatment programs, and in many areas, general practice may need to take on broader care roles with complex patients. In this case, GPs may need additional training and should seek advice from distant specialist services (eg addiction medicine specialists).

## 2. Laws and regulations

### 2.1 Legislative requirements

There are strict legal requirements around the prescription of drugs of addiction or controlled drugs, known as Schedule 8 (S8) medicines. The legislative requirements vary in each state and territory. Importantly, the legislative requirements for prescribing S8 drugs vary depending on the person's dependence:

- For drug dependent persons, 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), via an authority/permit/approval, to patients who are known or suspected to be drug dependent.<sup>22</sup>
- 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.<sup>22</sup>

Before prescribing an S8 drug, GPs must take all reasonable steps to ensure a therapeutic need exists. Once a therapeutic need is established, GPs are required to comply with state- or territory-specific health legislation (refer to [Appendix C.1](#)) and the fact sheets listed below and, where necessary, obtain an authority/permit from the relevant PSU. These authorities are distinct from, and in addition to, any authority under the PBS for scripts.<sup>23</sup>

When a PBS or Repatriation Pharmaceutical Benefits Scheme (RPBS) authority application is for an S8 medicine (other than dexamphetamine sulphate or methylphenidate), the following guidelines apply:<sup>24</sup>

- the maximum quantity is generally for 1 month's supply (eg 1 week's therapy with three repeats)
- where supply for a longer period is warranted, quantities are usually for up to 3 months' therapy
- telephone approvals are limited to 1 month's supply.

Prescribers need to state the interval of repeat where repeats are called for and ensure state or territory health authorities are notified about ongoing treatment. Review by a second doctor is required for PBS prescription of an opioid beyond 12 months.<sup>24</sup>

Inappropriate S8 prescribing may result in criminal prosecution, financial penalties, the loss of a doctor's authority to prescribe S8 drugs or disciplinary action.<sup>22</sup>

Refer to the appropriate state and territory legislation and contacts at [Appendix C.2](#).

There are useful fact sheets available at:

- New South Wales – Summary of Controls on the Prescribing and Handling of Drugs of Dependence, [www.health.nsw.gov.au/pharmaceutical/Documents/drugsofdependence-controls.pdf](http://www.health.nsw.gov.au/pharmaceutical/Documents/drugsofdependence-controls.pdf)
- Northern Territory – Remote Health Atlas; Restricted S4 Medicines, [http://remotehealthatlas.nt.gov.au/restricted\\_schedule\\_4\\_medicines.pdf](http://remotehealthatlas.nt.gov.au/restricted_schedule_4_medicines.pdf)
- Queensland – Regulatory requirements and resources, [www.health.qld.gov.au/clinical-practice/guidelines-procedures/medicines/drugs-of-dependence/regulation/default.asp](http://www.health.qld.gov.au/clinical-practice/guidelines-procedures/medicines/drugs-of-dependence/regulation/default.asp)
- South Australia – Drugs of Dependence, [www.sahealth.sa.gov.au/wps/wcm/connect/Public+Content/SA+Health+Internet/Clinical+resources/Clinical+topics/Medicines+and+drugs/Drugs+of+dependence/](http://www.sahealth.sa.gov.au/wps/wcm/connect/Public+Content/SA+Health+Internet/Clinical+resources/Clinical+topics/Medicines+and+drugs/Drugs+of+dependence/)
- Victoria – Things medical practitioners need to know – key prescribing requirements, <http://docs.health.vic.gov.au/docs/doc/Things-medical-practitioners-need-to-know--key-prescribing-requirements>
- Western Australia – Requirements for the prescribing of S4 and S8 Medicines in Western Australia, [www.public.health.wa.gov.au/cproot/3565/2/Prescribing\\_S4\\_S8\\_080825.pdf](http://www.public.health.wa.gov.au/cproot/3565/2/Prescribing_S4_S8_080825.pdf)

## 2.2 Regulatory, professional and monitoring bodies

### Therapeutic Goods Administration

All products for therapeutic use are controlled by the Therapeutic Goods Administration (TGA), which is a division of the Federal Department of Health. The TGA controls regulated (or scheduled) medicines and listed medicines, which are unscheduled.

Scheduled medicines are included in the *Standard for the Uniform Scheduling of Medicines and Poisons* (SUSMP or Poisons Standard). The Poisons Standard is maintained by the TGA, but is implemented as state-level legislation.

To view the Poisons Standard, go to [www.comlaw.gov.au](http://www.comlaw.gov.au)

### Drugs of dependence units (state and territory based)

State and territory departments and government-funded drugs of dependence units provide information for medical practitioners in each state and territory.

Refer to [Appendix C.2](#) for details.

### Australian Health Practitioner Regulation Agency

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.<sup>22</sup>

For further information, go to [www.ahpra.gov.au](http://www.ahpra.gov.au)

### The RACGP

The RACGP's Standards, are standards developed by the profession for the profession. The Standards are designed as a template for safe, high-quality care in the increasingly complex environment of Australian general practice.

Accreditation by an independent body against the Standards demonstrates that a practice is serious about providing high-quality, safe and effective care to standards of excellence determined by the general practice profession.

Accreditation is an important component of the regulatory framework for quality and safety in health.

The Standards requires practices to comply with jurisdictional requirements on Schedule 4 (S4, prescription only) and S8 medicines.<sup>20</sup>

The Standards is available at [www.racgp.org.au](http://www.racgp.org.au)

### Australian Medical Association

The Australian Medical Association (AMA) provides resources to help prescribers navigate laws and regulations.

For more information, visit <https://ama.com.au/prescribing-drugs-addiction-members-support-page>

### Medicare

Medicare Australia regularly reviews PBS prescribing data, looking for inappropriate prescribing by doctors.<sup>25</sup>

### 3. General practice systems of care

Recommendations	Reference to the Standards
General practices should undergo and attain accreditation according to the Standards	
General practices should have clinical leaders who have designated areas of responsibility regarding safety and quality improvement systems	(Criterion* 3.1.3 Flagged indicator A) <sup>20</sup>
Practice systems of care and treatment should seek to maximise health outcomes and social functioning for all patients prescribed drugs of dependence while minimising drug and alcohol misuse, abuse, diversion and crime	
General practices should promote the development of competency in prescribing drugs of dependence – this may have particular relevance to registrars	(Extrapolated from Criteria 4.1.2, 3.1.2 and 5.3.1) <sup>20</sup>
General practices should support relevant training, education and resources for staff to be able to identify patients with more complex needs and those at higher risk.	
General practices should support GP-based dependency programs with suitably qualified staff, organised support and ongoing quality assurance arrangements	(Extrapolated from Criteria 3.1.2, 3.1.3, 3.2.1 and 3.2.3) <sup>20</sup>
General practices should have agreed clinical policies regarding prescribing drugs of dependence	(Extrapolated from Criterion 5.3.1. Flagged indicator D) <sup>20</sup>
General practices should consider having policies regarding the management of patients according to mental health status and use of drugs of dependence to provide the appropriate level of service internally and externally	
General practices should have an effective handover system that ensures safe and continuing healthcare delivery for patients	(Criterion 1.5.2) <sup>20</sup>
General practices and GPs should insist on timely, high-standard referral and discharge letters for clinical handover or shared-care arrangements from secondary care	
General practices must implement strategies to ensure the occupational health and safety of GPs and other members of the practice team	(Extrapolated from Criterion 4.1.2. Flagged indicator B) <sup>20</sup>
General practices should facilitate GP access to information management data designed to monitor potential prescription drug abuse (eg state and territory health ministries' drug units and PSIS)	

\*Criteria from The RACGP's *Standards for general practice* (4<sup>th</sup> edition)

The quality and safety of patient care is no longer confined to the individual practitioner. General practices have responsibilities to work collaboratively with practitioners to continuously improve care for their patients. Practice systems of care and treatment should seek to maximise health outcomes and social functioning for all patients prescribed drugs of dependence while minimising drug and alcohol misuse, abuse, diversion and crime.

## 3.1 The medical home model of care

The healthcare system is complex and often fragmented. The complexity can be a barrier to patients seeking or continuing treatment. The lack of cohesiveness, especially with information sharing, can facilitate doctor or prescription shopping. To counter this, regular contact with a GP helps patients navigate the various systems and creates a chance to explore needs in more depth, while building rapport and continuity.

The medical home model of care aims to provide patients with continuous, accessible, high-quality and patient-centred care. Australian general practice encapsulates the medical home model.<sup>26</sup> This model is a way of organising primary care so that patients receive care coordinated by their GP, supported by information technology, delivered by a multidisciplinary team and adherent to evidence-based practice guidelines. Each patient's medical home is individualised to meet their needs and may change over time.

A central principle of the medical home is the 'personal doctor', where one GP provides the patient with first contact, and then continuous and comprehensive care.<sup>27</sup> The medical home is responsible for the patient's healthcare across their whole life journey, including acute, chronic, preventive and end-of-life care. This approach results in better health outcomes for patients and their families.<sup>28</sup>

The medical home model has measurable benefits, including improved continuity of patient care,<sup>29</sup> and improved quality and cost effectiveness of care for patients with a chronic disease.<sup>30</sup> Additionally, medical homes reduce disparities in access to quality care among traditionally difficult to reach groups,<sup>31,32</sup> which leads to improved overall population health<sup>33</sup> and lower overall healthcare spending.<sup>34</sup>

## 3.2 Practice accreditation

Practices should undergo and attain accreditation according to the Standards. Accreditation is a basic risk management strategy. Accreditation ensures that the practice is 'fit for purpose' in delivering high-quality, safe primary care services. Accreditation is an important component of the regulatory framework for quality and safety in health.

## 3.3 Clinical leaders

All practices should have clinical leaders who have designated areas of responsibility regarding safety and quality improvement systems (eg drugs of dependence, infection control). In small practices, one person may be the clinical leader of multiple areas. Appointment of a clinical leader is designed to ensure:

- an organisational culture that resources, supports, recognises and rewards participation and leadership in safety and quality improvement
- staff involved in monitoring and improving care and services are held accountable
- a problem solving, multidisciplinary team approach, that promotes a climate of safety and quality, as opposed to a blame culture.

Practices could consider appointing a drugs of dependence coordinator, who is responsible for developing strategies (policies, procedures and activities) to prevent harm, manage harm when it occurs and provide a safe, supportive work place and work culture.

## 3.4 Staff education and competency

The Standards requires all GPs in the practice to be appropriately qualified and trained, have current Australian medical registration and participate in continuing professional development (CPD).<sup>20</sup> All doctors must provide medical care to a standard that could reasonably be expected of clinicians in their positions. Practitioners should only prescribe drugs of dependence when they have demonstrated competency. This may have particular relevance to general practice registrars.

General practices should promote and support GPs to use non-pharmacological interventions. This may include simple interventions including patient drug information in the GP software, or promoting different cognitive and behavioural strategies and other allied health therapies as part of multidisciplinary care.

Practices should consider the needs of registrars. While some may view registrar exposure to these issues as an expected part of training, others may view this as a management of an occupational risk. It may not be beneficial for the registrar, or the patient, for a registrar to act without close supervision in highly complex situations, particularly early in their training.

Experiences, practices and training received by registrars in hospital may not always be appropriate for general practice. Before prescription of any benzodiazepines or opioid analgesia, all registrars should complete basic training on orientation to the medical practice. This will enable registrar prescribing rights and responsibilities to be individually negotiated and agreed with GP supervisors. Prescribing is to be monitored until an agreed training program has been completed.<sup>20</sup>

Examples of practice policy regarding limited prescribing rights are available in [Appendix D.2](#).

Other staff members may need training regarding identification of a high risk situation. For example, reception staff who are able to identify potential drug-seeking behaviour can ensure those patients are scheduled to see doctors experienced with this level of risk.

### 3.4.1 Dependency programs

GPs who wish to offer an addiction/opioid treatment program need to be suitably qualified and trained in addiction medicine. They should also have organised support from colleagues, including addiction specialists and services, and be involved in ongoing professional development.<sup>20</sup>

Dependency programs often require advanced administrative support services, care coordination, advanced clinical teams (eg case managers, nursing and allied health staff to support appropriate care provision) and quality assurance programs. However, for relatively straightforward cases there is no evidence that extensive on-site support is needed<sup>35</sup> and, therefore, depending on community need, practices may consider encouraging GPs to get training and authority to prescribe for opioid substitution.

## 3.5 Balancing patients' needs with practice capacity (risk stratification)

Practices should have policies regarding identification and stratification of patients with more complex problems and at higher risk to manage patient needs, clinical and occupational risks.

Often practices have to make clinical decisions regarding how to achieve the best outcome for the patient based on the capacity of the total practice, not just a single practitioner. This may mean developing referral standards that ensure patients can access services that exceed the capacity of the practice such as counselling, addiction agencies, mental health agencies and medication-assisted treatment of opioid dependence programs.

For example, a practice may deem the following populations or situations to be higher risk and in need of referral to public alcohol and drug facilities, or a GP with advanced training in addiction medicine, to support ongoing management:

- patients with serious mental illness comorbidities, or antipsychotic medication
- mixed use of opioids or illicit drugs
- mixed use of opioids and benzodiazepines
- recent discharge from correctional services facility
- patients discharged from other general practices due to problematic behaviour
- signs of potential high-risk behaviours.

Some practices, especially those in rural and remote locations, face significant issues accessing these services (Refer to [Appendix I.3](#)).

### 3.5.1 Patient management according to mental health and drugs of dependence use

One of the goals in an initial assessment of a patient is to obtain a reasonable assessment of clinical complexity and risk in the context of concurrent SUD or mental illness. In this context, patients' needs can be stratified into three basic groups. The following offers a practical framework to help determine which patients may be safely managed in the primary care setting, those who should be co-managed with specialist support and those who should be referred on for management in a specialist setting.<sup>36</sup>

GPs with advanced training (eg in addiction medicine, pain medicine) are suited to taking on higher responsibilities under this model.

#### Group 1 – Managed in primary care

Patients with no past or current history of SUDs. Patients in this group have a non-contributory family or past history with respect to SUDs and do not have a major or untreated mental illness. This group clearly represents the majority of patients who will present to primary care.<sup>36</sup>

#### Group 2 – Managed in primary care with specialist support

In this group, there may be a past history of a treated SUD or a significant family history of problematic drug use. They may also have a past or concurrent mental illness or chronic pain disorder. These patients are not actively addicted, but do represent increased risk, which may be managed in consultation with appropriate specialist support. This consultation may be formal and ongoing (co-managed) or simply with the option for referral back for reassessment should the need arise.<sup>36</sup>

#### Group 3 – Managed by specialist services

This group of patients represents the most complex cases. Patients may have a mix of diagnoses that include pain and addiction as well as mental illness and other medical comorbidities. These patients may be actively misusing prescription drugs and pose significant risk to themselves and to the practitioner.

It is important to remember that Groups 2 and 3 can be dynamic; Group 2 can become Group 3 with relapse to active addiction, while Group 3 patients can move to Group 2 with appropriate treatment. In some cases, as more information becomes available to the practitioner, the patient who was originally thought to be low risk (Group 1) may become Group 2 or even Group 3. It is important to continually reassess risk over time.<sup>36</sup>

According to the National Comorbidity Project, the evidence suggests that an integrated mental health and drug and alcohol treatment for people with a range of dual diagnoses is beneficial across both mental health and substance use outcomes.<sup>37</sup>

## 3.6 Coordination of care

Clinical handover needs to occur whenever care is to be delivered by different providers. Within general practices there should be an effective handover system that ensures safe and continuing healthcare delivery for patients in the event of staff absences.

Failure of, or inadequate transfer of, care is a major risk to patient safety and a common cause of serious adverse patient outcomes. Inadequate handover can also lead to wasted resources, delayed treatment, delayed follow up of significant test results, unnecessary repetition of tests, medication errors and increased risk of medico-legal action.<sup>20</sup>

It is recommended that general practices and GPs insist on high standards for referral letters for clinical handover or shared care arrangements from secondary care before accepting the ongoing care of a patient. This facilitates the continuity of care and transfer back to higher levels of care if the need arises.

A practice or GP should not accept the ongoing management of a high-risk patient referred from a public sector facility, unless there is:

- a medical summary consistent with the Australian Commission on Safety and Quality in Health Care (ACSQHC) handover standards<sup>38</sup>
- a clear management plan
- patient-specific instructions, including specific clinical issues that would prompt referral back to secondary care
- contact details of a case manager and a clinically responsible person
- documentation that details mechanisms for rapid transfer back to specialty care if deterioration occurs.

This requirement should be supported by practice policies and communicated to referral agencies if information does not meet required standards.

It may be useful to document non-attendance by patients.

Refer to [Appendix E.2](#) for a sample letter to referral agencies.

ACSQHC handover standards are available at [www.safetyandquality.gov.au/wp-content/uploads/2012/10/Standard6\\_Oct\\_2012\\_WEB.pdf](http://www.safetyandquality.gov.au/wp-content/uploads/2012/10/Standard6_Oct_2012_WEB.pdf)

## 3.7 Practice policies

Good clinical governance is supported by comprehensive practice clinical policies aimed at a unified approach to drugs of dependence, which support individual GPs to prescribe these drugs safely and appropriately. Practices may choose to flag some of these policies to patients via a sign in the waiting room.

General practices should consider having, at minimum, agreed clinical policies regarding:

- **conditions for registrars** prescribing drugs of dependence
- handover standards from specialists and secondary care units
- first **presentations of new patients requesting drugs of dependence** continuation from another provider
- **'repeat' scripts** for drugs of dependence
- appropriate triaging and management of patients who are **assessed as high risk** (eg referral to specialised services)
- practice standard approach/management to **patients displaying drug-seeking behaviour**
- providing standard information on harms and risks to patients who are prescribed drugs of dependence
- setting ceiling limits for opioid prescribing in the practice (above which triggers review)

- standards for the 12-month review of patient opioid use
- prescription pad security
- staff safety – adopting a zero tolerance to violence towards staff.

In the clinical context of chronic pain, mental illness and addiction medicine, it can be difficult to balance benefits and harms. Some practitioners may be more vulnerable to excessive patient expectations – this can be prevented by agreed practice policies (eg setting opioid reiling limits).

Refer to *Appendix D* for examples of practice policies.

### 3.7.1 Staff safety

All practices must implement strategies to ensure the occupational health and safety of GPs and other members of the practice team. Concerns about violence in general practice continue to be raised by the profession, particularly following the deaths of GPs, and assaults and threats to general practice staff. To deal with these uncommon but distressing situations, the practice should have a risk management strategy that details the necessary steps to protect doctors and practice staff.

A doctor duress system is recommended in each consulting room and doctors should feel confident to use it in any situation where they feel under threat.

Practices can refer to *General Practice – A safe place* for tips and tools on minimising risks of violence, available at [www.racgp.org.au/your-practice/business/tools/safetyprivacy/gpsafeplace](http://www.racgp.org.au/your-practice/business/tools/safetyprivacy/gpsafeplace)

For advice on managing aggressive, violent or threatening patients, go to <http://www.miga.com.au/library/10RRAR08.pdf>

## 3.8 Using information – Government resources

Practices should facilitate GP access to information management data designed to monitor potential prescription drug abuse.

### Prescription Shopping Program

The Medicare Australia Prescription Shopping Program (PSP) is designed to identify those who are obtaining PBS pharmaceuticals in excess of medical need.<sup>39</sup>

There are two key elements to the PSP:

- The Prescription Shopping Information Service (PSIS) is available to registered prescribers 24 hours a day, seven days a week. It provides information on the prescription history of people identified by the program and is accurate up to the last 24 hours. The phone number is 1800 631 181.
- The alert service provides GPs with a letter and a PBS Patient Summary Report notifying them when they have prescribed to a patient of concern. The patient is notified when PBS medicine may have been supplied in excess of medical need.

The PSP can disclose some details to the prescriber if their patient has been identified. Once registered with the scheme, prescribers can call a hotline to find out if their patient has been identified under the PSP.<sup>39</sup>

The PSP does not provide real-time medication history nor does it provide information about private prescriptions or those written by specialists. Some coroners' reports detail how prescription shoppers do not meet the reporting thresholds of the scheme in some cases, and hence may falsely reassure GPs.

Further information is available from Medicare at [www.medicareaustralia.gov.au/provider/pbs/prescription-shopping](http://www.medicareaustralia.gov.au/provider/pbs/prescription-shopping)

## Medicare and PBS information releases

The Department of Human Services (DHS) holds information such as PBS and Medicare claim history for up to 5 years. GPs can request consent for release of this information by completing a freedom of information form along with a written letter to Medicare Australia, providing the same information as required on the form. This must be on appropriate letterhead and must include patient consent. Further consent is required for Medicare Australia to release this information to a third party (eg an insurance company).

Note that there may be significant delays in receiving requested material.

For further information, visit:

- Medicare PSP, [www.medicareaustralia.gov.au/provider/pbs/prescription-shopping](http://www.medicareaustralia.gov.au/provider/pbs/prescription-shopping)
- DHS information release, [www.humanservices.gov.au/corporate/freedom-of-information/](http://www.humanservices.gov.au/corporate/freedom-of-information/)
- DHS freedom of information, [www.humanservices.gov.au/corporate/freedom-of-information/2690](http://www.humanservices.gov.au/corporate/freedom-of-information/2690)

## Pharmaceutical services units

Local PSUs may be able to inform GPs if a patient is listed as drug dependent. The duty pharmaceutical officer can provide general advice on handling drug-seeking patients and whether another doctor holds an authority to prescribe an S8 medication for a patient. PSU websites contain information about handling drug-dependent patients.

Doctors are encouraged to phone both the PSIS and their local PSU to obtain information about a patient's drug prescription history – especially when it is a new patient.

Refer to [Appendix C.2](#) for PSU contact details.

# 3.9 Quality improvement activities

Activities such as audit and feedback, educational outreach visits, educational meetings and the provision of educational materials such as guidelines may have some clinically beneficial effect on improving the quality of prescribing. These initiatives are supported particularly if messages are tailored to those practitioners identified as over-prescribing and address individual barriers to change.<sup>5</sup>

Given the increasing problem of prescription drug abuse, it is relevant that all general practices consider undertaking quality improvement activities in this area. For example, after performing an audit of patients prescribed benzodiazepines, practices can send out a letter outlining the harms and risks, and inviting patients to have a consultation to explore alternative ways of managing their symptoms.<sup>40-42</sup>

Refer to [Appendix E.1](#) for a sample letter to patients.

Quality improvement activities should be more frequent and extensive if the practice has higher levels of drugs of dependence prescribing, opioid substitution therapy and mental illness or pain issues.

Practices should consider appropriate monitoring systems to ensure early alert and sentinel systems are in place. This would include simple systems for reporting adverse events (eg staff abuse, patient overdose, misuse) or system failings (eg patient not getting appropriate continued medication), to more complex auditing of practice populations (eg patients above therapeutic dose ceilings).

A simple checklist to assist practices in examining their quality management of drugs of dependence is available in [Appendix D14](#).

## 3.9.1 Clinical audit

Clinical audit is a broad term that encompasses several of the other quality improvement strategies such as record reviews, peer review, standard reviews (to see if standards are being met, guidelines followed and/or evidence-based practice used) and patient satisfaction surveys.<sup>43</sup> The purpose of clinical audits is to improve the quality of healthcare services by systematically reviewing the care provided against set criteria.<sup>43</sup>

The gap between the criteria and the assessed performance provides guidance for priority improvement strategies.<sup>43</sup> Clinical audit of prescribing drugs of dependence (eg new patients prescribed drugs of dependence, repeat prescriptions without review), patients at risk of problematic use (eg prior or current substance misuse) and patients misusing drugs of dependence may help practices improve or monitor safety of prescribing.

Evidence suggests that in terms of improving professional practice, audit and feedback leads to small (but potentially important) improvements.<sup>44</sup> The relative effectiveness of audit and feedback is likely to be greater when baseline adherence to recommended practice is low and when feedback is delivered more intensively.<sup>44</sup>

There are several clinical audit tools available. However, there are broad limitations to the effectiveness of clinical audit which may be relevant to prescribing drugs of dependence, these include clarity and measurability of the criteria and standards chosen, data quality, engagement of practitioners, and translation of findings into quality improvement strategies.<sup>43</sup>

## 4. Accountable prescribing

Recommendations	Reference to the Standards
GPs must prescribe within legislative frameworks and should comply with professional standards and approved clinical guidelines	(Extrapolated from Criterion 5.3.1) <sup>20</sup>
GPs must seek a permit or authority from the relevant state or territory health department when prescribing an S8 drug to a patient who is drug dependent	
GPs should maintain or improve their skills in relevant areas such as chronic pain, mental health or drugs of dependence	(Extrapolated from Criterion 3.2.1, Flagged indicator C) <sup>20</sup>
GPs should use universal precautions* to guide their approach to patient who require drugs of dependence	
GPs should inform patients that drugs of dependence are to be prescribed from only one practice and preferably by one GP, and drugs should be dispensed from one pharmacy	
GPs must maintain professional boundaries when prescribing drugs of dependence	
GPs have the right to discontinue care of a patient who has behaved in a violent or threatening manner	(Extrapolated from Criterion 2.1.1) <sup>20</sup>
GPs should be prepared to use specialist support to manage problematic drug use in patients with more complex issues or if the clinical situation deteriorates	(Extrapolated from Criteria 3.1.2, 3.1.3, 4.1.2, 5.3.1) <sup>20</sup>
GPs must ensure that patient records are clear, up-to-date and contain sufficient information for another practitioner to take over care	(Adapted from Criteria 1.7.1, 1.7.2, 1.7.3) <sup>20</sup>
*Universal precautions here refers to the 10 steps of universal precautions in pain medicine.	

Accountable prescribing has been defined as a commitment to evidence-based practice, the use of medicines with proven effectiveness and the avoidance of medicines when they do not help or cause harm.<sup>45</sup>

This is particularly relevant to prescription drug misuse.

Good prescribing practice involves careful and considered diagnosis, clear therapeutic goals, the use of non-drug therapies where suitable, prescribing appropriate types, formulations and amounts of medication, explaining the effects of medications and any risk of dependence, and implementing regular medication reviews.

GPs are required to be accountable prescribers of drugs of dependence and must prescribe within legislative frameworks, professional standards and approved clinical guidelines.

To minimise the harms associated with prescription drug misuse, GPs need to maintain vigilance in identifying substance misuse or dependence, assist patients in recognising misuse or dependence where it exists, set goals for recovery and assist patients to seek appropriate treatment. Clinical tools have been developed for these purposes.

## 4.1 Being an accountable prescriber of drugs of dependence

### 4.1.1 Professional boundaries

The public and health professions have an expectation that the therapeutic context is safe for patients. It is the health practitioner's responsibility to behave ethically at all times and maintain professional boundaries.

With decreasing formality in medicine, GPs are more likely to encourage the use of first names and to develop a relaxed, collaborative relationship with their patients. All GPs should be mindful of simultaneously maintaining clear professional and personal boundaries.

Boundaries represent the edge of appropriate behaviour and serve two important purposes: they structure the professional relationship in ways that maintain the identity and roles of the patient and the professional and they separate the therapeutic relationship from social, sexual, romantic and business relationships.

Setting professional boundaries may include:<sup>46</sup>

- practitioner behaviour standards
- using **universal precautions**
- not prescribing or dispensing controlled substances for self or family.

### 4.1.2 Legal obligations

All practitioners have a duty to act within state, territory and national legislative frameworks, and to manage their prescribing practices within the laws and clinical and professional standards.

Practitioners who are unaware of their legal obligations risk being the subject of legal prosecution and/or disciplinary action by the medical board.

GPs need to be aware of their obligations regarding the impact of medication on the patient's ability to safely perform usual activities such as driving (eg Jet's Law in Queensland [www.tmr.qld.gov.au/Licensing/Medical-condition-reporting/Medical-requirements.aspx](http://www.tmr.qld.gov.au/Licensing/Medical-condition-reporting/Medical-requirements.aspx)).

Medical defence organisations provide support and information on prescribing drugs of dependence. For more information, visit:

- [www.avant.org.au/Resources/Public/Risk-education-resources/Prescribing-Drugs-of-Dependence](http://www.avant.org.au/Resources/Public/Risk-education-resources/Prescribing-Drugs-of-Dependence)
- [www.mdanational.com.au/media/211359/mdan8264.1%20tta\\_prescribe%20sched%208%20drugs\\_av.pdf](http://www.mdanational.com.au/media/211359/mdan8264.1%20tta_prescribe%20sched%208%20drugs_av.pdf)
- [www.mips.com.au](http://www.mips.com.au)

### 4.1.3 Evidence-based medicine

Doctors should use evidence-based interventions where they are available.

Occasionally, doctors prescribe drugs of dependence to address perceived patient expectations, but without necessarily improving health and potentially resulting in harm.

Unfortunately, there are few quality measures for accountable prescribing.<sup>45</sup> Protocols may be useful to ensure consistent provision of good practice. The practice team should work within a clinical governance framework and be prepared to justify their clinical decisions, particularly when operating outside guidelines. Doctors should keep comprehensive notes to support their decisions and monitor the effectiveness of their care using clinical audit.

### 4.1.4 Skills and knowledge

GPs are expected to update their knowledge and skills according to emerging evidence and developments in professional practice. It is each practitioner's responsibility to ensure competency in the areas they choose to manage. Practitioners should also be aware of their clinical limitations.<sup>47</sup>

Doctors who are untrained<sup>48</sup> or become 'dated' in their clinical competencies can be at higher risk for inappropriate prescribing.<sup>49</sup>

Numerous educational interventions have been conducted to improve prescribing competency.<sup>50</sup> The World Health Organization's (WHO) *Guide to good prescribing*<sup>51</sup> has the largest body of evidence to support its use in a wide variety of settings.<sup>50,52</sup>

Doctors prescribing drugs of dependence should review their pharmacology, including pharmacokinetic and pharmacodynamic properties, drug–drug interactions and signs of intoxication and withdrawal. They should also be aware of the epidemiology of abuse and appropriate treatment indications and contraindications, and they should be able to perform basic alcohol and drug addiction screening assessments.<sup>53</sup>

Community pharmacists may be a valuable resource.<sup>54</sup>

### 4.1.5 Universal precautions

Adoption of a universal precautions approach (used in pain medicine) may improve patient care and minimise the risk of harm and medico-legal issues. The following universal precautions are a guide to the proper evaluation and management of patients, and are applicable to all drugs of dependence:<sup>55</sup>

- Make a diagnosis with appropriate differential diagnoses.
- Undertake a psychosocial assessment that includes risk of addictive disorders.
- Use informed consent.
- Use treatment agreements.
- Undertake a pre- and post-intervention assessment that includes pain score and level of function.
- Commence a trial of appropriate opioid therapy with an appropriate combination of adjunctive medications.
- Reassess pain score and level of function.
- Routinely assess the five As of pain medicine (analgesia, activity, adverse events, aberrant behaviour, affect).
- Periodically review the diagnosis and comorbid conditions, including addictive disorders.
- Carefully document initial assessment and each follow-up.

### 4.1.6 Prescription writing

GPs should use prescription-writing techniques to minimise misuse and abuse.

When writing prescriptions for drugs of dependence, GPs must:<sup>53</sup>

- prescribe the appropriate amount to carry through to the next appointment
- write out the number dispensed in letters and numerals (ie 14 and fourteen)
- draw a large 'Z' at the bottom of the prescription so that further items cannot be added (if using paper prescription stationery).

Prescribers can decrease the risk of misuse by reducing access and temptation to overuse medication through much more frequent dispensing of smaller quantities of medications. This can range from weekly, twice weekly to daily (supervised) dispensing. This is aided by a one-practice and, preferably, one-GP approach, and the dispensing of medication through one pharmacy.

### 4.1.7 The 'prescription traps'

The following is a compilation of prescription issues that have been noted in coroners' proceedings. GPs are advised to consider these in reviewing their own prescribing habits.

- Patients requesting private scripts for drugs of dependence.
- Patients presenting with out-dated doctor's letter requesting medication.
- Excessive prescribing without proper assessment of potential psychiatric conditions.
- Excessive prescribing without proper assessment of pain management options, including specialist referral.
- Prescribing contrary to statutory guidelines or regulations.
- Prescribing dangerous (high-risk) medication to unknown patients, particularly opioids and benzodiazepines.
- Prescribing benzodiazepines as a first-line treatment for psychiatric disorders.
- The inappropriate use of benzodiazepines in pain management.
- The inappropriate use of opioids in pain management, particularly chronic non-malignant pain.
- The inappropriate combined use of benzodiazepines and opioids in pain management.
- The use of pethidine in pain management (particularly for the treatment of migraines).
- The use of injectable medication, particularly opioids, by GPs for pain treatment.
- Prescription of medications with potentially dangerous interactions, particularly, tramadol and antidepressant medication (risk of serotonin syndrome).
- The use of quetiapine to treat insomnia and anxiety.

### 4.1.8 Working collaboratively

Doctors need to work with a range of other professionals and may work as part of a wider organisation or in a multidisciplinary team. It is usually good practice to ensure that clinical practices are standardised through local area policies and protocols. Depending on the setting and nature of the organisation (eg community drug treatment, primary care-led drug treatment service, hospital-based drug treatment service), doctors should be aware of accepted best practice protocols and work in accordance with these.

Patients who are at higher risk for dependency or have more complex issues need to be jointly managed between primary care and specialised drug and alcohol/addiction services, and require the input of mental health and/or pain specialists as required.

### 4.1.9 Managing issues between multiple providers

Circumstances occasionally arise when GPs feel uncomfortable about continuing care from other practitioners. GPs are under no obligation to continue another prescriber's action if they deem this to be unsafe, inappropriate or impractical, such as:

- drugs being prescribed off label, particularly drugs used for mental illness
- disagreement between the GP and specialist about whether a drug of dependence is warranted
- excessive prescribing that the GP is uncomfortable continuing.

There needs to be provision within the system for case conference and collaborative discussion of evidence-based treatment where all views are taken into consideration. When a GP does not feel happy to provide a prescription, they should not feel pressured to do so. The ideal situation is to

have an independent drug and alcohol specialist review the case. Alternatively, referral back to the original provider for scripts may be warranted.

If taking over the care of an inherited patient, the GP should ask the following questions:<sup>56</sup>

- Does this patient have a clear chronic pain disorder and/or mental illness diagnosis?
- Is there justification for the drugs that have been prescribed?
- Are the prescribed amounts appropriate?
- If a patient is displaying drug-seeking behaviours, is this a sign of under-treated pain, addiction, or involvement in abuse or diversion of S8 opioids?

### 4.1.10 Getting support

Prescribing decisions around drugs of dependence can be difficult and new evidence is constantly emerging. GPs need to keep up to date with best prescribing practices. Formal and informal professional support (eg mentoring, clinical review, education, joining professional networks, using decision support tools) is important for all GPs and may be particularly relevant for GPs working in isolation.

There is some evidence that sole practitioners who are not affiliated with any professional college (ie not actively engaged in ongoing professional development programs) and treating opioid-dependent patients over a long period are at risk of inappropriate prescribing.<sup>5</sup> Inappropriate prescribing can be the result of not taking a drug history, not conducting a physical examination and not asking if patients have had these drugs prescribed for them before, and, if so, when. Quality improvement activities such as continuing audit, clinical review and educative support may help reduce inappropriate prescribing.<sup>57-59</sup>

#### Deciding when to seek advice or consider referral to a psychiatrist or pain/addiction specialist

The ongoing treatment of pain, addiction and mental illness comorbidities is a complex undertaking. Initial referral may be needed to obtain a comprehensive evaluation, or to clarify the optimal therapeutic strategies.

Referral is typically considered for patients who are at higher risk, who have more complex needs or in patients at risk of adverse events. For example, patients who:<sup>56</sup>

- are relatively young (eg <35 years old)
- have a comorbid psychiatric or psychological disorder
- have previous or current opioid, or SUDs
- have indeterminate pathology.

Once an optimal regimen and monitoring approach has been implemented, referral may be warranted for the following reasons:<sup>56</sup>

- unexpected drug dose escalation
- ceiling drug dosages reached
- suspected abuse or misuse
- risk category change
- high levels of patient distress
- unusual opioid requirements or suspicions of drug diversion
- poorly controlled comorbid psychiatric or psychological disorder.

## Deciding when to refer a patient for hospital admission (through emergency departments)

Patients may need referral to hospital if they are at risk to themselves, pose risks to others or at risk by others.

**Table 2. Identifying patient risk**

Risks to and by patients		
Risk to self	Risk to others	Risk by others
<ul style="list-style-type: none"> <li>• Self-harm and suicide, including repetitive self-injury</li> <li>• Self-neglect</li> <li>• Absconding and wandering (which may also be a risk to others)</li> <li>• Health including:                             <ul style="list-style-type: none"> <li>– Drug and alcohol abuse</li> <li>– Medical conditions (eg alcohol withdrawal, unstable diabetes mellitus, delirium, organic brain injury, epilepsy)</li> </ul> </li> <li>• Quality of life, including dignity, reputation, social and financial status</li> <li>• During pregnancy (both risk to mother and foetus)</li> </ul>	<ul style="list-style-type: none"> <li>• Harassment</li> <li>• Stalking or predatory intent</li> <li>• Violence and aggression, including sexual assault or abuse</li> <li>• Neglect or abuse to children</li> <li>• Property damage, including arson</li> <li>• Public nuisance</li> <li>• Reckless behaviour that endangers others (eg drink driving)</li> </ul>	<ul style="list-style-type: none"> <li>• Physical, sexual or emotional harm or abuse by others</li> <li>• Social or financial abuse or neglect by others</li> <li>• Deviation of supply of medication from elders who are dependent on medication (form of elder abuse)</li> </ul>

Adapted from Mental Health Division, WA Department of Health (2008). Clinical Risk Assessment and Management (CRAM) in Western Australian Mental Health Services: Policy and Standards. Perth, Western Australia: Department of Health. Based on material originally sourced from: Ministry of Health (1998). Guidelines for Clinical Risk Assessment and Management in Mental Health Services. Wellington, New Zealand: Ministry of Health; Top End Mental Health (2004). Risk Assessment Tracking Tool. Northern Territory: Department of Health and Community Services. Adapted with permission from Department of Health, State of Western Australia.

### 4.1.11 Record keeping

GPs must maintain adequate, accurate and timely records regarding pain assessment, treatment plan, informed consent, ongoing assessment and consultation of the patient.

'Adequate records' refers to legible records containing, at a minimum, sufficient information to identify the patient, support the diagnosis and justify the treatment; adequate documentation of the results; advice and risks provided to the patient; and sufficient information for another practitioner to assume continuity of the patient's care at any point in the treatment.

GPs also need to document the process of shared decision making and what information is shared.

## 4.2 Assessment of patient risk

All drugs of dependence have the potential to be misused. Even when used as prescribed, they can cause harms. Before prescribing or continuing to prescribe them to any patient, the patient should be assessed and their needs and risks determined.

More detailed information will be available in the RACGP's separate guidelines on benzodiazepines and opioids.

## 4.2.1 General assessment

Drug-seeking patients can often provide well-developed clinical histories which may seem very 'real'. There is often a strong aim to work on the desire of doctors to minimise the distress of patients. Rather than being aggressive, many will be very pleasant with a credible story.

In addition, not all drug-seeking patients are faking symptoms. They may have a legitimate complaint and, over time, have become dependent or tolerant and require larger doses of medication to function in their daily life.

In patient presentations where drugs of dependence may be indicated, a full assessment includes:

- a full history, including the use of alcohol and other drugs (including over-the-counter medications medicines containing codeine combined with ibuprofen or paracetamol), psychiatric comorbidity, family history and family/social situation – this also helps identify people at higher risk of developing problems
- adequate physical examination (including looking for signs of intoxication or withdrawal or intravenous drug use)
- problem/diagnosis list
- management plan
- communication with other providers (eg methadone prescriber, pharmacist, other GP)
- prescription shopper communication (refer to [Section 3.8](#) for more information)
- consider urine drug screening/testing (refer to [Appendix H](#)).

This should enable a diagnosis of a patient with genuine medical need and no dependence, a patient with genuine medical need and dependence,\* or a patient that may be looking for drugs of dependence for non-medical use.

Once a full assessment, including assessment of dependence (refer to [4.2.2 Assessment of substance use disorder](#)), has been carried out, a care or treatment plan can be established.

\*This may also be pseudo-addiction where a patient with undiagnosed and/or inadequately treated painful condition adopts drug-seeking behaviour in an attempt to achieve relief.<sup>60</sup>

## 4.2.2 Assessment of substance use disorder

Patients who have current or previous substance-related problems have a greater risk of harm and ongoing problematic use, therefore specialist support and advice should be considered as part of ongoing management.

The new Diagnostic and Statistical Manual of Mental Disorders (5th edition) (DSM-5) criteria combine the old DSM-IV categories of substance abuse and substance dependence into a single condition of SUD, which is measured on a continuum from mild to severe.<sup>61</sup> This diagnosis can be applied across all drugs of dependence (as well as drugs such as nicotine and alcohol) and should reduce confusion associated with the terms dependence, addiction and abuse (which have been inconsistently and often incorrectly used to describe points on a spectrum of disordered use).

The essential feature of SUD is a cluster of cognitive, behavioural and physiological symptoms indicating the individual continues using the substance despite significant substance-related problems.<sup>61</sup>

Diagnosing SUD requires the presence of at least two of 11 criteria, across four categories: impaired control, social impairment, risky use and pharmacology. Based on the total number of criteria the patient has, the SUD can be classified as mild (2–3 symptoms), moderate (4–5 symptoms) or severe (6 or more symptoms). It is hoped these severity classifiers may potentially help clarify treatment options ([Table 3](#)).

Although the term SUD is a helpful addition, the term addiction will necessarily be used when discussing any drugs of dependence.

**Table 3. DSM-5 criteria for diagnosing an SUD**

**A problematic pattern of substance use leading to clinically significant impairment or distress, as manifested by at least two of the following 11 criteria, occurring within a 12-month period:**

Impaired control criteria	<ol style="list-style-type: none"> <li>1. Substances are often taken in larger amounts or over a longer period than was intended</li> <li>2. There is a persistent desire or unsuccessful efforts to cut down or control substance use</li> <li>3. A great deal of time is spent in activities necessary to obtain the substance; use the substance; or recover from its effects</li> <li>4. Craving or strong desire or urge to use the substance</li> </ol>
Social impairment criteria	<ol style="list-style-type: none"> <li>5. Recurrent substance use resulting in a failure to fulfil major role obligations at work, school or home (eg repeated absences from work or poor work performance related to substance use; substance-related absences, suspensions or expulsions from school; neglect of children or household)</li> <li>6. Continued substance use despite having persistent or recurrent social or interpersonal problems caused by or exacerbated by the effects of substances (eg arguments with a spouse about consequences of intoxication; physical fights)</li> <li>7. Important social, occupational or recreational activities are given up or reduced because of substance use</li> </ol>
Risky use criteria	<ol style="list-style-type: none"> <li>8. Recurrent substance use in situations in which it is physically hazardous (eg driving an automobile or operating a machine when impaired by sedative, hypnotic or anxiolytic use)</li> <li>9. Substance use is continued despite knowledge of having persistent or recurrent physical or psychological problem that is likely to have been caused or exacerbated by the substance</li> </ol>
Pharmacological criteria	<ol style="list-style-type: none"> <li>10. Tolerance, as defined by either of the following:                     <ol style="list-style-type: none"> <li>a. A need for markedly increasing amounts of the substance to achieve intoxication or desired effect</li> <li>b. A markedly diminished effect with continued use of the same amount of the substance</li> </ol> <p><b>Note:</b> This criterion is not considered to be met for individuals taking substances under medical supervision</p> </li> <li>11. Withdrawal, as manifested by either one of the following:                     <ol style="list-style-type: none"> <li>a. The characteristic withdrawal syndrome for substance</li> <li>b. Substance (or a closely related substance) is taken to relieve or avoid withdrawal symptoms</li> </ol> </li> </ol>

**Specifiers:**

**In early remission:** After full criteria for SUD were previously met, none of the criteria for SUD have been met for at least 3 months but for less than 12 months (with the exception that criterion 4 may be met)

**In sustained remission:** After full criteria for SUD were previously met, none of the criteria for SUD have been met at any time during a period of 12 months or longer (with the exception that criterion 4 may be met)

**In a controlled environment:** This additional specifier is used if the individual is in an environment where access to substance is restricted

**Current severity:**

**Mild:** Presence of 2–3 symptoms

**Moderate:** Presence of 4–5 symptoms

**Severe:** Presence of 6 or more symptoms

## 4.3 Providing patients with other (often better) management options

Prescribing drugs of dependence should be seen as an adjunct to care, and not regarded as the primary treatment regimen.

For many of the conditions which drugs of dependence are used, non-drug interventions are often more effective and have sustained results.<sup>62-67</sup> Where there is good evidence for non-drug interventions, GPs should consider these as first-line therapy. GPs need to be aware of the evidence for allied health treatments and be able to offer these (in-house or through referral) to patients when they need them.

There is substantial evidence that anxiety, depression, sleep and chronic pain problems, including headache and migraine, can be effectively treated with cognitive behaviour therapy (CBT) and other psychological approaches.<sup>62</sup> Further, there is evidence that in many cases, psychological therapies are at least equivalent and sometimes superior to the use of medicines to address these issues.<sup>62-67</sup>

In cases where the use of medicines is indicated, concurrent psychological therapy is typically superior to either therapy alone.<sup>68</sup>

Refer to individual drug guides for further information.

## 5. Patient focus

Recommendations	Reference to the Standards
General practices and GPs should provide patients with information (at the appropriate level and manner) about the purpose, realistic expectations, options, and benefits and risks of any treatments	(Extrapolated from Criterion 1.2.2) <sup>20</sup>
GPs may wish to consider using patient information resources to help patients understand their options and consequences of their decisions	
GPs should develop respectful, non-judgemental and clear responses to requests for drugs of dependence that are inappropriate	

Patients have the right to respectful care that promotes their dignity, privacy and safety.

Maintaining a patient focus for all patients ensures that care – including the prescribing or non-prescribing of drugs of dependence – is provided in partnership with patients, their families and carers, respecting their diverse needs, preferences and choices, and in coordination with other organisations whose services impact on patient wellbeing.<sup>21</sup>

This means balancing patient-centred care, evidence-based practice, legislative requirements and partnerships with other healthcare providers to patients across the spectrum of users of drugs of dependence. Further considerations include such things as driver's licence requirements and potential risks to others (eg children and others in the patient's care).

Clinical discipline is required as there can be elements of manipulation behind patient requests for drugs of dependence. Patient-centred care does not mean professional boundaries can be crossed, laws ignored or therapy continued if it is considered detrimental to the patient's health.

It also does not mean that practices and practitioners are obliged to take full responsibility for care in higher risk situations. These situations include those:

- where staff safety may be impacted
- where care is outside the expertise of practitioners
- where long-term health prospects of patients are being compromised by lack of access to state or territory facilities.

Appropriate referral is required in these circumstances.

Medication and illicit drug misusers have the same entitlement as other patients to respectful care. Treatment should seek to maximise treatment outcomes across a range of domains including drug and alcohol misuse, health, crime and social functioning.

## 5.1 Shared decision making

### 5.1.1 Patient information and informed consent

Shared decision making is vital to patient-centred care. For patients to be an active partner in their care, they need to be well informed. Information provided should allow realistic expectations about the likely or potential outcomes of their treatment. Shared decision making has been shown to build trust, prevent harm and reduce surprise and distress if complications or adverse events occur.<sup>69</sup>

Shared decision making respects a patient's autonomy. A patient with the capacity to consent to treatment also has the right to refuse medical treatment, even when the medical practitioner deems the treatment appropriate.

Consent is a basic legal principle that reflects autonomy. In a healthcare context, it means a person's agreement to something being performed on them or a sample being taken from them, as well as their agreement to undertake a medical investigation or treatment. Informed consent, in a legal sense, reflects that a patient has received information that enables the making of an informed decision on whether to undertake this treatment or investigation.

If a patient refuses the advice of a GP, they should be advised about the implications of deciding not to receive the healthcare offered. The patient should be given sufficient time to consider and clarify any information in order to make an informed decision, taking into account the context of the clinical situation.

There is a general paucity of evidence regarding long-term use of drugs of dependence. When starting a drug of dependence for long-term use, informed consent should be obtained and a contractual approach to prescribing is advised.

Patients need to be informed about the purpose, importance, benefits and risks of their medicines. GPs may consider using a written management plan to document patient and doctor responsibilities, goals and expectations, and desired outcomes in behavioural terms. This may assist in patient education.

An example of a benzodiazepine patient information sheet is available at [Appendix D.12](#).

An example of an opioid patient information sheet is available at [Appendix D.13](#).

### 5.1.2 Clinical responsibility in shared decision making

Whilst most patient involvement with drugs of dependence is clinically driven, there can also be elements of manipulation (and rarely criminal intent) behind patient requests for drugs of dependence.

The important caveat when prescribing drugs of dependence relates to healthcare benefits. Some patients with chronic non-management pain or drug dependence may request higher opioid analgesic doses on the basis that they have a 'right to analgesic drugs for pain' and are making a choice as an informed patient.

Patients have a right to good healthcare, and not a right to drugs of dependence. Patients need to be informed of this at the beginning of any trial using drugs of dependence. If the clinician feels that further therapy is detrimental to a patient's health, then clinical withdrawal of medication should begin.

Doctors typically have a strong desire to alleviate patient distress and suffering. The psychological phenomenon of transference in addiction, pain and mental illness can result in doctors having difficulty in these clinical areas. There are a number of GPs who find it difficult to set boundaries for patients and are at risk of being pressured to prescribe inappropriately. Others have difficulties in saying 'no' or hold the belief that they are 'helping' or using a harm minimisation approach by giving patients who are seeking drugs what they ask for.

All practitioners express difficulty responding to manipulative behaviour or techniques posed by some patients (eg 'I will suicide if I do not get my medication'). GPs should educate themselves about appropriate responses to common manipulative techniques and behaviours posed by some patients to access drugs of dependence. To aid GP negotiation skills, scripted replies have been developed to help with appropriate responses in difficult situations.

For examples of GP responses to patient requests for benzodiazepines, refer to *Appendix E* in the RACGP's *Prescribing drugs of dependence in general practice, Part B – Benzodiazepines* (available May 2015).

### 5.1.3 Setting patient behaviour standards

Prescribers have a responsibility to make patients aware of behaviour standards they expect when prescribing drugs of dependence or when changing a prescription in order to manage documented risk. This process is best undertaken where there is a good therapeutic alliance with the patient and in an empathetic, non-judgemental manner. Practice policies will help this process.

Behaviour standards may include:

- only obtaining scripts from one doctor and one pharmacy
- staged supply through pharmacy
- supervised dose to patient only at pharmacy
- attending appointments regularly
- engaging with other supports
- engaging with psychological supports
- agreement when a therapeutic trial of treatment will cease
- the consequences of inappropriate patient behaviour (eg formal review, possible referral or cessation of clinical relationship).

Any coercion or threat (physical or verbal) to prescribe is an immediate red flag and a breach of the therapeutic alliance. Where boundaries have been crossed and the GP no longer considers it appropriate to treat a patient who has behaved in a violent or threatening manner, the GP has the right to discontinue the care of that patient.<sup>20</sup> The GP may choose to end the therapeutic relationship during a consultation or, depending on the circumstances, by letter or telephone.<sup>20</sup> Safety should dictate the method chosen. It is advisable for the practice to document a process to be followed by practice staff if the patient makes any subsequent contact.<sup>20</sup>

## Appendix A. Key terms and definitions

### A.1 Drugs of addiction and drugs of dependence

Legal definitions of drugs of dependence and drugs of addiction vary between states and territories. Refer to [Appendix B.2](#).

This guide uses the following definitions:

**Drugs of addiction** refers to all Schedule 8 (S8) drugs. These have strict legislative controls regarding their manufacture, supply, distribution, possession and use to reduce abuse, misuse, and physical and psychological dependence. Examples of S8 drugs include morphine, oxycodone, dexamphetamine, flunitrazepam (Rohypnol) and, as of February 2014, alprazolam.\*

**Drugs of dependence** describes all S8 drugs plus specified Schedule 4 (S4) drugs that are subject to misuse, abuse and trafficking. All S4 drugs are restricted substances, but only some (eg benzodiazepines) can form dependence (these are called S4D drugs in New South Wales). Some other drugs, like anabolic steroids and amphetamines, are restricted and can only be prescribed by authority.

Each state and territory has its own legislative requirements. Refer to [Appendix C.1](#).

*\*Xanax (Pfizer) has been withdrawn from the Australian market, however generic alprazolam is still currently available.*

### A.2 Tolerance, dependence, substance use disorder and withdrawal

The two commonly used classification systems for data collection are the International Statistical Classification of Diseases and Related Health Problems, 10th revision, (ICD-10) and the DSM-5. Some of the terminology adapts poorly to the situation where prescription drugs are used to treat conditions, such as chronic non-malignant pain.

**Tolerance** is a decrease in response to a drug dose. It occurs with all chronically used drugs of dependence, including opioids and benzodiazepines. Increased doses are required to achieve the effects originally produced by lower doses.<sup>70</sup>

**Dependence**, in strict pharmacological terms, is a state that develops during chronic drug treatment in which drug cessation elicits an abstinence reaction (withdrawal).

Dependence can be associated with a whole range of psychoactive drugs or chemicals (eg caffeine, alcohol, opioid, cannabis or stimulant dependence). As awareness of problematic drug use grew, the definition of dependence changed to include addiction and abuse. Various definitions of dependence evolved with DSM-4, ICD-10, WHO and leading authors describing it as a cluster of behavioural, cognitive and physiological phenomena that may develop after repeated substance use. Now people link dependence with 'addiction' when in fact dependence can be a normal body response to a substance. Whilst drug dependence can be part of addiction, is not the same thing.

To reduce confusion, the new DSM-5 (2013) criteria has replaced drug dependence with **DSM-5 SUD** measured on a continuum from mild to severe. Refer to [Appendix A.3 Misuse, non-medical use and abuse](#).

**Note:** There are legal implications involving the term dependence (eg restrictions around prescribing to drug dependent persons). Characteristics of person who is drug dependent include having a history of substance misuse and being identified as a 'doctor shopper' or 'prescription shopper'.<sup>23</sup> (Refer to [Appendix A.4 Drug-seeking behaviour](#)).

**Withdrawal** or **withdrawal syndrome** is a group of symptoms of variable clustering and degree of severity which occur on cessation or reduction of use of a psychoactive substance that has been taken repeatedly, usually for a prolonged period and/or in high doses. Signs of physiological disturbance may accompany the syndrome.

## A.3 Misuse, non-medical use and abuse

**Misuse** refers to use of a substance for a purpose that is not consistent with legal or medical guidelines, and includes the non-medical use of prescription medication. Patients may inadvertently misuse prescription medication by taking them as prescribed but in response to inappropriate prescribing practices. Patients may deliberately misuse medication for non-medical purposes.<sup>70</sup>

**Non-medical use** describes use of a prescription drug, whether obtained by prescription or otherwise, for any purposes other than in the manner or for the time period prescribed, or by a person for whom the drug was not prescribed (ie diversion). Non-medical use occurs for a variety of reasons such as enjoyment of effects (especially when binge dosed), to enhance the effects of other drugs (eg benzodiazepines taken with opiates), to decrease withdrawal symptoms; to enhance confidence, to feel normal and to facilitate sexual assault (eg flunitrazepam used as 'date rape' drug).<sup>70</sup>

**Abuse** is a commonly used term with a variety of meanings. It is sometimes used disapprovingly to refer to any use at all, particularly of illicit drugs, while in other contexts, abuse has referred to non-medical or unsanctioned patterns of use, irrespective of consequences.<sup>70</sup> DSM-5 replaced this term with SUD.

The essential feature of SUD is a cluster of cognitive, behavioural and physiological symptoms indicating the individual continues using the substance despite significant substance-related problems.

**Problematic drug use** may be a wider, yet clearer, more descriptive and less judgemental term than misuse or abuse.<sup>70</sup>

**Note:** In DSM-5, substance **dependence** and substance **abuse** have been combined into a single category of **substance use disorders (SUDs)** (specific to each substance). Each SUD is divided into mild, moderate and severe subtypes, with the number of criteria present determining the severity.

## A.4 Drug-seeking behaviour

**Drug-seeking behaviour** is a poorly defined term that describes a range of activities directed towards attainment of sought after medications. The most common medications sought are opioids and benzodiazepines. Behaviours include attending multiple practitioners (prescription or doctor shopping) and employing manipulating tactics.<sup>71</sup>

A comprehensive list of tactics and behaviours used to obtain medication is available in [Appendix F](#).

**Prescription or doctor shopping** is when patients unknowingly or deliberately obtain more medicines than is medically needed. This is often done by visiting many doctors, without telling them about their other consultations.<sup>39</sup> The Medicare Australia Prescription Shipping Information Services (PSIS) defines prescription shoppers as anyone, within any 3-month period, that has been supplied with PBS items prescribed by six or more different prescribers (including nurse practitioners and midwives, but excluding specialists and consultant physicians), and/or a total of 25 or more target PBS items, and/or a total of 50 or more items.<sup>39</sup> Target items are analgesics, anti-epileptics, anti-parkinson medicine, psycholeptics (including antidepressants), and all other nervous system medicine.

## A.5 Prescriber behaviour

**Appropriate prescriber behaviour** refers to prescription decisions based on evidence at the time of assessment and taking into account the patient's perspective. This is related to the term **accountable prescribing**.

**Accountable prescribing** is defined as a commitment to evidence-based practice, the use of medicines with proven effectiveness, and avoidance of medicines when they do not help or cause harm.<sup>45</sup>

**Inappropriate prescriber behaviour** refers to persistent prescribing of drugs of dependence despite absence of sustained improvement in function, deterioration of function, and/or the development of unacceptable side effects.<sup>72</sup>

## Appendix B. Drug scheduling

The following information is from the Therapeutic Goods Administration (TGA).<sup>73</sup>

Scheduling is a national classification system that controls how medicines and poisons are made available to the public. The schedules are published in the *Standard for the Uniform Scheduling of Medicines and Poisons* (SUSMP) and are given legal effect through state and territory legislation.

The SUSMP is legally referred to as the **Poisons Standard**.

### B.1 Drug schedule

Schedule 1	Not currently in use
Schedule 2	Pharmacy medicine
Schedule 3	Pharmacist only medicine
Schedule 4	Prescription only medicine OR prescription animal remedy
Schedule 5	Caution
Schedule 6	Poison
Schedule 7	Dangerous poison
Schedule 8	Controlled drug
Schedule 9	Prohibited substance

Although all states and territories use the SUSMP, there are variations between state and territory schedules, and practitioners must be aware of their local legal requirements.

### B.2 S8 terminology variations across Australia

State/territory	Term for S8 drug
Australian Capital Territory	Controlled medicine
New South Wales	Drug of addiction
Northern Territory	Schedule 8 substance
Queensland	Controlled drug
South Australia	Drug of dependence
Tasmania	Narcotic substance
Victoria	Schedule 8 poison
Western Australia	Drug of addiction

## Appendix C. State and territory legislation and contacts

### C.1 Non drug-dependent persons – Legislative requirements when prescribing S8 drugs

State/territory	Legislative requirement
Australian Capital Territory	Approval is required to prescribe a controlled medicine for more than 2 months; or if the patient has been prescribed a controlled medicine within the previous 2 months. Where more than one doctor at a medical clinic is involved in the management of a patient, each doctor may prescribe under the approval in place for another doctor at the clinic, provided the prescribing is consistent with and does not exceed any limits or condition of the approval.
New South Wales	Authority is required if patient is to receive continued treatment with specified <sup>9</sup> drugs of addiction (Type B) for more than 2 months. No authority is required for the majority of oral and transdermal opioids.
Northern Territory	Notification is required to prescribe non-restricted S8 substances for a period exceeding 8 weeks; a high initial dose; a high daily dose; a high combination dose of different S8s; replacement of lost or stolen prescriptions; for 'early' prescriptions; for a patient who has another S8 prescriber; for a patient who wants to transfer from another S8 prescriber; for any patient previously notified, a renewal notification must be made after 12 months if there has been a significant change to the S8 medication or a change to the person's circumstances. Authority is also required to prescribe restricted S8 substances.
Queensland	Notification is required that the medical practitioner is prescribing or intending to prescribe an S8 drug for longer than 2 months. Approval needs to be sought prior to treating with any 'specified condition drug'.
South Australia	Authority is required before prescribing or supplying drugs of dependence for a patient's regular use during a period exceeding 2 months. Treatment provided by other prescribers must be considered when calculating the 2-month period.
Tasmania	Authority is required to prescribe opioids for more than 2 months. Relevant specialist reports endorsing opioid treatment and dose should be sent with application. Concurrent prescribing of alprazolam with an opioid requires authority after 1 month's prescribing.
Victoria	A permit is required to prescribe a person with any S8 drug for a continuous period greater than 8 weeks. Only one valid permit is needed for treatment of a person by more than one medical practitioner in a multi-practitioner clinic.
Western Australia	Prior written authority is required by medical practitioners wishing to prescribe an S8 medicine for a patient who is a notified addict, or if for a period longer than 60 days in any 12-month period. Consultant support is required for 'high risk criteria' as per the S8 medicines prescribing code.

Source: Cran A. Misuse of opioid drugs. Defence Update: A quarterly publication for MDA National Members [Internet]. 2013. Available at [www.defenceupdate.mdanational.com.au/misuseofopioiddrugs](http://www.defenceupdate.mdanational.com.au/misuseofopioiddrugs).<sup>23</sup>

For links to useful fact sheets, refer to [Section 2.1](#).

## C.2 State and territory contacts

State/territory	Legislation	Contact (web)	Legislative contact (phone)	24-hour clinical advisory services
Australian Capital Territory	<i>Medicines, Poisons and Therapeutic Goods Act 2008</i> <a href="http://www.legislation.act.gov.au/2008-26/default.asp">www.legislation.act.gov.au/2008-26/default.asp</a>	Pharmaceutical Services <a href="http://health.act.gov.au/health-services/population-health/health-protection-service/pharmaceutical-services/pharmaceutical-services">http://health.act.gov.au/health-services/population-health/health-protection-service/pharmaceutical-services/pharmaceutical-services</a>	Pharmaceutical Services Section, ACT Health 02 6205 0998	DACAS – Australian Capital Territory 03 9418 1082
New South Wales	<i>Poisons and Therapeutic Goods Act 1966</i> <a href="http://www.austlii.edu.au/au/legis/nsw/consol_act/patg1966307">www.austlii.edu.au/au/legis/nsw/consol_act/patg1966307</a>	Pharmaceutical Services <a href="http://www.health.nsw.gov.au/pharmaceutical/pages/default.aspx">www.health.nsw.gov.au/pharmaceutical/pages/default.aspx</a>	Pharmaceutical Services Unit, Legal and Regulatory Services Branch, NSW Health 02 9391 9944	DASAS – NSW 02 9361 8006 (Sydney) 1800 023 687 (Rural)
Northern Territory	<i>Medicines, Poisons and Therapeutic Goods Act 2014</i> <a href="http://notes.nt.gov.au/dcm/legislat/legislat.nsf/d989974724db65b1482561cf0017cbd2/86a3e80a889e330369257d4f001810d5?OpenDocument">http://notes.nt.gov.au/dcm/legislat/legislat.nsf/d989974724db65b1482561cf0017cbd2/86a3e80a889e330369257d4f001810d5?OpenDocument</a>	Poisons Control <a href="http://www.health.nt.gov.au/Environmental_Health/Poisons_Control/index.aspx">www.health.nt.gov.au/Environmental_Health/Poisons_Control/index.aspx</a>	Poisons Control Unit, Department of Health and Community Services 08 8922 7341	DACAS – Northern Territory 1800 111 092
Queensland	<i>Health (Drugs and Poisons) Regulation 1996</i> <a href="http://www.legislation.qld.gov.au/LEGISLATION/CURRENT/H/Health/POR96.pdf">www.legislation.qld.gov.au/LEGISLATION/CURRENT/H/Health/POR96.pdf</a>	Medicines Regulation and Quality <a href="http://www.health.qld.gov.au">www.health.qld.gov.au</a>	Medicines Regulation and Quality, Queensland Health 07 3328 9890	GPs can phone ADIS 1800 177 833 to be put through to ATODS for clinical advice
South Australia	<i>Controlled Substances Act 1984</i> <a href="http://www.legislation.sa.gov.au/lz/c/a/controlled%20substances%20act%20201984.aspx">www.legislation.sa.gov.au/lz/c/a/controlled%20substances%20act%20201984.aspx</a>	Medicines and Technology Policy and Programs <a href="http://www.sahealth.sa.gov.au/wps/wcm/connect/public-content/sa-health-internet/about-us/departments-of-health/public-health-and-clinical-emergency-services/medicines-and-technology-policy-and-programs">www.sahealth.sa.gov.au/wps/wcm/connect/public-content/sa-health-internet/about-us/departments-of-health/public-health-and-clinical-emergency-services/medicines-and-technology-policy-and-programs</a>	Drugs of Dependence Unit, Department for Health 1300 652 584	DACAS – South Australia 08 8363 8633
Tasmania	<i>Poisons Act 1971</i>	Pharmaceutical Services Branch <a href="http://www.dhhs.tas.gov.au/psbtas/welcome">www.dhhs.tas.gov.au/psbtas/welcome</a>	Pharmaceutical Services Branch, Department of Health and Human Services 03 6166 0400	DACAS – Tasmania 1800 630 093
Victoria	<i>Drugs, Poisons and Controlled Substances Act 1981</i> <a href="http://www.austlii.edu.au/au/legis/vic/consol_act/dpaca1981422">www.austlii.edu.au/au/legis/vic/consol_act/dpaca1981422</a>	Drugs and Poisons Regulation <a href="http://www.health.vic.gov.au/dpcs/index.htm">www.health.vic.gov.au/dpcs/index.htm</a>	Drugs and Poisons Unit, Department of Human Services 1300 364 545	DACAS – Victoria 1800 812 804
Western Australia	<i>Poisons Act 1964</i> <a href="http://www.austlii.edu.au/au/legis/wa/consol_act/pat1964121">www.austlii.edu.au/au/legis/wa/consol_act/pat1964121</a>	Pharmaceutical Services Branch <a href="http://www.public.health.wa.gov.au/1/872/2/pharmaceutical-services.ppt">www.public.health.wa.gov.au/1/872/2/pharmaceutical-services.ppt</a>	Pharmaceutical Services Branch, Department of Health 08 9222 6883	CAS 08 9442 5042

## Appendix D. Example practice policies

These practice policies are examples only. They are not individually approved or endorsed by the RACGP Council, or by the Standards. They are based on policies and practices from national and international sources. If practices wish to adopt any of these policies, they may be modified for relevance and applicability to the local context.

### D.1 Practice policy – Opioid prescribing policy for patients

#### Purpose

To inform patients about the practice's standards regarding the prescription of drugs of dependence.

#### Example policy

[Insert practice name]

Date effective:

Review date:

#### OPIOID PRESCRIBING POLICY

Many of our patients require strong, potentially addictive medication to help manage their condition(s). Of concern are 'drugs of dependence' (eg opioid medications and benzodiazepines), particularly when these are prescribed on an ongoing basis. Due to increasing reports of abuse of prescription drugs and patient behavioural problems, [insert practice name] has established a policy to ensure adequate treatment of your condition, while reducing the risk of problems with drug prescriptions.

The major points are described below.

If you are a new patient to the practice:

- It may take time to get accurate medical information about your condition. Until such information is available, your GP may choose not to prescribe any medication. It is our policy that GPs do not prescribe drugs of dependence until they have a full clinical picture.
- Your GP may decide not to continue prescribing an opioid medication previously prescribed for you. It may be determined that such a medication is not suitable. It is our policy that GPs do not prescribe drugs of dependence if they feel that previous prescriptions were inappropriate.
- Your GP will evaluate your condition and only prescribe an opioid of the strength necessary for you. This may be different than what another doctor may have given you in the past.

General practice standards:

- If the decision to prescribe is taken after a shared discussion of goals, plans, risks and benefits, you may be required to confirm your consent in writing.
- You may be asked to sign a contract that will detail our practice's expectations when prescribing drugs of dependence. This contract details your responsibilities as a patient taking a drug of dependence; any prescriptions issues; advice on taking your medications; how we will monitor your care; and the standards of behaviour that are expected.
- Patients may need to acknowledge that their care requirements may be complex, and that referral for ongoing care for all or part of your healthcare may be required. It is our practice policy that patient care is matched with the level of complexity.
- Patients are reminded that we have a zero tolerance on issues relating to staff abuse. Any threats to staff will result in transfer of your care.

## D.2 Practice policy – Restriction of prescribing rights for drugs of dependence

### Purpose

To specify the scope and limitations to prescribing of dependence by general practice registrars.

### Example policy

*[Insert practice name]*

Date effective:

Review date:

#### POSITION STATEMENT REGARDING PRESCRIBING AUTHORISATION OF REGISTRARS

Registrars at the *[Insert practice name]* are restricted in prescribing drugs of addiction and drugs of dependence to levels determined by the *[Insert practice name]* clinical governance team or supervising general practitioner. Quality use of these drugs is an essential component of primary care. Ongoing experience, training and self-education in the use of these medications is required as part of training at the *[Insert practice name]*.

#### Drugs restricted under this policy

- Opioid analgesics
- Benzodiazepines

**Scope and limitations** *[May be changed according to individual practice circumstances.]*

#### Opioid (and other prescription) analgesics

Registrars are permitted to **initiate** opioid analgesics as specified below:

1. To hospitalised and residential aged care facility patients:
  - a. for acute analgesia – on call
  - b. using the following medications:
    - i. Tramadol (currently S4) – ceiling dose 200 mg a day
    - ii. Morphine – ceiling dose 40 mg a day

Note that combinations of drugs that result in higher than 40 mg morphine equivalent per day will require senior GP review.
2. To general practice patients:
  - a. using the following medications:
    - i. paracetamol 500 mg codeine 30 mg – limited to 20 tablets
    - ii. tramadol 100 mg – limited to 20 tablets

Note that higher dose tramadol requires consultation with a senior practitioner within the practice.
  - b. Paracetamol/dextropropoxyphene derivatives (paradex, capadex, digesic) are prohibited
  - c. Codeine, oxycodone, buprenorphine patches, fentanyl patches and hydromorphone use requires discussion with a senior practitioner within the practice.

Registrars are permitted to provide opioid analgesic **continuation** as specified below:

1. Registrars are permitted to supply continuation therapy:
  - a. to long-term patients of the practice who are on stable medication regimes, in the absence of their usual practitioner
    - i. patients requesting increased analgesia will need to be referred back to their usual practitioner
  - b. to patients requiring continued postoperative analgesia (ie patients discharge from hospital) provided:
    - i. there is no increase in opioid analgesic requirements
    - ii. a plan to reduce and cease all opioid analgesia within a fortnight for most surgery, but up to 6 weeks for joint replacement or thoracotomy is undertaken
    - iii. a consultation with a senior general practitioner at the *[Insert practice name]* has occurred.
2. Registrars are not permitted to continue analgesic plans initiated at other practices or healthcare facilities without the review of a senior general practitioner at the *[Insert practice name]*.

#### Benzodiazepines

**Benzodiazepine initiation:**

1. Initiation is limited to a single pack (25 tablets) of temazepam 10 mg tablets with no repeats for short-term intermittent use.
  - a. This is in association with a full clinical assessment, documentation of indication for use, as a therapy adjunct to addressing the primary causal issue.

**Benzodiazepine continuation:**

1. Registrars are permitted to supply continuation therapy to:
  - a. long-term patients of the practice who are on stable medication regimes, in the absence of their usual practitioner.
2. The continuation of alprazolam is restricted to the usual senior general practitioner in the practice.

Refer to the RACGP opioid and benzodiazepine guides for other relevant information to include (eg driving ability).

## D.3 Practice policy – Handover standards

### Purpose

To clarify the management of patients in various risk categories with regard to drugs of dependence.

### Example policy

*[Insert practice name]*

Date effective:

Review date:

#### **HANDOVER OF PATIENTS IN MEDIUM- AND HIGH-COMPLEXITY GROUPS WITH REGARD TO DRUGS OF DEPENDENCE**

It is our practice policy that all patients regularly using drugs of dependence have their problems/needs assessed based on levels of complexity (ie low, medium or high). Patients in medium- or high-complexity groups should have an appropriate specialist review. Practice policy requires that patients with medium- or high-complexity problems are managed in a manner consistent with the universal precautions of pain medicine. That is:

- a clear diagnosis and reasons for prescription are documented
- a full psychosocial assessment is conducted including risk of addictive disorders
- informed consent for treatment plans is used
- pre- and post-intervention assessment of pain level and function is undertaken
- opioid therapy +/- adjunctive medication is commenced on a trial basis
- levels of pain and function are constantly assessed
- the 'five As' of pain medicine (analgesia, activity, adverse events, aberrant behaviour, affect) are constantly assessed
- the diagnosis is periodically reviewed and comorbidities are managed appropriately
- the level of documentation standards needs to be high.

These practice standards are required to ensure the ongoing provision of care in the event of the absence of the patient's usual doctor.

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With respect to new patients presenting to the practice, or being referred by other agencies, it is our practice policy that:

- The practice reserves the right not to accept these patients if either the practice or the practitioner is of the view that the current treatment plan is inconsistent with evidence-based guidelines, and the level of complexity exceeds the practice's capacity to manage the patient.
- If a doctor feels that a referral letter from an external agency does not meet handover standards, then communication should be sent to the original referrer seeking additional information (refer to [Appendix E.2](#)).

## D.4 Practice policy – Continuation of opioid management plans for new patients originating from external healthcare providers

### Purpose

To clarify the standards under which opioid management plans are continued (eg for patients with chronic non-malignant pain).

### Example policy

*[Insert practice name]*

Date effective:

Review date:

#### CONTINUATION OF OPIOID MANAGEMENT PLANS INITIATED BY EXTERNAL PROVIDERS

The purpose of this policy is to document the standards under which this practice agrees to continue the management of opioid treatment programs.

Patients often arrive from other practices or institutions requesting continuation of their opioid management programs. These practices and institutions can have prescribing practices which are variable, and may not be evidence based or safe. To ensure the safety of these programs and the quality of services provided by this practice, the following standards are to be observed.

**Policy statement** – Doctors at this practice should not prescribe drugs of dependence until evidence of clinical need is established.

- Opioids should not be prescribed until satisfactory evidence of need is established. Such evidence may be in the form of a full clinical assessment, medical records or direct communication with the previous prescriber. This is necessary to avoid the risk of outdated records, recent changes to therapy or aberrant drug-seeking behaviour.
- If it is difficult to confirm prior appropriate prescribing, you may request that the patient ask previous prescribers or pharmacists to contact you before you will continue the purported prescribing. Difficulty in obtaining this information may signal that the patient may be involved in deceptive behaviour. Drug-seeking patients often attend a practice after hours or when such information is difficult to obtain. Do not allow the patient to pressure you into prescribing. Politely inform the patient that a prescription will be considered only when the information becomes available.
- All records are required to enable a comprehensive evaluation of the patient. A signed release of information form is required.

**Policy statement** – Doctors at this practice should not continue to prescribe drugs of dependence until reasonable steps have been undertaken to exclude problematic drug use.

- Given that there is a high prevalence of drug-seeking behaviour for opioids, and there is a high risk these drugs may be sought and diverted for misuse or trafficking, it is important that each doctor independently makes a thorough clinical assessment of each patient's opioid use, and develops a pain management treatment plan consistent with clinical guidelines. Doctors must satisfy themselves that the full range of treatment options is used, which may or may not include opioid medications.
- Examination of the patient should include checking for evidence of intravenous or other injecting drug use, or drug or alcohol intoxication.
- Evidence that the state or territory drugs and poisons unit or pharmaceutical services unit has a notification of dependence or has issued a permit for long-term opioid prescribing may be sought (for contact details, visit [www.tga.gov.au/industry/scheduling-st-contacts.htm](http://www.tga.gov.au/industry/scheduling-st-contacts.htm)).
- Information may be sought from the Prescription Shopping Information Service (PSIS) operated by the Pharmaceutical Benefits Scheme. This requires prior registration with the PSIS (telephone 1800 631 181 or, for more information, [www.medicareaustralia.gov.au/provider/pbs/prescription-shopping/index.jsp](http://www.medicareaustralia.gov.au/provider/pbs/prescription-shopping/index.jsp)).
- A baseline urine drug test (UDT) will be performed at the initial visit, with a request to include detection of oxycodone and other drugs not usually recognised by immunoassay. Detection of oxycodone requires a gas chromatography–mass spectrometry (GC–MS) test.

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- Schedule a follow-up visit for when UDT results and medical records are available.
- A patient information leaflet regarding the practice policies and procedures for pain management should be provided.

**Policy statement** – In the event of problematic drug use being identified, doctors at this practice should:

- offer remedial programs if this is within the practitioner's skill set
- offer referral to appropriate drug misuse agencies. Appropriate nearby referral agencies include:
- *[Insert appropriate local agencies]*

**Policy statement** – This practice deems the following to be high risk and in need of referral to public alcohol and drug facilities, or a general practitioner with advanced training in addiction medicine:

- *[Strike out or add as required]*
- patients with serious mental illness, or antipsychotic medication
- past family or personal history of substance misuse
- mixed use of opioids and illicit drugs
- mixed use of opioids and benzodiazepines
- recent discharge from correctional services facility
- patients discharged from other general practices due to problematic behaviour.

**Policy statement** – In the event that clinical need for opioid therapy is justified, doctors at this practice should observe the following practice requirements:

- There is a comprehensive evaluation of the patient's condition and analgesic modalities which are documented within a treatment plan and recorded in the notes.
- Doctors should prescribe opioids according to their best clinical judgement, particularly if this is less than the wishes of patients, the recommendations of consultants, or the practices of the patient's previous doctors.
- Patients taking inappropriate doses should be advised that the dose will be tapered in the near future.
- Patients who are unwilling to comply with the taper should be referred to specialist or public health services.
- Relevant permits to prescribe should be obtained from the state or territory drugs and poisons unit or pharmaceutical services. In the case of continuing prescribing, this should be sought immediately if the patient has been receiving opioid treatment for 8 weeks or longer. This will enable coordination of treatment and reduce the risk that previous prescribers will continue prescribing concurrently.

**Policy statement** – Patients who satisfy criteria and are accepted under the continued care of a single doctor will be prescribed ongoing medication according to the practice protocols. This includes:

- continued prescribing and management by a single GP within the practice
- a comprehensive assessment
- a continued use of allied therapies
- a contractual approach to opioid use
- the adoption of universal precautions
- a treatment agreement based on informed consent regarding the risks of dependence
- clear boundaries surrounding the use of opioids
- registration with or under state or territory health laws.

## D.5 Practice policy – Drugs of dependence therapy agreement

### Purpose

To inform patients about their responsibilities and expected behaviours regarding drugs of dependence.

### Example agreement

Based on the Blaustein Pain Treatment Center/Johns Hopkins Medicine therapy agreement and to be modified by the practice to suit local circumstances.

*[Insert practice name]*

Date effective:

Review date:

#### **PATIENT AGREEMENT FOR DRUGS OF DEPENDENCE THERAPY**

The purpose of this agreement is to give you information about the medications you will be taking for pain and/or mental health management at this practice, and to ensure that you and your doctor comply with all state, territory and Federal regulations concerning the prescribing of drugs of dependence.

The doctor's goal is for you to have the best quality of life possible given the reality of your clinical condition. The success of treatment depends on mutual trust and honesty in the patient–doctor relationship and full agreement and understanding of the risks and benefits of using potentially addictive drugs to manage your condition.

A trial of long-term opioid therapy may be considered for moderate to severe pain with the intent of reducing pain and increasing function. A trial of long-term benzodiazepine therapy may be considered in very limited circumstances if other options have failed or are considered inappropriate.

In signing this agreement, you have agreed to a trial of long-term use of potentially addictive medications as part of your treatment. These drugs of dependence can be very useful, but have a high potential for misuse and are therefore closely controlled by state, territory and Federal governments. Because your doctor is prescribing such medication to help manage your condition, it is considered good practice to agree to the conditions outlined below.

#### **My responsibilities as a patient**

- I agree to see one doctor at one practice for all my health needs and prescriptions.
- I will have all my medications dispensed at one pharmacy.
- I agree that this medication is prescribed as a trial. If it appears to my doctor that there is no improvement in my daily function or quality of life from the controlled substance, my medication may be discontinued. I will gradually taper my medication as prescribed by the doctor.
- I will inform my doctor of all medications I am taking, including herbal remedies and illicit medication. Medications can interact with drugs of dependence and produce serious side effects.
- I will communicate fully with my doctor to the best of my ability at the initial and all follow-up visits my pain level and functional activity along with any side effects of the medications. This information allows my doctor to adjust my treatment plan accordingly.
- I will not request or accept drugs of dependence from any other doctor or individual while I am receiving such medication from my doctor at the *[Insert practice name]*.
- I understand the use of alcohol together with drugs of dependence is contraindicated.
- I will not use any illicit substances, such as cocaine, amphetamines or marijuana, while taking these medications. Use of these substances may result in a change to my treatment plan, including safe discontinuation of my opioid medications when applicable or complete termination of the patient–doctor relationship.
- If I have a history of alcohol or drug misuse/addiction, I must notify my doctor of such history since treatment with drugs of dependence may increase the possibility of relapse.
- I agree and understand that my doctor reserves the right to perform random or unannounced urine drug testing. If requested to provide a urine sample, I agree to cooperate. If I decide not to provide a urine sample, I understand that my doctor may change my treatment plan, including safe discontinuation of my opioid medications when applicable or complete termination of the patient–doctor relationship. The presence of a non-prescribed drug(s) or illicit drug(s) in the urine can be grounds for termination of the patient–doctor relationship. Urine drug testing is not forensic testing, but is done for my benefit as a diagnostic tool and in accordance with certain legal and regulatory materials on the use of controlled substances to treat pain.

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- I agree to allow my doctor/healthcare provider to contact any healthcare professional, family member, pharmacy, legal authority, or regulatory agency to obtain or provide information about my care or actions, if my doctor feels it is necessary.
- I understand my capacity to drive may be affected and I may be asked to cease driving.

#### My prescriptions

- I am responsible for my prescriptions. I understand that lost prescriptions will not be replaced.
- I understand that opioid prescriptions **will not** be mailed if I am unable to obtain my prescriptions monthly.
- Repeat prescriptions can be written for a maximum of 1 month supply and will be filled at the same pharmacy.  
Pharmacy: \_\_\_\_\_ Phone number: \_\_\_\_\_
- It is my responsibility to schedule appointments for the next opioid prescription before I leave the clinic or within 3 days of the last clinic visit.

#### Taking my medications

- I understand that the medication is strictly for my own use. My medication should never be given or sold to others because it may endanger that person's health and is against the law.
- I am responsible for keeping my pain medications in a safe and secure place, such as a locked cabinet or safe. I am expected to protect my medications from loss or theft. If my medication is stolen, I will report this to my local police department and obtain a stolen item report. I will then report the stolen medication to my doctor. If my medications are lost, misplaced or stolen my doctor may choose not to replace the medications or to taper and discontinue the medications.
- I am responsible for taking my medications as directed. I agree to take the medication only as prescribed.
- I understand that increasing my dose without the close supervision of my doctor could lead to drug overdose causing severe sedation and respiratory depression and death.
- I understand that decreasing or stopping my medication without the close supervision of my doctor can lead to withdrawal. Withdrawal symptoms can include yawning, sweating, watery eyes, runny nose, anxiety, tremors, aching muscles, hot and cold flashes, 'goose flesh', abdominal cramps and diarrhoea. These symptoms can occur 24–48 hours after the last dose and can last up to 3 weeks.
- Any evidence of drug hoarding, acquisition of any opioid medication or additional analgesia from other doctors (which includes emergency rooms), uncontrolled dose escalation or reduction, loss of prescriptions, or failure to follow the agreement may result in termination of the patient–doctor relationship.

#### Monitoring effects of treatment

- I accept that drug of dependence therapy is only part of my care, and that I must be fully compliant with additional care interventions deemed appropriate for my health.
- I accept that set appointments must be made to review ongoing therapy. This should be monthly and made at the last clinic appointment. No walk-in appointments for medication refills will be granted.
- If an appointment is missed, another appointment will be made as soon as possible. Immediate or emergency appointments will not be granted.
- I will be seen on a regular basis and given prescriptions for enough medication to last from appointment to appointment, and sometimes two to three days extra if the prescription ends on a weekend or holiday. This extra medication is not to be used without the explicit permission of the prescribing doctor unless an emergency requires your appointment to be deferred one or two days.
- It is my responsibility to notify my doctor of any side effects that continue or are severe (eg sedation, confusion). I am also responsible for notifying my doctor immediately if I need to visit another healthcare provider or need to visit an emergency room or if I become pregnant.
- I understand that during the time that my dose is being adjusted, I will be expected to return to the clinic as instructed by my clinic doctor. After I have been placed on a stable dose, I may receive longer term therapy from my doctor but will return to the medical centre for a medical evaluation at least once every 3 months.
- I understand that a reduction of medication will occur if I have deterioration at home or work, or reduction of social activities because of medication, or due to medication side effects.
- I understand that while physical dependence is to be expected after long-term use of opioids, any signs of addiction, abuse, or misuse shall prompt the need for substance dependence treatment as well as weaning and detoxification from the opioids.

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### My behaviour

I understand that there is a wide spectrum of drug misuse behaviours, including those documented below. I understand that cessation of the medication trial, or cessation of the patient–doctor relationship may occur if I display any of the following behaviours:

- presenting to the clinic intoxicated, as assessed by clinical staff
- making any physical threat to any member of staff or to other patients
- aggressively complaining about a need for medication
- persistently requesting to have my medication dose increased despite clinical advice
- taking a few extra, unauthorised doses on occasion
- visiting multiple doctors for controlled substances (doctor shopping)
- hoarding medication
- using a controlled substance for non-pain relief purposes (eg to enhance mood, sleep aid)
- starting frequent unscheduled clinic visits for early refills
- using consistently disruptive behaviour when arriving at the clinic
- obtaining drugs of dependence from family members (including stealing from older relatives)
- having a pattern of lost or stolen prescriptions
- displaying anger or irritability when questioned closely about pain
- being unwilling to consider other medications or non-pharmacologic treatments
- escalating my dose without authorisation
- testing positive for a non-prescribed drug(s) or illicit drug(s) in my urine
- injecting an oral formulation
- forging prescriptions
- selling medications
- refusing diagnostic workup or investigation
- obtaining controlled substance analgesics from illicit sources.

I understand that non-compliance with the above conditions may result in a re-evaluation of my treatment plan and discontinuation of opioid therapy. I may be gradually taken off these medications, or even discharged from the clinic.

I \_\_\_\_\_ have read the above information or it has been read to me and all my questions regarding the treatment of pain with opioids have been answered to my satisfaction. I hereby give my consent to participate in the opioid medication therapy and acknowledge receipt of this document.

Patient's signature \_\_\_\_\_

Date \_\_\_\_\_

Doctor's signature \_\_\_\_\_

Date \_\_\_\_\_

## D.6 Practice policy – Requests for repeat scripts for drugs of dependence

### Purpose

To inform patients about practice policies regarding repeat prescriptions for drugs of dependence.

### Example policy

*[Insert practice name]*

Date effective:

Review date:

#### **REQUESTS FOR REPEAT DRUG OF DEPENDENCE PRESCRIPTIONS**

Patients should be aware of their responsibilities in requesting prescriptions for drugs of dependence. These responsibilities are explained in the practice drugs of dependence policy for patients and in the 'Patient agreement for drugs of dependence therapy'.

Patients should note the following:

- All requests for repeat scripts for drugs of dependence will go to your usual doctor.
- All requests require a clinical review by your doctor. If it appears to your doctor that there is no improvement in your daily function or quality of life from the controlled substance, your medication may be discontinued.
- As a patient, you agree to, and understand that, your usual doctor reserves the right to perform random or unannounced urine drug testing. This is a safety issue.
- Patients are responsible for their prescriptions. Lost prescriptions will not be replaced.
- Repeat prescriptions are generally written for a maximum of 1-month supply and will be filled at the same pharmacy.
- Patients have the responsibility to schedule appointments for the next opioid prescription before leaving the clinic or within 3 days of the last clinic visit.
- Patients have the responsibility for keeping medications in a safe and secure place, such as a locked cabinet or safe. If medications are lost, misplaced, or stolen your doctor may choose not to replace the medications or to taper and discontinue the medications.
- Patients have the responsibility for taking medications as directed and understand that increasing the dose without the close supervision of your doctor could lead to the cessation of prescribing. Early requests for repeats scripts will not be performed.
- Patients have the responsibility to set appointments to review ongoing therapy. This should be monthly and made at the last clinic appointment. No walk-in appointments for medication refills will be granted.

## D.7 Practice policy – Risk assessment for patients with complex needs

### Example policy

*[Insert practice name]*

Date effective:

Review date:

#### **PATIENTS WITH COMPLEX NEEDS – RISK ASSESSMENT FOR ONGOING MANAGEMENT**

This practice deems the following patients to be at high clinical risk and in need of referral to public alcohol and drug facilities, or a general practitioner with advanced training in addiction medicine:

- patients discharged from other general practices due to problematic behaviour
- patients with a past family or personal history of substance misuse
- patients recently discharged from correctional services facility
- patients using drugs of dependence with serious mental health comorbidities, or antipsychotic medication
- patients using a mix of opioids and illicit drugs
- patients using a mix of opioids and benzodiazepines.

*[Strike out or add as required.]*

## D.8 Practice policy – Approach to drug-seeking patients

### Example policy

*[Insert practice name]*

Date effective:

Review date:

**Policy statement** – In the event of problematic drug use being identified, doctors at this practice should:

- offer remedial programs if this is within their skill set
- offer referral to appropriate drug misuse agencies.

**Policy statement** – Patients have the right to respectful care that promotes their dignity, privacy and safety.

**Policy statement** – Patients with substance use disorders have diverse needs and often complex social and psychological issues. Respecting their circumstances and assisting in offering referral to other organisations for support and management is recommended at this practice.

Doctors at this practice are reminded that the patient has a medical condition (substance use disorder) and they often present with manipulative or deceptive behaviour. Some doctors get offended and upset with this sort of behaviour, but it is important to remember that these are the presenting symptoms of a condition, and the medical and social circumstances of these patients can often be complex.

All patients, including those with drug-seeking behaviour, have the right to good medical care. This patient will be someone's son/daughter, sister/brother, etc. Their families will be hoping that you will provide appropriate care for the patient. Getting upset, angry or being offended does not help with the rapport needed to facilitate appropriate care.

This presentation may be the one opportunity in which proper care can be organised for these patients. Doctors need to be non-judgemental, use a neutral 'matter of fact' tone of voice and be empathetic to the individual circumstances. Don't be afraid to explore the issues around the patient's substance use.

Use your rapport. Ensure confidentiality. Acknowledge that it may be difficult for the patient to share this information. The less judgmental you are, the more likely the patient is to reveal information and long-term care can be facilitated.

Remember, this is a disorder that needs to be addressed in a professional manner. However, having a patient focus does not mean that you will continue prescribing drugs of dependence.

Some doctors have difficulty in knowing what to say in these circumstances. The following is a suggestion only:

*[patient name] I am very concerned about your health. From what you have told me today, and from what I can gather from the material you have here, I am concerned you may have a substance use disorder.*

*This is quite concerning, as ongoing use of [drug of concern] in the manner you have described may result in long-term harm for you or your health.*

*Under the state law, in these circumstances, it is actually forbidden for me to prescribe these medications to you.*

*The level of care needed to properly manage your case is outside my area of expertise, however I am happy to refer you to our [insert local drug and alcohol services] to ensure that you get the care you need.*

*I am also quite happy to provide other care outside these medications.*

*Are you interested in that?*

*Unfortunately, I cannot prescribe any tablets in the interim.*

## D.9 Practice policy – Opioid dosing threshold

### Purpose

To detail safe limitations for prescribing opioid medication in this practice. The policy relates to indications other than malignant pain.

### Example policy

*[Insert practice name]*

Date effective:

Review date:

#### **SAFE LIMITS FOR OPIOID PRESCRIBING**

The practice policy is to not prescribe more than an average daily morphine equivalent dose (MED) of 80–100 mg without further validation. Most patient's pain will be controlled on MEDs far less than this. Prescribed opioids have accepted individual and a combined morphine equivalent threshold, after which the risk of adverse events significantly rises.

Opioids should be reserved for patients who have not responded to non-opioid treatments and who have defined somatic or neuropathic pain conditions for which opioids have been shown to be effective.

Before prescribing an opioid:

- A diagnosis of the source of the pain must be made.
- Simple analgesia and other appropriate treatments should have been trialed.
- An opioid-risk tool should be used to determine if the patient is at risk of opioid misuse.
- A contract defining treatment goals, length of treatment and an exit strategy should be signed with the patient.
- There should be regular assessment of the patient using the 5As.

#### **Dosing thresholds**

- The prescriber should routinely evaluate the safety and effectiveness of opioid therapy for chronic non-cancer pain.
- Assessing the effectiveness of opioid therapy should include tracking and documenting both functional improvement and pain relief.
- Compared with patients receiving 1–20 mg per day of opioids, patients receiving 50–99 mg per day had a 3.7-fold increase in overdose risk. Patients receiving 100 mg per day or more had an 8.9-fold increase in overdose risk. Most overdoses were medically serious, and 12% were fatal.<sup>74</sup>

1. If <100 mg MED:<sup>75</sup>

- No assistance from a senior general practitioner or a pain management consultant needed if the prescriber is documenting sustained improvement in both function and pain.
- Consider getting assistance if frequent adverse effects or lack of response is evident in order to address:
  - evidence of undiagnosed conditions
  - presence of significant psychological condition affecting treatment
  - potential alternative treatments to reduce or discontinue use of opioids.

2. **Before** exceeding 100 mg MED per day threshold:<sup>75</sup>

- Seek assistance from a senior general practitioner or pain management consultant to address:
  - potential alternative treatments to opioids
  - the risks and benefits of a possible trial with opioid dose above 100 mg MED/d
  - the most appropriate way to document improvement in function and pain
  - a possible need for consultation from other specialists.

**Table D1. Calculation of morphine equivalent dose<sup>75</sup>**

For patients taking more than one opioid, the MEDs of the different opioids must be added together to determine the cumulative dose.

For example, if a patient takes four codeine 30 mg combined with paracetamol 500 mg and two 20 mg oxycodone extended release tablets per day, the cumulative dose may be calculated as follows:

- Codeine 30 mg x 4 tablets per day = 120 mg per day
- Using the MED dose table, 120 mg of codeine = 15 mg morphine equivalents
- Oxycodone 20 mg x 2 tablets per day = 40 mg per day
- Using the MED dose table, 20 mg oxycodone = 30 mg morphine, so 40 mg oxycodone = 60 mg morphine equivalents
- Cumulative dose is 15 mg + 60 mg = 75 mg morphine equivalents per day.

**Table D2. Dosing threshold for selected opioids<sup>75</sup>**

Opioid	High caution level (100 MED)	Recommended dose threshold (100 MED)	Recommended starting dose for opioid-naïve patients	Considerations
Codeine	240 mg per 24h	Not recommended	30 mg q 4–6h	Codeine has a limited role in the treatment of chronic pain. It is a short-acting opioid suitable only for mild to moderate pain. The <i>Australian Medicines Handbook</i> states that the maximum daily dose of codeine is 240 mg daily, and advises that an alternative opioid should be considered if this dose is reached <sup>76</sup>
Buprenorphine transdermal	52.5 mcg/h weekly		5 mcg/h weekly	
Fentanyl transdermal	25 mcg/h (q 72h)	37.5 mcg (q 72h)	Not for opioid naïve patients	Use only in opioid-tolerant patients who have been taking ≥ 60 mg MED daily for a week or longer
Hydromorphone	24 mg per 24h	30 mg per 24h	2 mg q 4–6h	

**Table D2. Dosing threshold for selected opioids<sup>75</sup>**

Opioid	High caution level (100 MED)	Recommended dose threshold (100 MED)	Recommended starting dose for opioid-naïve patients	Considerations
Methadone	33 mg per 24h	40 mg per 24h	2.5–5 mg BID–TID	Methadone is difficult to titrate due to its half-life variability. It may take a long time to reach a stable level in the body. Methadone dose should not be increased more frequently than every 7 days. Do not use as PRN or combine with other long-acting opioids
Morphine	100 mg per 24h	120 mg per 24h	Immediate release: 10 mg q 4h	Adjust dose for renal impairment. A metabolite of morphine can accumulate to toxic levels in patients with renal impairment
			Sustained release: 15 mg q 12h	
Oxycodone	64 mg per 24h	80 mg per 24h	Immediate release: 5 mg q 4–6h	See individual product labelling for maximum dosing of combination products. Avoid concurrent use of any OTC products containing same ingredient
			Sustained release: 10 mg q 12h	
Oxymorphone	33 mg per 24h	40 mg per 24h	Immediate release: 5–10 mg q 4–6h	Use with extreme caution due to potential fatal interaction with alcohol or medications containing alcohol
			Sustained release: 10 mg q 12h	
Tramadol	400 mg per day			Associated with seizures in patients at high risk of seizure or when combined with medications that increase serotonin levels (eg SSRIs)

**Table D2. Dosing threshold for selected opioids<sup>75</sup>**

Opioid	High caution level (100 MED)	Recommended dose threshold (100 MED)	Recommended starting dose for opioid-naïve patients	Considerations
Tapentadol				Therapeutic Guidelines (online) states 'Tapentadol has been approved by the Australian TGA, but at the time of writing experience with use in Australia is limited. It is reported to be a stronger mu-opioid agonist than tramadol, with noradrenergic but no serotonergic effects'

h, hours; q, every; BID, twice daily; TID, three times daily; PRN, as needed; OTC, over the counter; SSRIs, selective serotonin reuptake inhibitors; TGA, Therapeutic Goods Administration

**Table D3. Approximate\* potencies of various opioids relative to 10 mg parenteral morphine<sup>77</sup>**

Opioid	Parenteral	Oral	Conversion ratio (morphine:drug) <sup>75</sup>	Comment
Morphine (reference)	10 mg IM/IV/SC	30 mg	1:1	–
Buprenorphine (oral)	400 mcg IM/IV	800 mcg SL	–	–
Codeine	–	240 mg	1:8	Codeine is not suitable for patients with severe pain
Fentanyl 2.1 mg patch 4.2 mg patch 8.4 mg patch 12.6 mg patch 16.8 mg patch	15–30 mg/24 h 30–40 mg/24 h 60–80 mg/24 h 90–120 mg/24 h 120–160 mg/24 h	30–60 mg/24 h 60–100 mg/24 h 120–200 mg/24 h 180–300 mg/24 h 240–400 mg/24 h	2.5–5.0:1	–
Hydromorphone	1.5–2 mg IM/IV/SC	6 mg	5:1	–
Methadone	–	–	Complicated	When changing from morphine to methadone, conversion ratios vary considerably depending on the morphine dose. Methadone should only be prescribed for chronic pain by practitioners experienced in its use
Oxycodone	10 mg IV/SC	20 mg	1.5:1	–
Tramadol	100 mg IM/IV	150 mg	1:5	Tramadol may not be suitable as the sole analgesic for patients with moderate to severe pain

IM, intramuscular; IV, intravenous; SC, subcutaneous; SL, sublingual; h, hours

\* These are average equivalent doses because of pharmacokinetic variation between individuals. When changing from one opioid to another, commence with 50% to 75% of the calculated equianalgesic dose and then titrate to response.

**Table D4. Morphine equivalent doses<sup>78</sup>**

Drug (oral)	Equianalgesic dose	Conversion ratio (morphine:drug)
Morphine	10 mg	1:1
Codeine	80 mg	1:8
Hydromorphone	2 mg	5:1
Oxycodone	7.5 mg	1.5:1
Tramadol	50 mg	1:5

## D.10 Practice policy – One-year review of opioid prescribing

If opioid therapy is required for longer than 12 months, the Pharmaceutical Benefits Scheme (PBS) requires clinical review of the case and support by a second medical practitioner. The standards required for evaluation for the PBS review have not been documented. This policy details a protocol that *[Insert practice name]* feels is appropriate to make an informed evaluation of long-term opioid therapy.

*[Insert practice name]* believe this protocol should be considered for peer clinical review on a regular basis (eg every 2 years).

Evaluation criteria	Yes	No
<b>1. Clinical diagnosis</b>		
a) Is there a comprehensive documentation of the patient's pain condition, general medical condition, psychosocial history, psychiatric status and substance use history?		
b) Is the indication/diagnosis for prescribing opioids clearly supported and documented?		
c) Is opioid medication clinically appropriate in this condition?		
<b>2. Opioid treatment</b>		
a) Has opioid therapy produced and maintained a measurable improvement in the patient's functional capacity?		
b) Are the total doses of all opioids below 'ceiling' dose levels? (ie for <i>[Insert practice name]</i> 80 mg morphine equivalent a day)		
c) Is the patient substantially free from adverse side effects of opioid therapy?		
d) Is there continued absence of inappropriate dose escalation, aberrant behaviour, misuse or abuse of opioids?		
e) Has a reduction in opioid therapy been trialled?		
f) Have urine drug screens been used to investigate possible diversion, compliance, or other illicit drug use?		
<b>3. Additional treatment</b>		
a) Are non-drug therapies maximised?		
b) Given the clinical complexity and risk, is the current level of specialist care and multidisciplinary intervention adequate and appropriate?  In general the following scenarios are considered as complex and high risk by <i>[Insert practice name]</i> , and indicated for specialist and multidisciplinary review: <ul style="list-style-type: none"> <li>• those who use two or more psychoactive drugs in combination (polydrug use) (eg opioid, benzodiazepines, antipsychotic, anti-epileptics, and depressants)</li> <li>• patients with serious mental illness comorbidities, or antipsychotic medication</li> <li>• mixed use of opioids and illicit drugs</li> <li>• mixed use of opioids and benzodiazepines</li> <li>• recent discharge from a correctional services facility</li> <li>• patients discharged from other general practices due to problematic behaviour</li> <li>• signs of potential high-risk behaviours.</li> </ul>		
<b>4. Compliance</b>		
a) Is current opioid prescribing compliant with relevant state and territory laws and regulations for controlled substances?		

Answering 'no' to any of the above options should prompt a consideration to alter the management plan.

### Recommendations

- Continue therapy   
 Reduce opioid dose   
 Reduce and cease opioids  
 Pursue alternate therapies   
 Suggest specialist review

## D.11 Practice policy – Opioid reduction policy

### Purpose

To set a guideline for tapering or withdrawal of opioid medication.

### Example agreement

*[Insert practice name]*

Date effective:

Review date:

#### **TAPERING OR DISCONTINUING OPIOIDS**

Not all patients benefit from opioids, and general practitioners frequently face the challenge of reducing the opioid dose or discontinuing the opioid altogether.

Reasons to discontinue opioids or refer for addiction management include:<sup>79</sup>

- severe pain despite an adequate trial of several different opioids
- no improvement in function and pain
- opioid related complications (eg sleep apnoea, falls)
- as a component of 'structured opioid therapy' for addicted patients with a pain condition who do not access opioids from other sources or alter the route of delivery
- patient exhibits drug-seeking behaviours or diversion
- if in the general practitioners judgement, the health risks outweigh the benefits.

From a medical standpoint, weaning from opioids can be done safely by slowly tapering the opioid dose and taking into account the following issues.

- Precautions for opioid tapering
  - Pregnancy – Acute withdrawal can cause premature labour and spontaneous abortion.
  - Unstable medical and psychiatric conditions – While opioid withdrawal does not have serious medical consequences, it can cause considerable anxiety and insomnia that might exacerbate severe, acute medical or psychiatric conditions. Consider specialist review.
  - Opioid addiction – Outpatient tapering is unlikely to be successful if the patient regularly accesses opioids from other doctors or the street; methadone or buprenorphine treatment is advised.
  - Concurrent medications – Avoid sedative-hypnotic drugs, especially benzodiazepines, during the taper.
- Opioid tapering protocol
  - Before initiation
    - Emphasise that the goal of tapering is to make the patient feel better (ie to reduce pain intensity and to improve mood and function).
    - Have a detailed treatment agreement.
    - Be prepared to provide frequent follow-up visits and supportive counselling.
    - Physical rehabilitation is an important factor that should be integrated into the opioid reduction program, with adequate attention and management of other psychological issues.
  - Type of opioid, schedule, dispensing interval
    - Use controlled-release morphine if feasible.
    - Prescribe scheduled doses (not as needed).
    - Prescribe at frequent dispensing intervals (daily, alternate days, or weekly, depending on patient's control over opioid use); do not refill the prescription if the patient runs out.
    - Keep daily schedule the same for as long as possible (eg 3 times daily).

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- Rate of taper
  - Seek advice from a local drug and alcohol clinical advisory service or pain unit.
  - Can vary from 10% of the total daily dose every day to 5% every 1–4 weeks.
  - Slower tapers are recommended for patients who are anxious about tapering, those who might be psychologically dependent on opioids and those who have cardiorespiratory conditions.
  - Faster tapers may be used if the patient is experiencing serious adverse effects such as obvious sedation.
  - Once one-third of the original dose is reached, slow the taper to half of the previous rate.
  - Hold or increase the dose if the patient experiences severe withdrawal symptoms or worsening of pain or mood.
- Switching to morphine
  - Consider switching patients to morphine if the patient is addicted to oxycodone or hydromorphone.
  - A person addicted to opioids should be referred to an addiction specialist or a general practitioner with relevant training for management.
  - Ongoing prescription of morphine to addicted patients requires an authority. Most jurisdictions will not grant an authority unless it is for treatment with methadone liquid or sublingual buprenorphine (film).
  - Calculate the equivalent dose of morphine.
  - Start the patient on half this dose (tolerance to one opioid is not fully transferred to another opioid).
  - Adjust dose up or down as necessary to relieve withdrawal symptoms without inducing sedation.
- Monitoring during taper
  - See the patient frequently; at each visit, ask about the benefits of taper (eg improved pain, mood, alertness).
  - If a patient is not successfully reducing, or there is an escalation in dose beyond prescription, involve other practitioners.
  - Doses may need to be dispensed daily by pharmacy to assist wean process.
  - Use urine drug testing to ensure compliance.
- Completion of taper
  - Taper can usually be completed in between 2–3 weeks and 3–4 months.
  - Patients who are unable to complete the taper may be maintained at a lower opioid dose if they are compliant with the treatment agreement.

A decrease by 10% of the original dose per week is usually well tolerated with minimal physiological adverse effects. Some patients can be tapered more rapidly without problems (over 6–8 weeks).

If opioid abstinence syndrome is encountered, it is rarely medically serious although symptoms may be unpleasant.

- Symptoms of an abstinence syndrome, such as nausea, diarrhoea, muscle pain and myoclonus can be managed with clonidine 0.1–0.2 mg orally every 6 hours or clonidine transdermal patch 0.1 mg/d (Catapres TTS-1) weekly during the taper while monitoring often for significant hypotension and anticholinergic side effects. In some patients it may be necessary to slow the taper timeline to monthly, rather than weekly dosage adjustments.
- Symptoms of mild opioid withdrawal may persist for 6 months after opioids have been discontinued. Rapid reoccurrence of tolerance can occur from months to years after prior chronic use.
- Consider using adjuvant agents, such as antidepressants to manage irritability, sleep disturbance or antiepileptic for neuropathic pain.
- Do not treat withdrawal symptoms with opioids or benzodiazepines after discontinuing opioids.
- Referral for counselling or other support during this period is recommended if there are significant behavioural issues.
- Referral to a pain specialist or public health dependency centre should be made for complicated withdrawal symptoms.

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There are no foolproof methods for preventing behavioural issues during an opioid taper, but strategies implemented at the beginning of the opioid therapy are most likely to prevent later behavioural problems if an opioid taper becomes necessary

An Opioid Taper Plan Calculator is available and makes it easier for prescribers to calculate safe and effective taper plans for patients who would benefit from lower opioid doses. Washington State Medicaid developed it in collaboration with the University of Washington pain management experts. It can be accessed at [www.hca.wa.gov/medicaid/pharmacy/pages/index.aspx](http://www.hca.wa.gov/medicaid/pharmacy/pages/index.aspx) and then click on Medical Opioid Taper Plan Schedule.

#### **Recognising and managing behavioural issues during opioid tapering**

Opioid tapers can be done safely and do not pose significant health risks to the patient. Special care needs to be taken by the prescriber to preserve the therapeutic relationship at this time. Otherwise, taper can precipitate doctor shopping, illicit drug use or other behaviours that pose a risk to patient safety. Extremely challenging behavioural issues may emerge during an opioid taper.<sup>75</sup>

Behavioural challenges frequently arise when a prescriber is tapering the opioid dose and a patient places great value on the opioid they are receiving. In this setting, some patients may feel overwhelmed or desperate and will try to convince the prescriber to abandon the opioid taper. Challenges may include:

- a focus on the right to pain relief ('You don't believe I have real pain')
- arguments about poor quality of pain care with threats to complain to administrators or licensing boards
- attributing their deteriorating psychological state, including suicidal thoughts, to opioid withdrawal.

## D.12 Practice policy – Benzodiazepine fact sheet for patients

### What are benzodiazepines?

Benzodiazepines are a group of prescription-only medicines that have a sedating and calming effect on the brain and nervous system. They are also known as sedatives or tranquillisers. Examples of benzodiazepines include medicines containing one of the following active ingredients: diazepam, lorazepam, oxazepam, temazepam and alprazolam.

They come in tablet and capsule form, and some are available for intravenous use in hospital settings.

### How do benzodiazepines work?

Benzodiazepine medicines differ in how quickly the active ingredient starts to work and for how long the effect lasts. The effect of the medicine also depends on the dose prescribed and on the individual; height, weight, health status and previous experience with benzodiazepines can all impact on how the benzodiazepine medication will work.

Benzodiazepines can help treat symptoms of anxiety and sleeping problems (eg insomnia). As non-medicine therapies have proven benefit in these conditions, benzodiazepines are generally considered only if non-drug treatments are inappropriate or have failed.

If you have been diagnosed with an anxiety disorder, benzodiazepines can make you feel calmer. If you have insomnia, benzodiazepines may help you fall asleep. They are sometimes used for other reasons, such as before an operation to alleviate nervousness.

After taking benzodiazepines, people can describe feeling drowsy, relaxed, confused/fuzzy and having a heavy sensation in their arms and legs. Coordination and reflexes can be affected too, which means you should not take benzodiazepines if you need to be focused and coordinated (eg driving a car or operating heavy machinery).

Benzodiazepines are usually taken for a set period until the intended therapeutic effect is achieved, then the dose is reduced and plans to stop it are made.

If you take benzodiazepines for a prolonged time, the body may adapt and get used to the effects of the medication. Stopping the medication can lead to withdrawal symptoms that includes anxiety and restlessness. Withdrawal symptoms are often mild, but can be severe if you are on high doses of a benzodiazepine. Serious side effects, including seizures, can occur if you stop taking high doses suddenly.

### Can benzodiazepines be addictive?

Although addiction (cravings, abuse, misuse, compulsive or uncontrollable benzodiazepine-seeking behaviour) is possible with benzodiazepines, it is rare in people who are taking therapeutic doses for a specific reason over a short period as prescribed by their doctor.

You may be at a greater risk of developing an addiction to benzodiazepines if you have a history of drug dependence or if you are currently misusing any substance including alcohol or strong pain killers (opioid drugs).

Before prescribing a benzodiazepine, your doctor will ask you questions about these sorts of things to help prevent addiction.

### What are the possible side effects of benzodiazepines?

Benzodiazepine medicines are associated with a number of side effects including:

- drowsiness and unsteadiness, potentially increasing the risk of a fall
- impairment in judgement and dexterity, making tasks such as driving or using heavy machinery more difficult
- forgetfulness, confusion, irritability

- paradoxical aggression and excitability (although this is rare, it is the opposite effect to what is expected with these medicines).

Taking benzodiazepines in combination with other drugs or alcohol can be very dangerous and, in some cases, fatal.

### **Can I take benzodiazepines for a long time?**

Benzodiazepines are usually taken for a short length of time. In rare instances, some patients will require long-term therapy with benzodiazepines. This is after a serious consideration of risks and benefits of long-term therapy between yourself and your doctor. If you and your doctor have decided that benzodiazepines are an important part of your long-term treatment, then you should continue to take them as prescribed and keep checking in with your doctor for review.

If you have been taking benzodiazepines regularly for longer than 4 weeks and wish to stop them, your doctor would be happy to advise you on how to do this. Do not stop or significantly alter the dose abruptly. Many people can stop taking benzodiazepines without difficulty. For others, gradual reduction helps prevent or reduce any withdrawal symptoms.

### **Where can I get more information?**

Much of the information presented here comes from patient.co.uk, [www.patient.co.uk/health/benzodiazepines-and-z-drugs](http://www.patient.co.uk/health/benzodiazepines-and-z-drugs)

Other sources of information include:

- Reconnexion, [www.reconnexion.org.au](http://www.reconnexion.org.au), an Australian not-for-profit organisation that offers programs, counselling, telephone information and support for people with anxiety, stress, depression and benzodiazepine dependency and related conditions.
- The Victorian Government's Better Health Channel website, [www.betterhealth.vic.gov.au](http://www.betterhealth.vic.gov.au)
- The Australian Drug Foundation's help and support page, [www.druginfo.adf.org.au/contact-numbers/help-and-support](http://www.druginfo.adf.org.au/contact-numbers/help-and-support), lists sources of information and advice.

## D.13 Practice policy – Opioid fact sheet for patients

### Chronic opioid therapy safety guideline for patients with chronic non-cancer pain

#### Opioid treatment fact sheet

##### Using opioid medicines to treat your pain

You and your doctor have decided that opioid pain medicine might help reduce your pain and improve your function. Opioids are not likely to make your pain go away completely.

It is important to understand that this treatment involves potential risks and benefits. It is also important that you follow the guidelines in this handout and let your doctor know what you expect from your treatment. Your doctor may ask you to sign an 'Opioid patient care agreement'.

##### What are the goals and possible benefits of opioid treatment?

The goals of treatment are to reduce your pain and improve your daily function. The benefits of opioid medicines are different from person to person. Opioids typically reduce chronic pain by about 30%. Some people find that they can function better day to day, but research has shown this is not typical.

Experts agree that opioids may actually make pain worse, especially at high doses. 'Flare-ups' are common and should not usually be treated by increasing the dose or taking extra medicine.

Your doctor will monitor how you are doing by asking you to rate your pain level and your daily functioning. They may want to know how far you can walk, how long you can sit, whether you are able to work or do housework, and what kinds of activities you do alone or with family and friends.

##### What are the common side effects and risks of opioids?

Opioids cause common side effects that can be unpleasant. They can also increase risks of serious health effects that occur less often. Because opioids have risks that can be serious, your doctor may ask you for a urine or blood sample to help protect your safety.

Side effects vary from person to person. You and your doctor will work together to monitor how opioids affect you. Your doctor may need to adjust your dose until you find the right balance between pain reduction, improved function and side effects.

It is normal to develop physical dependence to opioids. Physical dependence means your body has adapted to the medicine and you will experience tolerance and withdrawal. Tolerance means you need to take more of the medicine to get the same effect. Withdrawal means you will have symptoms when you stop using the medicine.

Withdrawal symptoms are usually the opposite of the effects of the medicine. For example, if the medicine causes constipation, the withdrawal symptom would be diarrhoea. If the medicine reduces pain, the symptom would be increased pain. Withdrawal from opioids is temporary and usually not dangerous.

Babies born to mothers taking opioids will be dependent on opioids at birth. You should not take opioids if you are trying to get pregnant. If you do get pregnant while taking opioids, let your doctor know right away.

People who have had problems with mental health, drugs or alcohol are more likely to have problems with opioids. You must tell your doctor about any mental illness, substance abuse or addiction of any type you have experienced in the past. You must also tell your doctor if anyone in your family has had these problems. Research shows these problems sometimes run in families.

Experts agree that people with active substance abuse or addiction problems should not use opioids for chronic non-cancer pain. If you have problems with substance abuse or addiction, it is important to let your doctor know so you can get the help you need. Tell your doctor right away if you feel you are becoming addicted to opioids.

Common side effects	Other side effects	Withdrawal Symptoms
<p><b>Constipation</b></p> <p>Opioid medicines cause constipation. You may need to be treated for this while you are taking opioids.</p> <p><b>Sedation</b></p> <p>Many opioid medications can make you feel drowsy, slow your reaction time, and cause loss of coordination. They can also make it hard to concentrate and think clearly.</p> <p>Do not drive or use dangerous equipment until you are sure that opioids do not affect your reaction time or thinking ability. It may take a week or longer before you know if you can drive safely while taking opioids. If you are in a traffic accident while driving on opioids, you may be considered to be driving under the influence.</p>	<ul style="list-style-type: none"> <li>• Rash and/or itching</li> <li>• Dry eyes</li> <li>• Blurred vision</li> <li>• Nausea and vomiting</li> <li>• Inability to urinate</li> <li>• Low blood pressure</li> <li>• Slow heart beat</li> <li>• Depressed mood</li> <li>• Slowed breathing</li> <li>• Problems with balance</li> <li>• Decreased sex drive (decreased testosterone)</li> <li>• Decreased immune function</li> <li>• Swelling in hands and feet</li> <li>• Jerking of arms and legs</li> <li>• Increased sensitivity to pain</li> <li>• Disruption of normal sleep</li> <li>• Dental problems</li> <li>• Apathy</li> <li>• Falls resulting in fractures</li> </ul>	<ul style="list-style-type: none"> <li>• Sweating</li> <li>• Nausea</li> <li>• Abdominal pain/cramping</li> <li>• Diarrhoea</li> <li>• Trouble sleeping</li> <li>• Muscle aches</li> <li>• Fast heart beat</li> <li>• Anxiety</li> <li>• Runny nose</li> <li>• Goose bumps</li> </ul>

**Risk of serious bodily harm or death**

Opioid pain medicines can cause serious bodily harm or death. Higher doses appear to cause more side effects, some of which can lead to injuries like serious fractures due to falls. Higher doses increase the risk of overdose. An overdose of opioids, whether by accident or on purpose, can cause serious bodily harm or death. Research continues to show more and more problems with long-term opioid use, especially at high doses.

Using more opioids than your doctor prescribes can cause you to become dangerously sedated, stop breathing or overdose. Combining opioids with certain other medicines or with alcohol or drugs can have the same effect.

**Some opioids have higher risks**

There are special problems with some opioids. For example, pethidine and tramadol are associated with increased seizure risk. Methadone stays in the body for many days, which increases the risk of overdose. It can also cause heart rhythm problems. Opioids that contain paracetamol, such as Panadeine Forte, can harm the liver when taken long term or at high doses.

**Are there alternatives to opioid treatment for chronic non-cancer pain?**

Your doctor may prescribe other treatments to help your pain and to help you do daily activities better. These may include exercise, psychological counselling and medicines that are not opioids. Please be sure to discuss these options with your doctor.

## D.14 Practice policy – Simple checklist for a general practice to examine its quality management of drugs of dependence

This simple checklist was developed from content in this guide. It is designed to enable general practices to evaluate their status in managing drugs of dependence for their respective populations. As each general practice is different, findings should be interpreted individually.

<b>1. Quality and safety infrastructure</b>	
a. Is your practice accredited to The Royal Australian College of General Practitioners' (RACGP's) <i>Standards for general practices</i> ?	
b. Is there a clinical leader responsible for safety and quality within the general practice?	
c. Does the general practice support relevant training, education and resources for staff to be able to identify patients with more complex needs and those at higher risk?	
d. Does the general practice have policies regarding the management of patients according to their mental health status and use of drugs of dependence to provide the appropriate level of service internally and externally?	
e. If the general practice contains a general practice-based drugs of dependence management program, does it ensure suitably qualified staff, organised support and ongoing quality assurance arrangements?	
f. Does the general practice promote the development of competency in prescribing drugs of dependence for its clinical staff?	
g. Does the general practice have strategies to ensure the occupational health and safety of GPs and other members of the practice team?	
<b>2. Clinical policy</b>	
a. Does the practice have agreed clinical policies regarding prescribing drugs of dependence? (Refer to <i>Appendix D</i> )	
<b>3. Organisation of services</b>	
a. Does the general practice have an effective handover system to ensure safe and continuing healthcare delivery for patients (eg buddy system for continued care in the GP's absence)?	
b. Does the general practice facilitate GPs' access to information management data to monitor potential prescription drug abuse (eg state and territory health ministries' drug units and Prescription Shopping Information Service [PSIS])?	
c. Does the general practice allow GPs the right to discontinue care of a patient who has behaved in a violent or threatening manner?	
d. If the general practice contains a general practice-based drugs of dependence management program, does the general practice have a system of care to maximise health outcomes?	
<b>4. Preventive health and screening</b>	
a. Is there evidence that GPs use urine drug screening to detect misuse or abuse of drugs of dependence?	
<b>5. Clinical documentation</b>	
a. Do GPs ensure patient records are clear, up to date and contain sufficient information for another practitioner to take over care?	

<b>6. Clinical assessment</b>	
a. Is there evidence of an adequate assessment and management plan for each patient taking a drug of dependence?	
<b>7. Clinical management</b>	
a. Do GPs use principles of universal precautions to guide their approach to patients who require drugs of dependence?	
b. Do GPs use specialist support to manage problematic drug use in patients with more complex issues or if the clinical situation deteriorates?	
<b>8. Prescribing safety</b>	
a. Do GPs prescribe within legislative frameworks and comply with professional standards and approved clinical guidelines?	
b. Do GPs ensure a permit or authority from the relevant state or territory health department when prescribing a Schedule 8 (S8) drug to a patient who is drug dependent?	
c. Do GPs inform patients that drugs of dependence are to be prescribed from one practice and preferably by one GP, and drugs should be dispensed from one pharmacy?	
<b>9. Clinical practice review</b>	
a. Do GPs have a structured approach to reviewing opioid prescriptions after 12 months? (eg similar to <i>Appendix D.10</i> )	
<b>10. Populations for intervention</b>	
a. Does the general practice engage in population interventions to reduce use of drugs of dependence? (eg reducing benzodiazepines use through a practice letter similar to <i>Appendix E.1</i> )	

## Appendix E. Practice letters

### E.1 Practice letter – To patients regarding benzodiazepine reduction

#### Purpose

To detail safe limitations for prescribing opioid medication in this practice. The policy relates to indications other than malignant pain.

#### Example policy

[Insert practice name]

Address

Date

Dear [Patient name]

We are currently undertaking a review of prescriptions for medications collectively known as benzodiazepines and sleeping tablets. I am writing to you because our records show that you have received a number of prescriptions for one or more of these types of medications in the past 12 months.

A growing body of evidence suggests that if these medications are used for long periods, they can have harmful side effects, including anxiety symptoms, memory and sleep problems, and they can be addictive. We do not recommend long-term use.

We are writing to ask you to consider cutting down your dose of tablets and perhaps stopping them completely at some time in the future. As each person is different, we would like to discuss this with you in person within the next 3 months.

The best way to cut down your tablets is to take them only when you feel they are absolutely necessary. It is best to cut down gradually; otherwise you may have some withdrawal side effects. You should not stop your tablets suddenly. Once you start to reduce your dose you may start to notice that you feel a lot better and you may be able to think about stopping altogether.

Please make an appointment with your GP to discuss this further. If you have not attended to discuss this within the next 3 months, we may not be able to continue to prescribe this medicine for you. If you have already discussed this with your doctor, or have stopped your medications, this letter does not apply to you.

Yours sincerely,

[Dr name]

## E.2 Practice letter – To referring agencies

### Example policy

[Insert practice name]

Date effective:

Review date:

Dear [Referrer]

Thank you for your referral of [Patient name] back to primary care.

I am concerned that your referral does not meet the RACGP or Australian Commission on Safety and Quality in Health Care (ACSQHC) handover standards.

[Patient name] has a number of bio-psychosocial problems, which would put [him/her] in a [moderate/high] complexity group for ongoing management. It is our practice policy that before accepting a patient in this risk group back into primary care, we are fully conversant with [his/her] case to ensure we provide the highest care available to [patient first name].

To ensure proper coordination of care, we also require information about your plans regarding routine review of [patient first name], and your advice on situations that would prompt the need for your immediate review.

To facilitate this process, please provide the following information.

#### Diagnoses

- Please list all diagnoses with respect to pain management, addiction, and mental health. Please confirm that these diagnoses are consistent with DSM-IV/5 criteria or ICD-10.

#### Current status of patient

- Please document the patient's social issues that you are aware may impact on management.
- Can you please provide a current psychological assessment including risk of addictive disorders?
- Can you please provide an assessment of pain score (if applicable)?
- Can you please describe the patient's current level of function?
- Has the patient ever displayed any aberrant behaviour toward his/her treatment plan, or problematic use of his/her medication?
- Is there any relevant medical history (eg renal impairment) that may impede overall management?

#### Current treatment

- Please provide a summary of the treatment plan with medication, doses and times of administration. This includes how often you wish to review this patient's progress. Please also detail any non-drug interventions that have been organised.
- Have any of these medications been instituted as a trial of therapy (eg opioids)?
- Has a treatment plan been documented for the patient (please provide copy)? Has the patient consented to this treatment plan?
- Please document instances that would prompt immediate transfer back to your care.

#### Contact details

- Can you please provide contact details of a case manager and a clinically responsible person with whom case discussion can occur?
- Can you please provide documentation that details mechanisms for rapid transfer back to specialty care if deterioration occurs?

Thank you for this information. Please be aware that it is also practice policy not to accept high-risk patients if either the practice or practitioner is unhappy with the treatment plan.

Regards

[Dr name]

## Appendix F. Drug misuse behaviours

There is a wide spectrum of drug misuse behaviours – many will not be obvious during the consultation. Behaviours are described below.

<b>Table F1. Drug misuse behaviours</b>
<b>Typical requests and complaints</b>
<ul style="list-style-type: none"> <li>• Aggressively complaining about need for medication</li> <li>• Asking for specific medications by name</li> <li>• Asking for non-generic medication</li> <li>• Requesting to have medication dose increased</li> <li>• Claiming multiple pain medicine allergies</li> <li>• Anger or irritability when questioned closely about pain</li> </ul>
<b>Inappropriate self-medicating</b>
<ul style="list-style-type: none"> <li>• Taking a few extra, unauthorised doses on occasion</li> <li>• Hoarding medication</li> <li>• Using a controlled substance for non-pain relief purposes (eg to enhance mood, sleep aid)</li> <li>• Injecting an oral formulation</li> </ul>
<b>Inappropriate use of general practice services</b>
<ul style="list-style-type: none"> <li>• Visiting multiple doctors for controlled substances (doctor shopping)</li> <li>• Frequently calling the clinic</li> <li>• Frequent unscheduled clinic visits for early refills</li> <li>• Consistently disruptive behaviour when arriving at the clinic</li> <li>• Consistently calling outside of clinic hours or when a particular physician is on call who prescribes controlled substances</li> </ul>
<b>Resistant behaviour</b>
<ul style="list-style-type: none"> <li>• Unwilling to consider other medications or non-pharmacologic treatments</li> <li>• Frequent unauthorised dose escalations after being told that is inappropriate</li> <li>• Unwilling to sign controlled substances agreement</li> <li>• Refusing diagnostic workup or consultation</li> </ul>
<b>Manipulative or illegal behaviour</b>
<ul style="list-style-type: none"> <li>• Claiming to be on waiting list or unable to afford dental work and needing to manage dental pain</li> <li>• Obtaining controlled substances medications from family members (including stealing from older relatives)</li> <li>• Using aliases</li> <li>• Forging prescriptions</li> <li>• Pattern of lost or stolen prescriptions</li> <li>• Selling medications</li> <li>• Obtaining controlled substance analgesics from illicit sources</li> </ul>
<b>Other typical behaviours</b>
<ul style="list-style-type: none"> <li>• Being more concerned about the drug than their medical problem that persists beyond the third clinic visit</li> <li>• Deterioration at home or work or reduction of social activities because of medication side effects</li> </ul>

Drug-seeking patients can often provide very well-developed clinical histories and those histories may seem very 'real'. There is often a strong aim to work on the desire of doctors to minimise the distress of patients. Rather than being aggressive, many will be very pleasant with a credible story. In addition, not all drug-seeking patients are faking symptoms. They may have a legitimate complaint and, over time, have become dependent or tolerant and require larger doses of medication to function in their daily life.<sup>80,81</sup>

To minimise the resultant harms and risks occurring with drug-seeking behaviour, a practice of never prescribing drugs of dependence to new patients to the practice and a sign in the practice regarding this in the waiting room is advised.

We also advise a one doctor policy within the practice for prescribing any drugs of dependence unless special arrangements are made to cover leave. The aim of this practice is to minimise drug-seeking behaviour and its resulting harms and costs to the healthcare system. A consistent change across all of general practice to these recommendations would result in a shift in drug-seeking behaviour and provide the possibility of a future where doctor shopping may cease.

## *Appendix G. Assessment of current drug and alcohol use*

### History

History taking should include:

- types of drugs used
- quantity, frequency and pattern of use
- route of administration
- symptoms of dependence
- source of drug (including preparation)
- prescribed medication
- tobacco use
- alcohol use, including quantity, frequency and pattern of use.<sup>82</sup>

### Drug testing

There are a range of drug tests, including:<sup>82</sup>

- **Screening tests** – These are usually carried out first. They are quick, cheap and easy. They are usually done using immunoassay and can be performed in the laboratory or using point-of-care or dipstick tests. Negative results can be reliably accepted. Positive results usually need a confirmatory test.
- **Confirmatory tests** – These tend to use gas or liquid chromatography and mass spectrometry. They are slower and more expensive, but can detect drugs and their metabolites. These are the gold standard for drug testing.
- **Urine testing** – This is usually performed. It can show drug use over recent days and is a non-invasive test. Urine specimens may be adulterated (eg addition of chemicals, dilution by drinking large volumes of fluid), substituted or be prone to pre-collection abstinence of drugs that may produce a misleading result. It is only very occasionally necessary to directly observe a urine specimen being given, and the patient's informed consent is needed for this.
- **Oral fluid testing** – Oral fluid is easier to collect, but drugs are present in lower concentrations and only very recent drug use over the last 24–48 hours can be detected. However, it is less easy to adulterate.
- **Hair testing** – These tests can show drug use over the past few months. It is poor at detecting very recent use. However, it does not differentiate between continual and sporadic use. It is also more complicated and is only performed in some laboratories.

Written procedures should be in place for the collection and storage of biological samples, their dispatch to a laboratory and the discussion and management of reported results.

## Appendix H. Urine drug testing

Most urinalysis procedures are carried out using gas chromatography in specialist laboratories and there is usually a delay in receiving a result. The result establishes that the drug/s is/are present but does not measure the amounts in which the drug/s has/have been taken. It can therefore be very helpful to have a supply of on-site urine testing strips that provide a basic guide to the drugs being used within a couple of minutes. This is a screening tool, it is not confirmatory, and should always be used in conjunction with clinical signs and history. False positives and negatives can occur with on-site tests, though they are rare.<sup>83</sup>

**Table H1. Length of time drugs of dependence can be detected in urine<sup>84</sup>**

Drug	Time
Alcohol	7–12 h
Amphetamine	
• Methamphetamine	48 h
• 3,4-methylenedioxy-N-methylamphetamine (MDMA)	48 h
Benzodiazepine	
• Ultra short acting	12 h
• Short acting	24 h
• Long acting	3 weeks
Cocaine metabolites	2–4 d
Marijuana	
• Single use	3 d
• Moderate use (4 times/week)	5–7 d
• Daily use	10–15 d
• Chronic heavy use (> 3 times/day)	> 30 d
Opioids	
• Buprenorphine (and metabolites)	8 d
• Codeine	48 h
• Heroin (morphine)	48 h
• Hydromorphone	2–4 d
• Methadone	3 d
• Morphine	2–3 d
• Oxycodone	2–4 d

h, hours; d, days

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**Table H2. Interpreting unexpected results of urine drug tests<sup>85</sup>**

	Unexpected result	Possible explanations	Actions for the doctor
1	UDT <i>negative</i> for prescribed opioid	<ul style="list-style-type: none"> <li>• False negative</li> <li>• Non-compliance</li> <li>• Diversion</li> </ul>	<ul style="list-style-type: none"> <li>• Repeat test using chromatography; specify the drug of interest (eg oxycodone often missed by immunoassay)</li> <li>• Take a detailed history of the patient's medication use for the preceding 7 days (eg could learn that patient ran out several days prior to test)</li> <li>• Ask patient if they've given the drug to others</li> <li>• Monitor compliance with pill counts</li> </ul>
2	UDS <i>positive</i> for non-prescribed opioid or benzodiazepines	<ul style="list-style-type: none"> <li>• False positive</li> <li>• Patient acquired opioids from other sources (doctor shopping, street)</li> </ul>	<ul style="list-style-type: none"> <li>• Repeat UDT regularly</li> <li>• Ask the patient if they accessed opioids from other sources</li> <li>• Assess for opioid misuse/addiction</li> <li>• Review/revise treatment agreement</li> </ul>
3	UDS <i>positive</i> for illicit drugs (eg cocaine, cannabis)	<ul style="list-style-type: none"> <li>• False positive</li> <li>• Patient is occasional user or addicted to the illicit drug</li> </ul>	<ul style="list-style-type: none"> <li>• Repeat UDT regularly</li> <li>• Assess for abuse/addiction and refer for addiction treatment as appropriate</li> </ul>
4	Urine creatinine is lower than 2–3 mmol/L	<ul style="list-style-type: none"> <li>• Patient added water to sample</li> </ul>	<ul style="list-style-type: none"> <li>• Repeat UDT</li> <li>• Consider supervised collection or temperature testing</li> <li>• Take a detailed history of the patient's medication use for the preceding 7 days</li> <li>• Review/revise treatment agreement</li> </ul>
5	Urine sample is cold	<ul style="list-style-type: none"> <li>• Delay in handling sample (urine cools within minutes)</li> <li>• Patient added water to sample</li> </ul>	<ul style="list-style-type: none"> <li>• Repeat UDT, consider supervised collection or temperature testing</li> <li>• Take a detailed history of the patient's medication use for the preceding 7 days</li> <li>• Review/revise treatment agreement</li> </ul>

UDS, urine drug screen; UDT, urine drug test  
Reproduced with permission from Canadian Guideline for Safe and Effective Use of Opioids for Chronic Non-Cancer Pain © 2010 National Opioid Use Guideline Group (NOUGG).

## *Appendix I. Resources*

### **I.1 Staff safety**

- Personal safety and privacy for doctors, available at <http://ama.com.au/node/2182>
- RACGP Keeping the doctor alive: A self-care guidebook for medical practitioners, available at [www.racgp.org.au/peersupport](http://www.racgp.org.au/peersupport)
- RACGP General practice – a safe place, available at [www.racgp.org.au/gpsafeplace](http://www.racgp.org.au/gpsafeplace)

### **I.2 Risk assessment**

- Clinical risk assessment and management (CRAM) in Western Australian mental health services, available at [www.health.wa.gov.au/docreg/Education/Population/Health\\_Problems/Mental\\_Illness/HP10607\\_Clinical\\_risk\\_assessment\\_management.pdf](http://www.health.wa.gov.au/docreg/Education/Population/Health_Problems/Mental_Illness/HP10607_Clinical_risk_assessment_management.pdf)

### **I.3 24-hour drug and alcohol services**

- Alcohol and Drug Information Service (ADIS) – These state- and territory-based services offer information, advice, referral, intake, assessment and support 24 hours a day. They offer services for individuals, their family and friends, GPs, other health professionals and business and community groups.
- Drug and Alcohol Clinical Advisory Service (DACAS) – DACAS is available 24 hours a day, 7 days a week and provides clinical advice to health professionals in Victoria, South Australia, Tasmania and the Northern Territory, about the management of patients and clients with alcohol and other drug problems.
- Drug and alcohol Specialist Advisory Service (DASAS) – DASAS is available 24 hours a day, 7 days a week and provides patient management advice for health professionals treating those with drug and alcohol problems. It is part of the St Vincent's Hospital Alcohol and Drug Service in Sydney and services NSW.

State/ territory	Alcohol and Drug Information Service (for public and health professionals)	24-hour Clinical Advisory Services (for GPs and other health professionals)
Australian Capital Territory	ACT Alcohol and Drug services 02 6207 9977 <a href="http://health.act.gov.au/our-services/alcohol-and-other-drugs">http://health.act.gov.au/our-services/alcohol-and-other-drugs</a>	DACAS – ACT 03 9418 1082
New South Wales	St Vincent's Hospital Alcohol and Drug Service 02 9361 8000 (Sydney) 1800 422 599 (Rural) <a href="http://exwwwsvh.stvincents.com.au">http://exwwwsvh.stvincents.com.au</a>	DASAS 02 9361 8006 (Sydney) 1800 023 687 (Rural)
Northern Territory	Northern Territory Alcohol and Drug resources 08 8922 8399 (Darwin) 08 8951 7580 (Alice Springs) 1800 131 350 (Rural) <a href="http://www.health.nt.gov.au/alcohol_and_other_drugs">www.health.nt.gov.au/alcohol_and_other_drugs</a>	DACAS – NT 1800 111 092
Queensland	Queensland Alcohol, Tobacco and Other Drugs 1800 177 833 (all QLD) <a href="http://www.health.qld.gov.au/atod">www.health.qld.gov.au/atod</a>	GPs can phone ADIS and be put through to ATODS for clinical advice
South Australia	Drug and Alcohol Services South Australia (8.30 am – 10.00 pm) 1300 131 340 (all SA) 08 8363 8618 (interstate callers) <a href="http://www.dassa.sa.gov.au/site/page.cfm">www.dassa.sa.gov.au/site/page.cfm</a>	DACAS – SA 08 8363 8633
Tasmania	Alcohol and Drug services in Tasmania 1800 811 994 (Rural) 03 9416 1818 (Hobart) <a href="http://www.dhhs.tas.gov.au/mentalhealth/alcohol_and_drug">www.dhhs.tas.gov.au/mentalhealth/alcohol_and_drug</a>	DACAS – Tas 1800 630 093
Victoria	Drugs and Alcohol services in Victoria <a href="http://drugsandalcohol.dhs.vic.gov.au/index.htm">http://drugsandalcohol.dhs.vic.gov.au/index.htm</a>	DACAS – Vic 1800 812 804 <a href="http://www.dacas.org.au">http://www.dacas.org.au</a> Clinical advisory service Family Drug Helpline 1300 660 068 Information, support & counselling, trained volunteers who have supported a family member with a drug problem DirectLine 1800 888 236 Referral service Drug Info Clearinghouse 1300 858 584 Youth Drug and Alcohol Advice (YoDAA) 1800 458 685 Youth drug and alcohol workers. This number also accesses YSAS
WA	08 9442 5000 (Perth) 1800 198 024 (Rural) Drug and Alcohol office in Western Australia Parent Drug Information Service (PDIS) Perth: 08 9442 5050 Regional: 1800 653 203 <a href="http://www.dao.health.wa.gov.au">www.dao.health.wa.gov.au</a>	CAS 08 9442 5042

## *Appendix J. Process of guide development*

The RACGP convened a GP-led advisory group, drawing on GP members with expertise and experience in drugs of dependence, guideline development and clinical governance. A literature search and narrative review was conducted. Key resources and guidelines for clinical governance arrangements and prescribing addictive medications were sought from the English literature. Current Australian drug policy, strategies and position statements were also collated and reviewed. In addition to a literature search, guidance was also sought from the RACGP's *Standards for general practices* (4th edition) and issues were identified using the RACGP Quality Framework. Barriers and enablers to improving quality of prescribing addictive medicines were identified across each of the Quality Framework domains of capacity, competence, financing, knowledge and information management, patient focus and professionalism.

## References

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