Policy for maintenance pharmacotherapy for opioid dependence
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Further information

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4 Policy for pharmacists

Essentials of pharmacotherapy administration

Setting up a pharmacotherapy dosing service
  Approval
  Development of procedures
  Certification by managers of pharmacies
  Storage
  Patient records
  Records of administration
  Destruction of methadone or buprenorphine

Administration of pharmacotherapies
  1 Accepting new patients
  2 Prescriptions/authorisation
  3 Preparation of supervised doses
  4 Supervision of doses
  5 Take-away doses
  6 Patients who are new to pharmacotherapy
  7 Transfer of pharmacotherapy patients
  8 Temporary absences
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  11 Possible intoxication
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Appendix 2: Useful contacts
Appendix 3: Features of a pharmacotherapy prescription
Appendix 4: Example pro forma for assessing level of supervised dosing
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About this policy

This document describes the Victorian jurisdictional policy in relation to methadone and buprenorphine use in the treatment of opioid dependence. The policy is designed to be used as an adjunct to the current publications of National clinical guidelines and procedures for the use of methadone in the maintenance treatment of opioid dependence and the National clinical guidelines and procedures for the use of buprenorphine in the maintenance treatment of opioid dependence. These documents can be obtained from the Drugs and Poisons Regulation website at <http://www.health.vic.gov.au/dpcs/pharm.htm>.

The document provides ready access for prescribers and pharmacists administering pharmacotherapies to information about the policy that controls treatment of opioid dependence with pharmacotherapy (opioid replacement therapy) in Victoria. The policy is designed to advise practice standards for practitioners, and to enhance coordination and cooperation between professionals involved in patient management.

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 on advice from practitioners with expertise in the use of pharmacotherapies in treating opioid dependence. The policy is intended to 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 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 administering 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.

The policy is not intended to replace professional judgment in individual cases. 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.
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 an approved 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 becoming an approved pharmacy to supply 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, transfers.

Appendices
Useful contacts, features of a pharmacotherapy prescription, certification of pharmacists administering doses, pro forma for assessment of stability in treatment, suggested formats for dosing and attendance records, sample treatment agreement form, patient transfer forms.

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1 Introduction

The policy has been developed to assist practitioner and patient 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 $3.8 billion of this.

In the past most patients seeking treatment for opioid dependence were injecting drug users injecting heroin, and were actively involved in a drug-using subculture.

In recent years, pharmaceutical opioids have 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 and ibuprofen and codeine and paracetamol, in high daily doses
- prescription opioids such as morphine and oxycodone, particularly long-acting formulations.

Many people dependent on pharmaceutical opioids differ from heroin users in that they may never have injected or used illicit drugs or been involved in a drug-using subculture, and may be more highly functioning and have more social supports to assist in managing their dependence.

At the same time, pharmaceutical opioids are actively misused, and oral formulations such as tablets are injected by drug users who, in many cases, may prefer pharmaceutical opioids over heroin.

There appears to have been a steady increase in serious harm and deaths in the last ten years from problematic use or deliberate misuse of OTC codeine-containing analgesics and prescription opioids.

Harms associated with heroin dependence

To the individual:

- **health**: blood-borne infections, local infections, malnutrition, dental, mental health
- **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 those 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
- 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 NSAID toxicity in OTC codeine-ibuprofen and OTC codeine-aspirin products (peptic ulcer and complications including gastric and duodenal haemorrhage and perforation, small bowel enteropathy, hypokalaemia, rhabdomyolysis, renal tubular acidosis, blood loss anaemia, hypoproteinaemia), and hepatotoxicity in OTC codeine-paracetamol products
- risk of overdose, sometimes resulting in death
- social dysfunction and 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.

Maintenance pharmacotherapy represents an important part of Victoria’s community response to the problem of opioid dependence.
Pharmacotherapy is an effective treatment for opioid dependence

The use of 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 illicit opioid use. Maintenance pharmacotherapies can prove valuable in assisting these people to manage physical dependence, drug craving and compulsive drug use successfully.

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 can be taken orally, so injecting drug-dependent patients can avoid the reinforcing effects of injecting
- they are long acting, enabling less frequent dosing than heroin or short-acting pharmaceutical opioids.

Drugs 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 licit opioids, as well as increased transmission of blood-borne viruses if 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, require daily treatment, and have a high risk of adverse effects if compliance 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
- 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 and productivity.

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 Department of Health made a decision to move from clinics to a more 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 benefits of this were perceived to be improved integration of treatment of dependence with treatment of other physical disease and injury co-morbidity and mental health co-morbidity. General practice was perceived as being the best place to deliver this care, as often patients already had a family general practitioner who knew them, their families and family circumstances and was best placed to assess their social and personal circumstances.

At that time opioid dependence was largely the result of illicit use of heroin, and people injecting heroin experienced high levels of physical and mental health co-morbidity.
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.

Other benefits included preventing the congregation of large numbers of individuals outside clinics and dosing points, which could create a problem with public amenity as well as exposing patients to a drug-using community at a time they were seeking to distance themselves from this scene. Patients are better able to retain their anonymity in general practice and pharmacies with low patient numbers.

A further benefit included the geographic spread of services across Victoria that made attendance more convenient, and would contribute to better accessibility and attraction to and retention in treatment.

Providing this service in community settings was also seen as appropriate because many of the problems patients deal with already involve contributing to health behavioural changes, such as smoking cessation and nutrition. Providing pharmacotherapy services with the support networks provided was also seen as contributing 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 perception of themselves 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 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 in Victoria**

In July 2012 more than 14,000 Victorians were receiving pharmacotherapy maintenance for opioid dependence.

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).

While buprenorphine may be safer in relation to 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 generally limited to prescribers and pharmacists who have been adequately trained and approved by the Department of Health. Initial and ongoing approval to prescribe or to administer pharmacotherapies is conditional on observance of the policy. The Department of Health may withdraw approval of practitioners who practise outside the policy.
A structured approach to risk management

In Victoria, pharmacotherapy is structured to minimise the risks involved and maximise the benefits.

Table 1.1: Pharmacotherapy risks and countermeasures

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<th>Risk</th>
<th>Countermeasure</th>
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<td>Prescriber/dose administrator training; authorisation of prescribers/pharmacies</td>
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<td>Concurrent treatment by multiple prescribers</td>
<td>Coordination of treatment by appropriate professional communication between doctors and pharmacists; a permit system</td>
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<td>Poor compliance and diversion of doses to illicit use and trafficking</td>
<td>A system of supervised dosing, restrictions on the eligibility for take-away doses to patients who meet specified criteria for stability in treatment</td>
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<td>Trafficking and consequent overdosing of non-tolerant people not in pharmacotherapy</td>
<td>Adoption of anti-diversion strategies; clear, transparent criteria for eligibility for take-away doses</td>
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<td>Illicit injection of take-away doses</td>
<td>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</td>
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<td>Misuse of take-away doses by others</td>
<td>Rigorous assessment of risks of diversion and misuse prior to authorising take-away doses, and advice about secure storage and risks of sharing with others; poisoning prevention information provided at the time of take-away provision</td>
</tr>
<tr>
<td>Child poisoning with pharmacotherapies</td>
<td>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</td>
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<tr>
<td>Multiple dosing at time of transfer</td>
<td>Meticulous arrangements for transfer between prescribers and pharmacies; effective communication between pharmacists at transferring and receiving pharmacies</td>
</tr>
<tr>
<td>A high risk of drug overdose in the first ten days of treatment, particularly with methadone</td>
<td>Meticulous assessment and care and frequent patient review in the first ten days; start low, go slow; 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</td>
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<tr>
<td>A high risk of combined drug toxicity deaths</td>
<td>Alertness to signs of toxicity; comprehensive assessment of patients and the management of poly-drug abuse (including the use of the Medicare Australia privacy release), provision of warnings to patient about risk, and education of patient and family/friends about signs of overdose and coma (unrrousable, ‘snoring’, respiratory depression, cyanosis)</td>
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<td>Injury</td>
<td>Provision of warnings to patient about the risks of driving or operating machinery before dose stabilisation and while the dose is being adjusted</td>
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<td>Psychiatric co-morbidity, including suicide risk</td>
<td>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</td>
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<tr>
<td>Discontinuation of treatment by patient</td>
<td>Set up of supervised dosing as convenient as possible; access to take-away doses where safe and appropriate</td>
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Policy framework

With reference to the principles for the Quality Use of Medicines (QUM) as expressed in the National Medicines Policy, it is recommended that all forms of drug therapy, including pharmacotherapies for opioid dependence, should be applied within a QUM framework. 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.

The policy is consistent with the National pharmacotherapy policy for people dependent on opioids. It 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:

- National clinical guidelines and procedures for the use of methadone in the maintenance treatment of opioid dependence (2003), and

These documents can be obtained from the Drugs and Poisons Regulation website at <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 to 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-orientated 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 more than 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 them back into the community, and retaining them in treatment as appropriate. For those experiencing problematic pharmaceutical opioid use it assists in managing this problem. Pharmacotherapy patients should be treated as much as possible in the same way as other patients.
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 or tablet).

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/naloxone film is the preferred dosing formulation as it is absorbed more rapidly, requiring shorter supervision than the tablet formulation, and the film is adherent to the sublingual mucosa, making it more difficult to divert once placed sublingually.

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

Prevention of pharmacotherapy-related poisoning deaths

Every year there are a number of unintentional poisoning deaths involving methadone, usually in combination with other central nervous system (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 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 central nervous system and respiratory depression.
The injecting drug user’s risk of drug overdose death is considerably reduced once they are stabilised on pharmacotherapy maintenance. Nevertheless, a history of illicit and poly-drug abuse or alcohol misuse places the pharmacotherapy patient at greater risk of drug overdose than that of the general community. Some pharmacotherapy patients 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 such as suicide, homicide or trauma.

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 that have been abstinent for a period of time resulting in reduced neuroadaptation and tolerance to opioids (for example, after a detoxification program).

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).
- Undertake close supervision if the patient is 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.

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. The Coroner usually attributes these drug-related deaths to combined drug toxicity involving methadone or buprenorphine.

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.
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, family, friends and associates about the signs of coma and the need to take urgent action if toxicity is suspected. A patient who is unrousable and snoring (or making other sounds that suggest airway obstruction) is a medical emergency. Provide the patient with the information leaflet: Starting methadone or buprenorphine (Appendix 1).
- 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 usual. 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 the second most common cause 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.

5. Deaths due to other disease

Risk-taking behaviour exposes many pharmacotherapy patients 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 injecting drug users 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 injecting drug users in pharmacotherapy treatment to reduce injecting.
- Consider specialist referral and collaboration in management of patients with other chronic co-morbidities.
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 treated 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. Diluting the dose to 200 mL reduces 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 (film or tablet) 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 illicit injection 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 relevant national clinical guidelines 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 before prescribing methadone or buprenorphine. The Department of Health 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. 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 methadone, buprenorphine or combined drug toxicity and overdose during induction into treatment. This is particularly important for methadone, as the drug carries a high risk of toxicity during induction.

7. 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.

8. Before authorising take-away doses:
   - contact the pharmacy to check the regularity of dosing and the patient’s progress
   - ensure the patient is stable and meets all the criteria specified in the policy to determine the number of take-away doses that may be prescribed.

9. Send a termination notice to the Department of Health as soon as it is known that treatment has ceased.

10. 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.

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.

Approval to prescribe

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 funds training that is available free of charge to medical practitioners intending to become prescribers and to currently approved prescribers wishing to attend a clinical update or refresher training.
Buprenorphine/naloxone prescribing by practitioners who are not approved pharmacotherapy prescribers

All medical practitioners may prescribe buprenorphine/naloxone for up to five (5) patients without the requirement to undergo training or assessment to become an approved prescriber. 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 medical practitioners should follow the principles of risk-benefit assessment about 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. They 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 are not approved pharmacotherapy prescribers should seek advice from an approved prescriber (preferably a colleague in the same practice) before prescribing to a patient. Further information for prescribing of buprenorphine/naloxone by non-approved prescribers is available on the Drugs and Poisons Regulation website at <http://www.health.vic.gov.au/dpcs/pharm.htm>.

All medical practitioners who are confidently managing up to five (5) patients with buprenorphine/naloxone, are highly encouraged to undertake training and assessment for approval as a pharmacotherapy prescriber. Successful completion of training and assessment enables prescribers to provide a greater range and capacity of pharmacotherapy services to patients, that is, the ability to prescribe methadone, buprenorphine or buprenorphine/naloxone to more than five (5) patients.

Approval as a pharmacotherapy prescriber follows training and assessment. Approval is granted subject to initial conditions such as limits on the number of patients treated at any one time. Ongoing approval is conditional on observance of the policy and relevant clinical guidelines.

Initial approval 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 approval should be sought if the prescriber wishes to manage a larger number of patients.

Pharmacotherapy in Victoria aims to integrate treatment into general practice. The idea is to limit the congregation of opioid dependent people at the one medical practice or pharmacy, and to meet all of the patient’s needs for medical and drug misuse treatment in the framework of a normal general practice.

Arrangements for dispensing

Pharmacies approved to dispense pharmacotherapies provide supervised dosing. The prescriber should confirm the availability of a pharmacy that is suitable and accessible to the patient. Avoid misunderstandings and enhance the safety of treatment by maintaining good communications with the practitioners at the pharmacy. DirectLine (tel: 1800 888 236) can provide information about approved pharmacy locations.

Dosing fees

As with any other professional service, providers of dosing services are entitled to a fee determined by each individual pharmacy for dispensing pharmacotherapies. At the time of release of the policy, the Department of Health pays dispensing fees for patients aged 18 and under and patients on Youth Justice community orders. The Department of Justice pays dispensing 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 Pharmacotherapy Advocacy, Mediation Support (PAMS) service (tel: 1800 443 844) 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. Each prescriber is responsible for the management of each patient for whom they hold a permit and must always remain the main person treating the patient for whom the permit has been issued. To minimise any risks arising from the prescriber’s absence, the following arrangements should be made.

Preparation for anticipated or unexpected absence of a pharmacotherapy prescriber

- Document and maintain up-to-date individual management plans in the patient’s records.
- Make arrangements for a colleague (preferably an approved pharmacotherapy prescriber) to continue the documented management plan for each patient.
- Request that any deputising colleague record treatment changes in the patient notes.

Deputising by approved 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 permit to treat the patient with pharmacotherapy, a new permit is not required.

Deputising by practitioners who are not approved pharmacotherapy prescribers

Being potentially less familiar with the risks of pharmacotherapy, prescribers who are not approved to prescribe pharmacotherapy should adopt a cautious approach to treating patients.

Prescribers who are not approved pharmacotherapy prescribers may consider deputising for an approved 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, and
- the deputising prescriber is not re-starting treatment of a patient with pharmacotherapy (a patient is considered to be re-starting pharmacotherapy if not dosed for more than three (3) consecutive days in the case of methadone or more than five (5) consecutive days in the case of buprenorphine).

Note: Provided the usual prescriber is holding a 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 the Drug and Alcohol Clinical Advisory Service (DACAS (tel: 1800 812 804):
  - 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.

Drugs and Poisons Regulation can provide basic advice about safe prescribing and a list of the usual prescriber’s current permits.
All deputising prescribers (approved and non-approved prescribers) should manage the patient as described here:

Management by deputising prescribers

- 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

Note: The national clinical guidelines should be referred to 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 of the same person. 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, and 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 confronted with complex and difficult situations.

The Drug and Alcohol Clinical Advisory Service (DACAS) (tel: 1800 812 804) is funded by the Department of Health to provide advice to practitioners about treatment issues. DACAS takes calls from doctors, nurses and other health and welfare professionals seeking advice on the clinical management of alcohol and drug issues. DACAS consultants include specialist addiction medicine doctors and pharmacists. It is not the role of DACAS to provide authorisation or to sanction a proposed treatment.

DACAS may provide clinical advice which may assist health practitioners make safer and more evidence-based clinical decisions.

Patients with complex and difficult conditions may be also 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 maintenance
- the costs of medical treatment and advised to ask the pharmacist about pharmaceutical costs
- the PAMS service (Appendix 2)
- harm reduction (covering how to prevent the transmission of blood-borne viruses and how to inject safely)
- 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.

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 Drugs and Poisons Regulation for approval. (Exceptions to the requirement to obtain a permit are detailed below in 5: Circumstances where a notification of treatment is required.) The application can be completed and submitted online at <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 <http://www.health.vic.gov.au/dpcs/pharm.htm>) to indicate their intention to treat the patient with pharmacotherapy. Prescribers may start prescribing for the purpose of continuing treatment of a stable patient provided the notification is submitted as soon as practicable to Drugs and Poisons Regulation.

Practitioners who are not approved to prescribe pharmacotherapy should seek advice from their addiction medicine team (in hospital or prison) or DACAS (tel: 1800 812 804) before intending to prescribe for a patient who has not previously been treated with pharmacotherapy or who has not been dosed for more than three (3) consecutive days in the case of methadone or more than five (5) consecutive days in the case of buprenorphine.

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 and obtain relevant treatment information, including the current dose and when the last dose was administered or take-away dose provided.

If three (3) or more consecutive days have elapsed since the last methadone dose, do not recommence treatment unless advice has been obtained from the hospital addiction medicine team or DACAS.

If five (5) or more consecutive days have elapsed since the last buprenorphine dose, do not recommence treatment unless advice has been obtained from the hospital addiction medicine team or DACAS.

Prescribers are required to submit a Notification of Drug Dependent Person to indicate their intention to treat a hospital inpatient with pharmacotherapy. Prescribers may start prescribing provided the notification is submitted as soon as practicable to Drugs and Poisons Regulation.

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 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 the purpose of ensuring continuity of treatment, ensure that the patient has a valid prescription to continue dosing at the usual pharmacy. If the prescription that the patient was being dosed with 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.

Provision of pharmacotherapy in police custody or prison

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, endeavour 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 The pharmacotherapy prescription

As for any other Schedule 8 poison, methadone or buprenorphine may not be administered or supplied without holding 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 dispensed 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 dispensed
- the date the authorisation to dispense 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 dispensed.

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 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 Counselling

Counselling may help the patient address their drug dependence. This may be done by the prescriber, or the patient may be referred to another counsellor. Patients may call DirectLine (tel: 1800 888 236) 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).

8 Allied health professionals

A diverse range of organisations fund health professionals to support pharmacotherapy patients and other patients with their substance use and harm arising from it. When patient management involves 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 dispensing 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.
9 Dosing arrangements

Supervised dosing arrangements through community pharmacies:

- Confirm arrangements with the pharmacy that the patient wishes to attend for supervised dosing.
- Inform Drugs and Poisons Regulation of the pharmacy at which dosing is proposed.
- Forward the original prescription for methadone, buprenorphine or buprenorphine/naloxone to the pharmacy (except when provided with verbal instructions in an emergency, it is illegal for a pharmacist to supply a dose of a Schedule 8 poison if they are not in possession of the original prescription). 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.
- Advise Drugs and Poisons Regulation 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 for a review of management.
- The patient may have the benefit of previous experience 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. It is not permitted to provide a dose 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 (tel: 1800 812 804) 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.

10 Take-away doses
Pharmacotherapy in Victoria is based on the principle of supervised dosing.

Methadone and buprenorphine are Schedule 8 poisons (Controlled Drugs), subject to misuse and trafficking. People with a history of substance abuse may misuse pharmacotherapies to achieve intoxication, by taking them alone or by mixing them with other psychoactive drugs such as benzodiazepines and/or alcohol.

One characteristic of substance misuse is the phenomenon of sharing with other drug users. Pharmacotherapies are no exception, and patients may share their prescribed drugs with non-tolerant associates, with serious adverse consequences. Deaths have occurred as a result of patients sharing their take-away doses of pharmacotherapies with friends or partners. Deaths have also occurred where drug-dependent friends or partners have used a patient’s take-away dose without their permission. 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 milligrams of methadone tolerated by opioid tolerant 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, if taken with other respiratory depressants fatal overdose can occur. Injection of buprenorphine has also been one of the factors in fatal buprenorphine overdose together with other sedative use, including benzodiazepines or alcohol. The injection of buprenorphine diverted from the mouth has caused serious Candida endophthalmitis (fungal eye infection) resulting in partial or complete loss of vision. Injection of tablet material can cause cellulitis, thrombophlebitis and skin ulcers.

Risks of take-away doses of methadone and buprenorphine
- Compulsive use in excessive doses.
- Hoarding and deliberate overdose of self or others.
- Use in dangerous combination with other sedative drugs.
- Self-administration by injection, with the potential for microbial infection and blood-borne virus transmission.
- Diversion for illicit use or trafficking.
- Accidental overdose (by children or other non-tolerant substance misusers).
- Poor compliance with treatment plan.
- Sharing of dose with partner or associates.

Nevertheless, take-away doses can lessen the constraints on stable patients who are attempting to normalise their lives, integrate into the community and meet work and family commitments with minimal disruption from the demands of daily supervised dosing. There may be a benefit (contingency management in opioid substitution) behind recognising and ‘rewarding’ patient stability on opioid substitution treatment by providing incentives such as unsupervised or take-away doses for those who have been stabilised in treatment. Offering patients incentives for progress can improve outcomes in opioid substitution treatment. Take-away doses are also important for those who need them for unusual situations such as court appearances, visiting distant sick relatives, holidays or work commitments. Most 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 plays the key role in assessing patient stability. Take-away or unsupervised treatment should depend on the following conditions.
Requirements for take-away doses

- Only the prescriber can authorise take-away doses.
- To authorise take-away doses the patient should be stable in treatment.
- 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.
- The patient’s circumstances and details of the presence of children or other drug users in the household should be sought, and advice about safe, secure storage should be provided to reduce the possibility of use by others or poisoning of children or other adults.

Contra-indications to take-away doses

- Unstable patterns of substance use, including significant use of alcohol, illicit drugs, benzodiazepines or other sedating medication.
- Significant unstable psychiatric conditions, including active psychosis, significant suicidal ideation and depression.
- Unstable medical conditions (for example decompensated cirrhosis, pneumonia).
- Reasonable concerns about diversion of doses for illicit or unsanctioned use. This requires an assessment of the stability of the patient’s home environment (for example, whether they are living with another substance abuser), their means of securing the take-away doses away from children and other potential misusers, and their past performance with take-away doses.

Subject to the above considerations, 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.

Many patients are unsuitable for take-away doses regardless of the total period of continuous treatment if there are risks of compulsive use, trafficking, injection of pharmacotherapy agents, sharing with others, theft, or unintentional poisoning of children or other drug users. This document provides a checklist (Appendix 4) to evaluate an individual patient’s suitability for provision of take-away doses. It can be used to explain to the patient why it may be necessary to refuse provision, and as a means of encouraging progress towards suitability for take-away doses.

Levels of supervised dosing

Methadone

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

- **High intensity supervision**: involves no take-away doses on a regular basis. 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 one (1) continuous month 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 a low risk for misuse, to access up to five (5) take-away doses per week.
Table 3.1: Levels of supervised dosing with methadone

<table>
<thead>
<tr>
<th>Level of supervision</th>
<th>Number of take-away doses per week</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>High</td>
<td>Nil</td>
<td>Patients will attend for daily supervised dosing</td>
</tr>
<tr>
<td>Medium</td>
<td>1-2</td>
<td>After at least one (1) continuous month of stable treatment, patients will be required to attend for supervised dosing at least five (5) days per week</td>
</tr>
<tr>
<td>Low</td>
<td>3-5</td>
<td>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 twice per week</td>
</tr>
</tbody>
</table>

It is strongly recommended that methadone take-away doses not be provided in the first month of treatment and until there is sufficient time to assess the patient’s suitability for safe and responsible use of methadone.

Progression to medium intensity supervision after one month and low intensity supervision after six months is not automatic. The patient should also be assessed for stability and suitability for provision of take-away doses applicable to that particular level of supervised dosing using the form 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 to the patient or when increasing the number of take-away doses to be prescribed.

Buprenorphine/Naloxone

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

- **High intensity supervision**: involves no take-away doses on a regular basis. 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 a low risk for 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 a low risk for 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: Levels of supervised dosing with a combined buprenorphine/naloxone product

<table>
<thead>
<tr>
<th>Level of supervision</th>
<th>Number of take-away doses per week</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>High</td>
<td>Nil</td>
<td>Patients will attend for daily supervised dosing</td>
</tr>
<tr>
<td>Medium</td>
<td>1-2</td>
<td>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</td>
</tr>
<tr>
<td>Low</td>
<td>3-5</td>
<td>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</td>
</tr>
<tr>
<td>Very Low</td>
<td>6</td>
<td>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</td>
</tr>
</tbody>
</table>

Buprenorphine without naloxone should never 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 2mg). 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.

It is strongly recommended that buprenorphine/naloxone take-away doses not be provided in the first two weeks of treatment and until there is sufficient time to assess the patient’s suitability for safe and responsible use of buprenorphine.

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. The patient should also be assessed for stability and suitability for provision of take-away doses applicable to that particular level of supervised dosing using the form 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.
Table 3.3: Levels of supervised dosing

<table>
<thead>
<tr>
<th>Attendance at medical/case manager reviews</th>
<th>High</th>
<th>Medium</th>
<th>Low/Very Low</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regular attendance</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Occasional DNAs¹ (e.g. miss 1 in 4 appointments)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Regular DNAs (e.g. routinely miss ≥ 2 in 4 appointments)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Missed doses</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pharmacy not contacted</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No missed doses in past 4 weeks</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Occasional missed doses (≤ 1 per week)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Regular missed doses (≥ 2 per week)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Provision of Urine Drug Screens (UDS)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Provided on request</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>UDS not provided on request</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Heroin and other opioid use</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nil / infrequent additional opioid use</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Regular additional use (e.g. 1-2 times per week)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Frequent and regular additional use (e.g. ≥ 3 times per week)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Benzodiazepine use (particularly alprazolam)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No / low dose² prescribed and stable³ use</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>High dose prescribed and stable use</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>High dose and harmful use⁴, abuse or dependence⁵</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Alcohol use</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Low risk levels of alcohol use⁶</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Risky / high risk levels of alcohol use</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Harmful use, alcohol abuse or dependence</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stimulant use</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nil / infrequent use</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Regular use</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Harmful use, stimulant abuse or dependence</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mental state assessment</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nil concerns</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Concerns re: risk to self / others</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Continued overleaf
<table>
<thead>
<tr>
<th>Nil concerns</th>
<th>High</th>
<th>Medium</th>
<th>Low/Very Low</th>
</tr>
</thead>
<tbody>
<tr>
<td>Concerns re: medical condition (severe liver / respiratory disease)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stable accommodation</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Evidence of recent injecting sites</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No recent IV injection sites</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Evidence of recent IV injection</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intoxicated presentations at pharmacy or medical clinic / overdoses</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nil within past 2 months</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Recent (within past 2 months)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Recent (within past month)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Concerns re: abuse/diversion of take-away doses</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nil concerns</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Poor ability to ‘control’ large supplies of medications (e.g. using take-away doses in advance)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Recent history of abuse (e.g. injecting medications, double dosing), diversion to others</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

1. DNA = failure to attend scheduled appointment without advance notice / justification acceptable to medical officer. 2. Low dose BZD use is defined as equivalent to < 30 mg diazepam/day. High dose > 30 mg diazepam/day. 3. Stable use = no additional use to amounts prescribed, no binges, intoxicated presentations or recent overdoses. 4. ICD 10 diagnosis of harmful use. 5. DSM IV diagnosis of abuse and dependence. 6. Refer to Australian Alcohol Guidelines for risk levels and alcohol use.

The default level of supervision is high intensity supervised dosing. The level of supervised dosing for each patient should be the highest level scored on the checklist for any of the above criteria. If a patient scores ‘high’ on any single criterion, they should only be eligible for high level supervised dosing (for example, a patient who scores ‘low’ on 8 criteria, ‘medium’ on one criterion, and ‘high’ on one criterion should have high level supervised dosing).

It is recommended that the assessment tool in Appendix 4 be worked through with the patient and included in the patient record.
11 Issues for consideration when prescribing additional take-away doses

The policy is not intended to replace professional judgment in individual cases. In situations where additional take-away doses are being considered, prescribers should liaise with the pharmacist to discuss the appropriateness of the proposed treatment and to fully document the reasons for their decisions or actions. Prescribers and pharmacists should consider the risks involved and possible consequences that may arise when providing an increased number of take-away doses, particularly if harm to the patient or to any other person has occurred or might occur as a result of providing additional take-away doses.

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, that the medicine is for the patient’s personal use, contact details of the prescriber and pharmacy, and 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 <http://www.smartraveller.gov.au>.

Prescribers and pharmacists may also consider liaising with an addiction medicine specialist, a Specialist Pharmacotherapy Service or DACAS (tel: 1800 888 236) 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 14: 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 extra 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.

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- 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 <http://www.smartraveller.gov.au>.
Other issues for consideration in frequency of dispensing

There may be other situations where lower intensity administration may be considered for patient retention in treatment, for example where the patient:

- lives in a rural area where access to dispensing points is limited
- is engaged in full time employment or study where access to a dispensing point is limited
- has a significant medical condition restricting their capacity to attend for daily supervised dosing.

However, patients should still be able to demonstrate indicators of stability to be eligible for take-away doses of pharmacotherapies.

12 Review of patient’s progress

Assessment for suitability for unsupervised doses requires that the patient is seeing the prescriber on a regular basis.

Table 3.4: Methods to assess patient stability

<table>
<thead>
<tr>
<th>Method</th>
<th>Clinical records / patient history</th>
<th>Clinical examination</th>
<th>Urine toxicology</th>
<th>Discussion with other health professionals (e.g. pharmacist)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Attendance at medical/case manager reviews</td>
<td>•</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Missed doses</td>
<td></td>
<td>•</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Provision of Urine Drug Screens (UDS)</td>
<td></td>
<td></td>
<td>•</td>
<td></td>
</tr>
<tr>
<td>Heroin and other opioid use</td>
<td>•</td>
<td>•</td>
<td>•</td>
<td>• / -</td>
</tr>
<tr>
<td>Benzodiazepine use (particularly alprazolam)</td>
<td>•</td>
<td>•</td>
<td>•</td>
<td>• / -</td>
</tr>
<tr>
<td>Alcohol use</td>
<td>•</td>
<td>•</td>
<td>•</td>
<td>• / -</td>
</tr>
<tr>
<td>Stimulant use</td>
<td>•</td>
<td>•</td>
<td>•</td>
<td>• / -</td>
</tr>
<tr>
<td>Mental state assessment</td>
<td>•</td>
<td>•</td>
<td>•</td>
<td>• / -</td>
</tr>
<tr>
<td>Medical co-morbidity</td>
<td>•</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Stable accommodation</td>
<td>•</td>
<td></td>
<td></td>
<td>• / -</td>
</tr>
<tr>
<td>Evidence of recent injecting sites</td>
<td>•</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intoxicated presentations at pharmacy or medical clinic / overdoses</td>
<td>•</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Concerns re: abuse/diversion of take-away doses</td>
<td>•</td>
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</tr>
</tbody>
</table>

The following strategies are used to assess stability (see Table 3.4: Methods to assess 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. Additional indicators of stability include regular employment or study.

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

The assessment for stability should be transparent and open for discussion with the patient during clinical reviews – in this way patients can take an active role in accessing lower levels of supervised dispensing.
Frequency of review

Review by the prescribing doctor should be once or twice in the first week of treatment, then at least every two weeks during the initial phase of treatment (or until the patient has reached a stable dose) with their particular 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 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 above criteria (see Table 3.3: Levels of supervised dosing) should be assessed and documented, 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 discuss the case with an addiction medicine consultant, DACAS (tel: 1800 812 804) or refer the patient to a Specialist Pharmacotherapy Service for assessment and recommendations.

13 Minimal supervision regimens

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

Fellows of the Australasian Chapter of Addiction Medicine (FACHAM) may apply for a permit to prescribe a minimal supervision regimen. General practitioners 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 should re-apply for a permit to Drugs and Poisons Regulation and, if the permit is approved, terminate the current permit to prescribe buprenorphine.
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 contraindications for providing take-away doses apply to patients seeking transfer. All patient transfers should be organised well in advance of the intended date of transfer.

Patients may also require permanent transfer to another prescriber or another 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 transferring and receiving prescribers and pharmacies is important. DirectLine (tel: 1800 888 236) can provide advice on the locations of approved prescribers and pharmacies.

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 photograph (endorsed by the prescriber) of the patient
- the reason for transfer
- any other drugs of dependence prescribed for the patient (for example, benzodiazepines).

The receiving prescriber should also confirm the arrangements about 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 should be notified in writing 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, Drugs and Poisons Regulation will terminate the permit held by the transferring prescriber.

### Procedures for arranging transfers

#### Intrastate patient transfer

**Table 3.5: Intrastate patient transfer (within Victoria)**

<table>
<thead>
<tr>
<th></th>
<th>Temporary</th>
<th>Permanent</th>
</tr>
</thead>
<tbody>
<tr>
<td>To a different pharmacy</td>
<td>Provide the receiving pharmacy with:</td>
<td>As for temporary transfer, plus the prescriber will need to notify Drugs and Poisons Regulation of the change of pharmacy.</td>
</tr>
<tr>
<td></td>
<td>• patient details (name, date of birth)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• a photograph (endorsed by the prescriber) of the patient</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• the date and amount of final dose at the transferring pharmacy (including take-away doses if necessary).</td>
<td></td>
</tr>
<tr>
<td>To a new prescriber</td>
<td>The receiving prescriber should obtain the above details from the transferring prescriber.</td>
<td>As for temporary transfer, plus the transferring prescriber should send a Notification of Termination of Methadone or Buprenorphine form to Drugs and Poisons Regulation.</td>
</tr>
<tr>
<td></td>
<td>The receiving prescriber must obtain a permit before prescribing.</td>
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</tbody>
</table>
Temporary interstate patient transfer

In some states or territories it may be possible for approved 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 the Interstate prescriptions for opioid replacement therapy (ORT) section of the Drugs and Poisons Regulation website at <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 the Interstate prescriptions for opioid replacement therapy (ORT) section of the Drugs and Poisons Regulation website at <http://www.health.vic.gov.au/dpcs/pharm.htm> for contact details for interstate agencies for assistance with permanent interstate transfers.

Table 3.6: Interstate patient transfer

<table>
<thead>
<tr>
<th>Temporary</th>
<th>Permanent</th>
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</thead>
<tbody>
<tr>
<td>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).</td>
<td>As for temporary transfer, plus the transferring prescriber should send a Notification of Termination of Methadone or Buprenorphine form to Drugs and Poisons Regulation.</td>
</tr>
<tr>
<td>The receiving prescriber and/or pharmacist usually requires:</td>
<td></td>
</tr>
<tr>
<td>• patient details (name, date of birth)</td>
<td></td>
</tr>
<tr>
<td>• a photograph (endorsed by the prescriber) of the patient</td>
<td></td>
</tr>
<tr>
<td>• the date and amount of the final dose at the transferring pharmacy (including take-away doses if necessary)</td>
<td></td>
</tr>
<tr>
<td>• the expected dates of the temporary treatment</td>
<td></td>
</tr>
<tr>
<td>• contact details for the transferring pharmacy.</td>
<td></td>
</tr>
<tr>
<td>Make arrangements well in advance. Interstate regulatory agencies generally require at least 2–3 weeks’ notice for interstate transfers.</td>
<td></td>
</tr>
<tr>
<td>The PAMS service (tel: 1800 443 844) is available to provide advice and assistance with interstate patient transfers.</td>
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</tr>
</tbody>
</table>

International patient transfer

The website “The Coordinating and Information Resource Center for International Travel by Patients Receiving Methadone and other Substitution Treatments for Opiate Addiction ("The Travel Resource Center" - TRC)” at <http://www.indro-online.de/nia.htm> may assist with general information and contact details of prescribers and pharmacies for many international destinations.

Table 3.7: International patient transfer

<table>
<thead>
<tr>
<th>Temporary</th>
<th>Permanent</th>
</tr>
</thead>
<tbody>
<tr>
<td>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.</td>
<td>As for temporary transfer, plus the transferring prescriber should send a Notification of Termination of Methadone or Buprenorphine form to Drugs and Poisons Regulation.</td>
</tr>
<tr>
<td>The PAMS service (tel: 1800 443 844) is available to provide advice and assistance with international patient transfers.</td>
<td></td>
</tr>
</tbody>
</table>
15 Termination of treatment

Opioid pharmacotherapy is usually considered a long-term therapy option. Ceasing opioid 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 offers the patient 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.

Complete a Notification of Termination of Methadone or Buprenorphine Program form and forward it to Drugs and Poisons Regulation 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 clinical guidelines for methadone and buprenorphine.

16 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 their 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. 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.

17 Discontinuing prescriber participation in providing pharmacotherapy

Pharmacotherapy 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 (tel: 1800 888 236) and the PAMS service (tel: 1800 443 844) may provide assistance with patient transfers to other pharmacotherapy providers.

18 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 codeine, hydromorphone, morphine, oxycodone, pethidine, methadone, buprenorphine, fentanyl, dexamphetamine, methylphenidate, flunitrazepam and ketamine. Schedule 4 poisons include all other prescription only medicines.

Drugs of dependence are those substances in Schedule 11 of 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 prescribing doctor must take all reasonable steps to ensure a therapeutic need exists and then prescribe only for the medical treatment of a patient under his/her care.

• For drugs of dependence, the prescribing doctor 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 prescribing doctor must not prescribe merely 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 doctor may give verbal instructions for supply of Schedule 8 or Schedule 4 poisons. These verbal instructions must be confirmed in writing as soon as practicable.

• When a doctor 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 must be notified.

• In most circumstances, a permit from the Department of Health 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.

19 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 access to clinical or other records that may reveal that the patient is being treated with pharmacotherapy.

20 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 Department of Health funds the PAMS service (tel: 1800 443 844) to resolve disputes arising from the delivery of pharmacotherapy services. If these avenues prove unsuccessful, patients may contact the Health Services Commissioner (tel: (03) 8601 5200 or toll free: 1800 136 066).
4 Policy for pharmacists

Essentials of pharmacotherapy administration

The policy provides advice relating to the supply and administration of methadone, buprenorphine and buprenorphine/naloxone combinations to Victorian pharmacotherapy 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 (tel: 1800 812 804) for instructions and/or clinical advice
- contact Drugs and Poisons Regulation of the Department of Health (tel: 1300 364 545) 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 three (3) or more consecutive days have elapsed since the last methadone dose or if five (5) or more consecutive days have elapsed since the last buprenorphine dose.
  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

Approval

An application for approval as a pharmacotherapy supplier may be made by completing the application form and other required documentation. A Department of Health officer will conduct a review of the proposed systems and conduct an induction prior to approval.

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

- carrying OTC medicines as well as being approved to supply PBS subsided 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 approval of other pharmacies may be applicable in circumstances where pharmacies are located in areas of need not otherwise serviced.

Approval may be granted to the proprietor(s) of a pharmacy to administer pharmacotherapies to a specified maximum number of patients, possibly with conditions. Initial approval to supply pharmacotherapies is limited to treatment for up to five (5) patients. Further approval should be sought if a pharmacy wishes to manage a larger number of patients or 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 approved number of patients for any dosing point is 85. Further approval should be sought if a pharmacy wishes to manage more than 85 patients. 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 approval is conditional on continuing compliance with the policy and relevant clinical guidelines.

Development of procedures

A pharmacotherapy dosing service may be conducted in a number of ways, and all pharmacists administering doses employed 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 employed at the pharmacy are required to 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 5). Certification documents should be retained, with a copy readily available for reference.

The Department of Health funds training that is available free of charge to pharmacists involved in providing pharmacotherapy services, and to pharmacists wishing to attend a clinical update or refresher training.

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 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 be 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 and provide for signatures by the patient and the pharmacist who administered the dose to confirm that a dose has been administered (Appendix 6). Other details, like payments and prescription expiry dates, should also be included. 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 7). 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).

Pharmacotherapy 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 such that they will be visible to other customers.
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 8 and 9).

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 10). 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 11. The Pharmaceutical Society of Australia (Vic Branch) also has a format for an agreement that is available on request.

The patient should provide a 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 ample 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 (under or over) 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 and tablets) should not be removed from their original sachets or foil packs until the dose is to be administered.

Buprenorphine and buprenorphine/naloxone 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 which 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 be 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 the patient as they take the dose and engage them in conversation to ensure they consumed the dose.

Diversion may be a higher risk with buprenorphine and buprenorphine/naloxone 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.

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

Buprenorphine/naloxone films adhere to mucous membranes within seconds and are difficult to remove after thirty (30) to sixty (60) seconds. Hence, under normal circumstances, supervision of a buprenorphine/naloxone film dose does not need to exceed one (1) 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 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 provision of take-away doses applicable to that particular level of supervised dosing using the form provided in 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.

Contra-indications to take-away doses include unstable patterns of substance use, unstable psychiatric conditions, other risks such as the presence of other drug users or children in the household and/or concerns that the doses may be diverted or used inappropriately.

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 2mg)).

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 contains 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 2012 by John Citizen.

Prepared on 14 June 2012

**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 contains 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 2012.

Prepared on 14 June 2012

**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/tablets (that is, a combination of 2 mg and 8 mg films/tablets), the different strengths of films/tablets must be packaged separately. Ensure that the patient is aware of the dosing instructions for both strengths of film/tablet 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 2012 by John Citizen.
(Please note: buprenorphine/naloxone 8 mg films are packaged separately)
Prepared on 14 June 2012
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 2012 by John Citizen.
(Please note: buprenorphine/naloxone 8 mg films are packaged separately)
Prepared on 14 June 2012
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 inquire about the presence of children or other drug users in or accessing the house and to seek agreement about arrangements for safe and secure storage to help prevent unintentional poisoning of children or deliberate misuse by another person. In some circumstances a lockable box might be considered appropriate for safe 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 where appropriate.
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 professional judgment about the safety and appropriateness of providing replacement doses 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) to a patient, on the days where the patient attends for supervised dosing of the first dose of methadone at a pharmacy, the second dose of methadone 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 poly-drug use. If the initial dose exceeds 40mg, 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 (tel: 1800 812 804).

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

The prescriber should have advised the patient about the risks of poly-drug use and other related risks (for example, impairment of their ability to drive). However, when interviewing a prospective patient, endeavour to 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 with that pharmacy should be made 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 12).

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 not been dosed for more than three (3) consecutive days in the case of methadone or five (5) consecutive days in the case of buprenorphine 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 12).

Ensure a current prescription and photograph (endorsed by the prescriber) of the patient 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 missing doses, notify the prescriber so they can review the appropriateness of continuing take-away doses.

10 Multiple missed doses

If a patient attends after missing three (3) consecutive days since the last dose of methadone or five (5) consecutive days since the last dose of buprenorphine, 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 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, advice may be sought from DACAS (tel: 1800 812 804).

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. Where payments are the reason for the dispute, an attempt should be made to resolve the problem with the patient or by contacting the PAMS service (tel: 1800 443 844).

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 pharmacotherapy pharmacy, or the prescriber or DirectLine (tel: 1800 888 236) may be requested to make a referral.

13 Discontinuing pharmacy participation in providing pharmacotherapy

Pharmacotherapy dispensing 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 where possible
• make arrangements for the continuing medical care of all current patients, including the transfer or appropriate management of all patient records.

DirectLine (tel: 1800 888 236) and the PAMS service (tel: 1800 443 844) may provide assistance with patient transfers to other pharmacotherapy providers.
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.

Your doctor will start you on a low dose.

- This is for safety: to limit the risk of overdosing.
- Your dose will then be increased slowly until you no longer hang out.
- One dose is usually effective for 24 hours, so you will only need one dose a day.

Buprenorphine:
- Starting dose may be higher and increase more rapidly because of its relatively lower risk of overdose.
- Wait at least 6 hours after your last heroin use before starting buprenorphine, or you may suffer unpleasant withdrawal symptoms.

Caution:
Methadone and buprenorphine are drugs like heroin and other opiates, so you can overdose on them.
- Overdose usually only happens when they are being taken at the same time as other sedating drugs like alcohol, tranquillisers (benzodiazepines), sleeping drugs, anti-depressants or some other drugs (check with your doctor).
- Do not take these drugs without your methadone/buprenorphine doctor’s advice.
- Taking methadone or buprenorphine with alcohol increases their sedating effects and the risk of overdose.

Important Note:
The risk of overdose is highest in the first 14 days of treatment.
This is because of low tolerance or a dose that is too high. Use of other sedating drugs also adds to the risk.
- Learn the symptoms of drug overdose and tell the people you are living with to watch for them and help you if necessary.
- Talk to your doctor or pharmacist straight away if you have slurred speech, feel drowsy, can’t stand up, or are ‘out of it’ and confused.

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

Never leave a methadone patient to ‘sleep it off’
Call an ambulance immediately: Dial 000
Appendix 1: Starting methadone or buprenorphine

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
- tranquillisers – benzodiazepines (Hypnodorm, Valium, Normison, Temaze, Serepax, Xanax, Antenex, Ducene, Murelax and others)
- the antiepileptic drug clonazepam (brand names include Rivotril)
- pain killers containing dextropropoxyphene (brand names include Digesic and Doloxene)
- heroin, oxycodone, morphine and codeine
- combinations of any of these.

Your doctor 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 cause several deaths each year in Victoria.

Mixing drugs and alcohol with methadone or buprenorphine is dangerous.

"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 doctor.

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

- slurred speech
- unsteady walking and poor balance
- drowsiness
- slowed movement, slow eating
- stupor (‘out of it’, confused).

- mouth to mouth resuscitation may be needed if the person is not breathing properly
- unrousable, 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’.
Appendix 2: Useful contacts

Drugs and Poisons Regulation, Department of Health

Drugs and Poisons Regulation issues permits for approved practitioners to prescribe pharmacotherapies. It may also approve Health Service Permits to dispense pharmacotherapies.

GPO Box 4541
Melbourne 3001
Tel: 1300 364 545
Fax: 1300 360 830
Email: dpcs@health.vic.gov.au

Harm Reduction and Pharmacotherapy Services

Harm Reduction and Pharmacotherapy Services approves individual medical practitioners and pharmacies to prescribe or dispense pharmacotherapies.

Tel: 9096 5057
Fax: 9096 9170

DirectLine

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

- pharmacotherapy contact details
- 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)

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: http://www.dacas.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: http://www.ysas.org.au

YSASline

The service provides 24-hour access to information, telephone counselling and referral to YSAS outreach teams. The service is open to young people, their families, health and welfare workers, police and ambulance officers. Users call YSASline to contact an outreach team. To access the YSAS residential service, they can contact their local outreach team via YSASline.

Tel (toll free): 1800 014 446 (24-hour service)

Harm Reduction Victoria (HRVic)

The service provides a wide range of information on drugs. It also provides peer support, peer 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: http://www.hrvic.org.au
Pharmacotherapy Advocacy, Mediation and Support (PAMS) service

PAMS is a service that is available to pharmacotherapy patients, 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 attempt mediation before deciding to withdraw service provision to particular patients of the system.

Tel (toll free): 1800 443 844

Medicare Australia

Medicare Australia provides information about pharmaceutical benefits obtained via its Prescription Shopping Information Service (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)

Specialist Pharmacotherapy Services

These 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 Alcohol and Drug Services

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

Austin Health

Studley Road
Heidelberg 3084
Administration line: (03) 9496 5000
Pharmacy line: (03) 9496 5999
Fax: (03) 9459 4546
Web: http://www.austin.org.au

Southcity Clinic

Level 1, 61-69 Brighton Road
Elwood 3184
Tel: (03) 9525 7399
Fax: (03) 9525 7369
Web: 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: 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

Alcohol and Drug Service (WADS)
Cnr Grattan Street and Flemington Road
Parkville 3052
Tel: (03) 8345 3931
Fax: (03) 8345 2996
Web: http://www.thewomens.org.au/womensalcoholanddrugservicewads

Eastern Health Turning Point Alcohol and Drug Centre

54-62 Gertrude St
Fitzroy 3065
Tel: (03) 8413 8413
Fax: (03) 9416 3420
Web: http://www.turningpoint.org.au
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 (SMS)
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

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

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

Department of Health
The fact sheet Hepatitis C - The Facts is available from
the Department of Health website at:

Needle and Syringe Programs (NSPs)
Further information and contact details of NSPs are
available from the Department of Health website at:
and from DirectLine (tel: 1800 888 236)
Appendix 3: Features of a pharmacotherapy prescription

Dr William Pacemaker
123 Medical Street
Ash Park VIC 3999
Tel: (03) 1234 5678

Mr Barry Patient
88 Luck Street
Forktown VIC 3131

01/07/2012
Rx Methadone Syrup
60 (sixty) mg daily
from: 1 July 2012
last dose: 31 July 2012
take-away doses for Saturdays and Sundays

Rx Methadone Syrup
60 (sixty) mg daily
from: 1 July 2012
last dose: 31 July 2012
take-away doses for Saturdays and Sundays

To be dispensed at:
Mortarpestles Pharmacy
125 Fourth Street, Splotswood

William Pacemaker

< Prescriber’s name, address, contact details

< Patient’s name

< Date of prescription written

< Prescription written is legible and durable

< Dose in words and figures

< Date of first dose on this prescription

< Date of last dose on this prescription

< Take-away doses (if authorised)

< For computer-generated prescription, particulars of prescription also handwritten

< Pharmacy at which pharmacotherapy is to be dispensed

< Signature
## Appendix 4: Example pro forma for assessing level of supervised dosing

<table>
<thead>
<tr>
<th>Attendance at medical/case manager reviews</th>
<th>Level of supervision -</th>
<th>High</th>
<th>Medium</th>
<th>Low/Very Low</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regular attendance</td>
<td></td>
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<tr>
<td>Occasional DNA’s (e.g. miss 1 in 4 appointments)</td>
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<tr>
<td>Regular DNA’s (e.g. routinely miss ≥ 2 in 4 appointments)</td>
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<tr>
<td>Missed doses</td>
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<tr>
<td>Pharmacy not contacted</td>
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<tr>
<td>No missed doses in past 4 weeks</td>
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<tr>
<td>Occasional missed doses (≤ 1 per week)</td>
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<tr>
<td>Regular missed doses (≥ 2 per week)</td>
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<tr>
<td>Provision of Urine Drug Screens (UDS)</td>
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<tr>
<td>Provided on request</td>
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<tr>
<td>UDS not provided on request</td>
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<tr>
<td>Heroin and other opioid use</td>
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<tr>
<td>Nil / infrequent additional opioid use</td>
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<tr>
<td>Regular additional use (e.g. 1-2 times per week)</td>
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<tr>
<td>Frequent and regular additional use (e.g. ≥ 3 times per week)</td>
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<tr>
<td>Benzodiazepine use (particularly alprazolam)</td>
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<tr>
<td>No / low dose⁶ prescribed and stable⁷ use</td>
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<tr>
<td>High dose prescribed and stable use</td>
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<tr>
<td>High dose and harmful use⁸, abuse or dependence¹</td>
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<td></td>
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</tr>
<tr>
<td>Alcohol use</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Low risk levels of alcohol use⁹</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Risky / high risk levels of alcohol use</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Harmful, alcohol abuse or dependence</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stimulant use</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nil / infrequent use</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Regular use</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Harmful use, stimulant abuse or dependence</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mental state assessment</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nil concerns</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Concerns re: risk to self / others</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medical co-morbidity</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nil concerns</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Concerns re: medical condition (severe liver / respiratory disease)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stable accommodation</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Evidence of recent injecting sites</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No recent IV injection sites</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Evidence of recent IV injection</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intoxicated presentations at pharmacy or medical clinic / overdoses</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nil within past 2 months</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Recent (within past 2 months)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Recent (past month)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Concerns re: abuse/diversion of take-away doses</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nil concerns</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Poor ability to ‘control’ large supplies of medications (e.g. using take-away doses in advance)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Recent history of abuse (e.g. injecting medications, double dosing), diversion to others</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Authorised level of supervision (circle one)</td>
<td></td>
<td>High</td>
<td>Medium</td>
<td>Low / Very Low</td>
</tr>
</tbody>
</table>

1. DNA = failure to attend scheduled appointment without advance notice / justification acceptable to medical officer. 2. Low dose BZD use is defined as equivalent to < 30 mg diazepam/day. High dose > 30 mg diazepam/day. 3. Stable use = no additional use to amounts prescribed, no binges, intoxicated presentations or recent overdoses. 4. ICD 10 diagnosis of harmful use. 5. DSM IV diagnosis of abuse and dependence. 6. Refer to Australian Alcohol Guidelines for risk levels and alcohol use
Appendix 5: 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 three (3) consecutive days have elapsed since the last dose of methadone or five (5) consecutive days have elapsed since the last dose of buprenorphine. 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 they have taken the dose.

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 pharmacotherapy in Victoria.

In circumstances not specifically covered by the policy:

- Contact the prescriber or the Drug and Alcohol Clinical Advisory Service (DACAS) for instructions or clinical advice (tel: 1800 812 804).
- 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. However, concurrent use of pharmacotherapy with such drugs may represent a risk to the patient and 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. But 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, the 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, explaining its long duration of action. This strong affinity also explains 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 the product 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 poly-drug use.

Missed doses

If a patient misses a series of doses consecutively there is a likelihood that their tolerance to opioids is reduced, and they will be at higher risk of toxicity if administered their previous dose of pharmacotherapy. If three (3) consecutive days elapse since the last dose of methadone or five (5) consecutive days elapse since the last dose of buprenorphine, 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 6: 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.

<table>
<thead>
<tr>
<th>Date</th>
<th>Date</th>
<th>Drug and Dose</th>
<th>Patient's Signature Indicating Dose Received</th>
<th>Supervising Pharmacist’s Signature</th>
<th>Comment (Paid, etc.)</th>
</tr>
</thead>
<tbody>
<tr>
<td>26/7/12</td>
<td>3:30pm</td>
<td>Methadone 40mg</td>
<td></td>
<td></td>
<td>Paid</td>
</tr>
<tr>
<td>27/7/12</td>
<td>4:00pm</td>
<td>Methadone 40mg</td>
<td></td>
<td></td>
<td>Unpaid</td>
</tr>
<tr>
<td>28/7/12</td>
<td>2:30pm</td>
<td>Methadone 40mg</td>
<td></td>
<td></td>
<td>Paid</td>
</tr>
<tr>
<td>29/7/12</td>
<td>2:30pm</td>
<td>Methadone 40mg</td>
<td>Patient signed for dose and take-away dose</td>
<td></td>
<td>Paid</td>
</tr>
<tr>
<td>29/7/12</td>
<td></td>
<td>Take-away</td>
<td>Methadone 40mg</td>
<td>Collected 29/7/12</td>
<td></td>
</tr>
<tr>
<td>30/7/12</td>
<td>4:00pm</td>
<td>Methadone 40mg</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>31/7/12</td>
<td></td>
<td></td>
<td></td>
<td>Missed Dose</td>
<td></td>
</tr>
<tr>
<td>1/8/12</td>
<td></td>
<td></td>
<td></td>
<td>Missed Dose</td>
<td></td>
</tr>
<tr>
<td>2/8/12</td>
<td></td>
<td></td>
<td></td>
<td>Missed Dose</td>
<td></td>
</tr>
<tr>
<td>Patient not to be dosed</td>
<td></td>
<td></td>
<td></td>
<td>Signed by pharmacist</td>
<td>Refer prescriber</td>
</tr>
</tbody>
</table>
**Appendix 7: 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.

<table>
<thead>
<tr>
<th>Date</th>
<th>Time</th>
<th>Comments</th>
<th>Administered by</th>
</tr>
</thead>
<tbody>
<tr>
<td>21/7/12</td>
<td>9:30am</td>
<td>Patient appeared intoxicated or under influence of drugs. Withheld dose.</td>
<td>DF</td>
</tr>
<tr>
<td>21/7/12</td>
<td>9:35am</td>
<td>Rang Dr Smith to inform her of above. She gave instructions not to dose, and to refer patient back to her.</td>
<td>JM</td>
</tr>
<tr>
<td>23/8/12</td>
<td>6:00pm</td>
<td>Rang Dr Smith about patient frequently missing doses but still on take-away doses. Dr Smith unavailable.</td>
<td>CF</td>
</tr>
<tr>
<td>23/8/12</td>
<td>6:30pm</td>
<td>Dr Smith rang back. Gave instructions not to supply take-away doses, and to direct patient to make an appointment with her.</td>
<td>KM</td>
</tr>
<tr>
<td>1/10/12</td>
<td>10:00am</td>
<td>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 1/10/12. Instructed all other pharmacists NOT to dose today (see front of book).</td>
<td>FB</td>
</tr>
<tr>
<td>1/12/12</td>
<td>11:00am</td>
<td>Dr Smith phoned to authorise three take-away doses; confirmed by fax.</td>
<td>RB</td>
</tr>
</tbody>
</table>
Appendix 8: 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.

<table>
<thead>
<tr>
<th>Date</th>
<th>Patient</th>
<th>Dose of Methadone (mg)</th>
<th>Dose of Methadone Syrup (5mg/mL)</th>
<th>Doctor</th>
<th>Pharmacist</th>
</tr>
</thead>
<tbody>
<tr>
<td>1/2/12</td>
<td>J.J. Bowen</td>
<td>80mg</td>
<td>16mL</td>
<td>Black</td>
<td>To sign</td>
</tr>
<tr>
<td>1/2/12</td>
<td>B. Patienta</td>
<td>20mg</td>
<td>4mL</td>
<td>Grey</td>
<td>To sign</td>
</tr>
<tr>
<td>1/2/12</td>
<td>M. Jones</td>
<td>60mg</td>
<td>12mL</td>
<td>Green</td>
<td>To sign</td>
</tr>
<tr>
<td>1/2/12</td>
<td>A. Possi</td>
<td>40mg</td>
<td>8mL</td>
<td>Green</td>
<td>To sign</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td>200mg</td>
<td>40mL</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Note:** The daily total of methadone syrup should be transferred to the Schedule 8 drug register on a daily basis.
Appendix 9: Suggested format for maintaining daily dosing records for multiple patients

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

<table>
<thead>
<tr>
<th>Patient</th>
<th>Doctor</th>
<th>Admin. 1/6/12 (mg)</th>
<th>Dose of Methadone (5mg/mL)</th>
<th>Pharm. to sign</th>
<th>Admin. 2/6/12 (mg)</th>
<th>Dose of Methadone (5mg/mL)</th>
<th>Pharm. to sign</th>
<th>Admin. 3/6/12 (mg)</th>
<th>Dose of Methadone (5mg/mL)</th>
<th>Pharm. to sign</th>
</tr>
</thead>
<tbody>
<tr>
<td>J. Brown</td>
<td>Black</td>
<td>80mg</td>
<td>16mL</td>
<td>JD</td>
<td>80mg</td>
<td>16mL</td>
<td>CH</td>
<td>75mg</td>
<td>15mL</td>
<td>CH</td>
</tr>
<tr>
<td>B. Patient</td>
<td>Grey</td>
<td>20mg</td>
<td>4mL</td>
<td>JD</td>
<td>20mg</td>
<td>4mL</td>
<td>GP</td>
<td>20mg</td>
<td>4mL</td>
<td>GP</td>
</tr>
<tr>
<td>M. Jones</td>
<td>Black</td>
<td>60mg</td>
<td>12mL</td>
<td>JD</td>
<td>65mg</td>
<td>13mL</td>
<td>SK</td>
<td>65mg</td>
<td>13mL</td>
<td>SK</td>
</tr>
<tr>
<td>A. Possi</td>
<td>Red</td>
<td>40mg</td>
<td>8mL</td>
<td>JD</td>
<td>40mg</td>
<td>8mL</td>
<td>JD</td>
<td>35mg</td>
<td>7mL</td>
<td>JD</td>
</tr>
</tbody>
</table>

Daily total mg: 200mg, 205mg, 195mg

Daily total mL: 40mL, 41mL, 39mL

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 10: Suggested format for pharmacotherapy register

Use the normal Schedule 8 drug register.

<table>
<thead>
<tr>
<th>Date</th>
<th>Patient</th>
<th>In (mL)</th>
<th>Out (mL)</th>
<th>Balance (mL)</th>
<th>Pharmacist Signature</th>
<th>Name of Doctor, Invoice No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>31/5/12</td>
<td>Ex supplier</td>
<td>200</td>
<td>200</td>
<td></td>
<td>JD</td>
<td>23106</td>
</tr>
<tr>
<td>1/6/12</td>
<td>Doses as per daily</td>
<td>62</td>
<td>138</td>
<td></td>
<td>JD</td>
<td></td>
</tr>
<tr>
<td></td>
<td>dose sheet</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2/6/12</td>
<td>Doses as per daily</td>
<td>30</td>
<td>108</td>
<td></td>
<td>JD</td>
<td></td>
</tr>
<tr>
<td></td>
<td>dose sheet</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3/6/12</td>
<td>Doses as per daily</td>
<td>46</td>
<td>62</td>
<td></td>
<td>JD</td>
<td></td>
</tr>
<tr>
<td></td>
<td>dose sheet</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Note:** Methadone syrup 5 mg/mL
Appendix 11: 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 dispensed by this pharmacy between _____ and _____ Monday to Friday and _____ to _____ Saturday and _____ to _____ Sunday.

2. Cost
Time is taken to prepare, document and administer your dose, and 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. Unless you are leaving our pharmacotherapy service, no monies paid in advance will be reimbursed.

3. Prescriptions
You need a current prescription and a certified photograph from your pharmacotherapy prescriber before a dose may be administered. It is your responsibility to make sure you have a valid prescription at all times. Your dose cannot be dispensed if your prescription has expired.

4. Attendance
Regular attendance is required for a successful outcome to treatment. Given that pharmacotherapy is a supervised dosing program, your methadone or buprenorphine must be consumed in front of the pharmacist. Buprenorphine and buprenorphine/naloxone tablets will be broken into small pieces or granules.

If you miss more than three (3) consecutive doses of methadone or more than five (5) doses of buprenorphine or buprenorphine/naloxone, your doctor must review you and issue a new prescription before your dose can be dispensed and treatment can continue.

5. Take-away doses
Take-away doses are only authorised by your prescribing doctor. If you need to change your dosing 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 and 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. Threatening behaviour and acts of violence towards pharmacy staff or other customers will result in cancellation of your treatment program. Rudeness, personal abuse and disruptive behaviour will also result in termination of your treatment at this pharmacy.

Any suspicion of drug dealing or any other criminal activity on the premises or within the vicinity of the pharmacy will result in the police being called and termination of your treatment at this pharmacy.

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.

Where possible 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 participation in the pharmacotherapy program._

Patient's name: 
Address: 
Telephone: 
Signature: 
Date: 

Pharmacist’s name: 
Signature: 
Date: 
Appendix 12: Pharmacotherapy patient transfer facsimile

To: _______________________

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 (film / tablet)* ______________ milligrams

* Strike out where inapplicable.

Signature: _______________________


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<table>
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<th>Patient Transfers</th>
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</tr>
</thead>
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<td>Allied Health Professionals</td>
<td>19</td>
<td>International Transfer</td>
<td>31</td>
</tr>
<tr>
<td>Approval of Pharmacies</td>
<td>35</td>
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<td>31</td>
</tr>
<tr>
<td>Approval of Prescribers</td>
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<td>Intrastate Transfer</td>
<td>30</td>
</tr>
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<td>Assessing Patient Stability</td>
<td>23-29, 43, 51</td>
<td>Permit Application</td>
<td>17</td>
</tr>
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<td>Benefits of Pharmacotherapy</td>
<td>4</td>
<td>Permit Exceptions</td>
<td>17</td>
</tr>
<tr>
<td>Buprenorphine/naloxone Prescribing by Non-Approved Prescribers</td>
<td>14</td>
<td>Pharmacotherapy Advocacy, Mediation and Support Service</td>
<td>47</td>
</tr>
<tr>
<td>Certification of Pharmacists</td>
<td>36, 52, 53</td>
<td>Photograph</td>
<td>16, 35, 36</td>
</tr>
<tr>
<td>Closure of Practice</td>
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