

# Policy for maintenance pharmacotherapy for opioid dependence

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# About this policy

This document describes the Victorian jurisdictional policy for methadone and buprenorphine use in the treatment of opioid dependence. The policy should be used in conjunction with the *National guidelines for medication-assisted treatment of opioid dependence*, which can be downloaded from the Department of Health and Human Services website at [www.health.vic.gov.au/dpcs/pharm.htm](http://www.health.vic.gov.au/dpcs/pharm.htm).

This document provides prescribers and pharmacists supplying pharmacotherapies with information about Victorian policy that regulates treatment of opioid dependence with pharmacotherapy (opioid replacement therapy). The policy advises practice standards for practitioners and aims to enhance coordination and cooperation between professionals involved in patient management. It also provides contacts for a range of support services (Appendix 2).

In this policy, where the word 'must' is used, it refers to a practice that is required by legislation. Where the policy advises a practice to be adopted, but that practice is not specifically required by legislation, the word 'should' is used.

## Disclaimer

The policy has been prepared by the Department of Health and Human Services with advice from practitioners with expertise in the use of pharmacotherapies for treating opioid dependence. The policy is intended to convey the legislative requirements and provide advice to assist prescribers, pharmacists and other health practitioners to treat opioid-dependent patients in a legal, safe and effective manner.

The policy advises practice standards that are consistent with safe clinical practice. The policy is not intended to replace professional judgment in individual cases. The policy cannot provide detailed direction in respect to the management of every patient in every clinical situation and does not constitute treatment advice for specific cases. Individual prescribers, pharmacists and other health practitioners supplying doses are responsible for decisions about the safety and effectiveness of treatment used for each patient. In practice, ensuring safety of supply is paramount in these decisions. Each part of the policy should be used only for the purposes stated.

Where a practice is adopted that varies from the policy, practitioners are strongly advised to fully document the reasons for such variations. Notwithstanding that, practitioners may be subject to various statutory, common law and contractual obligations. They should seek specific legal advice on the existence and scope of these obligations.

# Acknowledgements

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# Overview

## Section 1: Introduction

Problems with opioids: heroin and pharmaceutical opioids (prescription and over-the-counter) and the effectiveness of pharmacotherapy. The features of pharmacotherapy in Victoria and the policy framework within which pharmacotherapy is delivered in Victoria.

## Section 2: Drugs available for pharmacotherapy

The main drugs currently used for pharmacotherapy maintenance. Responsibility of practitioners to adopt practices to minimise dose diversion.

## Section 3: Policy for prescribers

Procedures for training to become a prescriber of pharmacotherapies. Policy regarding the management of common practices associated with pharmacotherapy, including permits, intake procedures, prescribing policy, authorising take-away doses, communicating with pharmacists.

## Section 4: Policy for pharmacists

Procedures for pharmacies to become suppliers of pharmacotherapies. Policy regarding the management of common practices associated with pharmacotherapy dosing, including storage, records, accepting new patients, administering supervised doses, supply of take-away doses, minimising diversion, terminations and transfers.

## Appendices

Useful contacts, features of a pharmacotherapy prescription, certification of pharmacists administering doses, checklist for assessing appropriateness of take-away doses, suggested formats for dosing and attendance records, sample treatment agreement form, patient transfer forms. Area-Based Pharmacotherapy Networks.

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# 1 Introduction

**This policy has been developed to assist practitioners and patients make decisions about the legal, safe and effective use of pharmacotherapies in treating opioid dependence.**

## The scope of the problem

The cost to Australian society of illicit drug use in 2004–05 was estimated to be \$6.9 billion, the cost of related crime comprised \$3.6 billion of this.<sup>1</sup>

In the past, most patients seeking treatment for opioid dependence were people who inject drugs (heroin) and were actively involved in a drug-using subculture.

In recent years, pharmaceutical opioid use has become more prominent among those seeking treatment for opioid dependence, resulting from problematic use of:

- over-the-counter (OTC) codeine-containing analgesics, particularly those containing codeine combined with ibuprofen or paracetamol, in high daily doses
- prescription opioids, such as morphine and oxycodone, particularly long-acting formulations.

Pharmaceutical drug misuse has become a serious problem in Australia, with overdose deaths now exceeding the number of road deaths in Victoria.<sup>2</sup>

On a snapshot day in 2015, there were 48,522 people being treated with pharmacotherapy for opioid dependence in Australia. For the 33,668 of these people who reported the primary drug of concern responsible for treating opioid dependence, about two-thirds (64 per cent) reported heroin and one-third (36 per cent) reported pharmaceutical opioids.<sup>3</sup>

People dependent on pharmaceutical opioids are either those who have become addicted after commencing treatment with prescription or OTC codeine combination analgesics for the treatment of pain (accidental addicts) or those who have deliberately sought these drugs for their

1 Collins, D J & Lapsley, H M, 2008, *The costs of tobacco, alcohol and illicit drug abuse to Australian society in 2004/05*, Canberra ACT

2 Coroners Court of Victoria, 2013

3 Australian Institute of Health and Welfare, 2016, *National opioid pharmacotherapy statistics annual data collection 2015*

intoxicating effects (intentional addicts). The first group may never have injected or used illicit drugs or been involved in a drug-using subculture; they may be more highly functioning and have more social supports that assist in managing their dependence.

However, pharmaceutical opioids are also often deliberately misused and oral formulations such as tablets are crushed, dissolved and then injected by drug users who, in many cases, may prefer pharmaceutical opioids over heroin. People who inject drugs often procure pharmaceutical opioids for misuse illicitly, including from patients to whom they had been prescribed.

Opioid analgesics are among the most commonly misused drugs and contribute to an increasing number of overdose deaths and other serious harm. Despite the limited evidence about the efficacy and safety of opioids for treating chronic non-malignant pain, the supply of opioid analgesics in Australia has increased, with new opioids, new formulations and increased prescribing. For instance, between 1997 and 2012, oxycodone and fentanyl supply increased 22-fold and 46-fold respectively.<sup>4</sup>

There has been a steady increase in serious harm and deaths in the last decade from problematic use or deliberate misuse of OTC codeine-containing analgesics and prescription opioids.

### **Harms associated with heroin dependence**

#### **To the individual:**

- health: transmission of blood-borne infections (for example, hepatitis C, HIV), local skin infections, thrombophlebitis, malnutrition, dental problems, mental health problems, risk of overdose sometimes resulting in death
- financial: cost of drugs, unemployment
- social: stress on relationships, loss of self-esteem, homelessness.

#### **To the community:**

- increased crime
- burden of social costs: unemployment, increased medical costs, loss of productive members of society, impact on family members including children.

### **Harms associated with problematic use and dependence on pharmaceutical opioids**

#### **To the individual:**

- in the case of people injecting solid dose forms intended for oral use, harm includes vascular damage, inadvertent intra-arterial injection, talc pulmonary granulomatosis from the talc included as an excipient in these oral medications, other risks associated with illicit injection and opioid adverse effects
- transmission of blood-borne infections if injecting pharmaceutical opioids
- in the case of misuse of OTC codeine-containing analgesics, the risk of harm from high doses of the simple analgesics with which codeine is combined in these products. This includes nonsteroidal anti-inflammatory drugs (NSAID) toxicity in OTC codeine-ibuprofen and OTC codeine-aspirin products (peptic ulcer and complications including gastric and duodenal haemorrhage and perforation, gastric outlet obstruction, small bowel or protein-losing enteropathy, hypokalaemia, rhabdomyolysis, renal tubular acidosis, blood loss anaemia, hypoalbuminaemia) and hepatotoxicity in OTC codeine-paracetamol products
- risk of overdose, sometimes resulting in death
- social dysfunction
- mismanagement of pain
- drug-seeking behaviour.

#### **To the community:**

- a threat to the confidence with which medical practitioners prescribe opioids for pain because of the fear of diversion and misuse, and harms arising from misuse
- cost to Medicare and the Pharmaceutical Benefits Scheme (PBS)
- burden on medical care systems.

4 Dobbin M, 2014, *Pharmaceutical drug misuse in Australia*, Australian Prescriber 37:79-81

Maintenance pharmacotherapy is an important part of Victoria's community response to the problem of opioid dependence.

## Pharmacotherapy is an effective treatment for opioid dependence

Opioid replacement therapy (pharmacotherapy) is well established in Australia, as in many parts of the world, as an effective treatment for opioid dependence. Many long-term heroin users and those experiencing problematic use of prescription opioids and OTC codeine-containing analgesics can be successfully treated with detoxification and abstinence-based treatments. However, studies have shown that many will relapse to problematic opioid use. Maintenance pharmacotherapies can prove valuable in assisting these people to successfully manage physical dependence, drug craving and compulsive drug use.

Methadone and buprenorphine have been used to treat opioid dependence, both in detoxification from opioids and maintenance treatment. These drugs are useful for these purposes because:

- they exhibit cross-tolerance with other opioids, enabling them to be substituted for abused opioids such as heroin and pharmaceutical opioids
- they are taken orally, so injecting drug-dependent patients can avoid the rapid onset of hedonic and reinforcing effects of injecting
- they are long acting, enabling daily or less frequent dosing than heroin or short-acting pharmaceutical opioids.

Drug dependence is a complex condition involving social, psychological and biological components. Dependence on opioids is a serious condition associated with severe morbidity and a high risk of death. This risk arises from both drug overdose and the morbidity and injury that result from chronic illicit drug use or misuse of illicit opioids, as well as increased transmission of blood-borne viruses when these illicit and pharmaceutical opioids are injected. Maintenance

pharmacotherapies can be compared to other drugs that are effective in treating serious, chronic conditions, such as hypertension and diabetes. These conditions, like opioid dependence, are often chronic and relapsing; they require daily treatment and have a high risk of adverse effects if adherence to treatment regimens is poor.

Methadone and buprenorphine have been proven effective in reducing dependence on heroin and pharmaceutical opioids.

Supervised daily supply of an adequate dose of methadone or buprenorphine in a structured system has been demonstrated to have benefits for both the individual and society in:

- reducing illicit opioid drug use (heroin and illicit use of pharmaceutical opioids)
- reducing injecting
- reducing illness and death from illicit drug use
- decreasing criminal activity
- stabilising the patient's life
- reducing chaotic drug taking
- making it possible for heroin users to lead productive lives
- decreasing high risk practices such as needle sharing
- enhancing social responsibility.

Pharmacotherapy has also been effective in assisting people dependent on pharmaceutical opioids (OTC codeine-containing analgesics or prescription opioids) to stabilise their use of opioids and avoid the risks and other consequences of problematic use.

## Pharmacotherapy in Victoria

### Community-based services

In the mid-1990s, the Victorian Government made a decision to move from clinics to a community-based delivery model for treatment for opioid dependence in Victoria. This model includes general practice and community pharmacy.

A number of initiatives were developed to support community-based delivery of pharmacotherapy for opioid dependence, including:

- Specialist Methadone Services (now Specialist Pharmacotherapy Services) to consult on and manage more complex patients
- the Drug and Alcohol Clinical Advisory Service (DACAS) to support community prescribers and pharmacists
- training in pharmacotherapy for prescribers and pharmacists
- the Pharmacotherapy, Advocacy, Mediation and Support (PAMS) Service.

The following are the perceived benefits of community-based delivery:

- Improved integration of treatment of dependence with treatment of other physical disease and injury comorbidity and mental health comorbidity, the prevalence of which is higher in people misusing heroin and other opioids.
- General practice is considered the best place to deliver this care, as often patients have a long-standing relationship with their general practitioner who knows them, their families and family circumstances and is best placed to assess their social and personal circumstances.
- General practice provides a setting where multidisciplinary care planning can identify and address all the medical and psychosocial issues and involve patients in the care planning process.

- General practice and pharmacy delivery prevents large numbers of people congregating outside clinics and dosing points, which could affect public amenity and also expose patients to the drug-using community they want to avoid. The geographic spread of services across Victoria means attendance is more convenient and accessibility is improved, which contribute to attraction to, and retention in, treatment.
- Community settings are appropriate because many of the problems patients deal with already contribute to health behavioural changes, such as smoking cessation and nutrition.
- Delivering pharmacotherapy services with the support networks provided contributes to engaging general practitioners and community pharmacists in this care and encouraging a greater degree of involvement in identifying and managing substance use disorders generally.
- Integration into existing health services was also perceived as decreasing the stigmatisation of an already marginalised group of individuals and enabling them to change their self-perception as drug users.

### Pharmacotherapy for dependence on pharmaceutical opioids (prescription and OTC codeine-containing analgesics)

More recently, there has been an increase in the number of people seeking treatment for dependence on, or problems with, pharmaceutical opioids (both prescription and OTC). Most of these people may not have self-injected or been part of an illicit drug-using cohort and may, therefore, not feel comfortable being assessed and dosed together with injecting drug users.

There has also been an increase in serious adverse events resulting from problematic use of these opioids, including an increasing number of opioid-related unintentional poisoning deaths and NSAID toxicity from misuse of non-prescription OTC codeine-ibuprofen analgesics.

It is important to provide optimal environments for the assessment and dosing of people dependent on any opioid source, whether illicit

or pharmaceutical, to attract and retain them in treatment where appropriate.

### **Pharmacotherapy practice**

In July 2015, around 14,122 Victorians were receiving pharmacotherapy maintenance for opioid dependence (about two-thirds of patients on methadone and about one-third on buprenorphine).<sup>5</sup>

Despite the proven success of pharmacotherapy, there are some risks. Methadone, in particular, is a potentially toxic drug with a low therapeutic index (that is, the therapeutic dose is relatively close to the toxic dose). This places patients on methadone at risk if they use other sedating substances such as alcohol or central nervous system (CNS) depressant drugs such as benzodiazepines or antidepressants.

While buprenorphine may provide a lower overdose risk, pharmacotherapies are often used to treat patients who may have a history of compulsive and reckless drug use. Some patients have psychiatric and social problems. Using a potentially toxic drug to treat a patient whose behavioural history may put them at special risk warrants a cautious approach. Safety is paramount.

Patients treated for opioid dependence have often been involved with a complex culture of drug use. Much of their social network may have been associated with this culture and many have been involved in illegal activities to support their habit. These factors can create a risk of diversion of prescribed doses for illicit or unsanctioned use.

Because of the special characteristics of this field of treatment, practice in Victoria is coordinated through a permit system and is generally limited to prescribers and pharmacists who have been adequately trained and are granted permission by the Department of Health and Human Services. Initial and ongoing permission to prescribe or supply pharmacotherapies is conditional on continual observance of the policy's underlying objectives of ensuring the legal, safe and effective use of pharmacotherapies. The department may withdraw permission from practitioners who engage in consistent practice outside the policy without reasonable cause and without proper consideration of the risks.

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<sup>5</sup> Australian Institute of Health and Welfare, 2016, *National opioid pharmacotherapy statistics annual data collection 2015*

## A structured approach to risk management

In Victoria, pharmacotherapy is structured to minimise the risks and maximise the benefits. Table 1.1 outlines the risks and countermeasures.

**Table 1.1: Pharmacotherapy risks and countermeasures**

Risk	Countermeasure
<b>Complicated pharmacokinetics, prescriber/pharmacist unfamiliarity with pharmacotherapies</b>	Prescriber/pharmacist training; authorisation of prescribers/pharmacies
<b>Concurrent treatment by multiple prescribers</b>	Coordination of treatment by appropriate professional communication between doctors and pharmacists; the permit system
<b>Poor compliance and/or diversion of doses to illicit use and trafficking</b>	A system of supervised dosing, restrictions on the eligibility for take-away doses to patients who meet specified criteria for stability in treatment
<b>Trafficking and consequent overdosing of non-tolerant people not in pharmacotherapy</b>	Adoption of anti-diversion strategies; clear, transparent criteria for eligibility for take-away doses
<b>Illicit injection of take-away doses</b>	Dilution of each take-away dose of methadone to at least 200 mL; clear policy for assessing patient suitability for take-away doses; the use of buprenorphine/naloxone for most buprenorphine take-away doses
<b>Misuse of take-away doses by others</b>	Rigorous assessment of risks of diversion and misuse prior to supplying take-away doses; advice about secure storage and risks of sharing with others; poisoning prevention information provided at the time of take-away supply; use of the patient agreement form on take-away doses (see appendices 5 and 6)
<b>Child poisoning with pharmacotherapies</b>	Tight control of take-away doses; child-resistant packaging and dilution of methadone doses; use of water as diluent to reduce masking methadone taste; clear advice to patients regarding child safety and poisoning prevention; use of the patient agreement form on take-away doses (see appendices 5 and 6)
<b>Multiple dosing at time of transfer</b>	Meticulous arrangements for transfer between prescribers and pharmacies; effective communication between pharmacists at transferring and receiving pharmacies
<b>A high risk of drug overdose in the first ten days of treatment, particularly with methadone</b>	Meticulous assessment and care and frequent patient review in the first ten days; start low, go slow with methadone; alertness to signs of toxicity at the time of dosing; high level of communication of risks between prescriber and pharmacist administering doses during induction period; education of patient and family/friends (with patient consent) about signs of overdose and coma (unrousable, 'snoring', respiratory depression, cyanosis) and use of naloxone in overdose

Risk	Countermeasure
<b>A high risk of combined drug toxicity deaths</b>	Alertness to signs of toxicity; comprehensive assessment of patients and management of polydrug abuse (including the use of the Medicare Australia privacy release); provision of warnings to patient about risk; education of patient and family/friends (with patient consent) about signs of overdose and coma and use of naloxone in overdose
<b>Injury</b>	Provision of warnings to patient about the risks of driving or operating machinery before dose stabilisation and while the dose is being adjusted
<b>Psychiatric comorbidity, including suicide risk</b>	Assessment of suicide risk; assessment of patient psychiatric status; maintain a high index of suspicion, and make a timely response to suicide risk; referral to Specialist Pharmacotherapy Service if appropriate for management of patients with addiction and significant mental health disorders; appropriate treatment of the psychiatric disorder
<b>Discontinuation of treatment by patient</b>	Set up of supervised dosing as convenient as possible; access to take-away doses where safe and appropriate

## Policy framework

It is recommended that all forms of drug therapy, including pharmacotherapies for opioid dependence, be applied within the Quality Use of Medicines (QUM) framework, as expressed in the National Medicines Policy. The foundation principles for QUM include:

- establishing the best possible management option for a patient
- considering whether a medicine is necessary for treatment (and undertaking a 'risk versus benefit' appraisal)
- maintaining a commitment to a treatment plan that comprises ongoing evaluation of medication safety and efficacy.

This policy provides advice for practitioners to make legal, safe and effective choices about practices and procedures. The policy is not intended to provide comprehensive clinical guidelines and should be read in conjunction with the *National guidelines for medication-assisted treatment of opioid dependence* (2014), which can be obtained from the Department of Health and Human Services website at [www.health.vic.gov.au/dpcs/pharm.htm](http://www.health.vic.gov.au/dpcs/pharm.htm).

## Harm reduction

A harm minimisation philosophy involves accepting that, despite all efforts to control supply and reduce demand, many people will continue to have access to licit and illicit drugs and will use them in a way that puts them and society at risk of serious harm. Cigarettes, alcohol, prescription and some OTC medicines, and illicit drugs such as heroin and stimulants are readily accessible and are used in quantities and ways that can cause harm.

Harm minimisation does not condone drug use; rather, it refers to policies and programs aimed at reducing drug-related harm. It aims to improve health, social and economic outcomes for the community and the individual. Harm minimisation encompasses a wide range of approaches, including:

- supply reduction strategies to disrupt the production and supply of illicit drugs and the control and regulation of licit substances
- demand reduction strategies to prevent the uptake of harmful drug use, including abstinence strategies and treatment to reduce drug use
- harm reduction strategies to reduce drug-related harm to individuals and communities.

Pharmacotherapy provides an opportunity for patients to avoid the need to obtain, use and inject heroin or to manage problematic use of pharmaceutical opioids. This is useful for individuals for whom abstinence-based methods of dealing with their addiction and dependence have failed through recurrent relapse. Effective doses of methadone or buprenorphine have been demonstrated to reduce the quantity and frequency of illicit opioid use, along with the consequent criminal activity and the risk of transmission of blood-borne viruses.

With around 14,000 patients receiving pharmacotherapy treatment in Victoria, opioid replacement therapy (pharmacotherapy) is making a substantial contribution to reducing the demand for illicit opioids.

The goals of pharmacotherapy for heroin dependence include normalising the patient's life, integrating patients back into the community and retaining them in treatment as appropriate. Pharmacotherapy may also assist in managing patients experiencing problematic pharmaceutical opioid use. Patients receiving pharmacotherapy should be treated in the same way as other patients.

## 2 Drugs available for pharmacotherapy

### Methadone and buprenorphine

The two main drugs available for pharmacotherapy maintenance of opioid dependence are methadone and buprenorphine.

Methadone is supplied as an oral liquid preparation.

Buprenorphine is supplied as a film or tablet designed for sublingual absorption. These sublingual formulations are available as either buprenorphine alone (tablet) or as a 4:1 combination with naloxone (film).

When taken sublingually, the naloxone in the combination product is not extensively absorbed and has no clinically significant effect. When injected by a neuroadapted opioid dependent user, buprenorphine/naloxone will either precipitate unpleasant withdrawal symptoms or have less opioid effect than buprenorphine alone.

Buprenorphine combined with naloxone may, therefore, be less likely to be diverted and used illicitly than preparations containing buprenorphine alone. Consequently, risks associated with the misuse of buprenorphine may be countered by using the combination product, allowing for the possibility of access to take-away doses for carefully selected patients.

It is not within the scope of the policy to provide detailed clinical information about these drugs. Practitioners should be familiar with the *National guidelines for medication-assisted treatment of opioid dependence* (can be downloaded from the Department of Health and Human Services website at [www.health.vic.gov.au/dpcs/pharm.htm](http://www.health.vic.gov.au/dpcs/pharm.htm).

It is important to note, however, that both methadone and buprenorphine are potent opioids and are potentially dangerous and

subject to abuse. There are also potentially severe complications arising from the injection of drug formulations designed to be taken by mouth. Familiarity with the policy and clinical guidelines is essential before treating patients for opioid dependence with either methadone or buprenorphine.

### Prevention of pharmacotherapy-related poisoning deaths

Every year there are a number of unintentional poisoning deaths involving methadone, usually in combination with other CNS depressants, such as alcohol, prescription opioids or benzodiazepines.

The circumstances of death suggest a number of categories of risk, including:

- during induction when the patient may be engaged in chaotic use of other CNS depressants
- misuse by others of take-away doses, either shared or taken without the patient's permission.

### Cautious approach to induction of treatment – 'Start low and go slow'.

Some prescribers and pharmacists may be unfamiliar with the unusual pharmacokinetics of methadone: slow onset of action and a long half-life requiring about ten days for tissue and plasma levels to equilibrate. Given methadone's unique pharmacokinetics and potential to cause prolonged coma and respiratory depression in patients who may continue to misuse other substances, such as alcohol, heroin or other opiates and prescription CNS depressants, special care is needed in treatment, particularly during initiation and stabilisation in the first two weeks.

While buprenorphine may be safer than methadone in overdose, toxicity, including sedation, respiratory depression and death, may occur when buprenorphine is used in combination with other CNS depressant drugs. There appears to be a greater risk of poisoning deaths involving buprenorphine if it is injected and/or the patient is misusing benzodiazepines. There is less risk of unintentional poisoning of children with buprenorphine than with methadone, but a small proportion will experience significant CNS and respiratory depression.

The risk of drug overdose death for people who inject drugs is considerably reduced once they are stabilised on pharmacotherapy maintenance. Nevertheless, a history of illicit and poly drug abuse or alcohol misuse places a patient receiving pharmacotherapy at greater risk of drug overdose than the general community. Some patients receiving pharmacotherapy suffer from psychiatric conditions that expose them to the risk of suicide. Injecting drug use is hazardous and may co-exist with psychiatric illness or risk-taking behaviour, exposing patients to the risk of injury or violent death.

Several categories of pharmacotherapy-related drug deaths can be prevented:

### **1. Deaths during commencement of treatment while the patient is being stabilised**

The highest risk of drug overdose occurs during commencement of treatment with methadone when ingested methadone is equilibrating with tissue reservoirs and accumulating in the body. During this time the patient's lifestyle and drug taking may still be chaotic. Blood levels during this period may not be sufficient to prevent craving or may reach toxic levels if the clinical judgment about neuroadaptation is incorrect. The patient may continue using illicit opioids or high doses of prescription drugs to self-manage symptoms.

Additional caution is recommended when commencing treatment in patients who have been abstinent for a period of time resulting in reduced neuroadaptation and tolerance to opioids (for example, after a detoxification program or in police custody).

### **Countermeasures**

- Give a high priority to assessing the patient's risk of unsanctioned drug and alcohol use during initiation of treatment. If there is a high risk, arrange to review the patient frequently in the first few days before further dosing, and communicate any concerns to the pharmacist administering the doses.
- Provide advice about the risks of unsupervised drug and/or alcohol use, as well as symptoms of excessive opioid sedation, particularly while establishing an effective dose of methadone or buprenorphine. Provide the patient with the information leaflet: *Starting methadone or buprenorphine* (Appendix 1). Appendix 1 is also available in Arabic, Burmese, Chinese, Dinka, Farsi, Greek, Italian, Khmer, Macedonian, Serbian, Spanish, Turkish and Vietnamese.
- Closely supervise the patient if they are judged to exhibit a high risk of misusing other CNS depressant drugs or of experiencing pharmacotherapy drug toxicity.
- Frequently review the patient during the first ten days of treatment, particularly during the first three days.
- Maintain good communication with the patient's pharmacy, particularly about the recognition and management of pharmacotherapy drug toxicity while the patient is being stabilised.
- Educate the patient and their family or friends (with patient consent) about the signs of overdose and coma (unrousable, 'snoring', respiratory depression, cyanosis), and provide naloxone and educate on its use in overdose.

### **2. Combined drug toxicity deaths involving the misuse of other drugs (such as alcohol, illicit drugs and benzodiazepines)**

Deaths due to methadone or buprenorphine alone are unusual; deaths almost always involve

other CNS depressant drugs, particularly psychoactive prescription drugs such as benzodiazepines, opioids and alcohol. Some benzodiazepines, in particular alprazolam, appear to be overrepresented in methadone-related drug deaths.

Methadone or buprenorphine prescribed for pain or diverted from licit prescribing for misuse may contribute to pharmacotherapy-related deaths.

#### Countermeasures

- Advise the patient of the considerable risks of misuse of psychoactive drugs (such as benzodiazepines and prescription opioids) and alcohol while on pharmacotherapy, as well as the risk of injecting buprenorphine because of increased risk of poisoning death. Provide the patient with the information leaflet: *Starting methadone or buprenorphine* (Appendix 1).
- Ask the patient to sign a Medicare Australia privacy release form to enable access to information from the Medicare Australia Prescription Shopping Information Service about the provision of PBS medicines from other doctors and pharmacists.
- Conduct a drug screen of supervised urine collections or discuss drug use with the patient. Inform the patient of the risks of using CNS depressant prescription drugs and alcohol while in treatment with pharmacotherapy.
- Avoid providing take-away doses for patients with appreciable risk of diversion to others.
- Educate the patient and their family or friends (with patient consent) about the signs of overdose and coma (unrousable, 'snoring', respiratory depression, cyanosis), and provide naloxone and educate on its use in overdose.

### 3. Deaths preceded by a long period of coma during which the high risk of death is not recognised by others

Deaths from combined drug toxicity involving pharmacotherapies may involve a long period of coma, during which the deceased has been left to 'sleep it off' and subsequently dies. A patient who is unrousable and making noises suggestive of a blocked upper airway and depressed reflexes (for

example, snoring, gurgling, spluttering) is at very high risk of dying from drug overdose and requires immediate medical treatment.

#### Countermeasures

- Advise the patient and their family or friends (with patient consent) about the signs of coma and the need to take urgent action if toxicity is suspected. Provide naloxone and educate on its use in overdose.
- Provide the patient with the information leaflet: *Starting methadone or buprenorphine* (Appendix 1).
- A patient who is unrousable and snoring (or making other sounds that suggest airway obstruction) is a medical emergency. Position the comatose patient on their side with their head extended (left lateral position) and call an ambulance immediately.

#### Toxicity: symptoms and signs

Mixed poisoning is common. The usual opioid poisoning triad (coma, pinpoint pupils, respiratory depression) may be preceded by:

- slurred speech
- poor balance
- retarded movement
- unsteady gait
- drowsiness
- stupor.

**This is a serious medical emergency. The patient should be reviewed urgently.**

**Poisoning may proceed to:**

- coma (unrousable, snoring, flaccid, cyanosed)
- respiratory depression and hypoxia
- death.

## **4. Deaths involving psychiatric complications such as suicide and psychosis**

Suicide is one of the most common causes of death of pharmacotherapy patients (after combined drug toxicity). Practitioners should be skilled at suicide prevention. Some patients will have a history of psychiatric illness, such as depression or psychosis, which may predispose them to the risk of suicide. They may have suppressed harmful emotions and symptoms during the period of injecting drug use and these may become evident once the patient is stabilised in pharmacotherapy maintenance.

### **Countermeasures**

- Undertake a psychiatric assessment as part of the initial patient assessment. Maintain a high index of suspicion for signs of suicidal intent, depression and other psychiatric illnesses throughout treatment.
- Refer patients with addiction and significant mental health disorders to a specialist pharmacotherapy service for assessment and management, if appropriate.
- Avoid providing take-away doses for patients with appreciable risk of self-harm.

## **5. Deaths due to other disease**

Risk-taking behaviour exposes many patients receiving pharmacotherapy to a high risk of death from injury, such as road trauma and homicide. Lifestyle factors, such as poor nutrition and smoking, increase the risk of death from chronic non-communicable diseases, such as ischaemic heart disease and stroke. Smoking is highly prevalent among people who inject drugs and is more prevalent among those dependent on prescription opioids than in the general population. Injecting drug use is also associated with many infectious complications, such as cellulitis, septicaemia, infective endocarditis, and blood-borne viruses such as HIV and hepatitis B and C. Some disease states, including chronic liver disease (for example, cirrhosis) and renal impairment, may substantially alter the pharmacokinetics of methadone or buprenorphine and thereby raise the risk of adverse drug-related events.

### **Countermeasures**

- Integrate pharmacotherapy with management of the patient's general health and retain patients who inject drugs in pharmacotherapy treatment to reduce injecting.
- Consider specialist referral and collaboration in managing patients with other chronic comorbidities.
- Provide harm reduction information to reduce the likelihood of injecting harms and the transmission of blood borne viruses such as hepatitis C.
- Promote the new generation of hepatitis C treatments to all people who inject drugs (refer to Appendix 2 for hepatitis C information outlets).

## Naloxone injection for overdose prevention

People on pharmacotherapy for opioid dependence may be at an increased risk of opioid overdose and death. In many cases of methadone-related deaths, the ready availability of naloxone for administration by nearby family or friends may have ensured that the patient survived until ambulance assistance arrived.

Prescribers commencing patients on pharmacotherapy should consider providing a prescription for a naloxone injection, particularly in the case of methadone-based pharmacotherapy. The naloxone injection should also be considered when a patient commences on take-away doses or at the cessation of pharmacotherapy treatment.

Naloxone injection is available on the Pharmaceutical Benefits Scheme, which provides affordable access to this medicine. While it is only legal for a person to carry naloxone that is prescribed specifically to them, Victoria's 'Good Samaritan' legislation also makes it legal for a non-medical bystander to administer naloxone to a person to treat a potentially fatal overdose.

Information for health professionals, patients and their carers on how to use naloxone injection and how to recognise and respond to an opioid overdose is available on the Penington Institute's Community Overdose Prevention and Education website at [wwwCOPEaustralia.com.au](http://wwwCOPEaustralia.com.au) and on the Harm Reduction Victoria website at [www.hrvic.org.au](http://www.hrvic.org.au).

## Managing dose diversion

Both methadone and buprenorphine are susceptible to diversion for illicit or unsanctioned use. The non-prescribed use of pharmacotherapies has been associated with incidents of serious harm, including death, involving the patient, their associates or other third parties, including children. Practitioners prescribing pharmacotherapies, administering supervised doses or supplying take-away doses have a responsibility to consider the risks of diversion and should adopt practices that minimise diversion.

The main anti-diversion strategy employed for methadone is dose dilution. Supervised doses should be diluted before administration. Each take-away dose should be diluted with water (not cordial) to 200 mL to reduce the incidence of injection of take-away doses.

Because buprenorphine tablets are a solid dose form it is easier to divert during supervised administration than methadone. In addition, it is not possible to adopt anti-injection strategies analogous to the dilution of methadone, so the drug in tablet form is considered to be generally unsuitable for take-away doses. The main anti-diversion strategies adopted for buprenorphine are the use of supervised dosing and a combination buprenorphine/naloxone product as a film formulation for take-away doses. Supervised doses of buprenorphine/naloxone should also be considered for individual patients assessed as a high risk for diversion.

Pharmacists detecting patients who are suspected of diverting doses should refer those patients for clinical review. The risks of diversion and injection of take-away doses should be discussed. Possible strategies to manage diversion include:

- counselling by the prescriber to determine why doses are being diverted
- transfer to a drug or formulation less likely to be diverted, for example, from buprenorphine tablet to buprenorphine/naloxone film or from buprenorphine to supervised methadone dosing
- referral to a Specialist Pharmacotherapy Service for advice and/or management
- cancelling authorisation of take-away doses.

Incidents of attempted diversion or actual diversion should be communicated in writing by the pharmacist to the prescriber as soon as practicable after the event. Reports should indicate whether the incidents were directly observed or reported by a third party.

# 3 Policy for prescribers

## Essentials of pharmacotherapy prescribing

1. Become familiar with the unique benefits, toxicity and pharmacology of pharmacotherapies in the treatment of opioid dependence. Refer to the *National guidelines for medication-assisted treatment of opioid dependence* for detailed information on these subjects.
2. Establish:
  - the identity of the patient
  - that the patient is opioid dependent
  - the degree of neuroadaptation
  - agreed goals of treatment
  - arrangements for administration of doses, including location of the pharmacy and costs to the patient.
3. Establish an appropriate starting dose of either methadone, buprenorphine or a combination buprenorphine/naloxone product. With methadone, usually commence on a low dose and increase slowly only after careful assessment suggests the dose is inadequate - 'start low and go slow'.
4. Obtain a permit from the Department of Health and Human Services before prescribing methadone, buprenorphine or buprenorphine/naloxone. The department maintains records of active treatment permits to enable coordination of the patient's treatment to avoid the risk of inadvertent multiple dosing and poisoning with pharmacotherapies (or other opioids) by different prescribers.
5. Ensure the prescription gives clear, unequivocal directions to the pharmacist administering the dose, including:
  - the precise dose in words and figures
  - the precise starting date
  - the date of the last dose available on this prescription
  - the name of the pharmacy at which it is to be dispensed.
6. Advise the patient and the patient's family or friends (with patient consent) about the signs of overdose and coma and the need to take urgent action if toxicity is suspected. Provide naloxone and educate on its use in overdose.
7. Review the patient's condition before the third or fourth dose to determine the most effective dose and to assess and manage the risk of overdose during induction into treatment. This is particularly important for methadone, as the drug carries a high risk of toxicity during induction.
8. Before authorising take-away doses:
  - contact the pharmacy to check the regularity of dosing and the patient's progress and stability, and discuss the patient's suitability for take-away doses with the pharmacist
  - perform a risk assessment to determine the appropriateness of prescribing take-away doses (checklist provided in Appendix 4).
9. Diversion of doses for illicit use is a risk associated with pharmacotherapy. Practitioners have a responsibility to adopt practices that minimise the risk of diversion. The policy describes a number of practices that should be implemented to minimise diversion.
10. Send a termination notice to the Department of Health and Human Services as soon as it is known that treatment has ceased.

Take-away doses should not be provided where there are reported concerns of diversion, sharing or trading of doses with others within the last three (3) months of treatment.

When transferring a patient between pharmacies, avoid the risk of duplicated dosing by providing clear instructions in writing to both pharmacies about their respective finishing and starting dates. The patient's dosing patterns should be confirmed with the current pharmacy before finalising the prescription for the new pharmacy.

### **Collaborative approach to treatment**

Prescribers, pharmacists and other allied healthcare professionals each have important roles in a patient's treatment with pharmacotherapy. Good communication between all parties is essential to maximise the benefits of pharmacotherapy. Treatment goals and decisions should be discussed and agreed upon by all health professionals and with the patient. Responsibility of providing safe clinical care is shared equally among all healthcare professionals involved in the care of a patient.

### **Completion of pharmacotherapy training**

Familiarity with the pharmacology of the drugs used for pharmacotherapy and the management of drug addiction is necessary to ensure that treatment of opioid dependence with pharmacotherapy is performed successfully and safely. The Department of Health and Human Services funds training for medical and nurse practitioners intending to become prescribers and current prescribers wishing to attend a clinical update or refresher training. The training is free. Further information on training for prescribers is available on the department's website at [www.health.vic.gov.au/dpcs/pharm.htm](http://www.health.vic.gov.au/dpcs/pharm.htm).

### **Buprenorphine/naloxone prescribing by practitioners who have not completed a pharmacotherapy training course**

All medical practitioners and nurse practitioners with a notation for a category in which the prescribing of buprenorphine/naloxone is authorised, may prescribe buprenorphine/naloxone for up to five (5) patients without the requirement to complete pharmacotherapy training. Prescribers are still required to obtain a permit before prescribing buprenorphine/naloxone. With the recognised greater safety of buprenorphine/naloxone use (particularly with a film formulation) in the treatment of opioid dependence, this may provide better access for patients to receive both pharmacotherapy and other medical treatment from their usual prescriber.

All prescribers should follow the principles of risk-benefit assessment when prescribing for individual patients, as with normal clinical practice, and particularly taking into account the risk of providing buprenorphine with naloxone during pregnancy or breastfeeding and the risk of precipitating an unpleasant withdrawal syndrome in patients who are opioid dependent. Prescribers should also take into account the principles of pharmacotherapy treatment, as outlined in this policy document, to ensure the safe provision of buprenorphine/naloxone. Prescribers must also be fully aware of the legislative requirements of prescribing pharmacotherapy treatment, including the requirement to obtain a permit before prescribing to a patient.

Prescribers who have not completed pharmacotherapy training should seek advice from a trained prescriber (preferably a colleague in the same practice) before prescribing to a patient. A guide to prescribing buprenorphine/naloxone for prescribers who have not completed a pharmacotherapy training course is available on the Department of Health and Human Services website at [www.health.vic.gov.au/dpcs/pharm.htm](http://www.health.vic.gov.au/dpcs/pharm.htm).

All prescribers who are confidently managing up to five (5) patients with buprenorphine/naloxone are encouraged to complete a pharmacotherapy training course. The training enables prescribers to provide a greater range and capacity of pharmacotherapy services to patients, that is, to prescribe methadone, buprenorphine or buprenorphine/naloxone to more than five (5) patients.

## Initial and ongoing permission to prescribe pharmacotherapies

Permission to prescribe pharmacotherapies follows completion of training.

Initial permission to prescribe pharmacotherapies (methadone, buprenorphine or buprenorphine/naloxone) is limited to treatment for up to five (5) patients (unless under the close supervision of an established pharmacotherapy prescriber). Further permission must be sought if the prescriber wishes to manage a larger number of patients.

Ongoing permission to prescribe is conditional on continual observance of the policy's underlying objectives of ensuring the legal, safe and effective use of pharmacotherapies and relevant clinical guidelines.

## Arrangements for dosing at a pharmacy

Pharmacies permitted to supply pharmacotherapies provide supervised dosing. The prescriber should contact the pharmacy to confirm availability and discuss whether the pharmacy is suitable and accessible to the patient. Avoid misunderstandings and enhance the safety of treatment by maintaining good communications with the pharmacists. DirectLine can provide information about pharmacy locations permitted to supply pharmacotherapies.

### Pharmacy service fees

As with any other professional service, providers of dosing services are entitled to a fee determined by each individual pharmacy for supplying pharmacotherapies. At the time of release of the policy, the Department of Health and Human Services pays pharmacy service fees for patients under 19 years of age and patients on Youth Justice community orders. The Department of Justice and Regulation pays pharmacy service fees for patients for up to 30 days post-release from prison.

For all other patients, the patient is responsible for ensuring payment of all pharmacy fees. In cases of severe financial hardship, patients may contact the PAMS service for information and advice.

## Arrangements to cover absence from practice

There will be times when the prescriber is unavailable to supervise the treatment of patients, for example, anticipated absences (leave or sessions at other locations) or sudden and unexpected absences (leave for sickness, injury or family reasons). Interruptions to patients' treatment may jeopardise progress towards treatment goals. Other risks of interrupted treatment supervision include treatment by a colleague who has little experience with the hazards of pharmacotherapy or who is unfamiliar with the patients being treated. To minimise any

risks arising from the prescriber's absence, the following arrangements should be made.

### **Preparation for absence of a pharmacotherapy prescriber**

- Document and maintain up-to-date individual management plans in the patient's records.
- Arrange for a colleague (preferably a trained pharmacotherapy prescriber) to continue the documented management plan for each patient.
- Request any deputising colleague to record treatment changes in the patient notes.

### **Deputising by trained pharmacotherapy prescribers**

If the deputising prescriber is practising at the same practice where the usual prescriber is treating the patient, provided the usual prescriber is holding a Schedule 8 permit to treat the patient with pharmacotherapy, a new permit is not required.

### **Deputising by practitioners who have not completed pharmacotherapy training**

Being potentially less familiar with the risks of pharmacotherapy, prescribers who have not completed a pharmacotherapy training course should adopt a cautious approach to treating patients.

Prescribers who have not completed pharmacotherapy training may consider deputising for a prescriber to continue the treatment of a stable patient if the following circumstances are met:

- the deputising prescriber is practising at the same practice where the usual prescriber is treating the patient
- the deputising prescriber is not re-starting treatment of a patient with pharmacotherapy (a patient is considered to be re-starting pharmacotherapy if the patient has missed doses on four (4) or more consecutive days).

Note: Provided the usual prescriber is holding a Schedule 8 permit to treat the patient, a new permit is not required.

For stable patients requiring only the continuation of an expired prescription without an increase of dose or take-away frequency:

- take a history and examine the patient
- contact the pharmacy to check the patient's progress and that the patient has attended regularly for dosing
- contact DACAS:
  - if there are any management problems or concerns about the safety of the patient
  - if a dose increase or increase in number of take-away doses appears necessary
- document the advice given and the name of the DACAS consultant in the patient's notes
- do not provide an increased dose or increased number of take-away doses without seeking advice from DACAS and discussing changes to treatment with the pharmacist.

The Department of Health and Human Services can provide basic advice about safe prescribing and a list of the usual prescriber's current permits.

### **Management by deputising prescribers**

All deputising prescribers should manage the patient as described here:

- Continue the usual prescriber's management plan and dosage regimen as documented in the clinical record. (It is acceptable to reduce the dose if the patient is experiencing toxicity.)
- Note on the prescription that you are temporarily deputising for the patient's usual prescriber.
- Limit the duration of the prescription to the expected period of absence of the usual prescriber, indicating precise starting and finishing dates.
- Arrange for the usual prescriber to review the patient as soon as possible thereafter.
- Document details of the consultations and pharmacotherapy prescriptions in the patient's notes.

## Treatment procedures

Refer to the *National guidelines for medication-assisted treatment of opioid dependence for treatment procedures*. This section deals with additional practices that should be adopted in Victoria.

### 1. Establishing the identity of the patient

Establish the identity of the patient to avoid double dosing. The patient should provide at least two forms of identification (for example, passport, driver's licence or birth certificate). The patient also needs to provide three (3) current photographs:

- one to be attached to the medical record
- one to be attached to the prescription card at the pharmacy
- one to be kept for possible future transfers.

Endorse these photographs as being true images of the patient.

### 2. Managing complex and difficult situations

Two services are provided to support pharmacotherapy prescribers presented with complex and difficult situations.

#### The Drug and Alcohol Clinical Advisory Service

DACAS is funded by the Department of Health and Human Services to provide advice to practitioners about treatment issues. DACAS takes calls from doctors, nurses, pharmacists and other health and welfare professionals seeking advice on the clinical management of patients with alcohol and drug issues. DACAS consultants include specialist addiction medicine doctors and pharmacists. DACAS may provide clinical advice which may assist health practitioners make safer and more evidence-based clinical decisions. It is not the role of DACAS to provide authorisation or to sanction a proposed treatment.

Patients with complex and difficult conditions may also be considered for referral to a **Specialist Pharmacotherapy Service** for assessment and treatment or for initiation of treatment that a

general practitioner will continue later. Ensure that any psychiatric condition is receiving appropriate attention, either by the prescriber through an existing relationship with a specialist or via referral. Contact details for Specialist Pharmacotherapy Services are listed in Appendix 2.

### 3. Providing patient information

In addition to providing information about treatment advised in the national clinical guidelines, patients should also be told about:

- the policy for, and conditions on, participation in pharmacotherapy treatment
- the costs of medical treatment and advised to ask the pharmacist about pharmaceutical costs
- harm reduction (covering how to prevent the transmission of blood-borne viruses and how to inject safely)
- the PAMS service (Appendix 2)
- support and information services (Appendix 2).

Patients should also be provided with consumer information guides, including:

- the patient information leaflet: *Starting methadone or buprenorphine* (Appendix 1)
- patient information booklets for treatment with methadone or buprenorphine.

Patient information is also available from the Department of Health and Human Services website at [www.health.vic.gov.au/aod](http://www.health.vic.gov.au/aod).

### 4. Applying for a permit to prescribe methadone or buprenorphine

An *Application for a permit to treat an opioid-dependent person with methadone or buprenorphine* must be sent to the Department of Health and Human Services for approval. A separate permit is required for each patient. (Exceptions to the requirement to obtain a permit are detailed in 5: Circumstances where a notification of treatment is required.) The application can be completed and submitted online at [www.health.vic.gov.au/dpcs/pharm.htm](http://www.health.vic.gov.au/dpcs/pharm.htm). The application may also be completed by hand and sent by facsimile (1300 360 830).

It is not necessary to send originals of faxed applications. Online submission of applications is the preferred method, as this ensures that all required information is provided and avoids any unnecessary delays in processing applications.

To prevent inadvertent double dosing, do not commence treatment until a permit has been issued (usually within one working day after submitting the application). Permits are usually issued to prescribers for an indefinite period. A new permit for another prescriber will not normally be issued until the transferring prescriber has confirmed that the original permit holder has been made aware of the patient's transfer of treatment.

## 5. Circumstances where a notification of treatment is required

There are some circumstances where a prescriber does not require a permit to prescribe pharmacotherapy.

A permit is not required where a prescriber is treating a patient if that patient is:

- an inpatient being treated in a hospital
- a prisoner being treated in a prison for the period in prison and a period not exceeding seven (7) days after that prisoner's release from custody
- a resident being treated in an aged care service.

In these circumstances, prescribers are required to submit a *Notification of drug dependent person* (available at [www.health.vic.gov.au/dpcs/pharm.htm](http://www.health.vic.gov.au/dpcs/pharm.htm)) to indicate their intention to treat the patient with pharmacotherapy. Prescribers may start prescribing provided the notification is submitted as soon as practicable to the Department of Health and Human Services.

Prescribers who have not completed pharmacotherapy training should seek advice from their addiction medicine team (in hospital or prison) or DACAS before intending to prescribe for a patient who has not previously been treated

with pharmacotherapy or who has missed doses on four (4) or more consecutive days.

### Provision of pharmacotherapy in hospitals

When a patient is admitted to hospital as an inpatient, continuation of maintenance pharmacotherapy with doses prepared and administered by hospital staff is recommended if safe and clinically appropriate. Before providing treatment:

- ensure that the patient's usual prescriber and pharmacy are informed of the patient's admission to hospital
- obtain relevant treatment information, including the current dose and when the last dose was administered or take-away dose provided.

The practice of using a patient's own supply of take-away doses while admitted to hospital is not recommended due to the uncertainty of administering a dose that has not been prepared by the hospital. Take-away doses brought to hospital by a patient should be discarded to reduce the risk of a double dose being consumed during the patient's stay in hospital and after discharge from hospital. The patient's usual pharmacy should be informed about the circumstances of any take-away doses brought to hospital by the patient, including whether any take-away doses brought to hospital by the patient were discarded.

The destruction of any Schedule 8 poison must be carried out in accordance with the requirements set out in the Drugs, Poisons and Controlled Substances Regulations 2006 (refer to page 49 *Policy for pharmacists: destruction of methadone or buprenorphine* for further information).

When a patient is to be discharged and treatment with pharmacotherapy is to be continued, ensure that the patient's usual prescriber and pharmacy are aware of the patient's discharge from hospital and provide relevant treatment information,

including the current dose and when the last dose was administered.

For continuity of treatment, ensure that the patient has a valid prescription to continue dosing at the usual pharmacy. If the prescription has expired or the dose has changed, ensure that arrangements are made for the patient to be reviewed as soon as possible with the usual prescriber to avoid missing doses.

If there is no valid prescription at the patient's usual pharmacy and the usual prescriber is unable to review the patient as soon as possible after discharge from hospital, hospital prescribers may consider applying for a permit to prescribe, provided the patient's usual prescriber and pharmacy are made aware of the circumstances and that the date of review with the usual prescriber is known. It is important to include these details on the permit application form. Prescribing in these circumstances should be limited to the date for which the patient is to be reviewed by the usual prescriber.

Take-away doses should not be prescribed unless this has been agreed with the hospital's Addiction Medicine Specialist, DACAS or the patient's usual prescriber.

### **Pharmacotherapy in police custody**

Patients who are held in remand are entitled to continue pharmacotherapy until release or sentencing. For a patient being held in remand or sentenced to a short prison term, try to maintain a vacancy for that patient to return to treatment if they wish.

Custody arrangements should not arbitrarily interrupt the treatment of patients. Arrangements for continued treatment may include the following:

- The patient's usual prescriber may be invited to continue treatment in police custody.

- Police can arrange to have a special methadone or buprenorphine in police custody prescription form collected from the usual prescriber. This is placed in the patient's Prisoner Information File and moves through the police custody system with them.
- The Custodial Health Service has established arrangements with appropriate pharmacies near designated police cells to provide prescribed pharmacotherapies to a patient in police custody.
- Police arrange for the delivery of the prescription to the appropriate pharmacy where the pharmacist verifies the prescription, checks the timing of the last dose with the previous pharmacy and returns the original prescription to the Prisoner Information File.

### **Pharmacotherapy in prison**

There are two components to the provision of pharmacotherapy in prison: an induction program and a maintenance program. Prison prescribers assess and conduct regular reviews of patients receiving pharmacotherapy treatment in prison. Where safe and clinically appropriate, patients receiving pharmacotherapy prior to entering prison may continue treatment while in prison (maintenance program). Patients at risk of opioid-related harm while in prison or when released from prison may commence pharmacotherapy treatment (induction program).

### **6. Pharmacotherapy prescription**

As for any other Schedule 8 poison, methadone or buprenorphine may not be administered or supplied without a valid prescription. The prescription must comply with the requirements set out in the Drugs, Poisons and Controlled Substances Regulations 2006, including the requirement that the quantity to be supplied be written in words and figures (see Appendix 3 for more detail). Prescriptions are valid for the duration specified by the prescriber (which may not exceed six (6) months).

Additional information is required on the prescription (Appendix 3), including:

- the date the first dose is to be supplied
- the date the authorisation to supply will end (to encourage the pharmacotherapy patient to attend for review at an appropriate interval)
- the name of the pharmacy at which the pharmacotherapy dose is to be supplied.

#### **Verbal orders**

In accordance with regulation 27(1) of the Drugs, Poisons and Controlled Substances Regulations 2006, in an emergency, dosing instructions may be verbally communicated to the pharmacist administering the dose. With pharmacotherapy dosing, confirm the verbal communication by faxing or emailing a copy of the prescription, endorsed with the name of the pharmacy to which it is being sent. In all cases, verbal instructions must be confirmed in writing by forwarding the original prescription to the pharmacy as soon as practicable.

### **7. Dosing arrangements**

#### **Supervised dosing arrangements through community pharmacies:**

- Confirm arrangements with the pharmacy that the patient wishes to attend for supervised dosing.
- Forward the original prescription for methadone, buprenorphine or buprenorphine/naloxone to the pharmacy. See Appendix 3 for the features of a pharmacotherapy prescription.
- If the patient is given the original prescription to forward to the pharmacy, a copy of the prescription should be faxed, emailed or electronically transferred to the pharmacy for the pharmacist to verify the documents supplied by the patient.
- Provide the pharmacy with a recent photograph of the patient endorsed by the prescribing doctor.
- In an emergency, when it is not possible to provide a written prescription before dosing, verbal instructions may be provided. Confirm the verbal instructions by faxing, emailing

or electronically transferring a copy of the prescription to the pharmacy, endorsed with the name of the pharmacy to which it is being sent. The original prescription must be forwarded to the pharmacy as soon as practicable.

- Inform the pharmacy of any dose change using a prescription, which should reach the pharmacy before the change in dose is to be effected.
- Notify the Department of Health and Human Services of any change in pharmacotherapy dosing location.

#### **Communication between the prescriber, the pharmacist and the patient**

It is important that there is good communication with the patient and among the treatment team involved with the patient. Each party has particular information that is useful to the other.

- The prescriber has taken a history, examined the patient and run laboratory tests (where appropriate), and should also be aware of the patient's medical condition and social circumstances.
- The pharmacist sees the patient daily. They may notice irregular presentation for dosing, unsanctioned drug use, prescriptions from different prescribers and evidence of drug toxicity. They may refer the patient to the prescriber for a review of management.
- The patient may be able to offer feedback on previous experiences with pharmacotherapies.

The pharmacist should be able to contact the prescriber at all times; so it is recommended that full contact details, including after-hours contact numbers, are provided.

All information about dosing should be communicated in writing and telephone conversations should be recorded in the patient's notes. A dose cannot be provided to a patient in the absence of a valid order from the prescriber.

## Split dosing of methadone

A small proportion of patients metabolise methadone rapidly (that is, patients in whom peak methadone levels are adequate but levels are not maintained adequately). These patients may benefit from twice-a-day dosing (split dosing).

Split dosing may also be useful:

- early in treatment, when patients may exhibit a low tolerance to the nauseating side effects of methadone
- for pregnant patients who experience persistent nausea
- for patients with chronic pain.

When methadone is being prescribed as a split dose to a patient, on the days where the patient attends for supervised dosing of the first dose of methadone at a pharmacy, prescribers should assess the patient's stability in treatment to determine whether the second dose of methadone requires supervised dosing at the pharmacy or may be supplied as a take-away dose.

If split dosing is being considered for a patient, prescribers may contact DACAS to obtain clinical advice.

## Dual dosing locations

In exceptional circumstances, arrangements may be made for the patient to receive pharmacotherapies from two different pharmacies. This may be done where patients have work or family reasons for regularly and routinely moving between two locations. Ensure each location is provided with the necessary documentation to dispense the prescribed drug on specified days, to minimise the risk of double dosing.

## 8. Counselling

Counselling may help patients address their drug dependence. The prescriber can provide counselling or refer the patient to a counsellor.

Patients may call DirectLine for referral to drug and alcohol counselling services. Patients with special counselling needs may also be referred to a specialist pharmacotherapy service.

Counselling about risk behaviour and the prevention of transmission of blood-borne viruses (HIV and hepatitis B and C) should also be provided (Appendix 2).

## 9. Allied and other health professionals

A diverse range of organisations fund health professionals to support pharmacotherapy patients and other patients with their substance use and the harm arising from it. When patient management involves other doctors, pharmacists and allied health professionals, it is important to ensure their roles and responsibilities are clearly documented and understood. In any situation, decisions about the appropriateness and safety of prescribing and supplying pharmacotherapies remain the responsibilities of the treating prescriber and pharmacist. As with the prescribing or dispensing of any drug, such decisions should be based on an adequate clinical assessment. Both the prescriber and the pharmacist should be satisfied that changes to doses and clinical management are appropriate.

## 10. Take-away doses: introduction

Methadone and buprenorphine can be subject to diversion, trafficking and misuse, with serious and sometimes fatal results.

People who become dependent on opioids often come to pharmacotherapy treatment as a result of problems controlling their use of opioids. Many have made several unsuccessful attempts at maintaining abstinence after withdrawal. Pharmacotherapy enables opioid-dependent people to control their problematic opioid use and stabilise their lives.

Supervised dosing helps people avoid or manage the opioids responsible for their problematic dependence, whether illicit (heroin) or legal pharmaceutical opioids (OTC codeine combination analgesics or prescription opioids).

Supervised dosing is of greatest benefit to people until they are stabilised on treatment, assessed as likely to adhere to treatment regimens, and judged to be at minimal risk of misuse, diversion to others, injection of oral medication and overdose involving other CNS depressants such as benzodiazepines or alcohol.

Take-away doses may be appropriate once there is good evidence that the person is likely to adhere to the prescribed dosing regimen, is not continuing use of illicit drugs or using other CNS depressants in a manner likely to contribute to combined drug toxicity, and is unlikely to on-sell their doses to others or place others (especially children) at risk of accidental poisoning.

These medications are potentially dangerous if misused, so safety is paramount.

Careful clinical assessment of the safety of take-away doses is essential. This should be a clinical decision based on a thorough risk/benefit assessment; not based on length of treatment or in response to a request from the patient. Deaths have occurred as a result of patients sharing their take-away doses of pharmacotherapies with friends or partners. Deaths have also occurred where friends or partners have used a patient's take-away dose without the patient's knowledge. Pharmacotherapies, particularly methadone, can be toxic in overdose.

There is little margin between therapeutic and toxic doses of methadone. Blood levels achieved in treatment and those detected in drug overdose overlap. A critical issue here is the individual's level of tolerance or neuroadaptation. Doses of 30–40 mg of methadone tolerated by opioid-dependent people in treatment may be lethal in non-tolerant individuals. Children are particularly vulnerable to overdose.

Although buprenorphine may be safer in overdose than methadone, fatal overdose can occur if it is taken with other respiratory depressants. Injection of buprenorphine has also been one of the factors in fatal buprenorphine overdose, especially together with other sedative use, including benzodiazepines or alcohol. The injection of buprenorphine diverted from the mouth has also caused serious Candida endophthalmitis (fungal eye infection) resulting in partial or complete loss of vision.

### Risks of take-away doses when they are misused

- Using take-away doses in advance to consume an excessive dose.
- Hoarding take-away doses for deliberate overdose of self or others.
- Injecting take-away doses, with the potential for vein damage, microbial infection and blood-borne virus transmission.
- Diversion for illicit use or trafficking.
- Sharing of dose with partner or others increases risk of an overdose (especially when used in combination with other sedative drugs).
- Accidental overdose by children or others who gain access to take-away doses that are not stored safely and securely.
- Poor compliance with treatment plan.

## Benefits of take-away doses for stable patients

Take-away dosing can lessen the constraints on stable patients who are attempting to normalise their lives by reducing the need for daily supervised dosing. Take-away doses can increase the opportunity for patients to:

- participate in the workforce
- fulfil family and social responsibilities
- travel for work, family or leisure reasons
- re-integrate into the community
- be rewarded for long-term stability in treatment.

Importantly, take-away doses contribute to the acceptability of prolonged pharmacotherapy maintenance and patient retention in treatment.

Arrangements for take-away doses should balance the need to minimise the risk to the community with the stable patient's need to normalise their lives. The prescriber and pharmacist play a key role in assessing patient stability.

## Essential requirements for take-away doses

- Only the prescriber can authorise take-away doses.
- The patient should be clinically assessed and the patient's stability documented prior to authorising take-away doses.
- The pharmacist should be contacted to confirm that recent behaviour and dose collection has been regular and stable.
- Take-away doses should be the same dose as that normally consumed in the pharmacy.
- Take-away doses should not be available if there is concern they may be misused.

## 11. Take-away doses: checklist for assessing appropriateness of supply

Appropriateness of take-away doses is not solely determined by time in continuous treatment; assessment of treatment stability and suitability for take-away doses are key considerations.

This document provides an assessment tool, *Checklist for assessing appropriateness of take-away doses* (Appendix 4) to assist in evaluating an individual patient's suitability for take-away doses. It can be used to explain to the patient why it may be necessary to refuse provision of take-away doses and as a means of encouraging progress towards suitability for take-away doses. The assessment tool should be worked through with the patient and included in the patient record.

The four steps in the *Checklist for assessing appropriateness of take-away doses*

(Appendix 4) should always be considered when establishing the suitability for take-away doses. These steps are:

1. Absolute contra-indications to take-away doses
2. Relative contra-indications to take-away doses
3. Reasonable need for take-away doses established
4. Continuous period of stability in treatment

These matters are explained in further detail below.

### **Step 1: Absolute contra-indications to take-away doses**

- Overdose of any substance reported.
- Diversion of doses to others, sharing or trading doses.
- No safe and secure storage facility available.
- Concerns about risk of causing harm to self or others (for example, intentional poisoning).

**Take-away doses should not be supplied if any of these absolute contra-indications have been observed within the last three (3) months.**

### **Step 2: Relative contra-indications to take-away doses**

- Irregular attendance at medical/case manager reviews or missed doses at the pharmacy.
- Urine drug screens not provided on request or revealing unsanctioned drug use.
- Reported misuse of prescription medicines, alcohol or illicit drugs.
- Reported use of take-away doses in advance.
- Reported hoarding or 'stock-piling' of take-away doses.
- Reported lost or stolen take-away doses.
- No stable accommodation.
- Persons who are currently misusing drugs are present or likely to visit the home.
- Concerns about other medical condition (for example, severe liver or respiratory disease).

Take-away doses may be inappropriate if any of these relative contra-indications have been observed within the last three (3) months. Careful assessment and discussion with the pharmacist are needed if take-away doses are being considered in these circumstances.

Methadone or buprenorphine may be fatal or cause serious harm if ingested by opiate-naïve individuals.

Establish with the patient, their arrangements for safe and secure storage to prevent unintentional poisoning of children or misuse of a take-away dose by another person. In some circumstances a lockable box might be considered appropriate for safe and secure storage.

### **Step 3: Reasonable need for take-away doses established**

Patients who are stable should also be expected to demonstrate a reasonable need for take-away doses. This may include:

- work, study or family commitments where daily attendance at a pharmacy is not possible
- living in a rural or remote area where daily travel to a pharmacy is difficult
- significant medical condition restricting ability to attend a pharmacy on a daily basis
- urgent travel where alternative arrangements for supervised dosing cannot be organised
- incentive and reward for stability and progress in treatment.

There may also be some benefit (contingency management in opioid substitution) in recognising and 'rewarding' patient stability on opioid substitution treatment by providing incentives such as take-away doses. Offering patients incentives for progress can improve outcomes in opioid substitution treatment.

Take-away doses may be inappropriate if no reasonable need has been established. Careful assessment and discussion with the pharmacist are needed if take-away doses are being considered in such circumstances.

## Step 4: Continuous period of stability in treatment

**Reminder:** Appropriateness of take-away doses is not solely determined by time in continuous treatment. Ensure Steps 1 to 3 of the assessment have been completed before proceeding to Step 4.

Take-away doses may be authorised for patients who have demonstrated stability in treatment when clinically indicated. All patients should commence opioid pharmacotherapy under conditions of supervised administration. Those who demonstrate stability may progress to receiving take-away doses.

### Methadone

Three levels of supervised dosing are available for patients being treated with methadone:

- **High intensity supervision:** involves no take-away doses. This is the default level of supervision that should be adopted at the commencement of opioid substitution treatment.
- **Medium intensity supervision:** allows patients who have demonstrated stability in treatment and regularity of dosing for at least three (3) continuous months to access up to two (2) take-away doses of methadone per week.
- **Low intensity supervision:** allows patients who have demonstrated stability in treatment and regularity of dosing for at least six (6) continuous months, and who are assessed as at low risk of misuse, to access up to four (4) take-away doses per week, with no single supply exceeding three (3) consecutive doses.

**Table 3.1: Recommended levels of supervised dosing with methadone**

Level of supervision	Number of take-away doses per week	Description	
High	Nil	Patients will attend for daily supervised dosing	<p><b>Reminder:</b> Careful clinical assessment of the safety of provision of take-away doses is essential. This should be a clinical decision firmly based on a thorough risk/benefit assessment, not a decision based on length of treatment, or primarily on a request from the patient.</p> <p><b>Ensure Steps 1 to 3 of the assessment have been completed before proceeding to Step 4.</b></p> <p><b>Note:</b> This policy is not intended to replace professional judgment in the treatment of individual patients. In situations where a higher number of take-away doses than recommended in this policy are considered, prescribers should liaise with the pharmacist concerning the appropriateness of the proposed treatment and fully document the reasons for their actions. Refer to <b>13: Issues for consideration when prescribing additional take-away doses</b> for further information.</p>
Medium	0 to 2	After at least three (3) continuous months of stable treatment, patients will be required to attend for supervised dosing at least five (5) days per week	
Low	0 to 4	After at least six (6) continuous months in stable treatment a patient may be considered for a low supervision regimen, but will still be required to present for supervised dosing at least three times per week	

Progression to medium intensity supervision after three months and low intensity supervision after six months should not be automatic. Time in treatment is not the key consideration when assessing the appropriateness of take-away doses. Primarily, the patient should be assessed for stability and suitability for take-away doses using the assessment tool provided in Appendix 4. Consultation with the pharmacist is essential to assessing stability and suitability, especially when take-away doses are being considered for the first time for the patient or when considering increasing the number of take-away doses to be prescribed.

### **Buprenorphine/naloxone**

Four levels of supervised dosing are available for patients being treated with buprenorphine/naloxone:

- **High intensity supervision:** involves no take-away doses. This is the default level of supervision that should be adopted at the commencement of opioid substitution treatment.
- **Medium intensity supervision:** allows patients who have demonstrated stability in treatment and regularity of dosing for at least two (2) continuous weeks to access up to two (2) take-away doses of a combined buprenorphine/naloxone product per week. Take-away doses should not be provided in situations where supply would result in more than two (2) days without attendance for supervised dosing (relevant for patients who receive dosing every second or third day).
- **Low intensity supervision:** allows patients who have demonstrated stability in treatment and regularity of dosing for at least two (2) continuous months, and who are assessed as at low risk of misuse, to access up to five (5) take-away doses per week. Take-away doses should not be provided in situations where supply would result in more than five (5) days without attendance for supervised dosing (relevant for patients who receive dosing every second or third day).
- **Very low intensity supervision:** allows patients who have demonstrated stability in treatment and regularity of dosing for at least six (6) continuous months, and who are assessed as at low risk of misuse, to access up to six (6) take-away doses per week. Take-away doses should not be provided in situations where supply would result in more than six (6) days without attendance for supervised dosing (relevant for patients who receive dosing every second or third day).

**Table 3.2: Recommended levels of supervised dosing with a combined buprenorphine/naloxone product**

Level of supervision	Number of take-away doses per week	Description	
High	Nil	Patients will attend for daily supervised dosing	
Medium	0 to 2	After at least two (2) continuous weeks of stable treatment, patients will be required to attend for supervised dosing at least five (5) days per week	<p><b>Reminder:</b> Careful clinical assessment of the safety of provision of take-away doses is essential. This should be a clinical decision firmly based on a thorough risk/benefit assessment, not a decision based on length of treatment, or primarily on a request from the patient.</p>
Low	0 to 5	After at least two (2) continuous months in stable treatment a patient may be considered for a low supervision regimen, but will still be required to present for supervised dosing at least twice per week	<p><b>Ensure Steps 1 to 3 of the assessment have been completed before proceeding to Step 4.</b></p> <p><b>Note:</b> This policy is not intended to replace professional judgment in the treatment of individual patients. In situations where a higher number of take-away doses than recommended in this policy are considered, prescribers should liaise with the pharmacist concerning the appropriateness of the proposed treatment and fully document the reasons for their actions. Refer to <b>13: Issues for consideration when prescribing additional take-away doses</b> for further information.</p>
Very Low	0 to 6	After at least six (6) continuous months in stable treatment a patient may be considered for a very low supervision regimen, but will still be required to present for supervised dosing at least once per week	

Buprenorphine without naloxone should not be prescribed for take-away doses unless the patient is pregnant or breastfeeding, has a clinically-documented allergy to naloxone or to an inactive component of the film/tablet, or where there is no proprietary product available containing naloxone for certain doses (for example, for doses under 2 mg). If take-away doses of a buprenorphine/naloxone combination are authorised, the patient should be transferred to the combination for all doses, including the days when doses are supervised.

Progression to medium intensity supervision after two weeks, low intensity supervision after two months and very low intensity supervision after six months is not automatic. Time in treatment is not the key consideration when assessing the appropriateness of take-away doses. The patient should first be assessed for stability and suitability for take-away doses using the assessment tool provided in Appendix 4. Consultation with the pharmacist is essential to assessing stability and suitability, especially when take-away doses are being considered for the first time for the patient or when increasing the number of take-away doses to be prescribed.

## 12. Take-away doses: assessing patient stability

The level of supervised dosing is adjusted according to a patient's progress during treatment. A stepped approach should be adopted to allow the patient to progress across these levels. This approach requires review and documentation of the patient's stability in treatment.

In some cases, an increase in the level of supervision may be required in patients who relapse. When authorising take-away doses, the prescriber should document the patient's level of stability, in keeping with good clinical practice.

Many patients are unsuitable for take-away doses regardless of the total period of continuous treatment.

Assessment for appropriateness of take-away doses requires that the patient visit the prescriber on a regular basis.

The following strategies are used to assess stability (see **Table 3.3: Methods for assessing patient stability**): the patient's clinical records; taking the patient's history; clinical examination; urine toxicology and liaison with other health professionals involved in the patient's care (at a minimum this will include the pharmacy). Assessment across these domains should occur regularly during a patient's treatment and be documented.

**Table 3.3: Methods for assessing patient stability**

	Method of assessment			
	Clinical records / patient history	Clinical examination	Urine toxicology	Discussion with other health professionals (e.g. pharmacist)
Attendance at medical/ case manager reviews	•			
Missed doses				•
Provision of urine drug screens (UDS)			•	
Unsanctioned use of other drugs (prescription medicines, alcohol, illicit drugs) or overdose	•	•	•	•
Concerns about misuse or diversion of take-away doses	•			•
Stable accommodation, safe and secure storage	•			•
Physical and mental state assessment	•	•	•	•

Assessment of stability involves looking at whether patients are effectively engaged in treatment with their prescriber, adhering to their planned methadone or buprenorphine dosing regimen and attending for clinical reviews. Patients should receive an adequate dose of methadone or buprenorphine to suppress withdrawal symptoms and cravings and demonstrate markedly reduced use of illicit opioids, without adverse effects or toxicity. Patients should have demonstrated an improvement in overall functioning across broad biopsychosocial domains subsequent to their entry into treatment.

If the patient's level of stability changes, the availability of unsupervised medication should be reviewed. For example, if a patient on a low level of supervised dosing loses access to stable housing and cannot safely store take-away doses, the patient cannot continue to receive low-level supervised dosing until the patient is again in stable accommodation.

The assessment for stability should be transparent and openly discussed with the patient during clinical reviews. Patients can take an active role and develop an understanding of the requirements and responsibilities for accessing lower levels of supervised dosing.

#### **Patient agreement form**

A written agreement should be considered to ensure patients are fully aware of the structure and responsibilities of receiving take-away doses. An example of such an agreement is provided in appendices 5 and 6.

Appendices 5 and 6 are also available in Arabic, Burmese, Chinese, Dinka, Farsi, Greek, Italian, Khmer, Macedonian, Serbian, Spanish, Turkish and Vietnamese.

#### **13. Issues for consideration when prescribing additional take-away doses**

This policy is not intended to replace professional judgment in the treatment of individual patients. In situations where a higher number of take-away doses than recommended in this policy is considered, for example, where:

- methadone take-away doses are being considered for a stable patient before three (3) continuous months in treatment
- more than three (3) methadone take-away doses in a single supply are being considered for a stable patient
- more than four (4) methadone take-away doses per week are being considered for a stable patient,

prescribers should liaise with the pharmacist concerning the appropriateness of the proposed treatment and fully document the reasons for their actions.

When considering additional take-away doses, prescribers and pharmacists should:

- consider the risks involved and possible consequences
- carefully assess the risk of accidental overdose or diversion
- consider liaising with an Addiction Medicine Specialist, a Specialist Pharmacotherapy Service or DACAS for advice on optimal patient management.

#### **Prescribing take-away doses for travel purposes**

With prior planning, it may be possible for a prescriber to arrange a temporary intrastate, interstate or international patient transfer for continuation of supervised treatment. Refer to 17: Transfer of pharmacotherapy patients for further information.

When it is not possible to arrange a patient transfer (for example, urgent travel at short notice) and prescribing of additional take-away doses is being considered to allow a stable patient to continue treatment, the decision to prescribe

and dispense additional take-away doses is a matter of professional judgment for the prescriber and pharmacist.

Prescribing additional take-away doses should not be considered as routine practice for travel purposes and should only be considered if all reasonable attempts to arrange a patient transfer have been unsuccessful.

#### **International travel**

Prescribers and pharmacists should also note the following when considering prescribing additional take-away doses for international travel:

- Provide the patient with a letter as supporting travel documentation which details the quantity and daily dose the patient will be taking, states that the medicine is for the patient's personal use, and provides contact details of the prescriber and pharmacy. Attach a copy of the dispensed prescription certified by the dispensing pharmacist.
- Ensure that the take-away doses are clearly and correctly labelled, including the patient's name and dosage instructions.
- Further general advice on travelling overseas with medicines is available at [www.smartraveller.gov.au](http://www.smartraveller.gov.au).

In some circumstances, prescribers may consider prescribing methadone take-away doses in the tablet form as an option to enable a stable patient to travel overseas. The decision to prescribe and dispense methadone take-away doses in the tablet form is a matter of professional judgment for the prescriber and pharmacist.

When deciding on the safety and appropriateness of providing methadone tablets to a particular patient, prescribers and pharmacists should:

- discuss the appropriateness of the proposed treatment and both fully document the reasons for their decisions or actions
- consider the risks involved and possible consequences that may arise when providing methadone take-away doses in the tablet form

- carefully assess the risk of injection of methadone tablets, accidental overdose and diversion of doses.

The PAMS service can provide assistance with patient transfers and advice on travelling with take-away doses.

#### **14. Frequency of review**

The prescriber should review the patient's progress once or twice in the first week of treatment, then at least every two weeks during the initial phase (or until the patient has reached a stable dose) of pharmacotherapy. Patients considered to be at risk of overdose should be reviewed more frequently, even daily, in the first week or two, to assess for toxicity and stability. Thereafter, an ongoing treatment plan should comprise of regular patient reviews as appropriate to the clinical situation.

Throughout the first two years of treatment, medical review should be at least monthly. More frequent reviews may be indicated, especially if the patient does not appear to be progressing well or if the prescriber, pharmacist or the patient (or the patient's carer or case manager) has concerns. Reviews can include management of the patient in collaboration with a trained alcohol and drug worker (for example, a case manager).

During medical reviews, the assessment tool in Appendix 4 should be used to assess and document the patient's progress, in addition to other relevant issues including the patient's overall goals, satisfaction with treatment and other relevant health issues (for example, HCV testing, HBV vaccination, screening for depression).

In situations where it is difficult to assess a patient's stability or where there are complex clinical issues, the prescriber should consider discussing the case with an Addiction Medicine Consultant, DACAS or refer the patient to a Specialist Pharmacotherapy Service for assessment and recommendations.

## 15. Minimal supervision regimens

A small percentage of very stable, low risk patients may be considered for regimens where patients are provided buprenorphine/naloxone combinations for longer periods than listed under low-level supervision (**Table 3.2: Recommended levels of supervised dosing with a combined buprenorphine/naloxone product**). The maximum prescriptions provided are for up to 28 days' supply of a combined buprenorphine/naloxone product.

Fellows of the Australasian Chapter of Addiction Medicine (FACChAM) may apply for a permit to prescribe a minimal supervision regimen. Prescribers who have supporting advice from a fellow may also apply for a permit to prescribe a minimal supervision regimen to a particular patient. While the permit issued would not be time limited, regular patient reviews with the fellow are advised while in treatment. The interval between these reviews should be agreed with the fellow and based on the circumstances of the individual case.

Authorisation to prescribe minimal supervision regimens is managed through a separate permit approval system. Before initiating these regimens, a prescriber is required to apply to the Department of Health and Human Services for a minimal supervision permit.

## 16. Patients resuming community-based treatment after release from prison

Recent release from prison constitutes a period where there is a markedly heightened risk of death, often involving drug overdose. Many patients released from prison are highly vulnerable and will benefit from supervised dosing during this post-release period to ensure the safety of use of methadone or buprenorphine.

Patients released from prison may be provided with a prescription by the prison health service provider for supervised dosing at a community pharmacy as a temporary measure (usually less than seven (7) days' treatment) until they can be seen by a community-based prescriber to continue treatment. When confirming details of previous treatment with the prison health service provider, community-based prescribers should also confirm whether any prescription was written for the patient for dosing at a community pharmacy to avoid the risk of double dosing.

Since pharmacotherapy treatment in prison differs in many ways from treatment in the community, the length of time of treatment in prison does not equate to stability in treatment in the community. Provision of take-away doses is not recommended until patient stability and suitability for take-away doses is established after a period of supervised dosing in the community. As is the case for new patients receiving pharmacotherapy, a high level of supervision is recommended for patients resuming community-based treatment.

Similar issues relating to the resumption of community-based treatment may also be relevant to patients who have recently been discharged after a period of detoxification or hospitalisation.

Further information is available in the 'Issues that may impact on treatment – prisoners' section of the *National guidelines for medication-assisted treatment of opioid dependence*.

## 17. Transfer of pharmacotherapy patients

Patients may transfer to other dispensing locations temporarily for work, holiday or other reasons. Transfer may be intrastate, interstate or international. Consider the patient's suitability for transfer before making these arrangements. The usual requirements and contra-indications for providing take-away doses apply to patients seeking transfer. All patient transfers should be organised well in advance of the intended date.

Patients may also require permanent transfer to another prescriber or pharmacy. There is a risk of confusion about when the last dose was administered at the previous pharmacy, creating the possibility of double dosing on the same day, with resultant toxicity. Good communication between the transferring and receiving prescribers and pharmacies is therefore very important. DirectLine can provide advice on the locations of prescribers and pharmacies that provide pharmacotherapy services. The PAMS service can also provide assistance.

When the intended receiving prescriber and pharmacy have agreed to accept the patient for treatment, the receiving prescriber should obtain sufficient information from the transferring prescriber to ensure safety of treatment and continuity of care and to inform decisions about take-away doses. The receiving prescriber should contact the transferring prescriber and request appropriate documentation.

The documentation should include:

- patient's full name, date of birth, address in Victoria
- current pharmacotherapy dose in milligrams
- date and strength of the last pharmacotherapy dose provided under the transferring prescriber's care (including the number of take-away doses provided, if relevant)
- dates to be dosed (if a temporary transfer)
- a recent photograph of the patient (endorsed by the prescriber)
- the reason for transfer
- any other drugs of dependence prescribed for the patient (for example, benzodiazepines)
- any other history relevant to the treatment of patient (for example, medical history, mental health plans, social or employment status).

The receiving prescriber should also confirm the arrangements concerning the transfer of pharmacies. For safety reasons, ensure that clear written instruction is provided to both pharmacies about the timing of the last dose at the transferring location and the first dose at the receiving location. These arrangements are made to avoid the risk of double dosing and to check that doses have not been missed. Drugs and Poisons Regulation at the Department of Health and Human Services (see Appendix 2) should be notified in writing (letter, fax or email) of all permanent transfers to a new pharmacy.

The receiving pharmacotherapy prescriber is required to hold a permit before prescribing to the patient. If the patient is permanently transferring to the receiving prescriber, the Department of Health and Human Services will terminate the permit held by the transferring prescriber.

## Procedures for arranging transfers

### Intrastate patient transfer

**Table 3.4: Intrastate patient transfer (within Victoria)**

	Temporary	Permanent
<b>To a different pharmacy</b>	Provide the receiving pharmacy with: <ul style="list-style-type: none"><li>• patient details (name, date of birth)</li><li>• a recent photograph of the patient (endorsed by the prescriber)</li><li>• the date and amount of final dose at the transferring pharmacy (including take-away doses if necessary).</li></ul>	As for temporary transfer, plus the prescriber must also need to notify the Drugs and Poisons Regulation at the Department of Health and Human Services (Appendix 2) of the change of pharmacy.
<b>To a new prescriber</b>	The receiving prescriber should obtain the above details from the transferring prescriber. The receiving prescriber must obtain a permit before prescribing.	As for temporary transfer, plus the transferring prescriber should also send a <i>Notification of termination of methadone or buprenorphine</i> form to the Drugs and Poisons Regulation at the Department of Health and Human Services (Appendix 2).

### Temporary interstate patient transfer

In some states or territories it may be possible for Victorian prescribers to write a pharmacotherapy prescription intended for dispensing at a pharmacy in that state or territory for a temporary patient transfer, provided all interstate requirements are also met. For instance, some pharmacies interstate will not be able to dispense a pharmacotherapy prescription unless the prescription has been authorised in that state or territory. In other states or territories, only prescribers from within that state or territory are able to prescribe pharmacotherapy for dispensing in that state or territory.

Prescribers should refer to 'Interstate prescriptions for opioid replacement therapy' on the Department of Health and Human Services website at [www.health.vic.gov.au/dpcs/pharm.htm](http://www.health.vic.gov.au/dpcs/pharm.htm) for up-to-date information on interstate requirements for pharmacotherapy prescriptions and contact details for interstate regulatory groups for assistance with temporary interstate transfers.

### Permanent interstate patient transfer

Prescribers should refer to 'Interstate prescriptions for opioid replacement therapy' on the Department of Health and Human Services website at [www.health.vic.gov.au/dpcs/pharm.htm](http://www.health.vic.gov.au/dpcs/pharm.htm) for contact details for interstate agencies for assistance with permanent interstate transfers.

**Table 3.5: Interstate patient transfer**

Temporary	Permanent
<p>Arrangements for interstate transfer of patients from Victoria vary across states/territories, but in every case the Victorian prescriber is required to provide the information necessary for safe transfer to the receiving prescriber and/or pharmacy (either directly or through various clinics or agencies).</p> <p>The receiving prescriber and/or pharmacist usually requires:</p> <ul style="list-style-type: none"><li>• patient details (name, date of birth)</li><li>• a recent photograph of the patient (endorsed by the prescriber)</li><li>• the date and amount of the final dose at the transferring pharmacy (including take-away doses if necessary)</li><li>• the expected dates of the temporary treatment</li><li>• contact details for the transferring pharmacy.</li></ul> <p>Make arrangements well in advance. Interstate regulatory agencies generally require at least 2–3 weeks' notice for interstate transfers.</p> <p>The PAMS service can provide advice and assistance with interstate patient transfers.</p>	<p>As for temporary transfer, plus the transferring prescriber should send a <i>Notification of termination of methadone or buprenorphine</i> form to the Department of Health and Human Services (form available at <a href="http://www.health.vic.gov.au/dpcs/smartforms.htm">www.health.vic.gov.au/dpcs/smartforms.htm</a>).</p>

**International patient transfer**

For general information and contact details of prescribers and pharmacies in many international destinations, see the Travel Resource Centre website at [www.indro-online.de/nia.htm](http://www.indro-online.de/nia.htm).

**Table 3.6: International patient transfer**

Temporary	Permanent
<p>Patients should contact the consulate of the country to which they are travelling for information. Make arrangements well in advance (at least one month before making travel arrangements). These transfers are not always possible.</p> <p>The PAMS service can provide advice and assistance with international patient transfers.</p>	<p>As for temporary transfer, plus the transferring prescriber should send a <i>Notification of termination of methadone or buprenorphine</i> form to the Department of Health and Human Services.</p>

## 18. Termination of treatment

Pharmacotherapy is usually considered a long-term therapy option. Ceasing pharmacotherapy may be associated with relapse to illicit or problematic pharmaceutical opioid use. In most cases where there is a risk of relapse, patients should be encouraged to remain in treatment. In the case of heroin users, continued use of heroin should be discussed, but is not necessarily a reason to terminate treatment and most patients can still benefit from reduced drug use and decreased risk of opioid overdose. Treatment may offer patients relief from the need to obtain drugs, or control of opioid use, and for heroin users an opportunity to stabilise their lives and remove themselves from the drug-taking culture. Evidence suggests the benefits are maximised when the patient remains in treatment for at least 12 months.

Alcohol and other drugs treatment services can provide support for patients wishing to reduce or cease pharmacotherapy use. There are also specific residential rehabilitation programs available. DirectLine can provide more information (see Appendix 2).

Complete a *Notification of termination of methadone or buprenorphine* form and forward it to the Department of Health and Human Services as soon as practicable if treatment with methadone or buprenorphine has ceased.

More detailed clinical information about withdrawing from maintenance pharmacotherapies can be found in the *National guidelines for medication-assisted treatment of opioid dependence*.

## 19. Vomited dose of pharmacotherapy

Patients may vomit after ingesting their pharmacotherapy dose, creating uncertainty about whether they have absorbed it. Consider the interval between ingestion and vomiting.

Methadone is fully absorbed within 20–30 minutes of ingestion. Vomiting early after ingestion may prevent absorption of the dose, although the

patient may not vomit all the stomach contents.

If vomiting occurs more than 20 minutes after ingestion, the dose is likely to have been absorbed.

If vomiting occurs within 20 minutes of ingestion of the dose, review the patient. If the patient is reviewed within four to six hours after consumption of the dose, plasma levels will be at their peak. If there is good evidence of opioid withdrawal at this time, consider a supplementary dose of half the usual dose (up to a maximum of 40 mg). If there are doubts about the amount of pharmacotherapy absorbed despite vomiting, it is better to be cautious and not administer an additional dose. Review the patient the next day.

Take extra care with pregnant patients because withdrawal symptoms can cause foetal distress. If it is not possible to review the patient four to six hours after dosing and if vomiting is observed within five minutes of ingestion, consider supplementing with half the usual dose of methadone (up to a maximum of 40 mg).

As buprenorphine is absorbed sublingually within minutes, vomiting after a dose will not reduce the clinical effect.

## 20. Prescriber discontinuing pharmacotherapy services

Prescribers intending to discontinue pharmacotherapy services should prepare a contingency plan to transfer their existing patients to other providers. When discontinuing a medical practice, it is professionally responsible to:

- give advance notice where this is possible
- facilitate arrangements for the continuing medical care of all current patients, including the transfer or appropriate management of all patient records.

DirectLine and the PAMS service can provide assistance with patient transfers to other pharmacotherapy providers.

## 21. Legislative framework

The legislative framework for pharmacotherapy in Victoria is the *Drugs, Poisons and Controlled Substances Act 1981* and the *Drugs, Poisons and Controlled Substances Regulations 2006*. The requirements that directly affect pharmacotherapy prescribers are summarised here.

Schedule 8 poisons include opioid drugs and prescription stimulants. Specific drugs include buprenorphine, codeine, fentanyl, hydromorphone, methadone, morphine, oxycodone, pethidine, tapentadol, dexamphetamine, lisdexamfetamine, methylphenidate, alprazolam, flunitrazepam and ketamine. Schedule 4 poisons include all other prescription only medicines.

Drugs of dependence are those substances in Schedule 11 to the *Drugs, Poisons and Controlled Substances Act 1981*. This is an empirical list of drugs known to be misused, diverted and illicitly traded. All Schedule 8 and some Schedule 4 poisons, including benzodiazepines, anabolic steroids and anorectics (phentermine), are classified as drugs of dependence.

### Prescription and supply of Schedule 4 and Schedule 8 poisons and drugs of dependence

- The prescriber must take all reasonable steps to ensure a therapeutic need exists and then prescribe only for the medical treatment of a patient under their care.
- For drugs of dependence, the prescriber must take all reasonable steps to ascertain the identity of the patient.
- A person who has been treated with a drug of dependence in the previous eight weeks must not, without disclosing the earlier treatment, procure or attempt to procure the same or similar drug of dependence from a prescriber or pharmacist.
- The prescriber must not prescribe in order to support drug dependence.
- Prescribers are prohibited from self-prescribing and self-administering Schedule 4 and Schedule 8 poisons.

- A prescription for a Schedule 4 or Schedule 8 poison must contain full details of the prescriber, the patient, the drug, the quantity and the maximum number of repeats (in words and figures for Schedule 8 poisons). It must also include precise directions (except where complex directions are provided separately or where a nurse or medical practitioner is to administer the drug) and must be signed by the prescriber.
- Prescriptions may be handwritten or computer generated provided there is compliance with certain criteria.
- In an emergency, a prescriber may give verbal instructions for supply of Schedule 4 or Schedule 8 poisons. These verbal instructions must be confirmed in writing as soon as practicable.
- When a prescriber supplies a Schedule 4 or Schedule 8 poison (including samples), the pack must be labelled with specified details.

### Drug-dependent patients

- Where there is reason to believe that a patient is drug dependent, the Department of Health and Human Services must be notified (form available at [www.health.vic.gov.au/dpcs/smartforms.htm](http://www.health.vic.gov.au/dpcs/smartforms.htm)).
- In most circumstances, a permit from the Department of Health and Human Services must be held before treating a drug-dependent patient with a Schedule 8 poison.

### Prescription

- A pharmacist administering doses must possess a valid prescription or order before administering a Schedule 8 poison to a person.

### Storage and record keeping

- Schedule 8 poisons must be stored in a facility providing no less security than that provided by a steel drug cabinet specified in the *Drugs, Poisons and Controlled Substances Regulations 2006*.
- Details of the administration or supply of Schedule 4 or Schedule 8 poisons must be recorded and these records must be readily retrievable for up to three (3) years. In addition, Schedule 8 poison transaction records must be able to be readily sorted by drug and they must show a true and accurate balance of each drug.

## **22. Confidentiality**

As with other forms of medical treatment, patients are entitled to protection of their privacy. The collection, use and disclosure of health information pertaining to a patient should be conducted in accordance with the Health Privacy Principles in the *Health Records Act 2001*. Take special care to prevent unauthorised access to a patient's health records.

## **23. When a patient has a concern**

Patients who are unhappy with any aspect of their treatment should first seek to resolve their concerns with the prescriber, pharmacist or a member of the treatment team. The PAMS service can also assist in resolving disputes arising from the delivery of pharmacotherapy services.

If these avenues prove unsuccessful, patients may contact the Health Services Commissioner (refer to Appendix 2 for contact details).

## **24. Area-Based Pharmacotherapy Networks**

Prescribers are encouraged to make contact with their local Area-Based Pharmacotherapy Network. Networks assist pharmacotherapy providers with implementing a more integrated and cohesive service and can offer support and mentoring to prescribers. Networks facilitate regular meetings where like-minded health professionals can interact and can receive information on best-practice and emerging issues related to alcohol and other drugs.

More information on the Area-Based Pharmacotherapy Networks and contact details are provided at Appendix 15.

# 4 Policy for pharmacists

## Essentials of pharmacotherapy administration

This policy provides advice relating to the supply and administration of methadone, buprenorphine and buprenorphine/naloxone combinations to Victorian patients. This is conducted in accordance with the *Drugs, Poisons and Controlled Substances Act 1981* and the Drugs, Poisons and Controlled Substances Regulations 2006.

In circumstances not specifically covered by the policy:

- contact the prescriber or DACAS for instructions and clinical advice
- refer to the *National guidelines for medication-assisted treatment of opioid dependence* for further information on treatment procedures
- contact Drugs and Poisons Regulation, Department of Health and Human Services for advice about the policy or legislation
- address the situation in accordance with the following principles:
  1. Ensure positive identification of the patient before administering a dose. Refer to the patient's photograph, which the prescriber has endorsed.
  2. Ensure the dose is prepared as authorised by the prescriber. Examine the prescription to verify the dose and ensure the prescription is current.
  3. Determine that it is safe to administer a dose. Determine precisely when the previous dose was administered, contacting the previous pharmacy when necessary. Do not dose if the patient has missed doses on four (4) or more consecutive days.
  4. Assess the patient for signs of possible intoxication. If the patient appears intoxicated there may be a serious risk of toxicity if the pharmacotherapy dose is administered. In such cases consideration should be given to one or more of the following:
    - delaying the dose
    - contacting the prescriber

- consulting DACAS
- reducing the normal dose.

5. Ensure the dose is consumed with no possibility of diversion. Observe that the patient takes the dose.
6. Advise the prescriber of irregularities in a patient's attendance, behaviour or condition. Record details of the communication. Take a proactive role in interactions with pharmacotherapy prescribers.
7. Ensure that patient records, records of administration and details of communications with the prescriber are clearly and consistently maintained and available to all pharmacists administering doses. Also, ensure the relevant clinical guidelines and the pharmacotherapy policy are readily available for reference.
8. Ensure that a system is implemented that maintains patient privacy and confidentiality of records.

## Setting up a pharmacotherapy dosing service

### Permission to supply pharmacotherapies

To make an application for permission as a pharmacotherapy supplier, complete the application form available on the Department of Health and Human Services website at [www.health.vic.gov.au/dpcs/pharm.htm](http://www.health.vic.gov.au/dpcs/pharm.htm).

A departmental officer will conduct a review of the proposed systems and an induction prior to permission being granted.

To avoid stigmatisation of patients, congregation of large numbers of patients around dosing points and to normalise treatment, pharmacies permitted to supply pharmacotherapies should also be able to provide a full range of community pharmacy services to the general public, including:

- carrying OTC medicines
- being approved to supply PBS subsidised medicines to provide complete and affordable

- access to medicines for all of the patient's comorbidities
- having standard opening hours to enable patient retention and normalisation of treatment.

Special consideration for granting permission to other pharmacies may be applicable in circumstances where pharmacies are located in areas of need not otherwise serviced.

Permission may be granted to the proprietor(s) of a pharmacy to supply pharmacotherapies to a specified maximum number of patients, possibly with conditions. Initial permission to supply pharmacotherapies is limited to treatment for up to five (5) patients. Further permission must be sought if a pharmacy wishes to manage a larger number of patients and further permission must be sought if there is a change of proprietor.

Pharmacies should consider their overall capability for maintaining a professional and thorough service when intending to manage a larger number of patients. This includes taking into consideration the number of professional staff available, the size of the professional service area, and the usual workloads undertaken by pharmacists on duty. It is important that the number of patients is at a reasonable and manageable level to ensure that there is no reduction in the standard of care being provided to patients. Pharmacies may wish to refer to the Pharmacy Board of Australia's *Guidelines for dispensing of medicines* for further advice on managing pharmacists' workloads.

The maximum number of patients for any pharmacy is 85, unless special circumstances apply. Further permission should be sought if a pharmacy wishes to manage more than 85 patients, where a pharmacy is relocating to a different location or where there is a change of pharmacy ownership.

Where the pharmacy does not operate seven days per week, only stable patients for whom the prescriber has authorised take-away doses may be accepted (unless special arrangements are

made for dosing on the days when the pharmacy is closed).

Ongoing permission is conditional upon continual observance of the policy's underlying objectives of ensuring the legal, safe and effective use of pharmacotherapies and relevant clinical guidelines.

### **Development of procedures**

A pharmacotherapy dosing service may be conducted in a number of different ways. All pharmacists administering doses at the pharmacy should have access to accurate information about the systems in place at the pharmacy. The policy and relevant clinical guidelines should be readily available for reference by all staff involved in the administration of doses.

### **Certification by managers of pharmacies**

It is strongly recommended that all pharmacists administering doses at the pharmacy be familiar with the policy, clinical guidelines and procedures in place. Pharmacists should provide certification to confirm that they are familiar with these systems (Appendix 7). Certification documents should be retained, with a copy readily available for reference.

It is also recommended that pharmacists-in-charge carry out a self-assessment of the pharmacy's procedures periodically to ensure compliance with key regulatory and policy requirements.

The *Self-assessment form for pharmacists* is available on the Department of Health and Human Services website at [www.health.vic.gov.au/dpcs/pharm.htm](http://www.health.vic.gov.au/dpcs/pharm.htm). Pharmacists can use this form to review key issues and assess their day-to-day procedures with respect to key regulatory and policy requirements associated with the safe, appropriate and lawful provision of opioid-replacement therapy.

The department funds training that is available free of charge to pharmacists involved in providing pharmacotherapy services, including pharmacists wishing to attend for a clinical update or refresher training. Further information on training for pharmacists is available on the department website at [www.health.vic.gov.au/dpcs/pharm.htm](http://www.health.vic.gov.au/dpcs/pharm.htm).

### Storage

Methadone and buprenorphine are Schedule 8 poisons and must be stored in a facility providing no less security than that provided by a steel drug cabinet as specified in the Drugs, Poisons and Controlled Substances Regulations 2006. Keep the containers in use in a secure location and return them to the cabinet when no longer in use.

### Patient records

It is recommended that a separate record for each patient is maintained so all necessary information is readily available to the pharmacist administering doses. The records should:

- clearly record the date and time of each dose
- provide for signatures by the patient and the pharmacist who administered the dose to confirm that a dose has been administered (Appendix 8)
- include other details, like payments and prescription expiry dates.

Patient records may also be maintained in an electronic form.

Details should be recorded in a permanent, readily retrievable and consistent manner where they are not readily accessible to patients (for example, in chronological order on a separate page of the patient book) (Appendix 9). Each pharmacist administering a dose should have access to all relevant patient details, including details of communications with the prescriber, variations in dosage and details of take-away dose authorisation.

The current prescription and patient photograph should be readily available to the pharmacist administering the dose. It is recommended that these be prominently located in the patient

records (for example, the photograph firmly attached inside the front cover of the patient record book, with the current prescription firmly attached inside the rear cover).

Patients have a right to privacy, which should be ensured at all times. Separate records also help ensure that personal information relating to one patient is not available to another (for example, separate exercise books for each patient). Avoid large, bold lettering of patients' names on the covers of books that may be visible to other patients.

### Records of administration

In addition to the patient records, a pharmacy must retain an accurate record of each dose administered to each patient. These records may be maintained manually or by computer (appendices 10 and 11).

The volume of methadone syrup (expressed in millilitres) is commonly recorded, but these records should also clearly identify the dose of methadone (expressed in milligrams) so there is no possibility of misinterpretation.

The Drugs, Poisons and Controlled Substances Regulations 2006 require that records relating to Schedule 8 poisons must also show the true and accurate balance remaining after each transaction, and must be in a form that enables any amendments to be readily detectable.

It is necessary to record the remaining balance on at least a daily basis. The records of administration may be in a form that enables the daily reconciliation to be carried out therein or within the Schedule 8 drug register (Appendix 12). Records must show the actual balance, not merely a calculated balance, and these should be reconciled on a regular basis.

### Destruction of methadone or buprenorphine

The destruction of expired, damaged or returned stock of methadone or buprenorphine (including take-away doses that are not to be used) must be carried out in accordance with the requirements set

out in the Drugs, Poisons and Controlled Substances Regulations 2006. The destruction of any Schedule 8 poison by a pharmacist must be witnessed by another person who is a registered medical practitioner, pharmacist, veterinary practitioner, dentist, nurse or midwife. In addition, the details of the destruction must be recorded, including:

- name, strength and quantity of the Schedule 8 poison destroyed
- method and place of destruction
- name of the person carrying out the destruction
- name of the witness.

## Administration of pharmacotherapies

### 1. Accepting new patients

For new patients, contact the prescriber to ascertain whether the patient is new to pharmacotherapy or transferring from another pharmacy. Different management issues apply in each case.

To ensure potential patients are fully aware of the structure and requirements of pharmacotherapy treatment, interview them before accepting them as patients. A written agreement may be considered as the basis for accepting new patients. An example of such an agreement is provided in Appendix 13.

In addition to a written agreement, a further agreement should be considered to ensure patients are fully aware of the responsibilities associated with receiving take away doses (refer to appendix 5 and 6 for examples). Appendices 5 and 6 are also available in Arabic, Burmese, Chinese, Dinka, Farsi, Greek, Italian, Khmer, Macedonian, Serbian, Spanish, Turkish and Vietnamese.

The patient should provide a recent photograph (endorsed as being a true image of the patient by the prescriber) and the original written authorisation (for example, the prescription) before the initial dose is administered.

### 2. Prescriptions/authorisation

Generally, a patient must not be dosed until the prescriber has provided the original written authorisation (for example, a prescription). However, in accordance with regulation 27(1) of the Drugs, Poisons and Controlled Substances Regulations 2006, in an emergency the prescriber may verbally communicate instructions.

The prescriber should fax, email or electronically transfer a copy of the prescription (endorsed with the name of the pharmacy to which it is being sent) to the pharmacy concerned to confirm the details of emergency verbal instructions and/or a prescription delivered by the patient. In all cases, the prescriber must forward the original prescription as soon as practicable.

Prescriptions are valid for the duration specified by the prescriber (which may not exceed six (6) months) and dosing must not continue in the absence of a current prescription.

No increase in dose is permitted unless the prescriber has provided an original written authorisation. In an emergency, the prescriber's verbal communication of instructions together with a faxed confirmation is sufficient for increasing a dose. The original must be sent as soon as practicable.

### Managing expiry of prescriptions

There should be a consistent method for clearly identifying the impending expiry of prescriptions before this becomes a problem. Patients and/or prescribers should be given sufficient warning. Clearly record the expiry date on the cover and/or corresponding page of the patient book, for example, or provide reminder notes to patients to alert them to impending expiry dates. All expired or superseded prescriptions should be immediately cancelled.

Expired prescriptions must be retained for three (3) years and should be filed in a secure manner that will preclude the possibility of confusing such

prescriptions with the current prescription (for example, in a separate file or in chronological order with the current prescription on the top of the file).

### 3. Preparation of supervised doses

Conical measures may not be sufficiently accurate for measuring smaller volumes of methadone liquid, consequently a syringe or a displacement pump is recommended.

Dilute each dose of methadone liquid with water prior to administration.

Although it is recommended that doses are prepared at the time of a patient's attendance, some pharmacies have developed procedures in which doses are prepared in advance for all patients who are expected to attend during the day. Such procedures are not recommended unless all of the following tasks are completed:

- place the doses in clearly labelled containers with secure closures (for example, clearly labelled dispensing bottles)
- store the doses securely
- ensure transaction records clearly identify the person responsible for each transaction (that is, for the preparation and administration of doses)
- ensure transaction records clearly indicate how uncollected doses are disposed of or handled
- aim not to dilute the doses until the time of administration, to enable the pharmacist administering the dose an opportunity to verify the accuracy of the dose.

Sometimes methadone syrup is transferred to another container (for example, a bottle with a displacement pump) and diluted to create a working solution (for example, 1 milligram per 1 millilitre). In such instances, the container must be clearly labelled to indicate the concentration of the methadone syrup that is being used to prevent administration of an incorrect dose.

If a working solution is being prepared, purified water BP (water for irrigation) should be used to dilute methadone syrup. The shelf-life of a working solution should also be considered, as the dilution of methadone syrup would also result in diluting the concentration of preservatives in the solution.

Buprenorphine tablets and buprenorphine/naloxone films should not be removed from their original sachets or foil packs until the dose is to be administered.

Buprenorphine tablets should be broken into small pieces resembling granules and administered directly under the patient's tongue. Tablets should not be crushed into a fine powder, as this may cause pasting in the mouth and actually slow absorption.

Buprenorphine/naloxone films should not be cut or divided (for example, halving a 2 mg film to achieve a 1 mg dose). Prescriptions for doses that cannot be achieved with the available dosage units (that is, a combination of 2 mg and 8 mg films) should be clarified with the prescriber.

When a dose is to be administered, all sachets should be opened and presented to the patient, who removes each film from its packaging to place in the mouth. Alternatively, all films may be removed from their sachets into an appropriate container (such as a transparent plastic medication cup) for the patient to place in the mouth.

## 4. Supervision of doses

A discreet location for the administration of supervised pharmacotherapy doses is best for patient confidentiality, but patients must not access the dispensary. To prevent possible diversion of the dose, directly supervise patients as they take the dose and engage them in conversation to ensure they have consumed the dose.

Diversion may be a higher risk with buprenorphine tablet formulations because the solid dose form requires an extended time for the full dose to dissolve and be absorbed. It is important that specific procedures to minimise the opportunities for patients to divert doses are in place.

The most likely point of detection of buprenorphine diversion is when a supervised dose is administered. Behaviour that is consistent with diversion of buprenorphine may include patients:

- removing buprenorphine from the mouth
- refusing to demonstrate buprenorphine dissolving in the mouth
- leaving the pharmacy rapidly after being administered the dose
- attending for buprenorphine with others then attempting to pass the medication on (for example, tongue kissing immediately after the dose)
- presenting with objects in the mouth to contain the buprenorphine
- suspicious activities with cups, drink bottles and various kinds of containers
- walking out of the pharmacy with their dosing container.

When patients commence treatment with buprenorphine tablets, it should be explained to them that they need to wait until the buprenorphine dose has been dissolved (between 3–10 minutes).

Buprenorphine/naloxone films adhere to mucous membranes within seconds and are difficult to remove after 30–60 seconds. Hence, under normal circumstances, supervision of a buprenorphine/naloxone film dose does not need to exceed one minute. Patients should be advised not to overlap films when placing them in the mouth, as this may delay adherence to the mucosa and extend the time required for supervision.

Doses can be administered in disposable containers or the pharmacy must have some appropriate means of sanitising glass or similar dosage vessels. Ensure a satisfactory standard of hygiene at all times.

Observe the patient for signs of drug toxicity, and do not dose patients who appear intoxicated.

## 5. Take-away doses

Only the prescriber may authorise take-away doses. The prescriber should authorise take-away doses in writing on the prescription, and details of that authorisation should be prominently located (for example, in the patient book).

Pharmacotherapy is primarily based on supervised dosing and take-away doses should only be authorised for stable, consistently attending patients. Where a patient frequently misses doses, the prescriber should be notified in order to review whether it is appropriate to continue take-away doses.

The policy for prescribers contains a section that describes indicators of stable treatment behaviour and shows the level of access to take-away doses of methadone or a combined buprenorphine/naloxone preparation. Progression to each level of access to take-away doses is not only based on the length of time in treatment. Prescribers are also required to assess the patient for stability and suitability for take-away doses using the *Checklist for assessing appropriateness of take-away doses* (Appendix 4). The prescriber should contact the pharmacy to confirm that recent behaviour and dose collection have been regular and stable, and that there is no concern that the dose may be misused.

Pharmacists may also use the assessment tool in Appendix 4 and forward it to the prescriber periodically to report on a patient's progress in treatment and suitability for take-away doses. Where there are immediate concerns about the appropriateness of take-away doses, the prescriber should be contacted directly.

To deter injection or consumption by another person (especially a child), each methadone take-away dose should be **diluted with water to a volume of 200 mL** and supplied in a container with a child-resistant closure. Take-away doses **should not be diluted with cordial**, as doses prepared in this manner may result in microbial growth of the solution.

Take-away dose bottles should not be re-used unless a satisfactory standard of hygiene can be met. If take-away dose bottles are being cleaned by the pharmacist for re-use, ensure that patients receive the same bottles that were previously provided to them.

There is no provision for routine take-away doses of buprenorphine, unless supplied as a combination with naloxone, except in pregnancy, when breastfeeding, when a clinically documented allergy to naloxone or to an inactive component of the film/tablet has been identified, or where there is no proprietary product available containing naloxone for certain doses (for example, for doses under 2 mg).

Patients who are authorised to receive buprenorphine/naloxone take-away doses should be transferred to the combination for all doses, including those administered under supervision.

**Note:** Buprenorphine is an unstable drug once exposed to air, and when supplied as a take-away dose it should be supplied in the original blister or foil pack.

As for all dispensed Schedule 8 poisons, labels must comply with the provisions of the Drugs, Poisons and Controlled Substances Regulations 2006. In addition, the following sentence: 'May cause death or injury if taken by another person', should be included on the label.

Each methadone take-away dose bottle should only contain a single dose of methadone. The following example includes the key requirements for labelling a methadone take-away dose of 40 mg daily.

**METHADONE SOLUTION  
containing 40 mg in 200 mL**

This bottle contains a single daily dose of methadone to be taken on 15 June 2015 by John Citizen.

Prepared on 14 June 2015

**KEEP OUT OF REACH OF CHILDREN**

Pharmacy Name

Address & Phone Number

Pharmacist ID

'This medication may cause drowsiness and may increase the effects of alcohol. If affected do not drive a motor vehicle or operate machinery.' (commonly on an ancillary label)

'May cause death or injury if taken by another person' (on an ancillary label or the main label)

Buprenorphine/naloxone take-away doses may be packaged individually to contain only a single dose of buprenorphine. The following example includes the key requirements for labelling a buprenorphine/naloxone take-away dose as a single dose of 22 mg daily.

**BUPRENORPHINE/NALOXONE FILM**

This container contains a single daily dose of 22 mg of buprenorphine to be taken by John Citizen. Take the contents of this container as a single dose dissolved under the tongue on 15 June 2015.

Prepared on 14 June 2015

**KEEP OUT OF REACH OF CHILDREN**

Pharmacy Name

Address & Phone Number

Pharmacist ID

'This medication may cause drowsiness and may increase the effects of alcohol. If affected do not drive a motor vehicle or operate machinery.' (commonly on an ancillary label)

'May cause death or injury if taken by another person' (on an ancillary label or the main label)

Alternatively, buprenorphine/naloxone take-away doses may be packaged for multiple days of unsupervised dosing. However, if the patient is required to take different strengths of films (that is, a combination of 2 mg and 8 mg films), the different strengths of films must be packaged separately. Ensure that the patient is aware of the dosing instructions for both strengths of film to achieve the correct daily dose of buprenorphine.

The following example contains the key requirements for the labelling of buprenorphine/naloxone take-away doses of 22 mg daily packaged in two separate containers for multiple days of unsupervised dosing.

**BUPRENORPHINE/NALOXONE FILM  
2 mg (Qty 9)**

Dissolve under the tongue THREE films each day.

To be taken on 15 June, 16 June and 17 June 2015 by John Citizen.

*(Please note: buprenorphine/naloxone 8 mg films are packaged separately)*

Prepared on 14 June 2015

**KEEP OUT OF REACH OF CHILDREN**

Pharmacy Name  
Address & Phone Number  
Pharmacist ID

'This medication may cause drowsiness and may increase the effects of alcohol. If affected do not drive a motor vehicle or operate machinery.' (commonly on an ancillary label)

'May cause death or injury if taken by another person' (on an ancillary label or the main label)

**BUPRENORPHINE/NALOXONE FILM  
8 mg (Qty 6)**

Dissolve under the tongue TWO films each day.

To be taken on 15 June, 16 June and 17 June 2015 by John Citizen.

*(Please note: buprenorphine/naloxone 8 mg films are packaged separately)*

Prepared on 14 June 2015

**KEEP OUT OF REACH OF CHILDREN**

Pharmacy Name  
Address & Phone Number  
Pharmacist ID

'This medication may cause drowsiness and may increase the effects of alcohol. If affected do not drive a motor vehicle or operate machinery.' (commonly on an ancillary label)

'May cause death or injury if taken by another person' (on an ancillary label or the main label)

Clearly record details of take-away doses in the patient book and the administration records. Patients should be advised to store their take-away doses in a secure place out of the reach of children and other drug users. Take-away doses do not need to be refrigerated. Advise patients that placing take-away doses in the fridge creates risk of a dose being taken by children or other household members.

It is essential to establish with the patient arrangements for safe and secure storage to prevent unintentional poisoning of children or misuse of a take-away dose by another person. In some circumstances a lockable box might be considered appropriate for safe and secure storage.

Given that methadone or buprenorphine may be fatal or cause serious harm if ingested by opiate-naïve individuals, the reasons why take-away doses need to be safely and securely stored at all times should be discussed with patients.

Patients should be reminded that the only time a take-away dose should be removed from safe storage is immediately prior to consuming the take-away dose.

Take-away doses that are claimed to have been lost or stolen must not be replaced unless the prescriber's written authorisation has been obtained. However, pharmacists should exercise their own professional judgment about the safety and appropriateness of providing replacement doses even if given authorisation by the prescriber to do so.

#### Split dosing of methadone

When methadone is being prescribed as a split dose (for example, twice a day dosing), on the days where the patient attends for supervised dosing of the first half-dose of methadone at a pharmacy, the second half-dose may be supplied as a take-away dose if authorised by the prescriber.

When split doses of methadone are to be supplied as take-away doses for the days where the patient is not attending the pharmacy, the first dose and second dose of methadone should each be supplied in separate take-away dose bottles. Ensure that the day and timing of each dose is clearly indicated on the label. For example, if the prescriber has authorised three (3) days of unsupervised dosing for twice a day dosing, six (6) take-away doses should be supplied. All doses should be diluted to 200 mL with water.

#### 6. Patients who are new to pharmacotherapy

During the initial stabilisation period, methadone blood levels take some days to plateau. There is a significantly greater risk of toxicity due to lack of recognition of the long half-life of methadone and the possibility of concurrent polydrug use. If the initial dose exceeds 40 mg, the prescriber should be consulted before administration. If there are concerns, the pharmacist and/or prescriber may need to discuss the case with the DACAS.

Buprenorphine is generally safer than methadone during the induction phase, but the risk of polydrug use still requires caution while the maintenance dose is being established.

The prescriber should have advised the patient about the risks of polydrug use and other related risks (for example, impairment of their ability to drive). However, when interviewing a prospective patient, ensure the patient has been suitably informed of these risks, and reinforce them.

## 7. Transfer of pharmacotherapy patients

When accepting a patient who has been previously managed at another location, contact that pharmacy to confirm the date and amount of the final dose (including any take-away doses). Do not only rely on the information from the patient or prescriber, but confirm all relevant information directly with the previous pharmacy, preferably by fax or email (Appendix 14).

Transfer between pharmacies may create risks for the patient, for example:

- double dosing on the same day may cause severe toxicity
- a patient who has missed doses on four (4) or more consecutive days will have reduced tolerance for opioids, causing a risk of potentially dangerous opioid toxicity.

### Before administering a dose to a transferred patient

Contact the previous pharmacy to confirm the dose and verify precisely when the last dose was given. It is recommended that written confirmation of this information be sought (Appendix 14).

Ensure a current prescription and recent photograph of the patient (endorsed by the prescriber) is held.

## 8. Temporary absences

Some patients may be admitted to hospital, taken into police custody or temporarily transferred to another pharmacy. On these occasions the pharmacy to which the patient has been transferred should contact the usual pharmacy to confirm details (including the amount of the last dose and when it was consumed).

When patients are discharged from hospital, released from custody or wish to return to their usual pharmacy, there may have been a change in prescriber, a change in the patient's medication regimen or a period in which doses were not administered. The prescriber may not be

fully aware of all details, so confirm the relevant information with the previous pharmacy and pass any extra information on to the prescriber. Inaccurate or incomplete information could result in a patient receiving an excessive, and possibly toxic, dose or an insufficient dose for adequate maintenance.

## 9. Irregular attendance

Regular attendance leads to less fluctuation in pharmacotherapy levels and greater patient stability. Irregular attendance may be indicative of illicit drug use or a patient's need for counselling or review.

A single missed dose may not be significant but the prescriber should be advised when a patient attends irregularly for pharmacotherapy doses.

Take-away doses should only be authorised for stable, consistently attending patients. If a patient is observed to be frequently missing doses, the prescriber should be notified in order to review the appropriateness of continuing take-away doses.

## 10. Multiple missed doses

If a patient attends after missing methadone or buprenorphine doses on four (4) or more consecutive days, do not administer further doses without the prescriber's expressed authorisation. The prescriber may wish to review the patient. The patient's loss of tolerance to the pharmacotherapy or renewed risk of precipitated withdrawal may mean the prescriber will wish to reduce the dose, so a new prescription will be required. Notify the prescriber if a patient ceases attending for doses.

## 11. Possible intoxication

Given the risk of overdose or drug interaction, a dose should not be administered if a patient appears to be intoxicated.

Common signs of intoxication or toxicity are:

- slurred speech
- unsteady gait
- drowsiness
- pupil constriction
- shallow breathing.

In such circumstances, contact the prescriber immediately for instructions before dosing. Where the prescriber is unavailable, seek advice from DACAS.

It may be necessary to consider one or more of the following:

- instruct the patient to return later in the day (mild intoxication)
- instruct the patient to consult the prescriber (moderate intoxication)
- instruct the patient to attend a hospital (severe intoxication)
- administer a reduced or placebo dose (when the patient refuses to accept advice).

**Note:** A prescription represents authorisation to administer, but exercise professional judgment about the appropriateness of dosing in situations where safety is uncertain or there appears to be a risk of overdose. The pharmacist administering the dose has the final word. An authorised dose should only be administered if it is safe to do so.

## 12. Termination of treatment

Most treatment terminations are patient initiated, although involuntary termination may occur as a result of unacceptable behaviour. If treatment is to be terminated, abrupt cessation of pharmacotherapy should be avoided if possible. Patients discharged from treatment should be advised of other treatment options, the likely loss of tolerance and the risk of overdose.

A particular patient's dosing may be terminated because of failure to comply with the agreement made when treatment commenced. An attempt should be made to resolve the problem with the patient or by contacting the PAMS service.

Advise the prescriber if it is intended to cease treatment. Also, advise the patient of the intention to cease dosing, to allow time to enable arrangement of an alternative pharmacy. The patient may be referred to another pharmacy, or the prescriber or DirectLine may be requested to make a referral.

## 13. Pharmacy discontinuing pharmacotherapy services

Pharmacies intending to discontinue pharmacotherapy services should prepare a contingency plan to transfer their existing patients to other providers.

When discontinuing a pharmacy practice, it is professionally responsible to:

- give advance notice to patients
- make arrangements for the continuing medical care of all current patients, including the transfer or appropriate management of all patient records.
- notify Prevention, Population, Primary and Community Health at Department of Health and Human Services (Appendix 2).

DirectLine and the PAMS service may provide assistance with patient transfers to other pharmacotherapy providers.

## 14. Area-Based Pharmacotherapy Networks

Pharmacies are encouraged to contact their local Area-Based Pharmacotherapy Network, as Networks offer support and mentoring to dispensers.

More information on the role of the Networks and contact details can be found at Appendix 15.

# Appendices

## Appendix 1: Starting methadone or buprenorphine

### Starting methadone or buprenorphine

#### **Methadone or buprenorphine can help you deal with heroin or opioid use problems.**

- They are not a cure for heroin or opioid dependence, but help manage your drug use.
- You can reduce or stop injecting and reduce the risk of getting HIV and hepatitis.

You will have better control over your drug use, so there will be more time for other areas of your life.

**Arrangements:** you need to have one prescriber (a medical practitioner or nurse practitioner) and one pharmacy for methadone or buprenorphine treatment. You need to:

- see your prescriber regularly during the first few weeks, once or twice a week, until your dose holds you and you feel comfortable
- visit your pharmacy every day to pick up your dose when starting treatment.

**DirectLine:** provides a 24-hour telephone counselling and referral service to help you locate a pharmacy or prescriber providing methadone and buprenorphine or other related services.

**DirectLine: 1800 888 236**

For more information about methadone or buprenorphine treatment, ask your prescriber or pharmacist for a user information booklet.

**Never leave a methadone patient to 'sleep it off'**  
**Call an ambulance immediately:**  
**Dial 000**

#### **Methadone:**

- Your prescriber will start you on a low dose.
- Methadone is started low for safety.
- Your dose will then be increased slowly until you are comfortable.
- One dose is usually effective for 24 hours.

#### **Buprenorphine and buprenorphine/naloxone:**

- Doses of buprenorphine may increase rapidly as there is a lower risk of overdose than methadone.
- You will need to wait until you get symptoms of withdrawal (such as goosebumps, sweats, shivering, aches, watery nose and eyes) before starting buprenorphine.
- If you start buprenorphine too soon after last using heroin or another opioid you may suffer unpleasant withdrawal symptoms.

**Caution:** methadone and buprenorphine are sedating drugs like heroin - **you can overdose on them.**

- Overdose risk is higher when you are also taking drugs like painkillers, anxiety medications (benzodiazepines), anti-depressants or some other drugs (check with your doctor).
- Do not take medications without your prescriber's or pharmacist's advice.
- Taking methadone or buprenorphine with alcohol increases sedating effects and risk of overdose.

**IMPORTANT: The risk of overdose is highest in the first 14 days of treatment.**

Use of other sedating drugs also adds to the risk.

Learn the symptoms of drug overdose and tell your friends to watch for them and help you if necessary.

Talk to your prescriber or pharmacist **straight away** if you have slurred speech, feel drowsy, can't stand up, or are 'out of it' and confused.

## Overdose warning

There is a danger of overdose and death if other drugs that depress or sedate brain activity are taken in unsupervised quantities with methadone or buprenorphine.

The drugs to avoid are:

- alcohol
- heroin
- painkillers – opioid painkillers (including codeine, dextropropoxyphene, fentanyl, hydromorphone, morphine, oxycodone, pethidine, tapentadol, tramadol)
- tranquillisers – benzodiazepines (including alprazolam, clonazepam, diazepam, flunitrazepam, nitrazepam, oxazepam, temazepam)
- combinations of any of these.

Your prescriber may prescribe some sedating drugs to relieve unpleasant symptoms, but it is important that you take them only in quantities specified. Higher doses and uncontrolled combinations of drugs and alcohol with methadone or buprenorphine cause several deaths each year in Victoria.

**Mixing drugs and alcohol with methadone or buprenorphine is dangerous.**

## Overdose symptoms

'Overdose' usually involves the use of other sedating drugs (tranquillisers, sleeping pills, alcohol or heroin).

**The risk of overdose is highest in the first two weeks of treatment.**

If you experience the overdose symptoms described here, don't take another dose until you have discussed it with your prescriber.

**Symptoms vary from person to person and may include one or more of the following:**

### Stage one: Talk to the prescriber or pharmacist without delay

- slurred speech
- unsteady walking and poor balance
- drowsiness
- slowed movement, slow eating
- stupor ('out of it', confused)
- nodding off for prolonged periods.

### Naloxone injection for overdose prevention

Naloxone injection can reverse the effects of a methadone overdose – in an emergency, naloxone could save a person's life.

It is important to go to hospital after being given naloxone because it only acts for a short time, and methadone lasts for many hours. An ambulance should be called so that you can be observed safely in hospital.

Talk to your prescriber about naloxone for you. Keep naloxone in a place where friends or family can access it in case of an overdose.

For more information, including how to use naloxone and how to recognise and respond to an overdose, go to: <http://www copeaustralia com au>

### Stage two: Coma – serious emergency

- cannot be roused, unresponsive, can't be woken
- snoring, gurgling or spluttering when breathing
- slow or shallow breathing, or not breathing
- floppy limbs and neck
- blue lips and fingers
- clammy skin, pale
- eyes rolling back.

**Call an ambulance immediately and never leave the person to 'sleep it off'. Mouth-to-mouth resuscitation may be needed if the person is not breathing properly.**

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Please note: this information sheet is also available in Arabic, Burmese, Chinese, Dinka, Farsi, Greek, Italian, Khmer, Macedonian, Serbian, Spanish, Turkish and Vietnamese

## Appendix 2: Contacts

### Drugs and Poisons Regulation, Department of Health and Human Services

Issues permits for prescribers to treat a patient with pharmacotherapy and may also approve health service permits to supply pharmacotherapies.

GPO Box 4057  
Melbourne 3001  
Tel: 1300 364 545  
Fax: 1300 360 830  
Email: [dpcs@dhhs.vic.gov.au](mailto:dpcs@dhhs.vic.gov.au)  
Web: [www.health.vic.gov.au/dpcs](http://www.health.vic.gov.au/dpcs)

### Prevention, Population, Primary and Community Health, Department of Health and Human Services

Provides permission and information for individual medical practitioners, nurse practitioners and pharmacies who wish to prescribe or supply pharmacotherapies.

Tel: 9096 5057  
Fax: 9096 9170  
Web: [www.health.vic.gov.au/alcohol-and-drugs](http://www.health.vic.gov.au/alcohol-and-drugs)

### DirectLine

For the general public and health and welfare professionals, the service provides counselling, information and referral, including:

- pharmacotherapy contact details
- details of residential rehabilitation programs for slow-stream pharmacotherapy withdrawal
- details of needle syringe programs and bin locations
- details of drug and alcohol agencies and drug withdrawal beds
- HIV/AIDS information and referral
- drink driving education and assessment referral.

Tel (toll free): 1800 888 236 (24 hour service)  
Web: [www.directline.org.au](http://www.directline.org.au)

### Drug and Alcohol Clinical Advisory Service (Dacas)

Exclusively for health and welfare professionals, the service provides advice and information on the clinical management of patients with drug and/or alcohol problems, including:

- advice on recognising and managing withdrawal symptoms
- information about drug use complications
- drug information
- prescribing information
- assistance with cases of acute intoxication.

Tel (toll free): 1800 812 804 (24-hour service)  
Web: [www.dacas.org.au](http://www.dacas.org.au)

### Pharmacotherapy, Advocacy, Mediation and Support Service (PAMS)

PAMS is a service available to pharmacotherapy clients, prescribers or pharmacists to help resolve problems with accessing or delivery of pharmacotherapy. PAMS will assist in mediating outcomes to these problems and service providers are encouraged to contact PAMS before deciding to withdraw service provision to particular clients.

Phone: 1800 443 844 or (03) 9329 1500  
Web: [www.hrvic.org.au/pharmacotherapy](http://www.hrvic.org.au/pharmacotherapy)

### Area-Based Pharmacotherapy Networks

The five area-based pharmacotherapy networks throughout Victoria ensure a more local approach in connecting care, driving best practice and improving pharmacotherapy client outcomes. The Networks offer ongoing support and mentoring to providers. For further information, please see Appendix 15.

#### Area 1: Barwon South West Pharmacotherapy Network

Tel: (03) 5564 5888  
Fax: (03) 5564 5800  
Web: [www.westvicphn.com.au/health-professionals/alcohol-and-other-drugs/pharmacotherapy](http://www.westvicphn.com.au/health-professionals/alcohol-and-other-drugs/pharmacotherapy)

## **Area 2: ORTicare- Grampians and Loddon Mallee Pharmacotherapy Network**

Tel: (03) 5564 5888  
Fax: (03) 5564 5800  
Web: [www.bchc.org.au/services/pharmacotherapy-network](http://www.bchc.org.au/services/pharmacotherapy-network)

## **Area 3: Gippsland and Hume Pharmacotherapy Network**

Gippsland  
Tel: 1800 242 696  
Fax: (03) 5136 5475  
Web: [www.lchs.com.au](http://www.lchs.com.au)

Hume  
Tel: (03) 5823 3219  
Fax: (03) 5823 3299  
Web: [www.hapn.org.au](http://www.hapn.org.au)

## **Area 4: South and Eastern Metropolitan Pharmacotherapy Network**

Tel: (03) (03)9525 7399  
Fax: (03) 5823 3299  
Web: [www.semphn.org.au](http://www.semphn.org.au)

## **Area 5: North West Metropolitan Pharmacotherapy Network**

Tel: (03)9362 8100  
Fax: (03) 9362 8180  
Web: [www.cohealth.org.au/pharmacotherapy](http://www.cohealth.org.au/pharmacotherapy)

## **Harm Reduction Victoria (HRVic)**

Provides a wide range of information on drugs as well as peer support and education, referrals and advocacy to drug users, while promoting harm reduction to users and the community.

Tel: (03) 9329 1500  
Fax: (03) 9329 1501  
Web: [www.hrvic.org.au](http://www.hrvic.org.au)

## **Health Services Commissioner**

The Office of the Health Services Commissioner is an independent body established to receive and resolve complaints about health service providers. The Office also handles complaints

about disclosure of health information and access to health information.

Tel: 1300 582 113  
Fax: (03) 9032 3111  
Web: [www.health.vic.gov.au/hsc/index.htm](http://www.health.vic.gov.au/hsc/index.htm)

## **Hepatitis C and HIV/AIDS information outlets**

### **Hepatitis Victoria**

Suite 5, 200 Sydney Road  
Brunswick 3056  
Tel: (03) 9380 4644  
Fax: (03) 9380 4688  
Hepatitis Info Line: 1800 703 003  
Web: [www.hepcvic.org.au](http://www.hepcvic.org.au)

### **Melbourne Sexual Health Centre**

580 Swanston Street  
Carlton 3053  
Tel: (03) 9341 6200 or 1800 032 017  
(toll free outside Melbourne metropolitan area)  
Fax: (03) 9341 6279  
HIV Clinic: (03) 9341 6214 (for HIV positive people only)  
Web: [www.mshc.org.au](http://www.mshc.org.au)

### **Department of Health and Human Services**

*Hepatitis C - the facts*  
Web: [ideas.health.vic.gov.au/diseases/hepatitis-c.asp](http://ideas.health.vic.gov.au/diseases/hepatitis-c.asp)

### **Needle and Syringe Programs (NSPs)**

Further information and contact details of NSPs are available from the department.  
Web: [www.health.vic.gov.au/aod/about/needle.htm](http://www.health.vic.gov.au/aod/about/needle.htm)  
DirectLine (tel: 1800 888 236)

## **Prescription Shopping Information Service (PSIS), Medicare Australia**

Medicare Australia provides information about pharmaceutical benefits obtained via the PSIS. PSIS may be able to assist medical practitioners identify whether their patients are obtaining PBS drugs from other prescribers in excess of medical need. Prescribers must be registered with the service before information can be provided to

them. They can inquire by telephone and request a print-out of the patient's details. Forms and explanatory letters are available from Medicare Australia.

Tel: (toll free): 1800 631 181 (24 hour service)  
Web: [www.humanservices.gov.au/health-professionals/services/prescription-shopping-information-service/](http://www.humanservices.gov.au/health-professionals/services/prescription-shopping-information-service/)

### **Specialist Pharmacotherapy Services**

Provide a consultative service to pharmacotherapy prescribers seeking expert opinion about the management of patients with special problems, such as psychiatric, social, medical or treatment problems. Prescribers may refer patients by arrangement or seek advice by contacting the service.

### **Eastern Health Turning Point**

**Alcohol and Drug Centre**  
54-62 Gertrude St  
Fitzroy 3065  
Tel: (03) 8413 8413  
Fax: (03) 9416 3420  
Web: [www.turningpoint.org.au](http://www.turningpoint.org.au)

### **Eastern Health Alcohol and Drug Services**

Ground Floor, 43 Carrington Road  
Box Hill 3128  
Tel: (03) 9843 1288  
Fax: (03) 9843 1266  
Web: [www.easternhealth.org.au](http://www.easternhealth.org.au)

### **Austin Health Drug Dependency Clinic**

Studley Road  
Heidelberg 3084  
Administration line: (03) 9496 5000  
Fax: (03) 9459 4546  
Web: [www.austin.org.au](http://www.austin.org.au)

### **Southcity Clinic**

3/607 St Kilda Road  
Melbourne 3004  
Tel: (03) 9525 7399  
Fax: (03) 9525 7369  
Web: [www.southcityclinic.com.au](http://www.southcityclinic.com.au)

### **Western Health Drug Health Services**

3-7 Eleanor St  
Footscray 3011  
Tel: (03) 8345 6682  
Fax: (03) 8345 6027  
Web: [www.wh.org.au](http://www.wh.org.au)

### **Treatment of pregnant patients**

Specialist services are available for pregnant women with drug and alcohol issues.

### **Royal Women's Hospital**

Women's Alcohol and Drug Service (WADS)  
Cnr Grattan Street and Flemington Road Parkville  
3052  
Tel: (03) 8345 3931  
Fax: (03) 8345 2996

### **Mercy Health - Mercy Hospital for Women**

Transitions Clinic  
Studley Road  
Heidelberg 3084  
Tel: (03) 8458 4444

### **Barwon Health - Geelong Hospital**

Maternity Services - Chemical Dependency Unit (CDU)  
Ryrie St  
Geelong 3220  
Tel: (03) 4215 2088  
Fax: (03) 4215 2086

### **Eastern Health - Angliss Hospital**

Specialised Maternity Service  
Albert Street  
Ferntree Gully 3156  
Tel: (03) 9764 6292  
Fax: (03) 9764 6193

### **Eastern Health - Box Hill Hospital**

Birralee Maternity Service – Access Clinic  
Nelson Road  
Box Hill 3128  
Tel: (03) 9895 4641

**Peninsula Health - Frankston Hospital**

Speciality Midwife Clinic  
Hastings Road  
Frankston 3199  
Tel: (03) 9784 7455

**Southern Health - Monash Medical Centre**

Alcohol, Drugs and Pregnancy Team (ADaPT)  
Clayton Road  
Clayton 3168  
Tel: (03) 9594 5628  
Fax: (03) 9594 5607

**Western Health – Sunshine Hospital**

Maternity Outreach and Support Service (MOSS)  
Furlong Road  
St Albans 3021  
Tel: (03) 8345 1680  
Fax: (03) 8345 1055

**Youth Drug and Alcohol Advice Line  
(YoDAA Line)**

Available 24 hours to provide free and confidential advice about drugs and alcohol. The service is open to young people, their families, health and welfare workers, police and ambulance officers.

Tel (toll free): 1800 458 685 (24 hour service)  
Web: [www.yodaa.org.au](http://www.yodaa.org.au)

**Youth Support and Advocacy Service  
(YSAS)**

The service provides information, outreach and residential services for young people aged 12 to 21 years who are experiencing significant problems related to their use of drugs and/or alcohol.

Level 1, 131 Johnston St  
Fitzroy 3065  
Tel: (03) 9415 8881  
Fax: (03) 9415 8882  
Web: [www.ysas.org.au](http://www.ysas.org.au)

## Appendix 3: Features of a pharmacotherapy prescription

Dr William Pacemaker 123 Medical Street Ash Park VIC 3999 Tel: (03) 1234 5678	< Prescriber's name, address, contact details
Mr Barry Patient 88 Luck Street Forktown VIC 3131	< Patient's name
01/07/2015	< Date of prescription written
Rx Methadone Syrup	< Prescription written is legible and durable
60 (sixty) mg daily	< Dose in words and figures
from: 1 July 2015	< Date of first dose on this prescription
last dose: 31 July 2015	< Date of last dose on this prescription
take-away doses for Saturdays and Sundays	< Take-away doses (if authorised)
Rx Methadone Syrup 60 (sixty) mg daily from: 1 July 2015 last dose: 31 July 2015 take-away doses for Saturdays and Sundays	< For computer-generated prescription, particulars of prescription also handwritten
To be dispensed at: Mortarpestles Pharmacy 125 Fourth Street, Splotswood	< Pharmacy at which pharmacotherapy is to be supplied
William Pacemaker	< Signature

## Appendix 4: Checklist for assessing appropriateness of take-away doses

### Checklist for assessing appropriateness of take-away doses

Patient name:

Date of birth: / /

(Mark  each box that applies)

Review date: / /

The misuse of take-away doses by patients or others who have gained access to another person's take-away doses has contributed to a number of deaths in Victoria.

The supply of take-away doses is a significant clinical decision that requires thorough consideration of the risks and benefits. Prescribers should use this assessment tool when reviewing a patient to assess the appropriateness of take-away doses. Pharmacists may also use this assessment tool to provide treatment updates to the prescriber. **Follow steps 1 to 4 in sequential order.**

**There are increased risk and safety concerns for the patient and others if ANY of the following contra-indications are observed within the last 3 months:**

#### 1. ABSOLUTE CONTRA-INDICATIONS

Overdose reported to any substance	<input type="checkbox"/>
Reported diversion of doses to others, sharing or trading doses	<input type="checkbox"/>
No safe and secure storage facility available	<input type="checkbox"/>
Concerns about risk of harm to self or others	<input type="checkbox"/>

**STOP: DO NOT SUPPLY TAKE-AWAY DOSES IF ANY ABSOLUTE CONTRA-INDICATIONS HAVE BEEN OBSERVED.**

#### 2. RELATIVE CONTRA-INDICATIONS

<b>Attendance at medical/case manager reviews</b> Irregular attendance missed ≥1 in 4 appointments	<input type="checkbox"/>
<b>Missed doses</b> Missed doses (confirmed with pharmacist) missed ≥1 dose per week	<input type="checkbox"/>
<b>Provision of urine drug screens (UDS)</b> UDS not provided on request or reveals unsanctioned drug use	<input type="checkbox"/>
<b>Unsanctioned use of other drugs</b> Reported misuse of prescription medicines, alcohol or illicit drugs Evidence of recent injecting sites Intoxicated presentations at medical clinic or pharmacy	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
<b>Concerns about misuse of take-away doses</b> Reported use of take-away doses in advance Reported hoarding or 'stockpiling' of take-away doses Reported lost or stolen take-away doses	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
<b>Accommodation</b> No stable accommodation Persons with histories of drug misuse are present or likely to visit the home	<input type="checkbox"/> <input type="checkbox"/>
<b>Physical and mental state assessment</b> Concerns about other medical condition (e.g. severe liver or respiratory disease)	<input type="checkbox"/>

**Caution: If any relative contra-indications have been observed, prescribers should discuss the appropriateness of take-away doses with the pharmacist if take-away doses are still being considered.**

### Checklist for assessing appropriateness of take-away doses (cont.)

#### 3. REASONABLE NEED

A reasonable need for take-away doses should be established when considering take-away doses.

At least one of the following should be present:

Work, study or family commitments where daily attendance at a pharmacy is not possible	<input type="checkbox"/>
Living in a rural or remote area where daily travel to a pharmacy is difficult	<input type="checkbox"/>
Significant medical condition restricting ability to attend a pharmacy on a daily basis	<input type="checkbox"/>
Urgent travel where alternative arrangements for supervised dosing cannot be organised	<input type="checkbox"/>
Incentive and reward for stability and progress in treatment	<input type="checkbox"/>

Caution: If no reasonable need is established, prescribers should discuss the appropriateness of take-away doses with the pharmacist if take-away doses are still being considered.

**ENSURE STEPS 1 TO 3 OF THE ASSESSMENT HAVE BEEN COMPLETED BEFORE PROCEEDING TO STEP 4.**

#### 4. CONTINUOUS PERIOD OF STABILITY

Supply of take-away doses may be considered after a continuous period of stability in treatment.

The following schedule is recommended.

METHADONE	
< 3 MONTHS	No take-away doses
3 MONTHS – 6 MONTHS	Zero (0) to two (2) take-away doses per week
> 6 MONTHS	Zero (0) to four (4) take-away doses per week, with no single supply exceeding three (3) take-away doses

BUPRENORPHINE/NALOXONE	
< 2 WEEKS	No take-away doses
2 WEEKS – 2 MONTHS	Zero (0) to two (2) take-away doses per week
2 MONTHS – 6 MONTHS	Zero (0) to five (5) take-away doses per week
> 6 MONTHS	Zero (0) to six (6) take-away doses per week

**Caution:** Prescribers considering varying from this schedule are strongly advised to discuss with the pharmacist regarding the patient's stability in treatment and suitability for take-away doses. Mutually agreed treatment decisions should be reached and documented.

If take-away doses are supplied, prescribers should consider advising patients to carry naloxone injection with them and provide education on its use and how to recognise and respond to an opioid overdose.

Comments: (e.g. overall assessment, matters for follow-up at the next review)

Review conducted by: \_\_\_\_\_ (prescriber / pharmacist)

If the review has been conducted by the pharmacist, forward the assessment to the prescriber.  
Contact the prescriber if there are immediate risks and safety concerns to the patient or to others.

Date of next review: \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_

## Appendix 5: Patient agreement form: methadone take-away doses

### Patient agreement form: methadone take-away doses

Patient name: \_\_\_\_\_

Date of birth: \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_

**Methadone is an effective medicine when used in a safe and responsible way. However, when used inappropriately, methadone may cause serious harm or even death. The Victorian Coroners Court identified that from 2010 to 2013 there were 147 Victorian deaths involving a methadone take-away dose (in 89 of these deaths people took their own take-away dose, in 58 deaths the person took someone else's take-away dose).**

**This agreement is about safety with take-away doses, it's about YOU taking responsibility for the take-away doses prescribed for YOU, to protect the safety of yourself and others.**

1. I understand that my methadone dose is prescribed for me only, based on my level of opioid tolerance. If somebody else takes my dose, they could overdose or even die.
2. I know that take-away doses are not an automatic right.
3. I understand that take-away doses are only provided to me if my prescriber has assessed that I am stable and there is a legitimate need (such as being unable to attend the pharmacy due to work or study commitments, urgent travel or the pharmacy is closed).
4. I understand that the number of take-away doses I receive can be decreased or removed by my prescriber (in consultation with my pharmacist and myself) when there are verified concerns about my ability to manage my take-away doses safely or responsibly.
5. I understand that it is important not to share my take-away dose of methadone with anyone because of the risk of overdose.
6. I understand that it is important to store my take-away doses safely. Safe storage of take-away doses includes:
  - not leaving take-away doses unattended in cars, public transport, planes, public areas, etc.
  - not leaving take-away doses where someone else can see or access them (e.g. not in the fridge, in a bag, on a shelf or bench-top)
  - making sure take-away doses are locked away (e.g. in a cupboard, drawer, cash box or safe)
  - keeping take-away doses out of reach of children at all times.
7. I agree to take full responsibility for all take-away doses that are supplied to me and I understand that lost or stolen take-away doses or take-away doses used in advance may not be replaced.
8. If I am prescribed naloxone, I understand that I will need to learn how to use it to reverse a possible opioid overdose (including methadone).
9. I understand that my prescriber may reduce or stop prescribing take-away doses to me if I do not comply with any part of this agreement.

Patient signature: \_\_\_\_\_

Date: \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_

If you have any questions or concerns about treatment, if you are experiencing a problem, if you need independent advice or support, or feel you are being unfairly treated by your pharmacotherapy service providers – the Pharmacotherapy Advocacy, Mediation and Support (PAMS) service is available on 1800 443 844 (open from 10am-6pm, Monday to Friday).

Prescriber: \_\_\_\_\_

Date: \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_

## Appendix 6: Patient agreement form: buprenorphine/naloxone take-away doses

### Patient agreement form: buprenorphine/naloxone take-away doses

Patient name:

Date of birth: / /

Buprenorphine is an effective medicine when used in a safe and responsible way. However, when used inappropriately, there are risks of harm or death. Injection of buprenorphine and use together with benzodiazepines has been associated with a number of Victorian drug deaths. Injection of buprenorphine that has been in someone's mouth has led to several cases in Victoria of a fungal infection in the eye that causes loss of vision or blindness. Injection of preparations intended to be taken by mouth causes a risk of vein damage.

This agreement is about safety with take-away doses, it's about YOU taking responsibility for the take-away doses prescribed to YOU, to protect the safety of yourself and others.

1. I understand that my buprenorphine dose is prescribed for me only, based on my level of opioid tolerance. If somebody else takes my dose, they could overdose or even die.
2. I know that take-away doses are not an automatic right.
3. I understand that take-away doses are only provided to me if my prescriber has assessed that I am stable and there is a legitimate need (such as being unable to attend the pharmacy due to work or study commitments, urgent travel or the pharmacy is closed).
4. I understand that the number of take-away doses I receive can be decreased or removed by my prescriber (in consultation with my pharmacist and myself) when there are verified concerns about my ability to manage my take-away doses safely or responsibly.
5. I understand that it is important not to share my take-away dose with anyone because of the risk of overdose or other harm.
6. I understand that it is important to store my take-away doses safely. Safe storage of take-away doses includes:
  - not leaving take-away doses unattended in cars, public transport, planes, public areas, etc.
  - not leaving take-away doses where someone else can see or access them (e.g. not in the fridge, in a bag, on a shelf or bench-top)
  - making sure take-away doses are locked away (e.g. in a cupboard, drawer, cash box or safe)
  - keeping take-away doses out of reach of children at all times.
7. I agree to take full responsibility for all take-away doses that are supplied to me and I understand that lost or stolen take-away doses or take-away doses used in advance may not be replaced.
8. If I am prescribed naloxone, I understand that I will need to learn how to use it to reverse a possible opioid overdose.
9. I understand that my prescriber may reduce or stop prescribing take-away doses to me if I do not comply with any part of this agreement.

Patient signature: \_\_\_\_\_

Date: / /

Prescriber: \_\_\_\_\_

Date: / /

If you have any questions or concerns about treatment, if you are experiencing a problem, if you need independent advice or support, or feel you are being unfairly treated by your pharmacotherapy service providers – the Pharmacotherapy Advocacy, Mediation and Support (PAMS) service is available on 1800 443 844 (open from 10am-6pm, Monday to Friday).

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Please note: this form is also available in Arabic, Burmese, Chinese, Dinka, Farsi, Greek, Italian, Khmer, Macedonian, Serbian, Spanish, Turkish and Vietnamese

## Appendix 7: Certification of pharmacists administering doses

All pharmacists involved in the administration of pharmacotherapies should review the following information relating to pharmacotherapy and the principles for administering pharmacotherapy.

### Principles of pharmacotherapy administration

#### 1. Ensure positive identification of the patient before administering a dose.

Refer to the patient's photograph, which the prescriber has endorsed.

#### 2. Ensure the dose is prepared as authorised by the prescriber.

Examine the prescription to verify the dose and ensure the prescription is current.

#### 3. Determine that it is safe to administer a dose.

Determine precisely when the previous dose was administered, contacting the previous pharmacy when necessary. Do not dose if the patient has missed doses on four (4) or more consecutive days. Also, assess the patient for signs of possible intoxication.

#### 4. Ensure the dose is consumed with no possibility of diversion.

Observe that the patient takes the dose and have the patient speak to demonstrate that the dose has been taken.

#### 5. Ensure the prescriber is advised of irregularities in a patient's attendance, behaviour or condition.

Contact the prescriber and record details of the communication. Take a proactive role in interactions with pharmacotherapy prescribers.

#### 6. Ensure the necessary information is readily available to all pharmacists administering doses.

Ensure patient records, records of administration and details of communications with the prescriber are clearly and consistently

maintained. Also, ensure the Victorian pharmacotherapy policy is readily available for reference.

Refer to the policy for pharmacists on administration of pharmacotherapies for more information and specific examples relating to the supply and administration of methadone and buprenorphine to patients in Victoria.

In circumstances not specifically covered by the policy:

- contact the prescriber or DACAS for instructions or clinical advice (tel: 1800 812 804)
- refer to the *National guidelines for medication-assisted treatment of opioid dependence* for further information on treatment procedures
- contact Drugs and Poisons Regulation for advice about the policy or legislation (tel: 1300 364 545)
- address the situation in accordance with the above principles.

### Information relating to pharmacotherapy

#### About pharmacotherapy

Drug addiction is a chronic relapsing condition.

More than one period of treatment may be necessary before a patient's circumstances and condition may be considered stable.

Abstinence from illicit drug use may be one goal of treatment, but it is accepted that some patients will continue to inject heroin and use other drugs. As concurrent use of pharmacotherapy with such drugs may represent a risk to the patient, professionals need to be alert to symptoms of intoxication or toxicity.

Pharmacotherapy maintenance represents a relatively long-term commitment (usually expressed in years) for patients attempting to break with the routines and habits associated with the acquisition and use of illicit drugs.

It is a common misunderstanding that lower doses of pharmacotherapy are better for the patient, as

with other drugs. Evidence indicates that longer treatment programs and higher maintenance doses are generally more effective in achieving treatment outcomes such as decreased illicit drug use. It is therefore important that the patient is not encouraged to seek a lower maintenance dose or reduce their pharmacotherapy dose prematurely without consulting the prescriber. It is important that the patient receives consistent advice from all healthcare providers.

When pharmacotherapy is to be discontinued, the dose should be reduced gradually over an extended period.

#### **About methadone**

Following ingestion, blood levels rise for about four hours and then begin to fall.

After a single initial dose, methadone is distributed into the body tissues and the apparent half-life (approximately 15 hours) is shorter than that which applies during a period of extended treatment.

After successive daily doses, methadone blood levels equilibrate with the levels in body tissues and the half-life progressively increases until it reaches a mean of 25 hours. Once-daily dosing should then be sufficient to maintain a stable patient. Methadone has a low therapeutic index (overlap of toxic and therapeutic blood levels), so a double dose can be fatal.

#### **About buprenorphine**

Buprenorphine is a partial agonist poorly absorbed when swallowed. Pharmacotherapy for opioid dependence is administered by the sublingual route.

Buprenorphine has strong affinity for opioid receptors, which explains its long duration of action and the phenomenon of precipitated opioid withdrawal if administered to someone who is opioid-tolerant.

There is a 'ceiling' effect on maximum opioid activity at higher doses, including a ceiling effect on respiratory depression. Nevertheless, there has been a number of drug toxicity deaths associated with injection and/or combination with benzodiazepines.

To deter injection, buprenorphine is combined with naloxone, which is poorly absorbed by swallowing or by the sublingual route, but will act as an opioid antagonist if it is injected. It will also modulate and delay the euphoric effect of buprenorphine in non-opioid dependent individuals if injected.

#### **New patients**

The highest risk of overdose/toxicity occurs during the first few days of treatment when the half-life of the drug is shorter and there is a greater risk of concurrent polydrug use.

#### **Missed doses**

If a patient misses a series of doses consecutively there is a likelihood that their tolerance to opioids will be reduced and they will be at higher risk of toxicity if administered their previous dose of pharmacotherapy. If the patient has missed doses on four (4) or more consecutive days, do not administer a dose until the patient has been reviewed by the prescriber.

#### **Declaration**

I certify that I have familiarised myself with the policy for pharmacists on pharmacotherapy administration. I understand the requirements and undertake to act in accordance with the policy.

Name: \_\_\_\_\_

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

## Appendix 8: Suggested format for patient's daily attendance record

An exercise book may be used, for example. Be sure to show each day's transaction, including take-away doses and missed doses, on a separate line. Patient records may also be maintained in an electronic form.

Date	Time	Drug and dose	Patient's signature indicating dose received	Supervising pharmacist's signature	Comment (paid, etc.)
26/7/15	3:30pm	Methadone 40 mg			Paid
27/7/15	4:00pm	Methadone 40 mg			Unpaid
28/7/15	2:30pm	Methadone 40 mg			Paid
29/7/15	2:30pm	Methadone 40 mg	Patient signed for dose and take-away dose		Paid
30/7/15	Take-away	Methadone 40 mg	Collected 29/7/15		
31/7/15	4:00pm	Methadone 40 mg			
1/8/15			Missed Dose		
2/8/15			Missed Dose		
3/8/15			Missed Dose		
4/8/15			Missed Dose		
Patient not to be dosed				Signed by pharmacist	Refer prescriber

## Appendix 9: Suggested format for notes about history and dosing

This is a suggested format for recording relevant information and contemporaneous notes in each patient record book (exercise book or other record) showing patient history and dosing. You should initial and date all entries made. It is suggested that entries are made in a section of the patient's record book that is not readily visible to the patient. Treat comments as confidential.

Date	Time	Comments	Administered by
21/7/15	9:30am	Patient appeared intoxicated or under influence of drugs. Withheld dose.	DF
21/7/15	9:35am	Rang Dr Smith to inform her of above. She gave instructions not to dose, and to refer patient back to her.	JM
23/8/15	6:00pm	Rang Dr Smith about patient frequently missing doses but still on take-away doses. Dr Smith unavailable.	CF
23/8/15	6:30pm	Dr Smith rang back. Gave instructions not to supply take-away doses, and to direct patient to make an appointment with her.	KM
1/10/15	10:00am	Received phone call from hospital pharmacy department (pharmacist Mary Methadone). Patient has been discharged and has received today's dose. Requested confirmation by fax – received 1/10/15. Instructed all other pharmacists NOT to dose today (see front of book).	FB
1/12/15	11:00am	Dr Smith phoned to authorise three take-away doses; confirmed by fax.	RB

## Appendix 10: Suggested format for single day preparation sheet for multiple patients

An exercise book may be used, for example. Be sure to show each day's transaction, including take-away doses and missed doses, on a separate line. Patient records may also be maintained in an electronic form.

Date	Patient	Dose of methadone (mg)	Dose of methadone syrup (5 mg/mL)	Doctor	Pharmacist
1/2/15	J.J. Bowen	80 mg	16 mL	Black	To sign
1/2/15	B. Patienta	20 mg	4 mL	Grey	To sign
1/2/15	M. Jones	60 mg	12 mL	Green	To sign
1/2/15	A. Possi	40 mg	8 mL	Green	To sign
	Total	200 mg	40 mL		

**Note:** The daily total of methadone syrup should be transferred to the Schedule 8 drug register on a daily basis.

## Appendix 11: Suggested format for maintaining daily dosing records for multiple patients

An accounting ledger/two-column cash book is ideal.

Patient	J. Brown	B. Patient	M. Jones	A. Possi	Daily total mg:	Daily total mL:
Doctor	Black	Grey	Black	Red		
Admin. 1/6/15 (mg)	80 mg	20 mg	60 mg	40 mg	200 mg	
Dose of methadone (5 mg/mL)	16 mL	4 mL	12 mL	8 mL		40 mL
Pharm. to sign	JD	JD	JD	JD		
Admin. 2/6/15 (mg)	80 mg	20 mg	65 mg	40 mg	205 mg	
Dose of methadone (5 mg/mL)	16 mL	4 mL	13 mL	8 mL		41 mL
Pharm. to sign	CH	GP	SK	JD		
Admin. 3/6/15 (mg)	75 mg	20 mg	65 mg	35 mg	195 mg	
Dose of methadone (5 mg/mL)	15 mL	4 mL	13 mL	7 mL		39 mL
Pharm. to sign	CH	GP	SK	JD		

**Note:** The daily total of methadone syrup should be transferred to the Schedule 8 drug register on a daily basis. Alternatively, this record may serve as a Schedule 8 drug register (for example, a bound book with consecutive numbered pages), in which case the remaining balance should be recorded daily.

## Appendix 12: Suggested format for pharmacotherapy register

Use the normal Schedule 8 drug register.

Date	Patient	In (mL)	Out (mL)	Balance (mL)	Pharmacist signature	Name of doctor, invoice no.
31/5/15	Ex supplier	200		200	JD	23106
1/6/15	Doses as per daily dose sheet		62	138	JD	
2/6/15	Doses as per daily dose sheet		30	108	JD	
3/6/15	Doses as per daily dose sheet		46	62	JD	

**Note:** Methadone syrup 5 mg/mL

## Appendix 13: Sample patient agreement form for pharmacotherapy administration

Welcome to our pharmacotherapy service. We hope that our association will be a positive experience for all involved and that you will achieve a successful outcome.

You should be aware of the following conditions during treatment.

### 1. Dosing times

Pharmacotherapies will only be supplied by this pharmacy:

from \_\_\_\_ to \_\_\_\_ Monday to Friday

from \_\_\_\_ to \_\_\_\_ Saturday

from \_\_\_\_ to \_\_\_\_ Sunday

### 2. Cost

Time is taken to prepare, document and administer your dose, so payment is required for this.

The cost of our pharmacotherapy service is \$\_\_\_\_ per week in advance or \$\_\_\_\_ per day. No credit is allowed.

If you have paid in advance and you leave our pharmacotherapy service, you will be reimbursed any money that you have paid in advance after the date your prescription was cancelled or for the period after the pharmacy was notified that you have ceased treatment. If you are not leaving our pharmacotherapy service, no monies paid in advance will be reimbursed.

### 3. Prescriptions

Before a dose can be administered, you need:

- a current prescription
- a certified recent photograph from your prescriber

It is your responsibility to make sure you have a valid prescription at all times. Your dose cannot be supplied if your prescription has expired.

### 4. Attendance

For treatment to be successful, you must attend regularly. Pharmacotherapy is based on supervised dosing, so methadone or buprenorphine must be consumed in front of the pharmacist. Buprenorphine tablets will be broken into small pieces or granules.

If you miss doses on four (4) or more consecutive days, your doctor must review you and issue a new prescription before your dose can be supplied and treatment can continue.

### 5. Take-away doses

Take-away doses are only authorised by your doctor. If you need to change your dose in any way, it is your responsibility to contact your doctor to request this.

Take-away doses are only available for patients who do not routinely miss supervised doses. Take-away doses may be cancelled by your doctor if you fail to attend the pharmacy regularly for supervised doses or if there are concerns about your progress in treatment.

Take-away doses should be stored in a safe and secure place (not in the fridge) and away from the reach of children and other household members. They will not be replaced for any reason, without authorisation from your doctor.

### 6. Behaviour in and around the pharmacy

No methadone or buprenorphine will be administered if you appear to be affected by alcohol or drugs.

Your treatment at this pharmacy will be cancelled if:

- your behaviour is threatening or you are violent towards pharmacy staff or other customers
- you are rude, abusive or disruptive.

If there is any suspicion of drug dealing or any other criminal activity on the premises or near the pharmacy, the police will be called and your treatment at this pharmacy will be cancelled.

We expect an appropriate code of conduct from all our customers, including an appropriate standard of dress at all times. You should attend the pharmacy alone unless you have children in your care.

## **7. Medication safety**

While receiving methadone or buprenorphine you are reminded that taking other drugs (including alcohol) can be extremely dangerous and in some cases fatal. Methadone and buprenorphine are depressants and can interact with other depressants such as alcohol and tranquillisers.

Unless there are extenuating circumstances, only this pharmacy should dispense all medications prescribed by a doctor for you, to allow us to check your complete medication history and advise you of any possible drug interactions or side effects with your medications.

I have read this agreement and fully understand its contents. I agree to comply with these conditions at all times. I consent to my pharmacist exchanging information with my doctor, concerning my social wellbeing, medical history and any other relevant information related to my treatment with pharmacotherapy.

Patient's name: \_\_\_\_\_

Address: \_\_\_\_\_

Telephone: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

Pharmacist's name: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

## Appendix 14: Pharmacotherapy patient transfer facsimile

To: \_\_\_\_\_ (Pharmacy)

Fax or Email: \_\_\_\_\_

From: \_\_\_\_\_ (Pharmacist)

Place pharmacy label or stamp here with pharmacy name, address, telephone number and fax number or email address

Date: \_\_\_\_\_

Subject: transfer of pharmacotherapy patient

### Patient and prescriber details

Patient's name: \_\_\_\_\_

Address: \_\_\_\_\_

Date of Birth: \_\_\_\_\_

Prescriber: Dr \_\_\_\_\_

Clinic: \_\_\_\_\_

Telephone: \_\_\_\_\_

This pharmacy has provided pharmacotherapy doses (including take-away doses)\* to this patient for treatment up to and including \_\_\_\_\_ (date)

Final dose: methadone / buprenorphine / buprenorphine-naloxone\* \_\_\_\_\_ milligrams \* Strike out where inapplicable.

Signature: \_\_\_\_\_

## Appendix 15: Area-Based Pharmacotherapy Networks

### Victorian Area-Based Pharmacotherapy Networks

#### Background

The use of pharmacotherapy treatment has become established in Australia and many other parts of the world as an effective treatment for opioid dependence. Pharmacotherapy represents an important part of the Victorian Government's community response to the treatment of drugs and alcohol in the state.

The Victorian pharmacotherapy system is a community-based model where medical professionals and pharmacists work together to make pharmacotherapy available to clients in the community.

In 2014, five area-based pharmacotherapy networks were established throughout the state to ensure a more local approach in connecting care, driving best practice and improving pharmacotherapy client outcomes.

#### Service objectives

Each of the five Networks will contribute to assisting pharmacotherapy providers implement a more integrated and cohesive service that will be focused on improving client outcomes.

The Networks will:

- develop a strategic approach to addressing need in the Area
- identify and analyse gaps in service provision in their Area and provide local solutions
- work with other services in the Area (such as hospitals, health services, Specialist Pharmacotherapy Services, general practitioners, pharmacists, other AOD services) to form partnerships to facilitate integrated assessment and treatment referral pathways
- provide and distribute advice regarding best-practice and emerging issues relating to pharmacotherapy
- attract and retain pharmacotherapy providers to the Area to relieve pressure to existing services
- provide ongoing support and wrap around support and mentoring to providers
- facilitate access to ongoing training for pharmacotherapy providers and
- provide access for complex clients to Addiction Medicine Specialists.

#### Contacts

For further information please contact your local Pharmacotherapy Network.

Pharmacotherapy Network	Contact details
Area 1- Barwon South West Pharmacotherapy Network	Name: Aneill Kamath <b>Phone:</b> (03) 5564 5888 <b>Email:</b> <a href="mailto:Aneill.Kamath@westvicphn.com.au">Aneill.Kamath@westvicphn.com.au</a> <b>Fax:</b> (03) 5564 5800
ORTicare- Grampians and Loddon Mallee Pharmacotherapy Network	Name: Jacqueline Keevins <b>Phone:</b> (03) 5338 4500 <b>Email:</b> <a href="mailto:orticare@bchc.org.au">orticare@bchc.org.au</a> <b>Fax:</b> (03) 5331 5470
Area 3- Gippsland and Hume Pharmacotherapy Network	Name: Elizabeth Plunkett (Gippsland) <b>Phone:</b> 1800 242 696 <b>Email:</b> <a href="mailto:gnwnursing@lchs.com.au">gnwnursing@lchs.com.au</a> <b>Fax:</b> (03) 5136 5475 Name: Tim Griffiths (Hume) <b>Phone:</b> (03) 5823 3219 <b>Email:</b> <a href="mailto:TGriffiths@primarycareconnect.com.au">TGriffiths@primarycareconnect.com.au</a> <b>Fax:</b> (03) 5823 3299
Area 4- South and Eastern Metropolitan Pharmacotherapy Network	Name: Bernadette Lane <b>Phone:</b> (03) 9525 7399 <b>Email:</b> <a href="mailto:A4PN@semphn.org.au">A4PN@semphn.org.au</a> <b>Fax:</b> (03) 9525 7369
Area 5- North West Metropolitan Pharmacotherapy Network	Name: Andrea Calleja <b>Phone:</b> (03) 9362 8100 <b>Email:</b> <a href="mailto:pharmacotherapy@cohealth.org.au">pharmacotherapy@cohealth.org.au</a> <b>Fax:</b> (03) 9362 8180

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