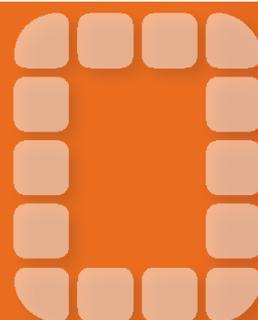
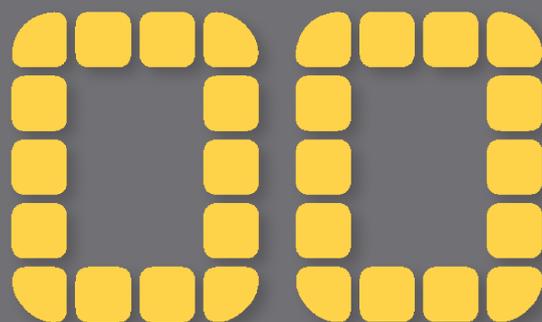
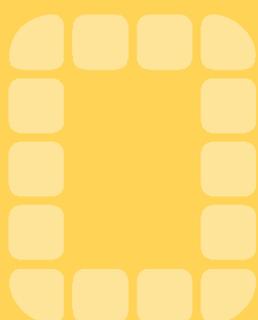


**WESTERN AUSTRALIAN**

# Community Program for Opioid Pharmacotherapy (CPOP)



**Clinical Policies and Procedures for the  
Use of Methadone and Buprenorphine  
in the Treatment of Opioid Dependence**



3rd Edition

## Acknowledgements

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The Drug and Alcohol Office and the Department of Health recognise the following sources as contributors to the development and review of this Manual:

*National Clinical Guidelines and Procedures for the Use of Buprenorphine/Methadone in the Treatment of Opioid Dependence (2006)*. The Australian Government Department of Health and Ageing.

*The New South Wales Opioid Treatment Program: Clinical guidelines for methadone and buprenorphine treatment of opioid dependence*. Mental Health and Drug and Alcohol Office. NSW Department of Health, 2011.

*Tasmanian Opioid Pharmacotherapy Program, Policy and Clinical Practice Standards*. Department of Health and Human Services, 2012. Hobart: Tasmanian Government.

Acknowledgement is extended to all contributors, including the Opioid Pharmacotherapy Advisory Committee (OPAC), Next Step Drug and Alcohol Services, Cambridge Clinic, and other health care service providers who provided invaluable feedback throughout the consultation process which preceded both the initial development and subsequent reviews of the WA policies.

This Manual reflects what is currently regarded as safe practice for medication assisted treatment of opioid dependence and has been compiled with all due care.

Changes in circumstances after the time of publication may impact on the accuracy or currency of information, and amendments may be forwarded for inclusion to this Manual at a later date.

### **Prepared by**

**The Community Pharmacotherapy Program, in consultation with the Community Program for Opioid Pharmacotherapy Management Committee.**

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## Preface

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This Manual details the policies and procedures that apply to the prescribing and dispensing of methadone and buprenorphine for the treatment of opioid dependence in Western Australia as part of the Community Program for Opioid Dependence (CPOP). All medical practitioners and pharmacies that apply to provide CPOP treatment agree to comply with the policies and procedures set out herein.

In Western Australia, the Community Program for Opioid Pharmacotherapy (CPOP) is managed jointly by the Department of Health and the Drug and Alcohol Office (DAO).

The *Western Australian Community Program for Opioid Pharmacotherapy (CPOP). Clinical Policies and Procedures for the Use of Methadone and Buprenorphine in the Treatment of Opioid Dependence (3<sup>rd</sup> Edition)* Manual has been developed with reference to national guidelines and incorporates legislative and administrative requirements specific to WA.

The 2014 review of the Manual has incorporated timely innovations and changes in treatment and policy that have occurred since the 2007 edition. Information contained within is accurate and up to date at the time of review.

Compliance with the policies, procedures and clinical practice set out in this Manual is a condition of authorisation for CPOP prescribers and dispensers of methadone and buprenorphine to opioid dependent clients in WA. There should be no variation from the legislative or administrative requirements set out in this Manual relating to regulatory requirements.

Additional resources and an electronic copy of the contents of this Manual are included with this edition. Visit [www.opioiddruginteractions.com](http://www.opioiddruginteractions.com) to access the online interactions database **Drug-Drug Interactions in Opioid Maintenance: A focus on buprenorphine and methadone** along with details of smartphone applications as they become available.

The arrangement of this edition is in five sections for simple, straightforward access and ease of use by service providers and others. The information contained within is supported by a range of resources that have been developed for service providers and consumers, and are available from the Community Pharmacotherapy Program (CPP).

### Section 1

**Framework for Medication Assisted Treatment of Opioid Dependence in WA** which contains general information relating to the Western Australian Community Program for Opioid Pharmacotherapy (CPOP) and the legislation within which it is regulated and administered.

### Section 2

**Clinical Features of Opioid Dependence** provides the definition for opioid dependence and discusses the associated clinical features of withdrawal, intoxication and overdose.



### **Section 3**

Clinical Pharmacology provides specific clinical pharmacological information regarding the pharmacotherapies approved for opioid substitution treatment in Australia.

### **Section 4**

Patient Management which contains information that is relevant to authorised WA CPOP prescribers regarding approved policy and clinical practice.

### **Section 5**

Pharmacist Guide which contains information that is relevant to pharmacists and dispensers of pharmacotherapies regarding approved policy and practice associated with CPOP.



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## ABBREVIATIONS

<b>ADIS</b>	Alcohol and Drug Information Service	<b>mcg</b>	Micrograms
<b>AOD</b>	Alcohol and Other Drugs	<b>mg</b>	Milligrams
<b>BBV</b>	Blood Borne Virus	<b>mL</b>	Millilitres
<b>CAS</b>	Clinical Advisory Service	<b>NA</b>	Narcotics Anonymous
<b>CNS</b>	Central Nervous System	<b>NAS</b>	Neonatal Abstinence Syndrome
<b>COWS</b>	Clinical Opiate Withdrawal Scale	<b>NSAIDS</b>	Non Steroidal Anti-Inflammatory Drugs
<b>CPD</b>	Continuing Professional Development	<b>NSP</b>	Needle and Syringe Program
<b>CPOP</b>	Community Program for Opioid Pharmacotherapy	<b>OOWS</b>	Objective Opioid Withdrawal Scale
<b>CPOPCRC</b>	Community Program for Opioid Pharmacotherapy Clinical Review Committee	<b>OPAC</b>	Opioid Pharmacotherapy Advisory Committee
<b>CPOPMC</b>	Community Program for Opioid Pharmacotherapy Management Committee	<b>ORPACS</b>	Opiate Replacement Pharmacotherapy Advocacy and Complaints Service
<b>CPOPMRC</b>	Community Program for Opioid Pharmacotherapy Mortality Review Committee	<b>OST</b>	Opioid Substitution Treatment
<b>CPP</b>	Community Pharmacotherapy Program	<b>PBS</b>	Pharmaceutical Benefits Schedule
<b>DAO</b>	Drug and Alcohol Office	<b>PSB</b>	Pharmaceutical Services Branch
<b>DD</b>	Drugs of Dependence	<b>S8s</b>	Schedule 8 Poisons or Controlled Drugs
<b>The Department</b>	Western Australian Department of Health	<b>S9s</b>	Schedule 9 Poisons or Prohibited Substances
<b>DSM-5</b>	Diagnostic and Statistical Manual of Mental Disorders, 5 <sup>th</sup> edition, 2013.	<b>SOWS</b>	Subjective Opioid Withdrawal Scale
<b>FACHAM</b>	Fellow of the Australasian Chapter of Addiction Medicine	<b>SSRIs</b>	Selective Serotonin Reuptake Inhibitors
<b>GP</b>	General Practitioner	<b>STIs</b>	Sexually Transmitted Infections
<b>HIV</b>	Human Immunodeficiency Virus	<b>WAADA</b>	Western Australian Alcohol and Drug Authority
		<b>WANDAS</b>	Women and Newborn Drug and Alcohol Service



# 1

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## Framework for Medication Assisted Treatment of Opioid Dependence in WA



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## 1. The WA Community Program for Opioid Pharmacotherapy (CPOP)

Dependence on opioids has wide ranging effects on individuals, their family, and the broader community. These negative impacts can be significantly reduced by treatment.

Medication assisted treatment for opioid dependence is a combination of medication (methadone or buprenorphine for substitution treatment, or naltrexone for relapse prevention treatment) and psychosocial support. Medication eliminates withdrawal, reduces cravings and blocks the euphoric effect of further opioid use. Psychosocial support refers to the many ways in which the psychological wellbeing, social environment and quality of life of the opioid user can be improved. Assistance can range from simple provision of food and shelter to complex structured psychotherapy.

Opioid substitution treatment (OST) is an effective strategy for helping drug dependent individuals reduce their drug use and stabilise their lives by reducing the demand for drugs, and the resulting harms.

In Western Australia, OST is available through the Community Program for Opioid Pharmacotherapy (CPOP), a partnership between government and community service providers. The Program adopts a shared care approach, with OST provided through general practices, Next Step and other drug and alcohol treatment services, correctional institutions, and community pharmacies.

The Drug and Alcohol Office (DAO) through the Community Pharmacotherapy Program (CPP) supports CPOP through provision of education and training, clinical consultancy and consumer liaison and support. The regulatory functions of the Program are administered through the Pharmaceutical Services Branch (PSB) within the Department of Health. Together, these agencies are responsible for policy development, and Program management and coordination.

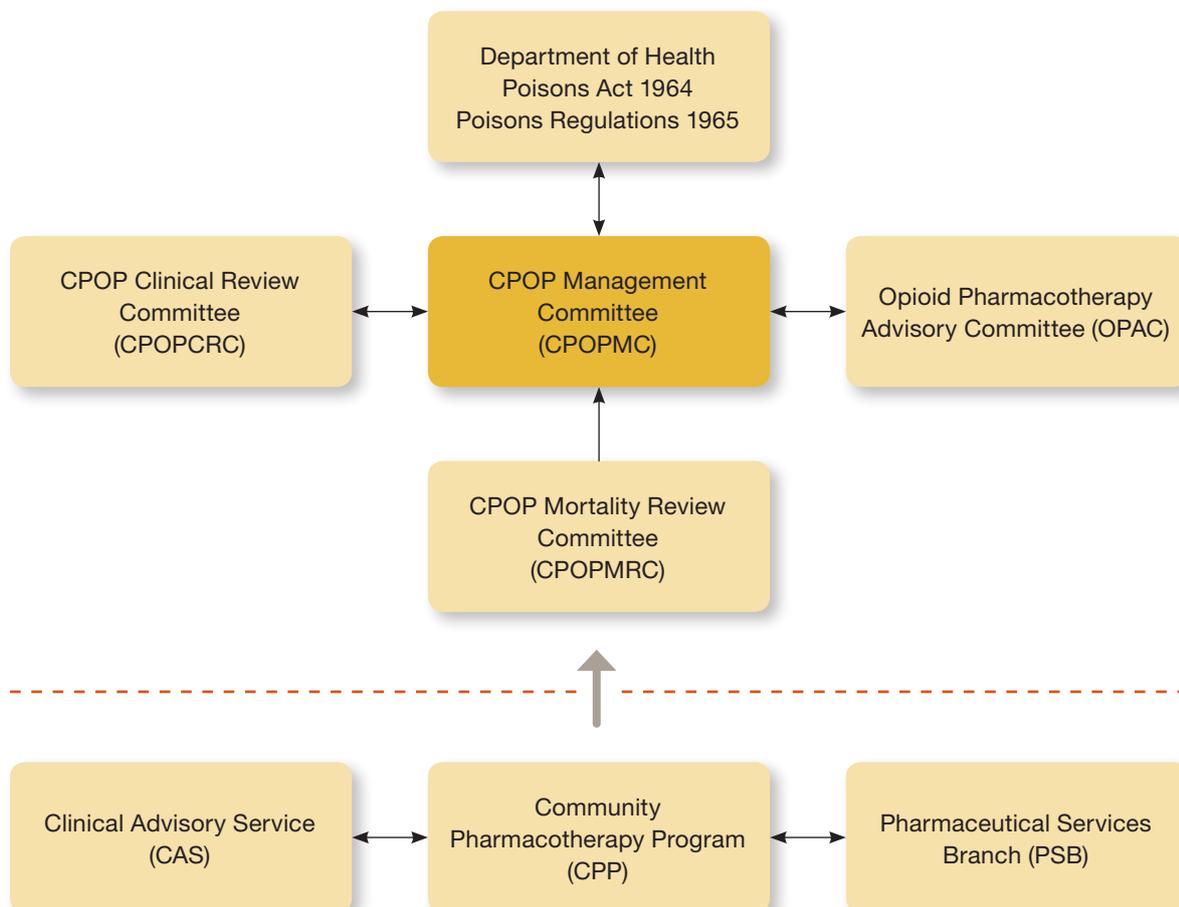
OST can be prescribed for short-term and longer-term maintenance treatment, and for the management of opioid withdrawal. Methadone and buprenorphine are the two opioid substitution medications approved for use in Australia, and are widely accepted as effective treatments for opioid dependence. Naltrexone is a relapse prevention pharmacotherapy. Treatment is shown to reduce opioid use and achieve improvements in a number of areas, including personal health and social inclusion.

The use of methadone and buprenorphine as treatments for opioid dependence is endorsed under the *National Drug Strategy 2010-2015* within the framework of harm reduction.



The Program management structure of CPOP is as follows:

**Figure 1 Program Management Structure**



**CPOP Management Committee (CPOPMC)**

The role of the CPOP Management Committee is to provide strategic direction and management of the operations of CPOP in Western Australia. The Committee oversees the development and implementation of relevant policies, procedures and clinical guidelines. It also ensures the delivery of appropriate training programs and revalidation protocols for prescribers and dispensers of methadone/buprenorphine. Membership is comprised of representatives from the Drug and Alcohol Office and the Department of Health.

**Opioid Pharmacotherapy Advisory Committee (OPAC)**

OPAC consists of a group of key stakeholders who support the operation of CPOP by representing service provider and consumer interests regarding policy and program initiatives. This group also has a role in identifying issues of concern regarding the delivery of methadone and buprenorphine treatment and making recommendations to the CPOP Management Committee. Membership comprises representatives from general practice, pharmacies, consumer groups, the Drug and Alcohol Office and the Department of Health.



### **CPOP Clinical Review Committee (CPOPCRC)**

The CPOP Clinical Review Committee meets to review and endorse applications for OST that fall outside the WA Policies and Procedures, to review the management of clients with special dosing approval, and to respond to clinical management issues which may impact upon service providers and clients of the Program.

The Committee comprises the Director of Clinical Services (Next Step), Addiction Medicine Consultants, the Manager of the Community Pharmacotherapy Program (CPP) and the Clinical Coordinator (CPP). The Committee provides specialist advice to prescribers and pharmacies participating in the Program, the Community Program for Opioid Pharmacotherapy Management Committee, and the Department of Health.

### **CPOP Mortality Review Committee (CPOPMRC)**

This Committee is convened by the Monitoring, Evaluation and Research Branch of the Drug and Alcohol Office. The Committee reviews mortality episodes where methadone or buprenorphine is implicated as a cofactor to identify potential safety issues or trends.

General recommendations for clinical practice when made are disseminated to CPOP service providers through the CPOP Update newsletter, the CPOP Seminar Series, and via other communication strategies which may include direct contact. Findings are reported to the CPOP Management Committee and may influence WA policy.

### **Pharmaceutical Services Branch (PSB)**

The Pharmaceutical Services Branch provides the regulatory controls associated with the prescribing and dispensing of methadone and buprenorphine through the *Poisons Regulations 1965*.

*PSB Contact Details:*

Phone: (08) 9222 6812

Fax: (08) 9222 2463

### **Community Pharmacotherapy Program (CPP)**

The Community Pharmacotherapy Program (CPP) is responsible for reviewing and processing applications for CPOP treatment and provides expert advice and information on all aspects of opioid pharmacotherapy treatment in WA.

CPP supports CPOP prescribers, pharmacists, and clients with prescribing and dispensing issues and provides referral to other services as appropriate. CPP supports prison release arrangements for continuing pharmacotherapy treatment in the community and assists with interstate and international transfers of pharmacotherapy clients from and to WA. CPP also delivers training, develops resources and supports ongoing professional development for CPOP prescribers, pharmacists, and ancillary staff.



*CPP Contact Details:*

Phone:

(08) 9219 1907 – Clinical Treatment Support

(08) 9219 1896 – Training and Resources

Fax:

(08) 99471 0444

**Clinical Advisory Service (CAS)**

The Clinical Advisory Services operates a 24/7 phone service for health professionals providing clinical advice on all issues relating to patient management involving alcohol and drug use. CAS is staffed by experienced CPP staff and medical practitioners from Next Step Drug & Alcohol Services.

*CAS Contact Details*

Phone: 9442 5042

**Freecall: 1800 688 847**

**1.1 Legislative and administrative requirements**

The legislative framework for the Community Program for Opioid Pharmacotherapy is underpinned by the *WA Poisons Regulations 1965*. Medical practitioners require prior authorisation from the Department of Health Chief Executive Officer to prescribe methadone and buprenorphine for the treatment of dependence. In addition the authorised prescriber must obtain an individual client authority from the Department of Health Chief Executive Officer, before prescribing methadone or buprenorphine to a drug dependent person.

The *Drugs of Addiction Notification Regulations 1980* also require a medical practitioner who, in the course of their practice, becomes aware of or suspects a person of being addicted to drugs, to inform the Executive Director Public Health.

A person listed in the register of information kept under the *Drugs of Addiction Notification Regulations 1980*, may make application for removal of their information where certain conditions are met. PSB should be contacted for further information.

**1.2 Becoming an authorised methadone/buprenorphine prescriber and prescriber re-authorisation in WA**

Authorisation as a prescriber involves the following:

1. The medical practitioner must complete an *Application to be authorised as a Community Program for Opioid Pharmacotherapy (CPOP) prescriber*.
2. The practitioner is required to satisfactorily complete the training and assessment package delivered by the Community Pharmacotherapy Program and agree to comply with the *Western Australian Clinical Policies and Procedures for the Use of Methadone and Buprenorphine in the Treatment of Opioid Dependence*.



3. CPP will notify the Department of Health that the prescriber has satisfactorily completed the training and assessment requirements.
4. The Department will provide the practitioner with written authorisation to participate in CPOP.

Authorised prescribers are expected to maintain authorisations to treat a minimum of 2 clients in any 12 month period. Where a prescriber fails to meet the 2 client minimum and wishes to continue their authorisation they may be required to attend refresher training provided by CPP, or apply for an extension in writing which will be considered by the CPOP Management Committee.

### **Prescriber re-authorisation in WA**

The process of re-authorisation as a CPOP prescriber in WA requires completion of a continuing professional development (CPD) activity each 3 years.

Where a prescriber chooses to withdraw from CPOP, appropriate notifications, administration requirements, and client transfer arrangements must be finalised.

## **1.3 Authority to prescribe**

Authorised methadone/buprenorphine prescribers must obtain from the Department of Health Chief Executive Officer an individual client authority for each client being commenced on treatment under *Regulation 51CA* of the Poisons Regulations 1965. The process of accessing an individual client authority is as follows:

1. An *Application to prescribe opioid substitution treatment* is completed by the prescriber. The client must also sign the completed application to indicate that they acknowledge that the information will be forwarded to the Department of Health and used for the management of the Program. The *CPOP Patient Contract to Receive Opioid Substitution Treatment* (see Appendix 1) should also be discussed and signed by the client.
2. The completed *Application to prescribe opioid substitution treatment* is forwarded to the Community Pharmacotherapy Program and the authorisation is subsequently issued by the Department of Health.
3. An authorisation number must be obtained prior to the writing of a prescription for methadone or buprenorphine. Authorisation is for a maximum daily maintenance dose for up to 120mg of methadone or 24mg of buprenorphine.

The authorisation number issued is unique to the treatment provided by the prescriber to each individual client. The authorisation number is generally issued for a period of 2 years. If the treatment or the prescriber's location changes, a new application must be made whereby a new authorisation number is issued by the Department and the previous number terminated. Where a client's prescriber changes within the existing practice, a new number is not required.



An *Application to prescribe opioid substitution treatment* is required when initiating OST for a client, when transferring from one practice to another, or for a client who has previously been treated by the same prescriber where the previous authorisation has expired or been terminated. A new application must also be made when the pharmacotherapy is changed (e.g. from methadone to buprenorphine).

### **Renewal of authority to prescribe**

The Department of Health will forward a *Renewal application to prescribe opioid substitution treatment* to the prescriber during the month prior to expiration of a client's authorisation. The prescriber must renew the authority by completing the form and returning it to the Department.

### **Terminating the authority to prescribe**

At completion of OST, or upon transfer to a new prescriber, a *Termination of opioid substitution treatment* form must be completed by the prescriber and forwarded to the Department.

### **1.3.1 Conditions associated with the authority to prescribe opioid substitution treatment**

The authorisation for a medical practitioner to prescribe methadone or buprenorphine is subject to the following conditions:

#### **Legal responsibility**

The prescriber is legally responsible for the treatment of the client until treatment is transferred or terminated.

#### **Client numbers policy**

Managing a high number of clients increases risk across three areas:

- ensuring continuity of care should the prescriber or dispensing location become unavailable, either temporarily or permanently
- ensuring quality of care
- the impact on local amenity.

#### **Client numbers per authorised prescriber**

When authorised to prescribe methadone or buprenorphine treatment, a sole medical practitioner will be permitted to prescribe for a maximum of 50 active pharmacotherapy clients.

**A sole regional prescriber will be limited to a maximum of 25 pharmacotherapy clients.**

The risk to continuity of care is particularly high where the prescriber is a sole practitioner and/or is located in a regional area. Other prescribers may not be available to continue treatment in the event that a prescriber withdraws from the Program.



A prescriber may apply to exceed these numbers by completing an *Application for a prescriber to increase client numbers* and forwarding it to the Pharmaceutical Services Branch of the Department of Health. The Department will forward the application to the CPOP Management Committee for consideration and review. The CPOP Management Committee will then make a recommendation to the Department of Health Chief Executive Officer on whether to increase the prescriber's client numbers to a determined limit.

In assessing the application, the CPOP Management Committee will consider the record of the prescriber in complying with the CPOP policies and procedures, the ability of the prescriber to maintain appropriate levels of client care for managing more than 50 clients, available support services and any other information considered to be relevant to the decision.

In exceptional circumstances authority may be provided by the Department of Health Chief Executive Officer for an approved prescriber to temporarily exceed their maximum numbers in order to ensure continuation of care for existing clients of the Program.

### **Specialist Practice model**

A practice may apply for conditional approval as a Specialist Practice where there are a minimum of 3 authorised prescribers, of whom at least one is a Fellow of the Australasian Chapter of Addiction Medicine (FACHAM), and where compliance with the standard CPOP policies and procedures has been demonstrated. A maximum number of clients will be authorised to a Specialist Practice as determined by the CPOP Management Committee.

In the event of concerns emerging about public amenity due to a large number of clients attending a particular medical centre or general practice, the matter may be considered by the CPOP Management Committee which may recommend changes to the maximum number of clients who can be treated at the service.

### **Appointment of Specialist Prescriber**

A Specialist Prescriber is designated by the CEO under *Regulation 51C* of the Poisons Regulations 1965 to provide support to CPOP authorised prescribers. Specialist Prescribers can provide assistance with pharmacotherapy scripting issues through CAS.

Please note that the designation of a Specialist Practice does not denote Specialist Prescriber status.

### **Appointment of co-prescriber**

A medical practitioner may be appointed as a co-prescriber for a client who remains under the authorisation of a specialist prescriber under *Regulations 51CA, 51CB, 51CC and 51D* of the Poisons Regulations 1965. The appointment of a co-prescriber may be approved for a specified period (up to 12 months) and is subject to the rules of the appointment as determined by the CPOP Management Committee.



## 1.4 Becoming a CPOP dispenser in WA

Pharmacies participating in the dispensing of methadone/buprenorphine for opioid dependence must be authorised by the Department of Health Chief Executive Officer.

The pharmacy licence holder is required to complete an *Application for a Pharmacy to Participate in the Community Program for Opioid Pharmacotherapy (CPOP)*. The Department of Health issues an authorisation to the pharmacy to participate in the dispensing of methadone/buprenorphine. It also notifies the nominated wholesaler that the pharmacy is participating in CPOP and is eligible for the PBS S100 supply of methadone and buprenorphine free of charge (a recording fee still applies).

The licence holder must ensure compliance with the *Western Australian Clinical Policies and Procedures for the Use of Methadone and Buprenorphine in the Treatment of Opioid Dependence* and the relevant provisions of the Poisons Act 1964 and its Regulations. The licence holder must also ensure that all pharmacists dispensing methadone and buprenorphine have the competencies required.

CPP provides an online training program which must be completed by all pharmacists participating in CPOP. Contact CPP for details on how to access the training program. Pharmacists participating in CPOP will also be required to show evidence of participation in ongoing professional development in the form of online training updates developed by CPP.

### **Client numbers per approved pharmacy**

Participating pharmacies are authorised to dispense to a maximum of 50 clients per day. To exceed this number a pharmacy may apply to the Pharmaceutical Services Branch of the Department of Health by completing an *Application for a pharmacy to increase client numbers*. The Department will forward the application to the CPOP Management Committee for consideration.

A review will be undertaken to determine the capacity of the pharmacy to manage a greater number of clients. In assessing the application, the CPOP Management Committee will consider the record of the pharmacy in complying with CPOP policies and procedures, the ability of the pharmacy to maintain appropriate levels of client care for managing more than 50 clients and any other information considered to be relevant. The CPOP Management Committee may then recommend to the Department of Health Chief Executive Officer an increase in client numbers in support of the application.

In the event of concerns emerging about public amenity due to a large number of clients attending a particular pharmacy or client issues arising, the matter may be considered by the CPOP Management Committee and a change to the maximum number of clients may be required.



## 2. Medication Assisted Treatment of Opioid Dependence

### 2.1 Rationale for opioid substitution treatment

OST with methadone or buprenorphine is appropriate for those with significant opioid dependence wishing to cease illicit opioid use.

Substitution treatment with methadone or buprenorphine replaces short-acting opioids such as heroin and oxycodone with a long-acting opioid that can be taken orally. OST is designed to have a minimal intoxicating effect, blocking the euphoria associated with use of exogenous opioids and preventing withdrawal. OST is highly effective in engaging opioid dependent people in treatment.

The objective of substitution treatment with methadone or buprenorphine is primarily to reduce and stop the use of illicit opioid drugs. Other important objectives are to:

- reduce risk behaviours associated with contracting and transmitting infectious diseases
- reduce the incidence of death associated with illicit opioid use
- improve the health, wellbeing and social functioning of clients
- reduce drug related crime
- reduce other social costs of illicit opioid use
- motivate and support clients to achieve their positive lifestyle goals.

While the achievement of an opioid-free state is a long-term goal of maintenance treatment, this may not be the initial objective of the client. Positive outcomes are to a large extent dependent on reduction of illicit opioid use and it is reasonable to expect that methadone and buprenorphine maintenance treatment will assist clients toward becoming opioid free.

### 2.2 Aim of opioid substitution treatment

The overall aim of OST is to enable opioid dependent people to reduce and stop their use of illicit opioids by substituting them with a regulated, safer alternative. This has the effect of reducing the harms associated with dependent opioid use to the individual, their families and the community.

Optimising the benefits of OST requires ease of access to treatment and quality standards of care. This can be achieved when general practitioners and pharmacists are trained to deliver OST, comply with CPOP policies and procedures and are able to consult with and refer clients to specialist drug and alcohol treatment services.

In WA, integrated models of care developed as partnerships across specialist treatment services and the non-government sector are also available. These services can provide a comprehensive response to client needs, employing case management often with direct access to psychiatry, counselling, psychology, social work and general medical care.

Clients commencing OST or with complex presentations may be seen within a specialist drug treatment service for assessment and initial OST management, and later be referred to a community prescriber for ongoing management. Clients can be referred back into specialist treatment services when necessary.



## 2.3 Duration of treatment

The benefits of OST are optimised when programs are readily accessible; entry into treatment is without delay and where retention in treatment is high. Outcomes improve as time in treatment increases, and clients should be encouraged to remain in treatment for at least 12 months to achieve enduring lifestyle changes.

For the majority of clients receiving OST, it is appropriate to encourage 1-2 years of treatment in order to realize the benefits for both the individual and the community. Removing people from treatment too early may result in a poor outcome.

There is no optimal specifiable duration of treatment, and regular reviews help to determine the need for continuing treatment or the development of a plan for completing treatment. Clients who have ceased all illicit opioid use for a period of 6-12 months should be presented with options for planned withdrawal of OST.

## 2.4 Treatment options and adjunctive treatment for opioid dependence

While treating people with opioid dependence can improve health and social outcomes, substitution treatment also presents risk, involves unwanted side-effects and considerably restricts lifestyle choices due to program requirements.

Clients considering OST must be fully informed of alternative treatment options and the implications of each of these treatments as part of the process of assessing their suitability for treatment.

### **Other treatment options for opioid dependence include:**

- Withdrawal – management of opioid withdrawal can be undertaken in an inpatient or outpatient setting and may include the provision of medication to reduce withdrawal symptoms. Opioid withdrawal typically takes one to two weeks to complete.
- Rehabilitation – rehabilitation programs provide a supportive environment within a residential setting to assist with development of healthy life skills. Residential rehabilitation programs usually require evidence of withdrawal or a significant period of abstinence prior to admission, and are generally longer term.
- Opioid antagonist treatment – naltrexone can assist with the prevention of relapse to opioid use. Naltrexone treatment should only be undertaken once a client has completed withdrawal.
- Counselling and support – psychosocial support can be obtained from a range of sources including community-based drug and alcohol services, psychologists, and self-help groups such as Narcotics Anonymous (NA). Counselling and support can provide a valuable adjunct to OST.

Clinical decision-making should be based on all available evidence and clients should be presented with the merits and the limitations of treatment outcomes associated with each approach. Print materials outlining the range of treatment options available to clients can be obtained from CPP. Clients requiring professional advice and information on the range of treatment options available can be referred to the Alcohol and Drug Information Service (ADIS).



Prescribing doctors and health care workers should be alert for the presence or emergence of concurrent problems, particularly mental health issues. Monitoring and documentation of response to treatment is a critical part of developing an effective treatment plan.

People with a background of opioid dependence often experience a range of problems (e.g. financial, employment, parenting, legal, housing) along with psychological difficulties which may include depression and anxiety. The stability afforded by long-term substitution treatment provides an opportunity for these issues to be addressed. One of the key roles for treating clinicians is to assist in this process, either as direct service providers or as case managers, referring the client on to appropriate services. Evidence suggests that counselling should be made available to all clients, who should also be actively encouraged to engage with these services.

## 2.5 Principles of case management/coordinated care

Integrated care models offer a coordinated set of services which are planned, managed and delivered to individuals. Shared care arrangements are characterised by improved information exchange and coordination of care where there is joint participation of GPs, pharmacists and specialists in the planned delivery of care to clients. Treatment outcomes can be improved with effective case management and coordinated service delivery.

### **Home Medicines Review (HMR)**

Client referral to an appropriate pharmacy for a Home Medicines Review is recommended where possible for any client commencing on OST with multiple medications or with complex health issues.

A HMR involves the patient, their OST prescriber, an accredited pharmacist and regular community pharmacy. In some cases other relevant members of the healthcare team such as nurses in community practice and carers are included. The pharmacist visits the client, reviews their medicine routine and provides their prescriber with a report. The prescriber and client then agree on a medicine management plan.

It is generally best practice for the HMR interview to take place in the client's home, however client preference (with daily attendance in the pharmacy) or potential safety concerns may warrant the interview to be conducted in the pharmacy or in a location other than the client's home.

The relationship between the client, their prescriber and the dispenser of methadone or buprenorphine treatment is critical to successful and safe treatment. Regular communication is needed to enhance safety and ensure consistency in the overall treatment program. Shared care models are also likely to attract and retain service providers due to a higher level of clinical support in the work.



## 2.6 Priority access

OST in Australia is highly regulated, with supervised administration of methadone and buprenorphine being an integral and essential part of the Program. Treatment is only available with an individual client authority, and requires the authorisation of participating doctors and pharmacies. Consequently, treatment places may be limited and entry into treatment may at times be delayed.

Opioid dependent people considered to be at substantial risk should be provided priority access to CPOP by direct referral to Next Step Drug and Alcohol Services, or referral through CPP to authorised community providers.

Priority access to OST should be provided to:

- clients currently engaged in an OST maintenance program
- pregnant women and their opioid dependent partners
- opioid dependent people recently released from prison
- people with HIV and their opioid dependent partners.

## 2.7 Opioid substitution treatment in prisons

OST is available in prisons throughout WA, and incarceration can provide an opportunity to offer treatment for opioid dependence.

Individuals who are receiving OST in WA prior to incarceration have access to uninterrupted continuation of treatment while in prison. As a general policy, patients who enter prison on buprenorphine treatment will be transferred to methadone to reduce the potential for diversion. Those patients who are remanded for a brief period may be maintained on buprenorphine until released. For opioid dependent people not receiving OST who are subsequently incarcerated, treatment may be made available. Evaluations of prison-based substitution programs have been consistently favourable, associated with a substantial decline in risk behaviour for blood-borne virus infection due to syringe sharing, decreased levels of drug use, reduced participation in the prison-based drug trade, and increased participation in drug treatment following release from prison. The risk of death from drug overdose is greatly increased for those not receiving OST post-release due to reduced tolerance.

CPP works closely with prison health services to ensure a smooth transition to the community post-release for prisoners who are receiving treatment. Liaison commences prior to release, and continues post release to ensure uninterrupted continuation of OST.



## 2.8 Children of clients – Child protection

On initial assessment, at treatment reviews, and when assessing eligibility for takeaway doses of an opioid pharmacotherapy it is important to consider the safety and wellbeing of any children in the client's care.

Child safety is of paramount concern, and all health workers are expected to take an active approach to any concerns about the care and protection of children. It should be noted that a parent's enrolment in an OST program alone is not a reason to make a report to the Department for Child Protection and Family Support.

Child abuse and neglect is defined as the harm, or likely harm experienced by a child as the result of the actions, or inactions of an adult who has a care responsibility for the child.

It is the responsibility of all health workers who become aware of children who have been subjected to, or who are at risk of abuse and/or neglect to take action that promotes their safety and wellbeing and when necessary, to make reports to the appropriate authorities (*WA Department of Health Guidelines for Protecting Children 2009*). Where there is an indication that any child has been maltreated or may be at immediate risk of harm or injury the Department for Child Protection and Family Support should be notified through a local district office.

It is a legal requirement in WA for doctors, nurses, midwives, teachers and police officers to report all reasonable beliefs of child sexual abuse. Mandatory report forms can be accessed at [www.mandatoryreporting.dcp.wa.gov.au](http://www.mandatoryreporting.dcp.wa.gov.au)

The death of a child whose parent or caregiver is known to the Program may be investigated by the Coroner and/or the Ombudsman.



### 3. Health Practitioner Reporting

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The *Health Practitioner Regulation National Law Act 2009* came into effect on 1 July 2010, requiring the mandatory reporting by health practitioners and employers of impaired practitioners or practitioners who may have engaged in inappropriate conduct.

When a health professional is receiving treatment for an alcohol or other drug issue, the treating health professional has an obligation to make a report if there is evidence of risk to public safety due to the effect of the person's substance use on their capacity to fulfill their role as a health professional. The Australian Health Practitioner Regulation Agency (AHPRA) should be contacted on **1300 419 495** between 9am – 5pm (local time) for advice and guidance in relation to these situations.

Where a health practitioner with access to S8 medications is commenced on OST, notification must be made in the appropriate section of the *Application to prescribe opioid substitution treatment*.

# 2

## Clinical Features of Opioid Dependence



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- 3. **Opioid Withdrawal**.....22
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## 1. Definition

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For the purpose of this Manual, a **drug-dependent person** refers to an individual who has acquired, as a result of repeated administration of a drug of addiction, a persistent desire to use and an inability to control their use of the drug of addiction.

Regular use of opioids over time causes the body to adjust to the continued presence of the drug in the central nervous system. This adjustment, called neuroadaptation, is characterised by tolerance to the drug's effects and the onset of withdrawal symptoms when use of the drug is suddenly ceased or significantly decreased. In addition, psychological attachments to drug use can develop, resulting in preoccupation with opioid drugs, strong urges to use, and behaviours which display the high importance of opioid use.

### Diagnostic criteria of substance dependence

No single feature is an indicator of dependence and dependent individuals may experience different characteristics in varying degrees. Establishing a diagnosis of opioid dependence is a requirement for opioid substitution treatment. The International Classification of Diseases (ICD-10 Version 2010) and *The Diagnostic and Statistical Manual of Mental Disorders* (5th ed.; *DSM-5*; American Psychiatric Association, 2013) provide widely accepted definitions of dependence.

### Tolerance and Withdrawal

Tolerance and withdrawal are considered the key indicators of neuroadaptation and physical dependence, resulting from physiological changes in response to the continued presence of opioids in the central nervous system. Establishing the pattern of opioid use in terms of quantity and frequency and identifying any level of withdrawal by the use of withdrawal scales (see Appendix 2, 3, and 4) will provide evidence to identify a client's levels of tolerance and withdrawal.

Tolerance and withdrawal do not occur in all instances of substance dependence and, by themselves, are not sufficient criteria for the diagnosis of dependence. Other psychological and behavioural indicators must also be present to satisfy the diagnostic criteria of dependence. These include:

- **Compulsion to use**

Experiencing strong desires or compulsions to use opioids are characteristic of opioid dependence. This is sometimes displayed as 'cravings' for the drug when opioids have not been used for a period. Preoccupation with using or obtaining opioids may become a major focus for dependent individuals.

- **Difficulties in controlling use**

Controlling use of opioids involves establishing limits with regard to when use occurs, for how long, and what amount is used. For instance, the treatment of pain conditions using opioid medications involves established limitations by the prescriber on the amount, frequency, and duration of medication use. Individuals with opioid dependence may display difficulties maintaining a regulated level of opioid use, including an inability to abstain from using or limiting the amount of opioids used. Escalating patterns of opioid use (quantity and frequency) and unsuccessful attempts at reducing or abstaining from use are characteristic of opioid dependence.



- ***Drug use prioritised over other activities***

Individuals with an established opioid dependence may progressively disregard those interests that previously held significant importance. As dependence develops, the time spent using, obtaining, and recovering from the effects of opioid use increases, and the time spent engaging in other activities not related to drug use decreases. Obtaining opioids becomes increasingly important to people with opioid dependence, overshadowing personal responsibilities and priorities. Dependent individuals may prioritise access to opioids as more important than work or family commitments. The importance of acquiring opioids may prompt involvement in illegal activities to provide necessary finance. With severe dependence, individuals may resort to dishonesty, theft or physical violence as a means to obtain opioids.

- ***Continued use despite harmful consequences***

People with opioid dependence may continue to use despite the awareness of negative consequences. Health issues, social, financial or legal harms resulting from opioid use may be experienced by dependent individuals, however their use of opioids continues despite these negative impacts.

Research has shown that all these features are highly positively correlated to each other. If a person experiences high tolerance, severe withdrawal (or frequently uses the drug to avoid withdrawal) and a strong compulsion to use, it is likely that they will also experience difficulties in controlling use, prioritise drug use over other activities, and continue their use despite an awareness of the harmful consequences.

The key elements of opioid dependence involve patterns of opioid use that cause significant harms in combination with a personal loss of control over opioid use. Individuals who display high levels of dependence should be considered for assessment for treatment with methadone or buprenorphine.

**If there is no current physical dependence on opioids at the time of presentation, OST will not usually be appropriate unless a sound clinical rationale is provided.**



## 2. Opioid Intoxication and Overdose

Clients presenting in an intoxicated state due to opioid use or combined effects of other drugs need careful assessment and review. Opioid overdose presents a particularly dangerous medical situation, especially when associated with use of benzodiazepines or alcohol. These clients must be assessed and managed carefully or death may result. Those with moderate to severe intoxication will require close monitoring for an extended period, and may require hospitalisation.

The signs and symptoms of opioid overdose are shown in Table 1.

*Table 1 Signs and Symptoms of Opioid Overdose*

Signs and Symptoms of Opioid Overdose	
<ul style="list-style-type: none"> <li>• Feeling intoxicated</li> <li>• Pinpoint pupils</li> <li>• Nausea</li> <li>• Dizziness</li> <li>• Unsteady gait, slurred speech</li> <li>• Sedation/nodding off</li> <li>• Snoring</li> <li>• Slow pulse (bradycardia)</li> </ul>	<ul style="list-style-type: none"> <li>• Hypotension</li> <li>• Shallow breathing (hypoventilation)</li> <li>• Cyanosis (blueness of the skin and mucous membranes due to hypoxia)</li> <li>• Frothing at the mouth (sign of pulmonary oedema)</li> <li>• Coma</li> <li>• Death</li> </ul>



In Australia, more than 90% of deaths during stabilisation on methadone involve concurrent use of other drugs, in particular other opioids, alcohol, benzodiazepines and antidepressants.

Clients must be warned of the risks associated with using other drugs when taking methadone or buprenorphine, and particularly during the first weeks of treatment. Full quantities of benzodiazepines should not be prescribed and dispensed to clients during the induction period.



### 3. Opioid Withdrawal

Drug withdrawal is a substance-specific syndrome following cessation or reduction in the use of the drug. The syndrome can cause significant physical distress and impairment in social and occupational functioning and may require medical treatment. The characteristic features of opioid withdrawal are shown in Table 2.

*Table 2 Features of Opioid Withdrawal*

Early symptoms of withdrawal include:	Late symptoms of withdrawal include:
<ul style="list-style-type: none"> <li>• Agitation</li> <li>• Anxiety</li> <li>• Muscle aches and back pain</li> <li>• Lacrimation (increased tearing)</li> <li>• Rhinorrhoea (runny nose)</li> <li>• Diaphoresis (sweating)</li> <li>• Yawning</li> <li>• Insomnia</li> </ul>	<ul style="list-style-type: none"> <li>• Abdominal cramping</li> <li>• Nausea</li> <li>• Vomiting</li> <li>• Diarrhoea</li> <li>• Mydriasis (dilated pupils)</li> <li>• Piloerection (goose bumps)</li> </ul>

#### **Clinical features of short-acting opioid withdrawal syndrome**

Physical symptoms generally commence 6–24 hours after last opioid use, peak in severity 2–4 days later, and generally subside by day 7. The psychological features of dysphoria, anxiety, sleep disturbance and increased cravings may continue for weeks or even months.

# 3

## Clinical Pharmacology



## Section 3 Contents

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## 1. Methadone

### 1.1 What is methadone

Methadone is a potent synthetic  $\mu$ -opioid receptor agonist which is well absorbed orally and has a long plasma half-life. Two preparations are registered for the treatment of opioid dependence in Australia:

- **Methadone Syrup.** This formulation contains 5mg/mL methadone hydrochloride, sorbitol, glycerol, ethanol (4.75%), caramel, flavouring, and sodium benzoate.
- **Biodone Forte.** This formulation contains 5mg/mL methadone hydrochloride and permicoloured colouring. Biodone Forte has the advantage of being both sugar and alcohol free.

#### Effects of Methadone

The effects of methadone are qualitatively similar to morphine and other opioids. Most people who have used opioids will experience few side-effects from methadone. Once a stable dose has been achieved and tolerance develops, cognitive skills and attention return to normal. Symptoms of constipation, sexual dysfunction and occasionally increased sweating can continue to be troubling for the duration of methadone maintenance treatment.

Methadone as a full opioid agonist also reduces the effect of additional opioid use. This is due to cross-tolerance and is largely dose dependent. The client develops tolerance and some resistance to other opioids due to their exposure to methadone.

*Table 3 Effects of Methadone*

Effects of Methadone			
<b>Actions</b>	Analgesia Sedation Respiratory depression Euphoria		
	<table border="1"> <tr> <td><b>Endocrine Actions</b></td> <td>Reduced Follicle Stimulating Hormone Reduced Luteinising Hormone Elevated Prolactin Reduced Adrenocorticotrophic Hormone Reduced Testosterone Elevated Antidiuretic Hormone</td> </tr> </table>	<b>Endocrine Actions</b>	Reduced Follicle Stimulating Hormone Reduced Luteinising Hormone Elevated Prolactin Reduced Adrenocorticotrophic Hormone Reduced Testosterone Elevated Antidiuretic Hormone
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<table border="1"> <tr> <td><b>Other actions</b></td> <td>Decreased blood pressure Constriction of the pupils Antitussive Reduced gastric emptying Reduced motility Elevated pyloric sphincter tone Elevated tone of Sphincter of Oddi (can result in biliary spasm) Histamine release</td> </tr> </table>	<b>Other actions</b>	Decreased blood pressure Constriction of the pupils Antitussive Reduced gastric emptying Reduced motility Elevated pyloric sphincter tone Elevated tone of Sphincter of Oddi (can result in biliary spasm) Histamine release	
<b>Other actions</b>	Decreased blood pressure Constriction of the pupils Antitussive Reduced gastric emptying Reduced motility Elevated pyloric sphincter tone Elevated tone of Sphincter of Oddi (can result in biliary spasm) Histamine release		

**Table 3 Effects of Methadone continued**

Effects of Methadone	
<b>Side-effects</b>	<ul style="list-style-type: none"> <li>Sleep disturbances</li> <li>Nausea and vomiting</li> <li>Constipation</li> <li>Dry mouth</li> <li>Increased sweating</li> <li>Vasodilation and itching</li> <li>Menstrual irregularities in women</li> <li>Gynaecomastia in males</li> <li>Sexual dysfunction including impotence in men</li> <li>Fluid retention and weight gain</li> </ul>

## 1.2 Pharmacokinetics

Methadone is highly lipophilic and binds to a range of body tissues including the lungs, kidneys, liver and spleen such that the concentration of methadone in these organs is much higher than in blood. There is a fairly slow transfer of methadone between these stores and the blood.

Methadone is primarily broken down in the liver via the cytochrome P450 enzyme system with approximately 10% of orally administered methadone eliminated unchanged. What remains is metabolised with the (mainly inactive) metabolites eliminated in the urine and faeces. Methadone is also secreted in sweat and saliva.

There is wide individual variability in the process by which methadone is absorbed, distributed, metabolised and eliminated by the body.

**Table 4 Methadone Pharmacokinetics**

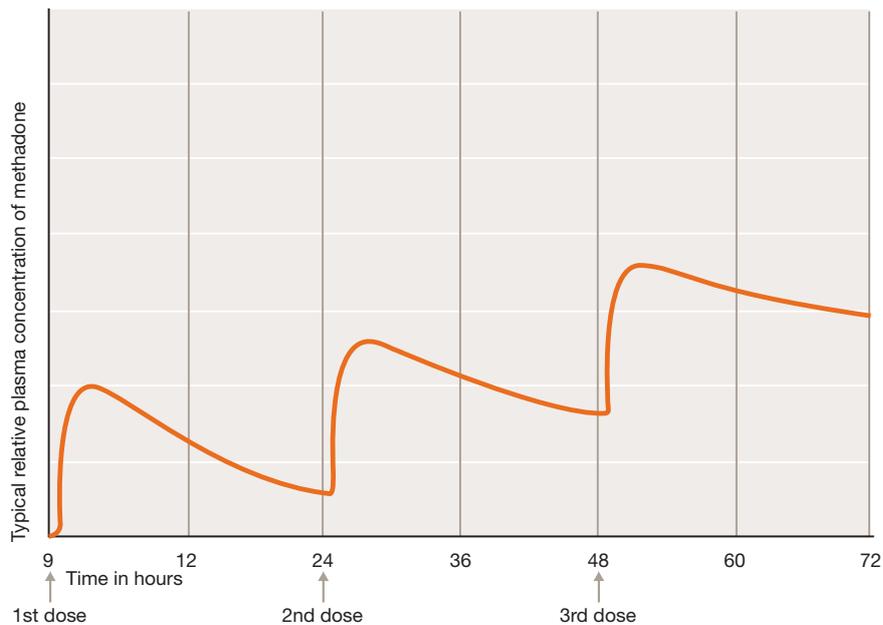
<b>Onset of methadone effects</b>	30 minutes
<b>Peak methadone effects</b>	Approx. 3 hours
<b>Methadone half life (in maintenance treatment)</b>	13–47 hours (mean 25 hours)
<b>Time to reach steady state</b>	7–10 days
<b>Withdrawal onset</b>	36–48 hours (peak intensity 5–7 days)

Onset of effects generally occurs approximately 30 minutes after ingestion, with blood levels rising over the following 3–4 hours, and then falling. The half-life of a single first dose is 12–18 hours with a mean of around 15 hours. With continued daily dosing, the half-life of methadone is extended to between 13 and 47 hours with a mean average of 25 hours. This prolonged half-life causes methadone blood levels to continue to rise during the first week of daily dosing and to fall relatively slowly between doses, (see Fig. 2).

Methadone reaches a steady state in the body (where drug elimination equals the rate of drug administration) after a period of approximately 3–10 days.

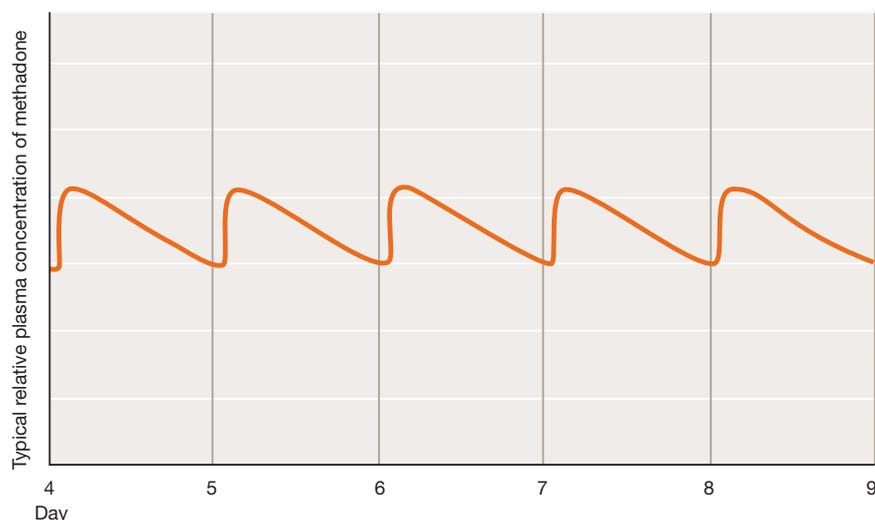
Because of excellent oral bioavailability and long half-life, methadone taken as a daily dose will preclude the onset of withdrawal symptoms.

**Figure 2 Plasma Levels of Methadone During the First 3 Days with Once-daily Dosing**



Once stabilisation has been achieved, variations in blood concentration levels are relatively small with good suppression of withdrawal syndrome (see Fig. 3). For some individuals fluctuations in plasma methadone concentrations may lead to withdrawal symptoms in the latter part of the inter-dosing interval. If dose increases do not prevent this, other agonist replacement treatment approaches such as buprenorphine should be considered.

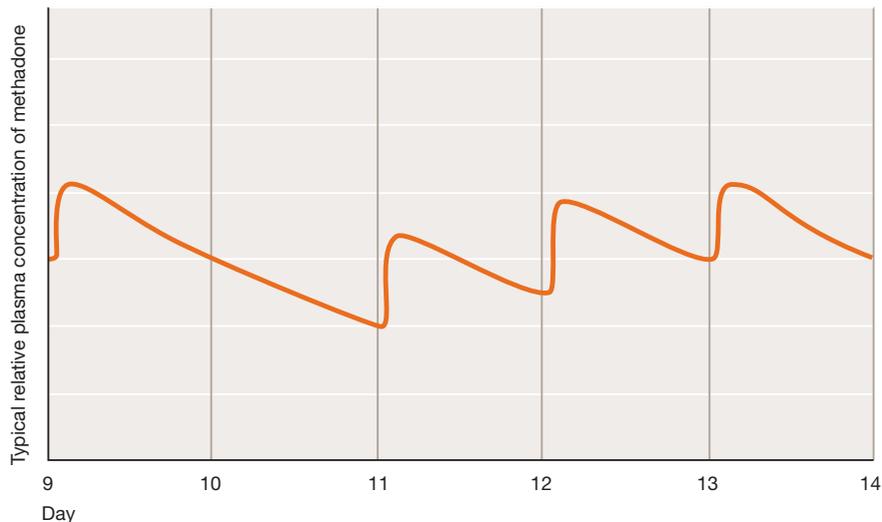
**Figure 3 Once-daily Dosing of Methadone at a Steady State**





If one dose is missed from a regular daily dosing methadone regime the blood concentration will continue to fall gradually over the following 24–48 hour period (see Fig. 4). Reestablishing a steady state of methadone levels can take between 3 and 10 days.

**Figure 4 3 Day Recovery to Steady State from Missed Dose at Day 10**



### 1.3 Drug interactions

Toxicity and death can result from the interaction between methadone and other drugs. Some psychotropic drugs may increase the actions of methadone due to additive effects (e.g. other opioids, benzodiazepines and alcohol increase the respiratory depressant effects of methadone). Other drugs interact with methadone by increasing or decreasing the rate of metabolism.

- **Sedatives.** The effects of methadone are enhanced when used in conjunction with other sedating medications. The combination of methadone with benzodiazepines, alcohol and other sedatives has been associated with fatal overdoses due to increased respiratory depression.
- **Opioid Antagonists** (naloxone and naltrexone). The effects of methadone can be reversed by the administration of opioid antagonists such as naloxone and naltrexone. Antagonists will precipitate a withdrawal reaction in clients on methadone, however a single dose administration of naloxone may be insufficient to treat overdose due to its short period of effect.
- **Opioid Agonists.** Opioid agonists have an additive effect when combined with methadone, increasing the risk for overdose and respiratory depression. The combination of methadone with other opioids has been associated with overdose deaths. This risk is greatest during induction and stabilisation on methadone.



- **Hepatic Enzyme Inducers and Inhibitors.** Cytochrome P450-3A inhibitors can decrease the metabolism of methadone and increase the risk of overdose. Drugs that stimulate the metabolism of methadone can cause a withdrawal syndrome if administered to clients maintained on methadone. If a cytochrome P450 inducing drug is clinically indicated for the treatment of another condition seek specialist advice.
- **Medication that is known to prolong the QTc.** Methadone produces QT prolongation and increases risk for torsades de pointes, particularly when given in high doses. Caution is advised when used in conjunction with other medications known to increase risk.

A comprehensive list of drugs which interact with methadone can be reviewed in the web-based resource ***Drug-Drug Interactions in Opioid Maintenance: A focus on buprenorphine and Methadone*** by visiting the website [www.opioiddruginteractions.com](http://www.opioiddruginteractions.com)

## 1.4 Safety

Methadone taken orally in controlled doses has few long term side-effects although some can cause distress and need to be managed. Side-effects which do occur are considerably less harmful than the risks of unsanctioned opioid use.

The major hazard associated with methadone is the risk of overdose. This risk is particularly high at the time of induction and when methadone is used in combination with other sedative drugs. The relatively slow onset of action and long half-life means that methadone overdose may not be obvious and may only become life threatening many hours after ingestion. Because methadone levels rise progressively with successive doses during induction into treatment, most deaths have occurred during the first week of treatment.



The major hazard associated with methadone is the risk of overdose.

## 1.5 Withdrawal from methadone

The initial phase of methadone withdrawal lasts between 5 and 21 days, and may be followed by a protracted withdrawal syndrome characterised by a period of malaise, insomnia, and a general feeling of reduced wellbeing. During this period, strong cravings for opioids may be experienced.

Untreated methadone withdrawal symptoms may be perceived as being longer and more unpleasant than from shorter acting opioids such as heroin or oxycodone. Factors that have been identified as having the potential to influence the severity of withdrawal include client expectation, the duration of opioid use, general physical health, and psychological factors such as motivation for undertaking withdrawal, and the fear of withdrawal.

A staged reduction of methadone will reduce the severity of withdrawal symptoms and associated discomfort.



## 2. Buprenorphine

### 2.1 What is buprenorphine (mono and combined products)

Buprenorphine is a derivative of the morphine alkaloid thebaine, and is a partial opioid agonist at the  $\mu$ -opioid receptors in the nervous system. Although buprenorphine is a potent  $\mu$ -receptor agonist at low doses, there is a 'ceiling' on its maximal opioid activity and many clients report less sedation on buprenorphine than on methadone. The side-effects of buprenorphine are similar to those of other opioids.

Buprenorphine has a higher affinity for the  $\mu$ -opioid receptors than most full opioid agonists, and can block the effects of other opioid agonists in a dose-dependent fashion. Because of its dual effects of reducing cravings and decreasing the response to administered opioids, buprenorphine reduces the self-administration of other opioids. Buprenorphine achieves its effect primarily by prolonged occupancy of a high proportion of opioid receptors, thereby blocking the action of other opioids. Buprenorphine also exhibits antagonist effects at the  $\kappa$ -opioid receptor; however the role of these receptors in humans is still poorly understood.

Unlike methadone which is a full opioid agonist, the effect of buprenorphine on respiratory depression reaches a ceiling. Higher doses do not increase respiratory depression to a significant degree. **However, if buprenorphine is used in combination with other central nervous system depressants such as benzodiazepines or alcohol, the combined effect on respiration can be life threatening.**

Three buprenorphine products are currently registered in Australia for the treatment of opioid dependence within a framework of medical, social and psychological treatment.

The mono product **Subutex** is a sublingual tablet containing buprenorphine hydrochloride in 0.4mg, 2mg, and 8mg strengths.

The combination product, **Suboxone** in the form of sublingual film preparation contains buprenorphine hydrochloride and naloxone hydrochloride in a ratio of 4:1. **Suboxone** is currently available in two dosage strengths:

- 2mg buprenorphine/0.5mg naloxone
- 8mg buprenorphine/2mg naloxone.

Note: Suboxone in tablet form was discontinued as a PBS Section 100 item in September 2013.

#### **Buprenorphine-naloxone combination product (Suboxone)**

The buprenorphine-naloxone combination product was developed to limit the abuse of buprenorphine by reducing the potential for injection, especially by opioid dependent users not in treatment. Suboxone is the standard preparation to be used for treatment of clients with opioid dependency.



The differing sublingual and parenteral potency profiles of buprenorphine and naloxone provide the rationale for the combination product. When buprenorphine is used sublingually, bioavailability is somewhere between 30% and 55% while the bioavailability of naloxone via this route is less than 10%. Consequently, when Suboxone is taken sublingually, it will act as if it was buprenorphine alone, with no apparent effect from the naloxone. However if the combined preparation is injected, the naloxone will have a substantial attenuating effect on the buprenorphine in the short-term. It is also likely to precipitate withdrawal in individuals dependent on full opioid agonists.

The bioavailability of sublingual buprenorphine is largely dependent on the length of time the drug is in contact with the oral mucosa and appears to improve as individuals practice taking their medication. Since Suboxone Sublingual film and Subutex Sublingual tablets do not meet all criteria for bioequivalence, dosage adjustment may be required when switching from one formulation to the other.

Research and clinical experience in different populations of opioid users of the effects of buprenorphine, alone and in combination with naloxone, are limited. Table 5 summarises current opinion of the likely immediate effects of buprenorphine in doses of 8 to 32mg.

**Table 5 Effect of Mono (Subutex) and Combination (Suboxone) Preparations of Buprenorphine in Different Situations**

Population	Combination product (Suboxone)		Mono product (Subutex)
	Sublingual (poor bioavailability of naloxone)	IV (high bioavailability of naloxone)	Sublingual or IV
<b>Dependent heroin user</b>			
Heroin 1hr ago	Withdrawal precipitated by buprenorphine	Severe withdrawal due to naloxone and buprenorphine	Precipitated withdrawal
Heroin >12hrs ago	Agonist effects	May be mild withdrawal	Agonist effects
<b>Non-dependent heroin user</b>	Agonist effects	Attenuated agonist effects	Agonist effects
Opioid naive	Agonist effects (reduced if swallowed)	Agonist effects initially attenuated	Agonist effects (reduced if swallowed)
Subutex maintenance	Agonist effect	Agonist effect may be attenuated initially	Agonist effects
Methadone maintenance (dose <24hrs ago)	Precipitated withdrawal	Severe withdrawal due to naloxone and buprenorphine	Precipitated withdrawal



All opioids have abuse potential, but as indicated in Table 5, people who are frequent or dependent users of opioids are unlikely to abuse buprenorphine. The effect of buprenorphine (taken sublingually or by intravenous injection) in people taking naltrexone may result in an attenuated agonist effect, particularly with low dose naltrexone as is generally the case with implanted preparations.

As with all opioid drugs, the prescription of the buprenorphine-naloxone combination as a takeaway medication for unsupervised administration needs to be based on a careful assessment of the risk of injection of the preparation by the person for whom it is intended as well as the potential for diversion and unauthorised use. Injection of drugs designed for sublingual administration is a health risk, and doctors have an obligation to monitor clients closely. Specifically, clients receiving unsupervised takeaway doses should be monitored for signs of fresh injecting sites indicating clinical instability.

**Takeaway doses should not be supplied to people with evidence of recent injecting.**

Buprenorphine is also registered in Australia as Temgesic sublingual tablets and ampoules for intramuscular or subcutaneous injection, for short-term (not more than one week) relief of moderate to severe pain including post-operative, and terminal and chronic pain. A low dose buprenorphine patch for transdermal administration (Norspan) is also available in Australia for pain relief.

## 2.2 Pharmacokinetics

Peak plasma concentrations are achieved 1 to 2 hours after sublingual administration. The major metabolite, norbuprenorphine, has some opioid activity but the extent of its contribution to the overall effects of buprenorphine is unknown.

Buprenorphine undergoes extensive first pass metabolism when taken orally and is principally metabolised via two hepatic pathways: conjugation with glucuronic acid and N-dealkylation, mediated by the cytochrome P450 3A4 isozyme. The metabolites are excreted through the biliary system, with enterohepatic cycling of buprenorphine and its metabolites. Most of the drug is excreted in the faeces and, to a lesser extent, in the urine.

Buprenorphine is a long-acting drug with a bi or tri-exponential, long terminal elimination phase (half-life of 20 to 73 hours). Peak clinical effects occur 1 to 4 hours after sublingual administration. Typically effects will continue to be experienced for up to 12 hours at low doses (2mg), and as long as 48 to 72 hours at higher doses (16–32mg). The prolonged duration of effect at high doses enables alternate day, and even third daily dispensing regimes.

**Table 6 Buprenorphine Pharmacokinetics**

<b>Onset of buprenorphine effects</b>	30–60 minutes
<b>Peak buprenorphine effects</b>	1–4 hours
<b>Buprenorphine half life</b>	20–72 hours (mean 35 hours)
<b>Time to steady state</b>	7–10 days
<b>Withdrawal onset</b>	2–5 days



## 2.3 Drug interactions

The principal drug interactions of buprenorphine relate to its opioid activity.

- **Sedatives.** Buprenorphine exerts additive sedative effects when used in conjunction with other sedating medications. These include benzodiazepines, alcohol, tricyclic antidepressants, sedating anti-histamines, and major tranquilisers. The combination of buprenorphine with benzodiazepines, alcohol and other sedatives has been associated with fatal overdoses.
- **Opioid Antagonists** (naloxone and naltrexone). Buprenorphine has affinity for  $\mu$ -opioid receptors similar to the opioid antagonists. In the event of overdose of buprenorphine, very high doses of naloxone are required to reverse its effects. Cases have been reported in which naloxone in doses of 10 to 35mg were required, while in other cases doses of 2mg or less were reported to be effective in reducing respiratory depression. **Because of the uncertain response to naloxone, prolonged ventilatory support may be required in overdoses involving buprenorphine.**

Naltrexone can precipitate a withdrawal reaction in clients on buprenorphine, although the effect may be delayed (2 to 4 hours, and occasionally up to 8 hours).

- **Opioid Agonists.** Buprenorphine exerts a degree of blockade to the effects of full agonist opioids, which may complicate the prescribing of additional opioids for pain management. The initial dose of buprenorphine can precipitate opioid withdrawal in clients who have recently used an opioid drug.
- **Hepatic Enzyme Inducers and Inhibitors.** Buprenorphine metabolism can be influenced by the presence of drugs and other compounds that affect activity or are metabolised by the cytochrome system. Clients who are concurrently prescribed or are using inhibitors of cytochrome P450 3A4 may have increased buprenorphine blood concentrations, and those taking inducers may have decreased blood concentrations.

A comprehensive list of drugs which interact with buprenorphine and methadone can be reviewed in the resource ***Drug-Drug Interactions in Opioid Maintenance: A focus on buprenorphine and methadone*** which can be found by visiting [www.opioiddruginteractions.com](http://www.opioiddruginteractions.com) (Further clinically relevant information specific to medications metabolised by Cytochrome P450 3A4 can be sourced at <http://medicine.iupui.edu/flockhart/table.htm>).

## 2.4 Precipitated withdrawal

The phenomenon of precipitated withdrawal has particular clinical relevance during the induction of heroin users and methadone clients to buprenorphine. Due to its high receptor affinity and low intrinsic activity buprenorphine displaces other agonists from opioid receptors, and may not produce sufficient agonist effects initially to compensate for the displaced methadone or heroin. The client may experience opioid withdrawal within 1–4 hours after first administration.



## 2.5 Safety

Dose response studies show that, because of the ceiling effects of buprenorphine, high doses (16mg daily or more) do not result in substantially greater peak opioid effects than lower doses (8 or 12mg). Doses many times greater than normal therapeutic doses appear to be well-tolerated, and rarely result in clinically significant respiratory depression except in individuals who are not opioid tolerant. However, even low doses of buprenorphine can be toxic when combined with sedatives such as benzodiazepines and alcohol. Naloxone may be of limited use in resuscitating individuals who have overdosed on high doses of buprenorphine.

The majority of fatalities reported to date have involved the injecting of buprenorphine along with benzodiazepines, or use of large amounts of buprenorphine outside of a doctor's care. Legitimate and appropriate prescribing, coupled with responsible use by clients, is unlikely to lead to adverse consequences.

## 2.6 Withdrawal from buprenorphine

The partial agonist properties of buprenorphine along with its slow dissociation from opioid receptors results in a delayed withdrawal syndrome. This may be milder than withdrawal from heroin, morphine and methadone. Typically, the withdrawal syndrome following the abrupt cessation of long-term buprenorphine emerges within 3 to 5 days of the last dose, with mild withdrawal features continuing for up to several weeks.

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4

Patient Management



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## 1. Opioid Withdrawal

### 1.1 Opioid withdrawal in context

Withdrawal symptoms are experienced by drug-dependent people following cessation or significant reduction in their use of the drug. These withdrawal symptoms can cause significant physical distress and impairment in social and occupational functioning, and may require medical treatment. The characteristic features of opioid withdrawal include:

- increased sweating, lacrimation, rhinorrhoea, hot and cold flushes
- nausea, vomiting, abdominal cramps, diarrhoea
- muscle spasm, cramps, backache, bone pain
- piloerection, pupillary dilatation, yawning, tachycardia, elevated blood pressure
- anxiety, agitation, irritability, disturbed sleep, and increased cravings for opioids.

Physical symptoms of withdrawal from shorter acting opioids (e.g. morphine, fentanyl, oxycodone, or heroin) generally commence between 6 and 12 hours after last use and peak in severity during days 2–3. Physical symptoms generally begin to subside by day 4, while the psychological features of dysphoria, anxiety, sleep disturbance and increased cravings may continue for weeks or even months. Opioid withdrawal, though unpleasant, is rarely life-threatening. It can, however, complicate other medical or psychiatric conditions and increase the risk of overdose following withdrawal.

Opioid users present for treatment of withdrawal for a range of reasons and the motivation and goals of individuals may vary considerably. In general, an episode of withdrawal treatment alone has little long-term impact on a person's drug use. Withdrawal services should not be seen as a stand-alone treatment that will result in prolonged periods of abstinence.

**A realistic set of objectives for withdrawal treatment are to alleviate symptoms and prevent complications by breaking a pattern of heavy and regular drug use and providing linkages to enable engagement in ongoing treatment.**

Alleviating the discomfort of opioid withdrawal symptoms is an important reason for patients presenting for treatment and one of the primary aims of medically assisted withdrawal treatment.

Many patients seek treatment to end their opioid use. Giving up entirely, however, is not the goal for everyone. Many see withdrawal as a means of reducing levels of opioid use and reducing the severity of their dependence along with its associated harms. Hence, although the cessation of opioid use is an optimal outcome, a reduction in opioid use following a withdrawal attempt may still represent a very positive outcome for some patients.

Many patients seek benzodiazepine medication to assist with withdrawal symptoms, and it is important to consider the increased risk of overdose that these may cause with any ongoing opioid use.

*Footnote: Reference is made to 'patients' rather than 'clients' in this section as the intended audience are medical practitioners who generally use this terminology.*



Following full or partial withdrawal there is an increased risk of overdose with resumption of opioid use due to the reduction in opioid tolerance that accompanies withdrawal. Overdose risk can be increased due to the combined sedative effects of opioid use and the misuse of medications prescribed for the management of withdrawal (e.g. benzodiazepines).

Withdrawal treatment is an acute service with short-term outcomes, whereas opioid dependence is a chronic relapsing condition, with positive long-term outcomes more often associated with longer participation in treatment. Following withdrawal treatment patients should be advised of access to drug treatment services. This should include:

- outpatient counselling
- naltrexone treatment
- residential therapeutic communities
- self-help programs
- OST programs.

Patients may also benefit from case management and referral to welfare, accommodation and employment services.

Patients, families, friends, and health and welfare professionals can become disappointed and disillusioned when patients fail to complete withdrawal treatment, or relapse to regular use soon after a withdrawal attempt. Information and counselling about withdrawal treatment and ways to assist should be made available to families and other social supports.

Families need to be made aware of the increased risk of overdose following withdrawal. This can occur with resumption of opioid use following the reduction in opioid tolerance that accompanies withdrawal, and is frequently due to the combined sedative effects of opioid use and the misuse of medications prescribed for the management of withdrawal (e.g. benzodiazepines).

### **Optimal setting**

Withdrawal can occur in a continuum of settings, ranging from intensive residential (an inpatient withdrawal unit or hospital) to outpatient (ambulatory or home-based) withdrawal services.

Residential withdrawal settings generally provide a range of services including assessment, medical treatment, monitoring, and supportive counselling.

Most opioid withdrawal attempts can occur in outpatient settings with the support of a general practitioner, an alcohol and drug worker, or other health professional.

Some patients may wish to undertake an outpatient withdrawal, despite unsuitable home environments or repeatedly unsuccessful previous attempts. Careful consideration should be given to further outpatient withdrawal attempts in these circumstances.

It may be sensible to review patient requests when an alternative treatment from that which the person is requesting is clinically indicated. Clinicians should negotiate with their patient some mutually agreed criteria (e.g. no significant progress within a week) at which point an alternative treatment pathway will be undertaken.



Patients who may be considered least suitable for withdrawal treatment in an outpatient setting are those with:

- unstable medical or psychiatric conditions
- polydrug dependence requiring withdrawal from multiple drugs
- an unsupportive home environment
- repeated failure with outpatient withdrawal.

### **Preparing for withdrawal**

Commencing an outpatient withdrawal requires planning and the mobilisation of important supports and services. Patients should prepare themselves and their home environment in advance to maximise their chance of a positive outcome. It is very hard to get through withdrawal if living and associating with others who continue to use opioids.

A 'safe' place should be organised at the beginning of the withdrawal episode. This is a place where drugs won't be easily accessible, and where patients will not be confronted by other drug users. It is important to have caring people available during the withdrawal period, and those providing support will need guidance and information about the process and what they can reasonably do to help.

### **Supportive care**

Information should be provided regarding:

- the nature and duration of withdrawal symptoms
- strategies for coping with symptoms and cravings
- strategies to deal with high-risk situations
- the role of medication.

Patients often have limited concentration during withdrawal and information may need to be repeated to ensure that it is fully understood. Written information is also recommended for nominated support people. Such information can be provided by the Alcohol and Drug Information Service (ADIS) and CPP.

Counselling during the withdrawal episode should be aimed at supporting the patient and facilitating post-withdrawal referral and follow up. Crisis intervention may be needed during a withdrawal episode to ensure that adequate accommodation, food or other urgent welfare issues are addressed.

Some patients may want to deal with a range of personal, emotional or relationship problems during the withdrawal episode, but this should be deferred until acute withdrawal symptoms abate. Attempting to work through such issues may be emotionally difficult and anxiety-provoking, which may intensify cravings and place withdrawal progress in jeopardy. Patients in withdrawal are likely to be irritable, agitated, tired and run-down. They can suffer from mood swings and poor sleep, as well as difficulty in concentrating. This is not the best frame of mind in which to try to solve significant life problems.



Patients should be assured that it is understood that they have many important issues to work through to get their lives together again, but it is best to take one step at a time. There will be opportunities for these problems to be addressed as part of their ongoing recovery after withdrawal is completed.

In addition to supportive counselling from health professionals and the support of family, friends and others, opioid users may also benefit from telephone counselling for help when others are unavailable. ADIS provides a 24-hour telephone counselling service and can put patients in touch with other helpful and appropriate services.

### Monitoring

An important component of withdrawal is regular and frequent monitoring of the patient's:

- general progress
- drug use
- response to medications
- severity of withdrawal symptoms (which can be facilitated by the use of withdrawal scales)
- complications or difficulties
- ongoing motivation.

Doses of medication can be adjusted according to patient progress. It is recommended that patients undertaking outpatient withdrawal be reviewed by an experienced health professional (alcohol and drug worker, general practitioner, or pharmacist) **at least daily** during the first few days of treatment.

### Opioid withdrawal scales

There are a number of opioid withdrawal scales available for use. Subjective scales are far more sensitive to changes in withdrawal severity, and are better predictors of patient outcomes. Objective scales are less sensitive, and usually need to be administered by a health professional. They may nevertheless be useful in corroborating subjective ratings, particularly in individuals who are thought to be over or under rating their withdrawal severity. The *Clinical Opiate Withdrawal Scale (COWS)*, the *Subjective Opioid Withdrawal Scale (SOWS)*, and the *Objective Opioid Withdrawal Scale (OOWS)* are provided as Appendices 2, 3 and 4 in this Manual.

## 1.2 Overview of buprenorphine in the management of opioid withdrawal

The efficacy of buprenorphine in the management of opioid withdrawal has been compared to other withdrawal approaches in both inpatient and outpatient settings. In general, buprenorphine has been found to be more effective than clonidine and symptomatic medications in reducing withdrawal symptoms, retaining patients in treatment, and in reducing opioid use during withdrawal.

The prescriber should discuss the patient's expectation of medication assisted withdrawal and address any misconceptions. In particular, the following principles regarding the prescribed dose of buprenorphine should be understood by the patient:



- Doses that are too high can result in rebound withdrawal, prolonged duration of symptoms, and increased side-effects.
- Doses that are too low can result in unnecessary withdrawal discomfort, continued opioid use and treatment drop-out.
- Continued opioid use or cravings may not be due to inadequate doses of medication. Patients who continue to associate with other opioid users and are present when others are acquiring or using opioids can expect to have cravings regardless of their dose of buprenorphine.
- Buprenorphine will not reduce symptoms of withdrawal or cravings related to the use of non-opioid drugs.

As prescription opioid dependence is increasingly common it is important to consider which opioid medications the patient has been using. A number of long acting opioid medications are currently used including Oxycontin, Kapanol, MS Contin, and Jurnista. Such medications have an intermediate to long duration of action, and pharmacotherapy prescribers should be mindful of this when determining timing and initiation doses of buprenorphine.

Buprenorphine can precipitate opioid withdrawal in someone who has recently used opioids (within the past 6 hours) or methadone (within 24 hours).



Patients should not receive the first dose of buprenorphine until they are experiencing opioid withdrawal symptoms.

### **Preventing precipitated withdrawal upon commencing buprenorphine**

- no heroin for at least 6 hours prior to first dose of buprenorphine
- no methadone for at least 24 hours
- no buprenorphine if there are obvious acute opioid intoxication effects – wait for withdrawal signs or ask the patient to return the next day.

### **Use of ancillary medication in conjunction with buprenorphine**

Buprenorphine provides general relief from withdrawal symptoms, so that other symptomatic medications for opioid withdrawal are not routinely required. While it is not uncommon for opioid dependent patients to report difficulty sleeping, the use of sedative hypnotic medications should be resisted. Where sleep is a problem, it is safer to increase the dose of buprenorphine rather than to prescribe benzodiazepines, with non-pharmacological approaches also being encouraged (sleep hygiene strategies). Non-pharmacological methods may not have an instant effect on sleep, but if continued for days to weeks such strategies will help to establish normal sleep patterns.

If considered necessary, low doses of a hypnotic (e.g. temazepam tablets 10–20mg nocté) should be used with daily dispensing from the pharmacy. Under normal circumstances, benzodiazepines should not be continued beyond a week.



The unsupervised use of other sedative drugs, such as benzodiazepines, alcohol, other opioids, and tricyclic antidepressants in combination with buprenorphine can be extremely dangerous, resulting in respiratory depression, coma and death.

### **Continued use of opioids and other drugs during withdrawal**

Patients who continue to use opioids during buprenorphine withdrawal treatment may have difficulty stabilising on the medication and may continue to experience features of precipitated withdrawal after each dose.

Persistent features of precipitated withdrawal discomfort may be appropriate grounds for transfer to other withdrawal medications or inpatient admission.

All patients should be informed verbally and in writing of the risk of overdose and the advice documented in the clinical record.

Intoxicated patients should not be dosed with buprenorphine or sedative medications.

## **1.3 Buprenorphine withdrawal regimes in the outpatient setting**

Buprenorphine is long-acting and is well suited for use in outpatient withdrawal settings, allowing for once-a-day supervised dosing. Patients who are unable to attend for supervised daily dispensing should consider alternative withdrawal medication support. Contact CAS for additional information.

Induction onto buprenorphine for the purpose of detoxification should follow the same principles as for buprenorphine maintenance. In general, daily buprenorphine doses in the range of 4mg to 16mg appear to be most effective in reducing withdrawal severity and opioid use. Once a stable dose is achieved, the rate of dose reductions should be decided in consultation with the patient.

Some flexibility in dose reduction to accommodate a range of factors is appropriate. The degree of physical dependence and psychological condition will impact on a patient's individual dosing requirement and withdrawal severity.

The appropriate starting dose of buprenorphine and duration of withdrawal treatment will vary according to the clinical presentation of each individual.

Various dosing regimes have been used for detoxification from opioids using buprenorphine, differing in the duration of treatment and maximum doses of buprenorphine prescribed.



One suggested schedule is as follows:

- Day 1 6mg
- Day 2–3 10mg+/-2mg
- Day 4 8mg+/-2mg
- Day 5 4mg.

In general, higher doses and longer duration of treatment is preferred in outpatient settings where the risk of unsanctioned opioid use is greater.

The first dose of buprenorphine should be administered once mild withdrawal is apparent to avoid the risk of precipitated withdrawal. If there are doubts or concerns, the patient should be asked to come back for dosing later in the day, or alternatively, a lower initial dose can be dispensed (2 or 4mg) as it is less likely to precipitate withdrawal than a high initial dose.



Review by a trained health professional is recommended on a daily basis during the first few days of the withdrawal regime.

Patient review is important so that doses can be adjusted if necessary, and any difficulties being experienced by the patient on the medication can be addressed. It is also needed to ensure that progress toward treatment goals is monitored and patients are provided with appropriate care and support.

### Flexible doses

It is advised to attempt a short-term regime (4–5 days), and schedule a formal review of progress within a few days of commencement. At review, the clinician and patient can together consider available post-withdrawal treatment options. Longer-term reduction regimes (over 2 to 3 weeks) may also be effective and permit more time for relapse prevention and after-care planning.

Patients who remain ambivalent about long-term post-withdrawal treatment and who have not been able to cease their opioid use may need referral to an inpatient supervised withdrawal program. Alternatively, an extension of the withdrawal regime over several weeks may be warranted.

There are good reasons for not prolonging buprenorphine treatment:

- Administration of buprenorphine for more than several days commonly produces rebound withdrawal when ceased, typically starting 1–3 days after the last dose of buprenorphine, peaking 2–5 days after the last dose, with some symptoms persisting for several weeks.
- Prolonged, unsuccessful attempts at withdrawal can be demoralising for the patient resulting in reduction in self-esteem and confidence in both themselves and in the treatment provider. For this reason, a limit on the time spent on a gradual reduction regime should be discussed with the patient.



Longer-term opioid substitution treatment (with buprenorphine or methadone) should be recommended to patients who:

- cannot stop or markedly reduce their opioid use during the withdrawal episode
- relapse into regular opioid use as the dose of buprenorphine is reduced or ceased
- do not feel confident about maintaining abstinence and do not want to relapse to dependent opioid use and the associated harms.

It is recommended that such patients stabilise on opioid substitution medication for a longer period of time before coming off treatment. This will provide them the opportunity to distance themselves from opioid use, and attend to any psychological and social issues which may be present.

#### 1.4 Buprenorphine for withdrawal from opioids in residential settings

Buprenorphine is well suited for use in inpatient withdrawal settings given its ability to alleviate the discomfort of withdrawal symptoms without significantly prolonging their duration. Duration of dosing will be determined by the length of admission time available (e.g. for a 7 day admission, treatment will be limited to the first 4–5 days).

Approaches to dispensing in inpatient settings will depend on the level of supervision and staff resources available. Titration regimes generally require staff who can administer withdrawal scales and S8 medications, so settings with limited access to appropriately qualified staff may be better suited to fixed regimes with the option of additional ‘rescue’ doses as required. The additional rescue doses should **only** be administered at least 4 hours after the earlier dose **and** when the patient is experiencing moderate or severe withdrawal discomfort.

Buprenorphine doses in inpatient settings can generally be lower as outpatient regimes must accommodate higher cravings and exert blockade effects, and are generally limited to once-a-day dosing.

An evening dose (between 5pm and 10pm) can be given to provide relief of withdrawal symptoms until the morning. Buprenorphine should not be administered if there are any features of intoxication or sedation.

The following regime is recommended for an admission time of approximately one week, and can be tailored accordingly.



## Proposed Inpatient Withdrawal Regime

*Table 7 Buprenorphine Assisted Inpatient Withdrawal Regime*

DAY	Buprenorphine Regime	Total Daily dose
Day 1	4mg at onset of withdrawal, with an additional 2–4mg evening dose prn.	4 to 8mg
Day 2	4mg mane, with an additional 2–4mg evening dose prn.	4 to 8mg
Day 3	4mg mane, with additional 2mg evening dose prn.	4 to 6mg
Day 4	2mg mane prn; 2mg evening prn.	0 to 4mg
Day 5	2mg prn.	0 to 2mg
Day 6	No dose.	0mg
Day 7	No dose.	0mg

Total proposed dose = 12 to 28mg

The above regime serves as a guide only, and considerable individual variation in withdrawal severity and medication requirements should be expected. Post-withdrawal options should be explored before discharge.

### Gateway model of treatment with buprenorphine

Buprenorphine is particularly useful in managing opioid withdrawal and also facilitates links to post-withdrawal treatment. Many patients entering withdrawal treatment do so without necessarily having considered all treatment options, hopeful that an attempt at withdrawal will be sufficient to stop opioid use.

The use of buprenorphine for several days generally alleviates withdrawal symptoms without significant sedation, thereby allowing patients and clinicians to examine post-withdrawal issues relatively early on in the withdrawal episode.

A formal review of treatment plans should occur several days into the withdrawal episode, at which time treatment can be tailored according to the patient's progress and goals. Patients who are making good progress with withdrawal can undertake a short course of buprenorphine with minimal rebound discomfort. Some patients who successfully refrain from opioid use during withdrawal may consider longer-term naltrexone treatment, which can be initiated after a short course of buprenorphine is completed.

Those patients who want to extend the duration of their withdrawal program or who are considering a maintenance treatment program can continue buprenorphine treatment. Caution should be exercised in transferring patients with short histories of opioid dependence from a withdrawal program onto long-term OST.



## 1.5 Transition to post-withdrawal treatment

### 1.5.1 Transition to buprenorphine maintenance treatment

Transition to a buprenorphine maintenance treatment program simply requires the continuation of treatment, often with upward titration of the dose to achieve optimal maintenance dose levels (e.g. 12–16mg per day).

### 1.5.2 Transition to methadone maintenance treatment

The transition to methadone maintenance treatment requires the cessation of buprenorphine, with the first dose of methadone given at least 24 hours later.

### 1.5.3 Commencing naltrexone treatment after short duration buprenorphine withdrawal

When commencing naltrexone after a short period of use of buprenorphine (less than 10 days), the simplest approach is to wait 5–7 days after the last dose of buprenorphine before commencing naltrexone. Precipitation of withdrawal by naltrexone is unlikely following a 7-day opioid-free period; however the pharmacology of buprenorphine does enable the commencement of naltrexone earlier than this.

Administration of naltrexone within 5 days of stopping buprenorphine use is likely to result in opioid withdrawal following the first dose of naltrexone. This typically commences 1½ to 4 hours after the first naltrexone dose, peaks around 3 to 6 hours after the naltrexone dose, and generally subsides in severity within 12 to 24 hours. The withdrawal is frequently experienced as moderate to severe at its peak. This approach is best undertaken in an inpatient or intensive day-care setting that is able to respond to serious withdrawal symptoms if they occur.

Most patients undergoing this procedure request symptomatic medication. Clonidine (100–150mcg every 4 hours as required) and a benzodiazepine (e.g. diazepam 5mg 4 hourly, maximum of 30mg in a day, as required) can be prescribed.



## 2. Entry into Opioid Substitution Treatment

There is widespread evidence that OST is an effective treatment for people with established opioid dependence, by keeping patients engaged in treatment, and reducing drug use related harms.

OST is appropriate for patients with a significant history of opioid dependence who want to stop or reduce their opioid use and do not wish to access withdrawal treatment, residential rehabilitation or naltrexone treatment. For those patients who have previously accessed these treatments and had limited success in achieving treatment goals, OST may be the preferred option.

The diagnosis of opioid dependence should be made by eliciting the features of opioid dependence through clinical interview and physical examination. Other treatment alternatives should always be presented and discussed, and should include consideration of the merits and limitations of each treatment option.

### 2.1 Criteria for treatment

OST is generally only recommended for people diagnosed as being physically dependent on an opioid; however there may be other situations where treatment might be considered appropriate. A person with a long established history of dependence may seek OST following a period of abstinence or infrequent use (such as may occur while in prison) to avoid the risk of relapsing back to regular opioid use.



If in doubt as to whether a person is suitable for OST, specialist opinion should be sought.

#### **Specialist opinion**

Next Step Drug and Alcohol Services offer a consultancy service to GPs and health services through CAS and the Metropolitan Community Drug Services. Addiction Medicine Specialists are available for direct consultation, review of complex cases and joint management of patients on OST.

### 2.2 Initial assessment

All opioid users seeking treatment should receive a comprehensive assessment of past and current drug use, medical, psychological, and social circumstances, previous treatment history and current treatment goals. This information must be documented in the clinical record.

Specific attention should be given to the assessment of dependence and opioid tolerance, the patient's state of intoxication or withdrawal, along with indications, contraindications, and precautions for OST.



Corroborative evidence of dependence should be obtained where possible. The best evidence is observed signs of opioid withdrawal, or a verifiable history of previous treatment for opioid dependence (detoxification or maintenance). Accuracy of clinical assessment can be improved by using corroborating evidence such as urine tests and examination of veins for evidence of injecting drug use.

### **Key features of the assessment**

The following information forms the basis of a comprehensive patient assessment, and includes:

#### ***Drug use and treatment***

- illicit (e.g. heroin) and prescription opioid use
  - quantity and frequency (amount, cost, number of times used per day)
  - duration of use
  - route of administration (injected/non-injected)
  - when last used
  - features of physical dependence (tolerance and withdrawal)
- use of other drugs (including benzodiazepines, psychostimulants, alcohol, cannabis) and assessment of degree of dependence on each drug type
- history of prior attempts at withdrawal, OST and other treatment – what has worked and not worked before
- motivation and treatment goals. Finding the right approach requires an understanding of the **reasons for seeking treatment** along with **patient goals and expectations**.

#### ***Risk factors***

- presence of risk behaviours, particularly overdose events, self-injury, or polydrug use
- medical and psychiatric history, with particular attention to conditions which might potentially complicate treatment
- other medications including QTc prolonging medications and CNS depressants
- pregnancy and contraception.

#### ***Social circumstances***

- home environment, parenting responsibilities, relationships, other service involvements, social supports, legal problems, financial problems, employment.

#### ***Physical Examination***

- evidence of injection marks consistent with the stated history
- vital signs (blood pressure, pulse, respiratory rate)
- evidence of intoxication or withdrawal from opioids or other drugs consistent with stated history
- evidence of complications of injecting drug use, including injection site problems, hepatic disease, systemic infections.



### **Investigations**

- **urine drug screens** can be helpful in clarifying or confirming a drug use history. While delays in obtaining the results of routine urine tests may limit their usefulness at initial assessment, conducting a urine drug screen prior to commencing OST provides supportive evidence of opioid use that can otherwise be difficult to obtain.
- **tests for infectious diseases** including HIV, Hepatitis A, B and C, and sexually transmitted infections should be considered with appropriate pre-test and post-test counselling
- **other blood tests** including U&Es, LFTs and FBC.

The initial assessment informs the case formulation, enables a diagnosis to be made and an initial treatment plan to be developed. Additional information will need to be gathered at subsequent reviews so that a more comprehensive treatment plan can be developed over time.

## **2.3 Patient information**

Patients should be appropriately counselled and provided with the booklet ***Methadone and Buprenorphine for the Treatment of Opioid Dependence in WA*** prior to commencing an OST program. This booklet outlines the rights and responsibilities of patients on the WA Program and can also be found as a PDF resource included with this Manual. This is to ensure that the conditions and constraints of program participation are properly considered and understood by the patient. Methadone and/or buprenorphine information booklets should also be provided according to the treatment being considered. All booklets can be ordered through CPP.

## **2.4 Patient must be able to give informed consent**

The participation of an informed patient in the clinical decision-making process is essential in the treatment of opioid dependence. This is particularly important when incorporating addictive opioid medications such as methadone or buprenorphine as part of the treatment plan. The treatment provider should explore alternative treatment options with the patient before considering OST.

All patients commencing opioid pharmacotherapy must give their informed consent to treatment. This process requires that patients are fully informed and given the opportunity to discuss the following:

1. Information about methadone and buprenorphine as pharmacotherapy treatments including how they are administered, how they work, side-effects, and the advantages and disadvantages of OST.
2. What the likely duration of treatment will be, the cost of treatment, the associated routines and the requirements of treatment. This should include specific information about supervised dosing, urine testing, access to takeaway doses, and transfer of treatment.
3. What the impacts and limitations are on lifestyle including travel, driving, employment and pregnancy.



4. Under what circumstances the prescriber or pharmacist may withdraw their services and cease providing treatment.

Patients must sign the *Application to prescribe opioid substitution treatment* and should also sign a *CPOP Patient Contract to Receive Opioid Substitution Treatment* (see Appendix 1), a copy of which should be retained on the patient's clinical record.

## 2.5 Patient conduct and involuntary discharge

Patients of CPOP are expected to maintain an appropriate standard of behaviour to ensure that issues of public safety and treatment engagement are not compromised. This should be made explicit as part of the patient's initial treatment agreement, outlining the behaviours that can lead to discharge from the Program and possible police involvement.

These behaviours include:

- violence – including physical or verbal threats of harm or acts of harm against staff or other patients
- property damage or theft from the service or dosing facility
- diversion of prescribed medications
- dealing of substances in or around the service or dosing facility
- forgery or alteration of scripts

## 2.6 Confidentiality/Privacy Legislation

The Commonwealth *Privacy Act 1988* applies rules known as Information Privacy Principles and National Privacy Principles to acts and practices engaged in by agencies and organisations in relation to access, collection, use and disclosure of personal information, including a person's health information.

The National Privacy Principles apply to private health services, medical practitioners and pharmacists in private practice. CPOP endorses and supports the National Privacy Principles in relation to personal health information.

In signing the *Application to prescribe opioid substitution treatment* at the commencement of treatment patients indicate consent to prescribers, pharmacists, the Department of Health, DAO and other health workers involved in the patient's care to share information regarding their OST participation. This also advises the patient that their details will be included on the Register of Notified Addicts.

Freedom of information legislation allows patients the right to access their clinical records held by public health services and to correct any inaccuracies.



## 2.7 Contraindications to opioid substitution treatment

The following conditions indicate that patients are not suitable for treatment with either methadone or buprenorphine.

- **Severe hepatic disease**

Patients with severe hepatic impairment or decompensated liver disease are not suitable for methadone or buprenorphine treatment. Caution needs to be taken in considering methadone or buprenorphine treatment for people with clinically significant liver disease (i.e. acute hepatitis or Child's B/C cirrhosis) as severe hepatic disease may alter drug metabolism. However, the presence of elevated enzyme levels on liver function testing, in the absence of clinical evidence of liver failure, does not exclude someone from treatment.

- **Compromised respiratory function**

Methadone and buprenorphine, like other opioids, should be used with caution in patients with a sustained decrease in respiratory reserve, pre-existing respiratory depression, sleep apnoea, hypoxia, or hypercapnia (such as chronic obstructive airways disease or cor pulmonale). In such patients, even normal therapeutic doses of opioids may decrease respiratory drive.

- **Hypersensitivity**

Patients with known hypersensitivity or severe side-effects from previous exposure to methadone or buprenorphine or other ingredients in the various formulations should not be considered appropriate for that particular opioid pharmacotherapy or formulation. An ADRAC form should be submitted where hypersensitivity is evidenced.

**It is recommended that specialist advice be sought from CAS in these cases.**

## 2.8 Precautions

A significant number of patients who present for OST will have multiple problems and complex presentations. It is important that prescribers and case managers involved in the delivery of OST are aware of other services that may be involved in their patient's care, and ensure that services are provided in a collaborative manner.

### 2.8.1 High risk polydrug use or co-occurring alcohol dependence

Methadone or buprenorphine treatment should be approached with caution in individuals using other drugs, particularly those likely to cause sedation such as alcohol, benzodiazepines, additional opioids, antipsychotics and antidepressants. Particular attention should be given to assessing the level of neuroadaptation to opioids, the likelihood of continued use of other drugs, and overdose risk. Due to the significant management challenges presented by patients with co-occurring alcohol dependence, consideration should be given to concurrent use of acamprosate or disulfiram therapy. Where disulfiram is used, Biodone Forte solution should be prescribed as it contains no alcohol.



### **2.8.2 Low or uncertain levels of neuroadaptation to opioids**

Commencing methadone or buprenorphine treatment in someone who is not currently using opioids may be warranted where that person is likely to relapse and develop dependence in the near future. This may be a case for a person with a history of dependence after release from prison. Caution with induction and frequent review is required in these circumstances as even low doses of methadone or buprenorphine can cause sedation and respiratory depression. The use of concomitant sedating medications such as benzodiazepines, neuroleptics and tricyclic antidepressants further increase this risk.

### **2.8.3 Co-occurring psychiatric disorders**

When assessing individuals with coexisting mental health disorders for OST, consideration should be given to the capacity of the individual to manage within the conditions of the Program.

At entry to treatment most patients exhibit some features of depression which resolve quickly once methadone or buprenorphine treatment is initiated. Some patients may benefit from antidepressant treatment where symptoms of depression persist.

Opioid substitution treatment should not be initiated for anyone with a psychiatric condition likely to severely compromise their capacity to give informed consent. People whose mental state impairs their capacity to provide informed consent (such as those with an acute psychotic illness, severe depression, cognitive impairment or a severe adjustment disorder) should receive appropriate treatment for the psychiatric condition in order that informed consent can be obtained before initiation of OST.

The prescribing doctor should seek specialist advice or assistance with such cases.

### **2.8.4 Co-existing medical problems**

A significant proportion of deaths related to opioid pharmacotherapy have involved individuals who were in poor health and had other disease conditions (particularly hepatitis, HIV and other infections) which may have contributed to their deaths. Patients who exhibit poor compliance with treatment for major intercurrent illness such as asthma or diabetes pose a particular challenge when receiving methadone or buprenorphine treatment.

### **2.8.5 Chronic pain**

It is recommended that patients with chronic pain be managed under the supervision of a specialist multidisciplinary pain service and appropriate referral or consultation should be considered. Methadone and buprenorphine can be useful analgesics in the management of ongoing chronic pain conditions; however these patients need a comprehensive management plan.



### 2.8.6 Risk of self-harm or suicide

Individuals at moderate or high risk of suicide should not be given access to unsupervised doses of methadone or buprenorphine and specialist consultation should be sought. Where there is concern that the patient poses a significant risk to themselves they may require hospitalisation.

### 2.8.7 Cardiac vigilance recommended for methadone patients

Methadone produces QTc prolongation and increases the risk of torsades de pointes, particularly when given in high doses. Patients who experience palpitations or unexplained syncope while on prescribed methadone should be referred for an ECG to exclude QTc prolongation. Patients with clinical manifestations of QTc prolongation or with a QTc greater than 450ms should have their methadone treatment reviewed and transfer to buprenorphine should be considered.

It is also recommended that a baseline ECG be undertaken prior to the commencement of methadone for patients with significant risk factors for QTc prolongation. These include co-prescription of medication known to prolong the QTc interval, coronary heart disease, increased age, family history, electrolyte disturbance (hypokalaemia, starvation or malnutrition) or symptoms that may be attributable to arrhythmia. Among these patients additional testing should be performed annually. Treatment options for patients with a prolonged QTc should be discussed with an addiction medicine specialist or cardiologist. With all applications for high dose methadone treatment the CPOP Clinical Review Committee requires and reviews ECG results and provides recommendations regarding cardiac monitoring.

Great caution is advised if methadone is to be prescribed in conjunction with other medications known to increase the risk of QTc prolongation or inhibit the metabolism of methadone (liver P450 inhibitors). Patients should be advised to raise the question of potential drug interactions when being prescribed any medication by another doctor.

**Table 8 Medications Known to Prolong the QTc Interval**

QTc Interval Prolonging Medications	
Antiarrhythmics	Sotalol Amiodarone Disopyramide Dofetilide Procainamide Quinidine
Antihistamines	Terfenadine Astemizole



**Table 8 Medications Known to Prolong the QTc Interval continued**

QTc Interval Prolonging Medications	
Anti-infective agents – Antibiotics	Azithromycin Clarithromycin Erythromycin Pentamidine Sparfloxacin Moxifloxacin
Anti-infective agents – Antiparasitics	Chloroquine Quinine
Anti-infective agents – Antifungals	Itraconazole Ketoconazole
Antipsychotic/antidepressants	Chlorpromazine Haloperidol Quietapine Risperidone Amitriptyline Citalopram Venlafaxine
Miscellaneous agents	Ephedra Cisapride Levacetymethadol (LAAM) Organophosphates Cocaine

Source: Schmittner, J and Krantz, M. QTc Prolongation in Methadone Maintenance: Fact and Fiction. *Heroin Addict Relat Clin Probl* 2006; 8(4): 41-52

**Table 8 is not a complete list, and prescribers should consider all medications with caution when prescribing for patients on high dose methadone.**

## 2.9 Prescriptions

Patients participating in CPOP should only be prescribed a single dose (excluding split doses) of methadone or buprenorphine per day.

The prescription must include:

- the patient's full name, address and date of birth
- date of prescription
- the patient's WA Health authorisation number
- the drug to be administered\*
- the date of administration of first dose\*
- the finish date\*
- the daily dose expressed in milligrams, written in both numbers and words\*



- any variations to daily dosing to be written in milligrams and words\*
- number of takeaway doses allowed (refer to WA Schedule)\*
- the pharmacy/dispensing point at which the script is valid\*
- the signature of the prescriber\*
- the name and practice address of the prescriber.

\* To be in the authorised prescriber's own handwriting.

CPOP prescriptions must be posted directly to the dosing pharmacy. In urgent situations a copy may be faxed or emailed to the pharmacy to ensure ongoing dosing.

In order to reduce the potential for dosing at multiple sites to occur when multiple prescriptions are written for a patient, the prescriber must ensure that an additional prescription does not authorise additional doses to be obtained from another pharmacy on the same day.

\* If authorisation is provided verbally to a pharmacist for change of prescription, written confirmation of the verbal instruction must be provided within 24hrs clearly indicating that it is confirmation of the direction given. PSB will be advised if the script has not been received within 72hrs.

**Takeaway doses of methadone and buprenorphine must not be provided to a third party on behalf of any CPOP patient without the approval of the CPOP Clinical Review Committee.**

### 2.9.1 Prescriptions for benzodiazepines

Alprazolam should not be prescribed for patients on OST. There is a high incidence of benzodiazepine use and dependence associated with opioid dependence. The combination of an opioid and a benzodiazepine is hazardous and requires close monitoring by the prescriber(s) and the dispenser. Only in exceptional circumstances would the dispensing of a full PBS quantity of benzodiazepine be appropriate for an OST patient. Prescriptions should restrict dispensing to small quantities of benzodiazepines. High risk patients may require daily dispensing.

### 2.9.2 Urgent prescriptions due to unforeseen circumstances

Where a patient's authorised prescriber is contactable it is recommended that any changes to dosing arrangements or extension to a patient's prescription be undertaken by that prescriber.

If the patient's authorised prescriber cannot be contacted and an alternative prescriber within the same practice is not available, a specialist prescriber (as designated under Regulation 51C(2) of the Poisons Regulations 1965) may prescribe under the following conditions:

1. An authorised prescriber is appointed for the person.
2. The specialist prescriber
  - is satisfied that the patient is unable to obtain a prescription for a pharmacotherapy
  - is satisfied that it is safe to prescribe a pharmacotherapy for the patient
  - does so in accordance with the appointment of the authorised prescriber for the patient.



The specialist prescriber must notify the Department and the patient's authorised prescriber of having prescribed a pharmacotherapy for a patient under this regulation. A prescription for the supply of a pharmacotherapy under this regulation **may not cover a period of more than one month.**

An interim script may be supplied for current patients of CPOP to ensure continuation of OST in the following circumstances, and where it is considered safe to do so:

- where the patient's usual authorised prescriber is not available due to unplanned leave, sickness, or exit from the Program
- where a patient of the Program is released from prison and awaiting a scheduled appointment with their usual or new prescriber
- where a dosing patient of the Program is discharged from hospital and is awaiting a scheduled appointment with their usual prescriber
- where a patient of the Program fails to attend a scheduled review appointment, and is awaiting a re-scheduled appointment date
- where an alternative appointment is unable to be made (e.g. due to after hours closure on a weekend) a script will be provided for the minimum period required for the patient to contact the prescriber. This should generally not exceed a four day time period.
- where a patient of the Program is awaiting finalisation of transfer to an alternative prescriber within WA
- other circumstances which may be considered appropriate by the CPP/CAS team.

Interim scripts will only be written to maintain continuity of treatment for the minimum period of time needed for a patient to engage with an appropriately authorised prescriber. The conditions of an existing valid script will be continued, except where there is a concern regarding patient stability and safe use, particularly in relation to takeaway doses. In these situations the specialist prescriber may vary the conditions of the usual treatment.

**Where a report is received concerning diversion or intoxication, all takeaway doses will be suspended until the patient is reviewed by their authorised prescriber.**



## 3. Commencing Opioid Substitution Treatment

### 3.1 Selecting an Opioid Substitution Treatment

Patients commonly present for treatment at a time when they are in crisis, often when their use of opioids has escalated to the point of being out of control. Ideally all eligible patients should be admitted promptly into treatment. This is especially important for people being released from correctional institutions, pregnant women, people with HIV and/or hepatitis carriers, and their opioid using partners.

Sometimes a change in circumstance such as an ultimatum from family or being charged with a criminal offence may be the precipitant to entering treatment. In crisis situations, patients are often resolved to cease drug use and change their lifestyle. They often seek short-term treatment without necessarily having considered all treatment options, simply 'hoping' that an attempt at withdrawal will be sufficient to stop opioid use. The motivation to remain abstinent, however, may be short-lived. This may be more of an issue for patients requesting buprenorphine as a short-term treatment option rather than for maintenance. Most patients requesting methadone are generally seeking longer term treatment.

There is strong evidence that longer-term treatment is associated with a greater likelihood of continuing abstinence from opioids than shorter periods of treatment. Decreased drug use and improved psychosocial stability generally become significant after three months on OST, with major improvement noted after one year.

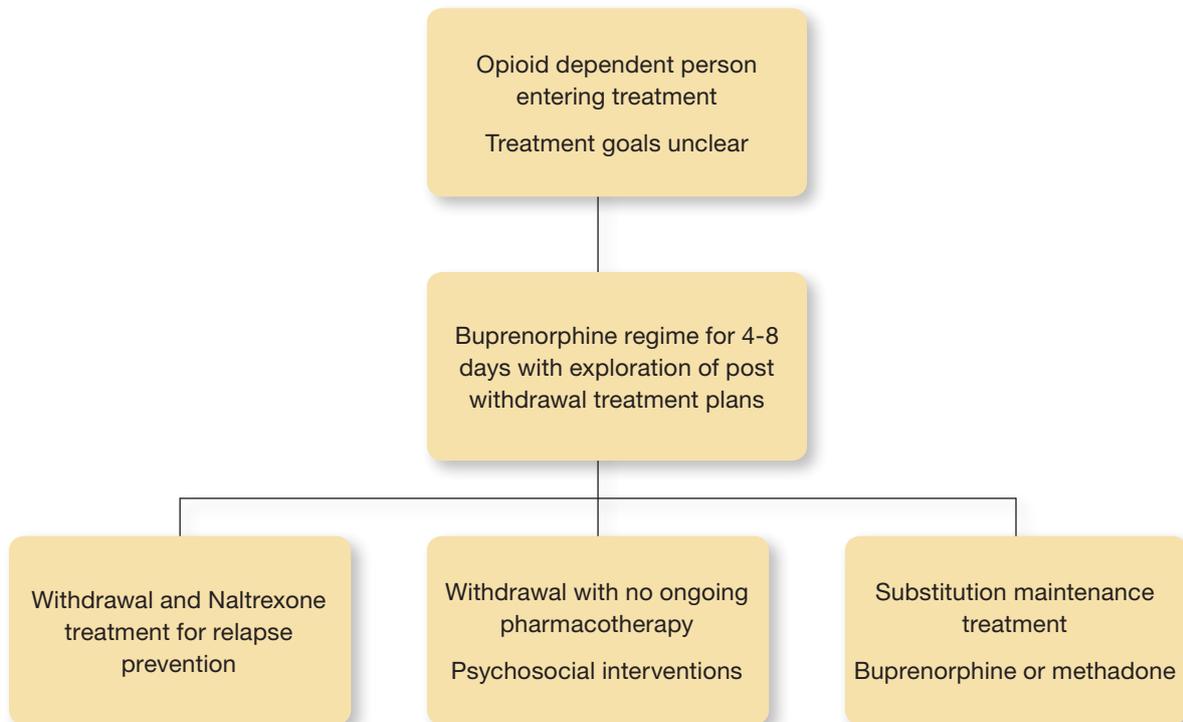
Buprenorphine is particularly useful in managing opioid withdrawal and can also facilitate links to other treatment options. The use of buprenorphine for several days will alleviate withdrawal symptoms without significant sedation, and a formal review of the treatment plan can occur when the patient's goal may be clearer.

A short course of buprenorphine can be withdrawn with minimal rebound discomfort for those patients who choose not to continue with maintenance treatment. Alternatively, those wishing to extend the duration of their withdrawal program, or who have decided on a maintenance treatment program, can simply continue buprenorphine treatment. An added benefit of buprenorphine is that naltrexone can be initiated after buprenorphine administration with less delay and less severe withdrawal than in the case following methadone maintenance treatment. These treatment pathways are shown in Figure 5.

It is not uncommon for clinicians to receive requests for repeated, short-term episodes of buprenorphine treatment, with perhaps three or four detoxification episodes within a year. In this situation, where people have relapsed to drug use, it may be more useful to recommend maintenance OST rather than a further short-term episode of buprenorphine assisted withdrawal.



**Figure 5 Gateway Model of Treatment with Buprenorphine**



### Choosing between pharmacotherapies

Current evidence suggests that key treatment outcomes for methadone and buprenorphine are comparable under optimal treatment conditions. Patient or clinician preferences might reflect:

- **Response to treatment**

Ultimately, the continued use of a medication should depend on its ability to meet the aims and objectives of treatment. This requires patient treatment goals, an appropriate treatment plan, and clarity about how treatment outcomes will be assessed.

Where goals in treatment are not being met, a review of the treatment plan should occur, including:

- the role of psychosocial and other interventions
- levels of supervision, monitoring and review
- the dose of pharmacotherapy
- consideration of alternative opioid pharmacotherapies.

- **Individual variation in absorption, metabolism and clearance**

There may be considerable pharmacokinetic and pharmacodynamic differences between individuals in their response to methadone or buprenorphine. Patients who cannot stabilize their continued use of opioids even on high doses of buprenorphine may be better suited to higher doses of a full agonist (methadone).



- **Side-effects**

Individuals experiencing significant side-effects from one opioid medication may benefit from treatment with an alternative medication. Buprenorphine may be preferred by individuals complaining of continued sedation resulting from methadone. A small but significant proportion of patients may experience headaches related to buprenorphine treatment and may be better suited to methadone treatment.

- **Logistics of participating in treatment**

These include issues such as ease of access, frequency of dispensing, and the costs to patients. Once stabilised on a daily dosing regime, some patients on buprenorphine may be able to move to an alternate-day, or four-times-a-week dosing regime. This is generally more convenient for patients and reduces the need for takeaway doses.

- **Ease of withdrawal from maintenance buprenorphine treatment**

A limiting factor for many patients considering OST is the problem of dependence upon the maintenance opioid. As it is only a partial agonist and dissociates slowly from receptors, buprenorphine appears to have a milder withdrawal syndrome than methadone. It is not clear if this translates into greater success for patients discontinuing OST.

- **Patient (and clinician) expectations**

The expectations of a medication may impact on treatment outcome. The introduction of new treatments can give rise to unrealistic expectations in patients, their families, and service providers.

- **Ease of transfer between pharmacotherapies**

Transferring from buprenorphine to methadone is relatively straight forward. However, patients on more than 30mg methadone will experience precipitated withdrawal symptoms when transferring to buprenorphine if commenced too soon after their final methadone dose.

### 3.2 Administrative requirements for entry into treatment

Authorised methadone/buprenorphine prescribers must obtain from the Department of Health an individual patient authority for each person being commenced on treatment (*Regulation 51CA of the Poisons Regulations 1965*).

An *Application to prescribe opioid substitution treatment* is completed by the prescriber. The prescriber is required to establish the identity of patients by sighting identification, and the patient must sign the declaration on the application. This declaration indicates that the patient acknowledges that their information will be forwarded to the Department and will also be used in support of the management of the Program.



The completed *Application to prescribe opioid substitution treatment* is forwarded to CPP for required checks and the authorisation is subsequently issued by the Department.

1. An authorisation number must be obtained prior to the writing of a prescription for methadone or buprenorphine.
2. Authorisation is for a maximum daily maintenance dose of 120mg of methadone or 24mg of buprenorphine.
3. On completion the authority number should be documented on the application form which is then filed with the patient's clinical record.

**Please note:** An *Application to prescribe opioid substitution treatment* is required when initiating prescribing for a patient transferring from another prescriber or for a patient that has previously been treated by the same prescriber where the previous authorisation has expired or been terminated.

### **Patient Identification**

Patients need to provide the following approved combination of **original documentation** to the prescriber that supports their identity:

#### **Category A – One original document required**

- Current driving licence issued by an Australian state or territory (with photo)
- Current Australian Passport
- WA Proof of Age Card (with photo)
- Current firearms licence issued by an Australian state or territory (with photo)

***If Category A documentation is not available then two documents from Category B may be provided.***

#### **Category B – Two documents required**

- Medicare card issued by the Health Insurance Commission
- Centrelink card issued by Centrelink
- Health Care Card
- Department of Veterans' Affairs (DVA) card issued by DVA
- Credit or debit card or account issued by a financial institution in Australia
- Department of Immigration and Multicultural Affairs (DIMA) certificate of evidence of residence status
- Citizenship certificate
- Current overseas passport with current Australian entry permit
- DIMA immigration papers
- Photo identification issued by a Government Authority (e.g. prison ID)
- Original birth certificate



***If Category A or B documentation is not available then three documents from Category C may be provided.*** (Any documents presented from category C must be not more than 12 months old and show a current residential address.)

- Motor vehicle registration or insurance papers
- Property rates notice
- Property lease agreement
- Home insurance papers
- Utilities bills (e.g. telephone, electricity or gas)
- Bank or credit card statements
- Trade certificate
- School certificate

#### **Patient identification provided by the prescriber to the pharmacy and CPP**

The prescribing doctor should ensure that the pharmacy is provided with a recent photo of the patient, endorsed by the prescriber and attesting to the patient's identity. A photo provided to CPP at this time will also aid identification when assisting patients with scripting issues and transfers. A Next Step identity form may be provided.

Where available and upon agreement between the prescriber and pharmacist, an endorsed digital image can be provided electronically by the prescriber to the pharmacy for their record.

#### **Conditions associated with the authority to prescribe OST**

The authorisation for a medical practitioner to prescribe methadone or buprenorphine is subject to the following conditions:

- ***Legal responsibility***

The prescriber remains legally responsible for the treatment of a patient until that prescriber's authorisation is terminated.

- ***Patient numbers policy***

The prescriber must not exceed the maximum number of patients as set out in Section 1 of this Manual.



## 4. Induction and stabilisation

### 4.1 Methadone

#### 4.1.1 Introduction to methadone treatment

Induction to methadone needs to occur slowly over a minimum of 2 weeks since induction can be associated with overdose and death. The risk of overdose and death can be minimised by proper assessment, prescribing a low starting dose with gradual dose increase and frequent review of the patient throughout the induction period. The main objectives during the induction period are to engage and retain the patient in treatment by minimising withdrawal effects, and employing strategies that minimise the risk of overdose.

Deaths during the induction phase of methadone treatment have been related to:

- simultaneous use of other drugs (particularly sedatives such as other opiates, alcohol, benzodiazepines, other CNS depressants and psychiatric medications)
- inadequate assessment of tolerance
- commencement on doses that are too high for the level of tolerance
- inadequate monitoring and review
- lack of understanding of the cumulative effect of methadone over time
- inadequate observation and supervision of dosing
- individual variation in metabolism of methadone
- concomitant medical conditions (e.g. sleep apnoea, QTc prolongation).

**Extra caution is required when there is a history of polydrug use.** Consideration should be given to specialist referral and management for polydrug users commencing methadone treatment. Individuals with high-risk patterns of polydrug use or concurrent medical, psychiatric or social problems may warrant more frequent review and case management from a specialist service. Patients on OST should not be prescribed Alprazolam due to its enhanced abuse liability.

#### 4.1.2 Commencing methadone from opioid use

It is particularly important to advise patients that it takes time to complete induction onto methadone and they will experience increasing effects from methadone over the first few days of treatment even if the dose is not increased.

While doses of methadone that are too high can result in toxicity and death, an inadequate commencing dose may result in some patients experiencing withdrawal symptoms. This may result in patients 'topping up' their prescribed dose of methadone with use of heroin or other opioids, benzodiazepines, or alcohol to relieve withdrawal discomfort. This situation can have potentially lethal consequences.

**For most patients withdrawal symptoms will be reduced but not entirely eliminated by doses of methadone less than 30mg.**

It is important to educate patients on the risks associated with use of other drugs and to also assess the need for symptomatic treatment of breakthrough withdrawal symptoms.



### 4.1.3 Observation and monitoring by a significant other

Methadone induction deaths can occur many hours after methadone dosing. Administration of methadone in the morning will ensure that peak methadone concentrations occur when patients are normally awake. It is also more likely that other people will be around if overdose does occur.

Wherever possible for the first week the person should be monitored for signs of intoxication by a responsible adult. Family members should be warned that deep snoring while sleeping during induction to treatment could be a sign of dangerous respiratory depression and the person should not be left alone. **The prescriber should be advised of signs of sedation, laboured breathing or heavy snoring during induction.**

Family members should also be made aware that the risk of overdose is greater if the person is drinking alcohol, or taking benzodiazepines or other sedating medication.

### 4.1.4 Size of the first dose

While the first dose of methadone should be determined for each patient based on the severity of dependence and level of their tolerance to opioids **the maximum first dose of methadone should not exceed 25mg**. For patients with low or uncertain levels of opioid tolerance a lower initial dose should be given.



Consultation with CAS is required if an initial dose of methadone exceeding 25mg is considered necessary.

The history of opioid use (quantity, frequency and route of administration), withdrawal symptoms, findings on examination, corroborative history and urine testing together provide an **indication of the level of tolerance** a patient has to opioids, but do not predict it with any certainty.

A period of observation for signs and symptoms of opioid toxicity and withdrawal is a more accurate method of assessing opioid tolerance than history alone. In circumstances where there is doubt about the degree of tolerance, a review of the patient at a time when withdrawal symptoms are being experienced may help to resolve uncertainty about a safe starting dose.

Where there is doubt prescribers should make every effort to speak with other practitioners who may have seen the patient previously in order to corroborate the patient's history. This will assist in decision making about commencing treatment. Information can also be obtained from a partner or family member.



Deaths in the first two weeks of treatment are most commonly associated with commencement doses in excess of 25mg/day.

New patients should be dosed with caution. Where there is uncertainty about the level of tolerance the patient should be observed 3–4 hours after the first supervised dose for signs of toxicity or withdrawal (i.e. at the time of peak effect). If the patient is experiencing significant observable withdrawal symptoms at 4 hours, a supplementary dose of 5mg can be given.



When deciding on the commencing dose, also consider:

- **Where dosing is to occur** – contact the dispensing site to confirm that the patient is accepted to dose at that facility and discuss the observation and assessment of the patient before and after dosing. Clarify who will assess withdrawal or intoxication prior to dosing the patient and the preferred methods of communication between the prescriber and dispensing staff.
- **Time since last opioid use** – the greater the length of time (days or weeks) since last opioid use the more the patient's tolerance will have reduced.
- **Concurrent use of benzodiazepines or alcohol** – the risk of overdose increases markedly when other central nervous system depressants are also used. If the patient shows signs of intoxication with benzodiazepines or alcohol, the starting dose should be withheld or reduced.

A dose of less than or equal to 20mg for a 70kg patient can be presumed to be safe, even in opioid-naïve patients as this is the lowest dose at which toxicity has been observed. Caution should be exercised for starting doses of more than 25mg.

#### 4.1.5 Induction

The main aim during the first 2 to 3 weeks of induction onto methadone treatment is to stabilise the patient. Doses should be gradually increased (5mg at a time) so that the final dose is sufficient to prevent the re-emergence of withdrawal symptoms within a 24 hour period, but not high enough to result in excessive intoxication at the time of peak effect.

- Do not increase the methadone dose for at least the first 2–3 days of treatment unless there are clear signs of withdrawal at the time of peak effect (i.e. 3–4 hours after dose) as the patient will experience increasing effects from daily methadone dosing.
- The maximum dose at the end of the first week should be no more than 35–40mg and the total weekly increase should not exceed 15–20mg.
- Dose should be decreased if there are features of intoxication at the time of peak effects (3–4hrs after dosing) or if there are intolerable side-effects.

Patients should be advised not to drive or operate machinery during periods of dose adjustment.



The methadone dose should not be increased for at least the first 2–3 days of treatment. Dose increments of 5mg every 2–3 days may be made subject to clinical assessment. The maximum dose at the end of the first week should typically be no more than 35–40mg and total weekly increases should not exceed 15–20mg in the following weeks.

Patients must be observed and assessed for intoxication before daily dosing, generally by the pharmacist at the dispensing site (see Appendix 5 – *Assessment of Acute Intoxication*). If there are any concerns the patient should be referred and seen by the prescriber before the dose is administered.

Consultation with CAS is required when a more rapid induction to methadone is considered necessary.

#### 4.1.6 Patient reviews

An appropriate pattern of review by the treating doctor is as follows:

- the day of the first dose
- 2–3 days after the first dose and every 2–3 days thereafter until a stable dose is reached
- every week during the following 4–6 weeks
- every 2–4 weeks until 6 months on treatment
- monthly to three monthly reviews thereafter for stable patients.

#### 4.1.7 Dose titration during the induction period

Stabilisation is achieved by titration of the dose against the needs of the individual patient with the aim of avoiding states of intoxication and withdrawal. Dose adjustments should be made slowly, with increases of not more than 5mg every 2–3 days. Many prescribers may not be able to review the patient more than every two or three days (e.g. because of work practices, weekends etc.). A period of 2–3 days on a specific dose allows the patient time to adjust to the current dose before further dose alteration. High risk patients should be seen prior to each dose increase. High risk patients include those with uncertain tolerance, patients taking benzodiazepines or other psychotic or sedative medications or binge drinking.



Dose decrease should be considered where the patient reports excessive sedation or somnolence at time of peak effect.

Monitoring the efficacy and safety of opioid substitution therapy:

- Pay particular attention to methadone dose during induction (start low, go slow)
- Regular review of treatment progress and any new drug therapy – assess risk of interaction or diversion
- Regular communication with the pharmacist who frequently sees the patient
- Engage family or significant others in treatment monitoring (e.g. occasional family inclusive consultations)
- Educate family or significant others in drug risk management (e.g. recognising possible toxicity)
- Regular physical examination includes looking for any injection sites and any signs of drug-related impairment (e.g. is patient fit to drive?). Always document these findings.
- Random urine drug screening
- Consider use of breathalyser and selected blood tests where appropriate (e.g. gamma-glutamyl transferase)
- Careful consideration of risk before approving any take-away, unsupervised, doses
- Compliance with treatment guidelines.



#### 4.1.8 Methadone dose levels

An individualised dosing strategy is associated with higher treatment retention rates and less opioid use. Patients on methadone treatment are cross-tolerant to the effects of other opioids. This effect is increased with higher dose levels. Effective methadone treatment doses are generally achieved in the range of 60–100mg per day.

Patient input to treatment decisions, including determination of dosing levels, promotes a good therapeutic relationship by enhancing trust and self-responsibility. When making decisions about changes in dosage the following should be taken into consideration:

- patient's adherence to dosing regime
- patient's perception of dose adequacy and satisfaction with treatment
- frequency and amount of drug use prior to treatment
- concurrent use of illicit opioids and continued injecting drug use
- individual variation in methadone metabolism
- use of other medications which may interfere with methadone metabolism
- pregnancy
- polydrug use (patient's self report, urine testing).

Daily administration of methadone is recommended to ensure that plasma methadone levels are maintained, and to avoid withdrawal symptoms. Where plasma levels are not maintained, cross-tolerance is lessened, reducing the capacity of methadone to moderate the euphoric effect of other opioids if used. Irregular dosing or lower doses are associated with an increased risk of relapse to opioid use and an increased risk for overdose.



A daily methadone dose of 60mg or greater should be sufficient to ensure a substantial level of tolerance to effects of other opioids in the majority of individuals.

Doses in excess of 100mg/day may be necessary to achieve successful maintenance; however there is no evidence from treatment outcome studies that routine dosing at levels in excess of 120mg/day results in any additional benefit for the majority of patients.



Approval is required to prescribe more than 120mg of methadone.

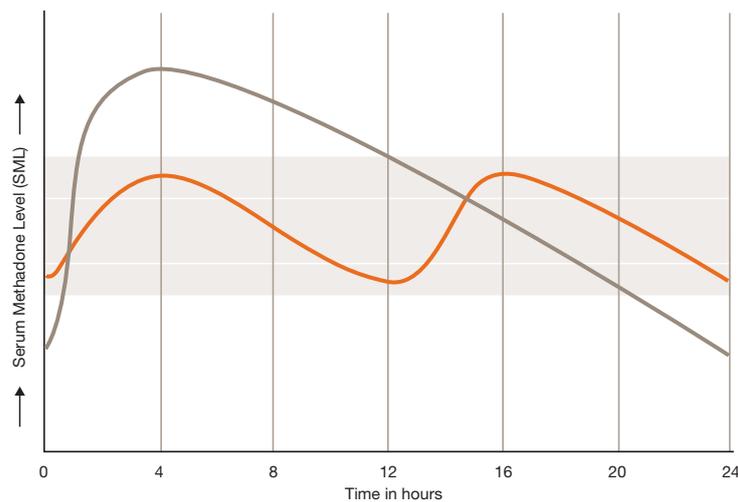
An *Application to prescribe high dose opioid substitution treatment* should be faxed to CPP for approval by the CPOP Clinical Review Committee before patients can be prescribed greater than 120mg of methadone.

### 4.1.9 Split dosing of methadone

Some individuals metabolise methadone rapidly so while their dose level may in fact be adequate they do not maintain plasma levels throughout the day. These patients may require their dose to be split and administered twice daily, rather than once a day.

If the patient is clinically sedated following supervised dosing and experiences withdrawal before the next day's dose, and/or the peak serum methadone level is more than twice the trough level (P:T ratio  $>2.0$ ) splitting the dose may be considered. In these patients, **further once-a-day dose increases will elevate the peak level, not the trough level, and will not make the dose last longer** resulting in overmedication in the hours after dosing and continued opioid withdrawal later.

**Figure 6 Methadone Split and Single Dose Comparison**



Adapted from Payte 2002. In *Addiction Treatment Forum*. Methadone dosing and safety in the treatment of opioid addiction. Leavitt, S. PhD (2003).

The above figure illustrates that splitting the dose (red line) keeps the serum methadone level within the therapeutic range (grey zone), which corrects a high peak and a low trough level (black line).

While split dosing may well improve the duration over which a patient's methadone level remains within the therapeutic range, in practice split dosing is difficult as patients are required to attend the dosing pharmacy twice each day. Provision of the second half of the daily dose as a takeaway is outside the scope of supervised pharmacotherapy and should not be provided without support from the CPOP Clinical Review Committee.

Split dosing may be considered in the short term for patients suffering nausea in the early stages of treatment, or due to pregnancy. Consult CAS for advice and further information.



#### 4.1.10 Transfer from other opioid substitution treatments to methadone

Prescribers may need to seek specialist advice when prescribing for patients who are transferring from other pharmacotherapies with which they are unfamiliar.

##### *From buprenorphine*

Consideration should be given to transferring a patient from buprenorphine to methadone under the following circumstances:

- the patient is experiencing intolerable side-effects from buprenorphine
- there has been an inadequate response with buprenorphine treatment
- the patient is transferring to a service where buprenorphine is not available
- there has been a problem with supervision of buprenorphine dosing (e.g. diversion, patient uncooperative at pharmacy)
- the patient will be incarcerated.

Patients should be stabilised on daily doses of buprenorphine and their buprenorphine dose reduced to 16mg or less for several days prior to transfer. Methadone can then be commenced 24 hours after the last dose of buprenorphine.

The initial methadone dose should not exceed 30mg where the buprenorphine maintenance dose has been  $\leq 16$ mg; and should not be more than 40mg where the buprenorphine maintenance dose has been  $> 16$ mg. Subsequent methadone dose increases should be no more than 5mg every 2–3 days.

Patients transferring from doses of buprenorphine 4mg or less should be commenced on methadone as per normal induction, with care not to increase the dose of methadone too quickly.

##### *From naltrexone*

Patients who have been taking naltrexone lose tolerance to opioids. Consequently, patients transferring from naltrexone should be treated as if they were naïve to opioids and non tolerant to their effects unless the clinical circumstances clearly indicate a return to regular, heavy opioid/heroin use.

Patients who have relapsed to opioid use following cessation of naltrexone (oral or implant) can be considered for treatment with an opioid pharmacotherapy. Because of its safety profile during induction buprenorphine is the drug of choice in this situation.

Extreme caution should be exercised if commencing methadone and the starting dose should be no greater than 20mg. The first dose of methadone should not be given until at least 72 hours after the last dose of naltrexone.



## 4.2 Buprenorphine

### 4.2.1 Introduction to buprenorphine treatment

Research evidence indicates that the mono buprenorphine product (Subutex) and the buprenorphine/naloxone combination (Suboxone) formulation are largely interchangeable; however there are some circumstances when the mono product will be preferred. Suboxone **in tablet form** is not available as a PBS Section 100 item.

In WA all OST patients are required to be treated with Suboxone unless there is evidence to support the use of Subutex in the following special circumstances:

- pregnant and breastfeeding women (patients must sign a consent form)
- patients with an established allergy to Suboxone (prescribers must complete an adverse drug reaction form and submit with the application)
- patients on a low dose (<6mg) short-term withdrawal regime.

These special circumstances should be fully specified on the *Application to prescribe opioid substitution treatment* for Subutex. An *Adverse drug reaction reporting (ADRAC) form* must accompany the application to prescribe for clients with reported allergy. A copy of this form can be requested from CPP, or can be easily accessed on line at <http://www.tga.gov.au/pdf/forms/problem-medicine-forms-bluecard.pdf>

Where an application is made for pregnant or breastfeeding women, authority will be provided for a maximum 1 year period. For clients on less than 6mg and reducing, a proposed treatment plan must be provided and authorisation will be limited to an initial six month period. Where an extended authority is required, the application will be reviewed by the CPOP Clinical Review Committee prior to the Department's approval.

### 4.2.2 Induction to buprenorphine from opioid use

The unique pharmacology of buprenorphine allows for a more rapid induction than is possible with methadone.

Doses of 2 or 4mg should be considered where there is some doubt regarding the degree of neuroadaptation prior to commencing treatment. Patients in mild withdrawal may be commenced on a starting dose of 4mg with the possibility of a further dose of 4mg 1–2 hours later if withdrawal symptoms have not improved. Patients in severe withdrawal at the time of the first dose may be given an initial dose of 8mg.

Rapid dose induction to achieve a maintenance dose of 12 to 16mg by day 3 or day 4 may be associated with better retention in treatment. This approach needs to be responsive to individual reactions to initial dosing and safety considerations.

Higher initial doses will increase the risk of precipitated withdrawal (if the patient has recently used opioids) or sedation (if the patient has a lower level of opioid dependence or also consumes other sedatives such as benzodiazepines). Higher initial doses will also facilitate rapid dose induction.



Patients should ideally be observed for a few hours after the first dose, and a further dose administered on the same day if there are no signs of sedation. An appropriate dose to achieve on the first day is 6 to 8mg. This may be given as a single dose or, if resources permit, in two doses of 4mg, four hours apart to reduce the risk of precipitated withdrawal and adverse effects.



Prescribers should aim to achieve a buprenorphine dose of 12mg-16mg per day by day 3 or 4.

Prescriptions may be written as a fixed, increasing dose regime over the first week (e.g. 8mg day 1, 12mg day 2, 16mg day 3). Doses should only be expressed in combinations of 2mg and/or 8mg doses for Suboxone.

The following factors must be taken into consideration when deciding on the initial dose of buprenorphine:

- **Time since last opioid use**, and whether long-acting opioids such as methadone have been taken in the last one to two days.
- **The perceived likelihood of concurrent drug abuse**, including alcohol consumption, use of prescription sedative drugs (particularly benzodiazepines), or illicit drug use. In such instances, lower doses of buprenorphine should be prescribed with frequent reviews.
- **Concurrent medical conditions**, particularly severely impaired hepatic function and interactions with other medication can warrant the use of lower initial doses of buprenorphine with regular monitoring.



The first dose of buprenorphine should be administered when the patient is experiencing early features of opioid withdrawal.

Scales for assessing opioid withdrawal (see Appendix 2, 3 and 4) can be useful for confirming the presence of opioid withdrawal prior to administration of the first dose of buprenorphine. Opioid withdrawal will generally become apparent six hours after the last use of a short acting opioid like heroin but may not become apparent for a longer period of time if longer acting opioids have been used.



Particular care should be taken not to administer buprenorphine to a patient who has recently used opioids.

Patients administered buprenorphine soon after opioid use may experience opioid withdrawal, as the buprenorphine displaces other opioids from the opioid receptors. Where the first dose of buprenorphine is delayed until the presence of early opioid withdrawal symptoms, the occurrence of withdrawal precipitated by buprenorphine will be relatively rare.



Buprenorphine precipitated withdrawal typically begins 1–4 hours after the first buprenorphine dose, is generally mild to moderate in severity, and lasts for up to 12 hours. If precipitated withdrawal occurs, patients may require symptomatic withdrawal medication, and should be directed to see their doctor. Administration of the first dose of buprenorphine early in the day provides an opportunity to manage precipitated withdrawal if it occurs. If precipitated withdrawal occurs following the initial buprenorphine dose, subsequent doses of buprenorphine (taken the following day) should result in minimal discomfort if the patient has not used additional opioids during the intervening period. Patients who continue to use additional opioids between their first and second doses of buprenorphine may have difficulty stabilising on the treatment, with ongoing features of opioid withdrawal. They should be advised to cease all opioid use prior to the next dose of buprenorphine.

### 4.2.3 Managing precipitated withdrawal

The key factors which may affect a precipitated withdrawal are discussed below in Table 9. If the patient is experiencing highly unpleasant precipitated withdrawal, a single dose of 50–100mcg clonidine may be given. Due to the risk of hypotension and the abuse potential of clonidine, it should not be provided on an ongoing basis. **A prescription for a full quantity of clonidine must not be given to the patient.**

*Table 9 Key Factors Affecting Precipitated Withdrawal*

Factor	Discussion	Recommended Strategy
Dose of methadone when transferring to buprenorphine	Doses greater than 30mg of methadone are more often associated with precipitated withdrawal. In general, the higher the methadone dose, the more severe the withdrawal experienced.	Attempt transfer from low dose of methadone (e.g. <30mg where possible).
Time between last methadone dose and first buprenorphine dose	Buprenorphine should not be taken within 24 hours of last methadone dose. Increasing the interval between last dose of methadone and first dose of buprenorphine reduces the incidence and severity of precipitated withdrawal.	Cease methadone and delay first dose of buprenorphine until patient is experiencing features of methadone withdrawal.
Dose of buprenorphine	Very low doses of buprenorphine (e.g. 2mg) are generally inadequate to substitute for methadone for 24 hours (unless the methadone dose is very low). High first doses of buprenorphine are more likely to precipitate withdrawal, as there is greater displacement of methadone from the receptors. This is a common mistake by inexperienced prescribers.	First dose of buprenorphine should generally be 4mg, with review of the patient 2–4 hours later (or early the following day). Check response for precipitated withdrawal.



Factor	Discussion	Recommended Strategy
Patient expectation	Patients who are not prepared for the possibility of precipitated withdrawal are more likely to be distressed and confused by its onset, with potential negative consequences (e.g. treatment drop-out, abuse of other medications).	Inform patients fully (and partners, family and carers where relevant). Provide written information. Prepare a contingency management plan for severe symptoms.
Use of other medications	Symptomatic medication (e.g. clonidine) can be useful in relieving any precipitated withdrawal.	Prescribe and dispense in accordance with a management plan.

#### 4.2.4 Stabilisation

##### To achieve stabilisation of the buprenorphine dose:

By the end of the first week, reported symptoms of both withdrawal and intoxication should be minimal with stabilisation achieved. The optimal dose for the patient is one which is sufficient to prevent the discomfort of withdrawal for the full interdosing interval, and to support cessation or a significant reduction in other opioid use without inducing significant toxicity or side-effects. Typically the dose at the end of the first week would be in the range of 12–16mg/day.

Patients should be regularly reviewed for the first few weeks to assess adequacy of dose, withdrawal symptoms, side-effects, and any additional drug use. Doses should only be increased when indicated at review.



The optimal maintenance dose needs to be individualised according to the patient's response to buprenorphine. Typically however, a maintenance dose of buprenorphine will be in the range of 12 to 20mg/day.

#### 4.2.5 Patient reviews

An appropriate pattern of review by the treating doctor is as follows:

- the day of the first dose
- 2–3 days after the first dose and every 2–3 days thereafter until a stable dose is reached
- every week during the following 4–6 weeks
- every 2–4 weeks until 6 months on treatment
- monthly to three monthly reviews thereafter for stable patients

Individuals with continuing high-risk patterns of drug use, or concomitant medical, psychiatric or social problems will require more frequent review.



#### 4.2.6 Buprenorphine dose levels

The optimal maintenance dose needs to be individualised according to the patient's response to buprenorphine. Responses vary considerably according to the following factors:

- Rates of absorption or metabolism of buprenorphine. The duration of contact with the oral mucosa is a significant factor for the absorption of buprenorphine. Hence, instructing patients in the technique of administering buprenorphine is important.
- Adherence to the dosing regime. This may depend on the patient's perception of dose adequacy, their satisfaction with treatment, and their experience of side-effects.
- Continued use of other drugs.

These variations require the clinician to titrate the buprenorphine dose to optimise treatment objectives.

Effective maintenance doses, resulting in reduced opioid use and improved treatment retention, may be achieved with buprenorphine doses in the range of 12–20mg per day. Doses of 4mg or less in general will not be as effective in retaining patients in treatment or reducing opioid use. Most patients will require at least 12mg–16mg/day daily for effective buprenorphine maintenance treatment. Doses greater than 20mg increase the duration of action of buprenorphine but do not in general increase receptor blockade.

The buprenorphine dose should be decreased where there are reports of intoxication, overdose, or there are concerns regarding the patient's safety.

Continued opioid/heroin use despite adequate daily doses of buprenorphine may indicate that the patient would benefit from more intensive psychosocial interventions, or an alternative opioid substitution treatment (methadone).

Approval is required to prescribe daily doses of more than 24mg buprenorphine. Patients on second daily doses can receive doses of up to 32mg on alternate days (i.e. a maximum daily dose of 16mg/day) without the prescriber having to apply for approval.

#### 4.2.7 Approval process for daily buprenorphine doses greater than 24mg/day

Application can be made to exceed a daily buprenorphine dose of 24mg/day by completing the *Application to prescribe high dose opioid substitution treatment* and faxing to CPP. All applications for doses in excess of 24mg daily will be forwarded for consideration by the CPOP Clinical Review Committee. Daily doses greater than 24mg per day are rarely needed and a review of dosing technique is a critical factor in assessing the adequacy of a patient's dose.



#### 4.2.8 Changing dose levels

**Doses can be increased** if there is continuing opioid use, increasing craving for opioids or features of withdrawal in the period immediately prior to the next dose.



Doses can be increased or decreased by between 2mg and 4mg/day.

**Doses should be decreased** if there are features of intoxication with buprenorphine (e.g. sedation) particularly at peak effect times (1–4 hours after dosing) or where severe or intolerable side-effects are present.

#### 4.2.9 Split dosing

Due to its long half life split dosing is not appropriate. Buprenorphine is not provided more frequently than once a day for those on a maintenance regime.

#### 4.2.10 Frequency of dosing: alternate day and four days per week dosing regimes

The characteristics of buprenorphine enable dosing regimes ranging from daily to once every 2 or 3 days to be considered. The chief reason for considering a reduced-frequency dosing regime is convenience for patients who are stable in treatment.

Patients should first be stabilised on a regular daily dose for 2–3 months, after which time consideration can be given to alternate day dosing for a trial period. This period of stability on a single day dosing regime will enhance treatment compliance and continuing stability for those considering a change to alternate day dosing.

It is recommended that suitable patients initially be trialled for 2 weeks on a four-days-a-week or an alternate-day dosing regime of buprenorphine. If a patient cannot be stabilised on such dosing regimes due to the onset of withdrawal, relapse to illicit opioid use, cravings, side-effects or features of intoxication, they should be returned to a more frequent dosing regime.

##### ***Four days per week regime:***

This requires attending the pharmacy four times a week for 3 x 48 hour doses and 1 x 24 hour dose each week (e.g. Monday 20mg, Wednesday 20mg, Friday 20mg, and Sunday 10mg). The advantage of this approach is that the patient is on a regular attendance schedule each week, with less likelihood of conflict interactions, attendance errors on the patient's part, or dosing errors by the pharmacist.

**Alternate-day/second daily dosing:**

This regime involves attending the pharmacy for dosing on alternate days (i.e. a dose every 48hrs). This regime can be confusing for patients as the dosing days change from week to week. Patients who miss doses on this regime should be transferred to a 4 days per week regime.

Prescriptions must be clearly written with instruction for the dispenser where an alternate day or a four days per week regime is considered. For example, a Suboxone prescription for 10mg as a 24 hour dose can be written in one of the following ways:

1. Suboxone **10mg** (ten mg) **daily**. *The patient would receive 10mg each day and would not have access to second daily dosing.*
2. Suboxone **20mg** (twenty mg) **second daily**. *The patient would receive 20mg every second day without the option of a single day dose.*
3. Suboxone **10mg** (ten mg) **daily or 20mg** (twenty mg) **second daily** (and where possible specify the days). *The patient would have the option of dosing daily on 10mg or alternate days on 20mg providing flexibility for a 4 day per week dosing regime.*

A prescription for Suboxone written as **10mg daily or second daily** is not acceptable.

The registration of buprenorphine in Australia specifies 32mg as a maximum dose. The dose dispensed for a 48-hour period is double the usual daily (24 hour) buprenorphine dose to a maximum of 32mg at a time. When patients are initially switched to less frequent dosing they should be reviewed following the first or second 48-hour dose. Dose adequacy can be inferred if patients report:

- being as comfortable on the second day as on the first
- sleeping as well on the second night as on the day of dosing
- no increase in cravings on the second day than experienced on the first.

If the patient reports the onset of withdrawal, cravings, or sleep difficulties in the second day the 48-hour buprenorphine dose should be increased. If the patient reports features of intoxication from the dose of buprenorphine during its peak effects (normally at about 4hrs), the 48-hour dose should be reduced.

Patients on low doses of buprenorphine may find that doubling the dose does not last for 48 hours. Patients on reducing doses of buprenorphine may need to switch to daily dosing as the dose becomes lower (i.e. below 4mg).

Some patients may tolerate dosing with buprenorphine every 3 days (ie. a dose every 72hrs). A 3 day dose should not exceed 32mg. As with alternate day regimes the third daily dose should be titrated against symptoms of withdrawal or intoxication with frequent review following transfer to the regime. If a patient cannot be stabilised on a third daily dosing regime, the four days per week dosing regime should be considered.



### 4.2.11 Transferring from other medication-assisted treatments

#### From methadone

Transfer from methadone to buprenorphine may be appropriate when the patient wishes to change, perhaps in anticipation of using buprenorphine as a transitional detoxification agent, or to enable a reduced frequency dosing schedule.

There is a risk that previously stable patients may become destabilised when transferring from methadone to buprenorphine with a return to illicit drug use. Careful monitoring and support should be provided to any patient undertaking transfer, particularly those reducing their methadone dose prior to transfer. If destabilization occurs, a return to methadone treatment may be the best option.

When methadone patients take a dose of buprenorphine, the methadone is displaced from the  $\mu$ -opioid receptors by buprenorphine. Patients on low doses of methadone (e.g. less than 30mg) generally tolerate this transition with minimal discomfort. Patients on higher doses of methadone may find that replacement of methadone with buprenorphine causes significant discomfort.



The occurrence of precipitated withdrawal can be greatly minimised by careful initial dosing and rapid titration to an appropriate maintenance dose of buprenorphine.

#### **Patients on methadone should have their dose reduced and should be stabilised on this lower dose prior to transferring to buprenorphine.**

For most patients being treated in a general practice setting, it is recommended that the methadone dose prior to transferring to buprenorphine is below 30mg/day, and preferably less than 20mg.

Patients should be experiencing a mild to moderate degree of methadone withdrawal prior to transferring to buprenorphine. This would typically occur at least 24 hours after the last dose of methadone and is an indication that sufficient time has elapsed for there to be minimal risk that the first dose of buprenorphine will precipitate withdrawal.

Assessment of withdrawal can be aided by the use of a withdrawal scale.

#### Procedure

1. An initial dose of buprenorphine 2mg should be given and the patient observed for one to two hours. An additional dose of 4–6mg can then be administered if the initial dose does not precipitate withdrawal.
2. If withdrawal symptoms increase following the first dose, give no further dose that day. Medication for symptomatic relief may be required (e.g. clonidine 100mcg every 3–4 hours).
3. Review the patient again on day 2 when the dose can generally be safely increased to 8–12mg.

This approach of administering repeated small doses is preferred. Once the buprenorphine is on the opioid receptors, the risk of precipitated withdrawal is reduced. If resources are not available for onsite dosing and regular reviews as outlined above, or for patients wishing to transfer from 40mg methadone or more, referral should be made to a specialist service.



The likelihood of precipitating withdrawal is reduced as the time interval between the last methadone dose and the first buprenorphine dose increases.

The risk of precipitated withdrawal may be reduced by ensuring the last dose of methadone is taken early in the morning and the first dose of buprenorphine is taken late the following day.

### Principles of transferring from methadone to buprenorphine

The following principles should be observed for low dose transfers (<40mg methadone):

- delay the first buprenorphine dose until the patient is in early withdrawal (>24hrs after last dose)
- split dosing is preferable (administer doses >1–2 hours apart)
- give 2–4mg as an initial dose, then add 4mg after 1–2 hours.

Titrate the dose on the following days:

- increase by 4–8mg per day as required
- the target dose should be achieved by day 2 or 3.

Features of a precipitated withdrawal following the first dose of buprenorphine are typically mild to moderate in severity, but may distress the unprepared patient. Symptoms commence one to four hours after the first buprenorphine dose and last for up to 12 hours before subsiding. Patients experiencing discomfort may re-present to the prescribing doctor later in the day and require symptomatic withdrawal medication (e.g. clonidine 100mcg, 3 to 4 hourly). Subsequent doses of buprenorphine (the following day) are less likely to precipitate withdrawal symptoms.

### Transferring from higher doses of methadone (>40mg)

This is associated with a significant risk of precipitated withdrawal and is not recommended in an outpatient setting. Transfer from higher doses of methadone can be safely undertaken in inpatient settings where clonidine and diazepam can be used to manage withdrawal symptoms.

Due to concern for patient safety, transfer from doses of methadone >40mg require a completed *Patient Consent to Transfer to Buprenorphine from a Methadone Dose Greater than 40mg* (see Appendix 6) which is to be attached to the *Application to prescribe opioid substitution treatment*. The consent form is required if methadone dosing was ceased less than 5 days earlier. If it is 5 days or more since the last methadone dose the patient is treated as a new induction with completion of the *Application to prescribe opioid substitution treatment*, and the consent form is not required.

### From naltrexone

Transfer from naltrexone to buprenorphine is generally uneventful; however careful consideration should be given to the patient's low opioid tolerance level following a period of naltrexone treatment.



### 4.3 Fitness to drive/operate machinery

Methadone and buprenorphine can affect the capacity of people to drive or operate machinery, and it is the responsibility of the prescriber to ensure that patients are appropriately counselled and precautionary measures implemented.

Patients must be warned and be reminded about possible adverse effects:

- during the first 7–10 days of commencing treatment
- 3–4 days after an increase in dose
- when using other drugs while on OST (e.g. other opioids, alcohol, benzodiazepines, or other CNS depressants).

If a patient is deemed unfit to drive for an extended period, the prescriber must advise the patient of the need to notify the driver licensing authority. The prescriber should consider reporting directly to the licensing authority where the patient appears unable to appreciate the impact of their condition, is unable to take notice of safety recommendations due to cognitive impairment, or continues to drive despite appropriate advice where endangerment of the public is likely.



## 5. Maintenance

### 5.1 Ongoing patient reviews

Prescribers should have regular contact with their patients throughout the course of their treatment.

Patients should be seen as a minimum on the day of the first dose, every 2–3 days thereafter until a stable dose is reached and then weekly for the following 4–6 weeks. Contact every 2–4 weeks should continue for the first 6 months, as it is often during this period that the patient is most receptive to counselling and case management interventions. Regular monthly contact should continue until the prescriber is confident that the patient is meeting stability criteria. Thereafter, patients should be seen at least 3 monthly to monitor treatment compliance and stability.

A documented comprehensive review of the patient's treatment goals and treatment plan should be undertaken by the prescriber at six monthly intervals, and filed as part of the patient's record (see Appendix 7). The treatment plan should also be discussed at each review and the patient's goals revisited.

Comprehensive treatment reviews should take into account the following:

- use of drugs other than opioids
- impact of treatment on patient's use of illicit opioids
- treatment compliance (pharmacy dosing record)
- adverse effects and problems with treatment
- changes in lifestyle and social functioning
- mental and physical health and wellbeing
- legal issues
- other special considerations such as pregnancy/breastfeeding, hepatitis status.

A *Renewal Application for Authorisation to Prescribe Opioid Substitution Treatment* will be sent to the prescriber in the month prior to expiration of the authority. Prescribers should check that all details are correct and indicate the proposed treatment plan prior to forwarding to the Department.

Patients who have ceased use of illicit opioids and established a way of life that would support lasting abstinence can be encouraged to commence withdrawal from OST.

#### 5.1.1 Pharmacy liaison

The relationship between the prescriber and dispenser of methadone/buprenorphine treatment requires ongoing communication to ensure patient safety and to monitor treatment progress. This is especially relevant during the first 1–2 weeks of treatment.

The dispensing pharmacist is required to assess whether a dose of methadone or buprenorphine is appropriate and can withhold treatment when necessary. This may occur if the patient has missed doses, is intoxicated or if there are concerns about dose diversion. The pharmacist is required to notify the prescribing doctor of events relating to the patient's progress in treatment including any intoxicated presentations, missed doses, or any other issues impacting on treatment.



At least three monthly, a review of treatment progress should be undertaken. The prescribing doctor should contact the pharmacist to identify events relating to the patient's progress in treatment, dosing history and any other issues impacting on treatment.

### 5.1.2 Treatment planning

Treatment planning is an important component of treatment and begins at the initial assessment. A treatment plan provides an outline of treatment which takes into account the clinical diagnosis, the patient's goals, the planned interventions and treatment progress. The treatment plan should be further developed and reviewed with the patient at each attendance.

Treatment planning should include discussion with patients regarding duration of maintenance treatment, lifestyle changes, adjunct treatment requirements, other service involvement and post-treatment options.

### 5.1.3 Management of patients who fail to attend appointments

OST scripts should be dated to expire either on the day prior to or the day of the next scheduled review appointment. Management of OST scripting in line with prescriber reviews will reinforce the need for attendance to ensure uninterrupted dosing. Noting the next scheduled appointment date on the script will assist pharmacists to remind patients of the need for re-scripting.

#### Managing missed appointments

The objectives for managing missed patient appointments are aimed at maintaining the patient in treatment, minimising their potential for harm and reducing the occurrence of future missed appointments. Case managers, where employed, should actively follow up with patients who have missed their review appointments. Recommended management strategies for missed appointments are as follows:

##### 1. First non-attendance

Where the script is due for renewal and the patient has failed to attend their appointment, an interim script may be forwarded to the pharmacy by the prescriber to cover a minimum period until a further appointment can be scheduled. The pharmacy should be advised of any conditions imposed by the prescriber to be communicated to the patient. Takeaway doses may be suspended for the extension period where there is uncertainty as to the patient's stability.

##### 2. Second non-attendance

Where a patient fails to attend a second appointment without sufficient reason, it is recommended that all takeaway privileges be withdrawn and the patient advised that they must attend their prescriber for review of their treatment plan. A script may be provided by the prescriber to cover any further waiting period.



### 3. Third non-attendance

Where a patient misses a third consecutive appointment with their prescribing doctor, it is recommended that either treatment is stopped or a compulsory dose reduction regime is commenced until the patient is appropriately reviewed.

CAS can be contacted for discussion and advice about the management of patients who frequently miss appointments.

#### 5.1.4 Managing adverse effects during opioid substitution treatment

Patients may experience negative effects associated with OST and the effective management of adverse effects will improve retention in treatment. The following table lists strategies to manage common adverse effects.

*Table 10 Common Side-Effects with Methadone/Buprenorphine*

Side-Effect	Common Causes	Things that you can do
Feeling drowsy after dosing	Dose too high. Use of other drugs.	Lower the maintenance dose and review other medications the patient is taking. Review use of sedative and other drugs affecting cognition.
Withdrawal symptoms maximal before next dose	Dose too low. Changes in use of other drugs.	Review other drugs the patient is using. Raise maintenance dose.
Withdrawal precipitated by buprenorphine dose	Occurs early in treatment (or after absence from treatment) when dose is administered soon after other opioid use.	Aim to prevent through patient education. Delay buprenorphine dose until patient is experiencing opioid withdrawal.
Headache	Common in first week of buprenorphine treatment. Other causes of headache.	Transient and generally mild. Consider aspirin or paracetamol. Exclude other causes.
Nausea	Common early in treatment, particularly if dose is too high. Usually mild and transient.	Usually transient. Avoid rapid dose increases. Consider dose reduction if persistent.
Constipation	All opioids do this. Will be made worse by lack of dietary fibre, fluid intake or exercise.	Encourage fibre intake, fluids and regular exercise.
Weight Gain	Fluid retention caused by opioids – more likely on high doses. Eating more while in treatment. High salt intake.	Lower dose. Reduce fat and salt in diet, exercise.



**Table 10 Common Side-Effects with Methadone/Buprenorphine continued**

Side-Effect	Common Causes	Things that you can do
Poor sleep	Dose too low causing withdrawal at night. Dose too late at night, causing stimulation at time of peak effects. Other drugs (particularly stimulants in the evening). General anxiety or irregular sleep pattern.	Review maintenance dose and review other medications. Follow sleep hygiene recommendations.
Amenorrhoea/oligomenorrhoea	All opioids can do this. May be related to lifestyle stressors, poor diet, and general poor health	Periods may return after withdrawal and cessation of opioid use. Address other causes.
Reduced sex drive	More common with a high dose. Can be many other psychological factors (such as anxiety, poor relationship with partner etc.).	Review dose. Check LH, FSH, prolactin and testosterone levels.
Dental problems	All opioids reduce saliva flow. Poor diet, infrequent meals, poor dental hygiene.	Encourage dental hygiene and use of sugar free gum. Reduce consumption of sugary drinks and sweet food.
Reduced bone density	Some evidence of lowered bone density in patients on long term opioids. Often multiple risk factors present.	Check bone density and treat as required. Address other causes.

## 5.2 Use of other drugs

Concurrent use of other drugs by patients on methadone or buprenorphine treatment may threaten patient safety. It is important to monitor the use of other drugs to assess the risk for overdose, evaluate patient stability and measure progress toward treatment goals.

Self report, urine testing and clinical observation provide useful information. There is little evidence to show that drug monitoring alone is a deterrent against unsanctioned drug use. Urine monitoring can however support behaviour change in the context of court diversion programs and contingency management.



### 5.2.1 Self report

Self report can be a reliable guide to drug use in settings where there are no negative consequences resulting from disclosure. In the clinical situation there are always contingencies which patients may perceive as punitive. Consequently, caution should be exercised when making clinical decisions based solely on self-reported drug use. A more reliable assessment will draw on information provided by the patient's dispensing pharmacy and urinalysis collectively.

### 5.2.2 Urine drug screening

Urine drug screening may be useful in the following circumstances:

- during initial assessment to confirm history/diagnosis
- during stabilisation to ensure safety
- during maintenance to confirm that goals are being achieved
- to assess suitability for takeaways
- in unstable patients where polysubstance use is of concern.

Urinalysis provides an objective measure of drug use however this is not necessarily a reliable indication of drug use if the collection is not observed. The reliability of unobserved urine collection may be increased by checking the temperature of the urine sample. Observed urine collection should be considered where confirmatory results may be critical to clinical outcomes.

Urinalysis will only detect recent drug use. The actual time frame for detection varies depending on the drug being measured and will also depend on the threshold level set by the testing laboratory. Approximate detection times are shown in Table 11 however it is important to note that false positives and false negatives do occur.

**Table 11 Approximate Detection Times for Drug Urinalysis**

Drug	Approximate detection time
Amphetamines	2 days
Barbiturates	Short acting – 1 day Long acting – 2–3 weeks
Benzodiazepines	Therapeutic dose 3 days Long-term dosing up to several weeks
Cannabinoids	Several days to several weeks
Cocaine	2–4 days
Methadone	3 days
Buprenorphine	1-6 days
Oxycodone	8–24 hours
Opiates (includes codeine, morphine, heroin)	2–3 days



Urine testing should be conducted only if the results are likely to be important, and Chain of Custody procedures should be observed where applicable. Pathology laboratories do not routinely test for buprenorphine or methadone in urine and they will not be detected as an opioid.

Medicare allows for a maximum of 36 standard urine drug screens per patient per year (\*valid 2012). It is expected that the average number of tests will be significantly lower than this maximum and will decrease the longer a patient has been in treatment.

### 5.3 Stabilised patients seeking dose increases

While the aim of OST is to enable and promote stability in patients, fluctuations in stability are common. A variety of experiences and situations will contribute to the level of stability exhibited by a patient at any one time.

For most patients an effective therapeutic dose of methadone will be in the range of 60–100mg and for buprenorphine 12–20mg. In some circumstances patients will seek a dose increase in response to increased illicit opioid use. Requests for rapid dose increases should be declined. Such changes are potentially dangerous and in many cases unnecessary.

For many individuals, the learnt response to life stress is to consume a substance with the goal of chemically altering one's mood. OST prescribers need to be vigilant of this issue when previously stabilised patients request dose increases. Patients may seek a dose increase in response to such stressors as an upcoming court case, relationship difficulties, or fluctuations in mental health conditions such as anxiety and depression. At such times it is prudent to carefully explore the reasons for requesting a dose increase.

Patients may be seeking an effect from OST that methadone and buprenorphine cannot deliver (such as emotional solace, anxiety management etc.). It is important to educate patients as to what OST can reasonably achieve and to discuss appropriate alternative therapies for mental health and psychosocial issues.

Following assessment where a dose increase is indicated:

- Methadone increases of 5mg every 2 or 3 days, with a limit of 10mg increase per week are generally appropriate.
- Buprenorphine dose increases should be in the order of 2mg to 4mg per day.
- Increased support and frequency of clinical review are also appropriate strategies.

By complying with requests for dose increases unquestioningly, prescribers may miss an opportunity to provide appropriate evidence based therapy and challenge unhelpful or inaccurate beliefs held by the patient.



## 5.4 Adjunct treatment

People with a background of opioid dependence often have a range of social problems and psychological difficulties. The stability afforded by OST provides an opportunity for these issues to be addressed.

Once treatment is stabilised, concurrent problems may emerge. It is important that service providers are aware of this, and appropriately respond to the person's changing needs. Close engagement with other health and welfare service providers is recommended during the course of OST.

## 5.5 Dosing issues

### 5.5.1 Missed doses and reintroduction

When patients miss pharmacotherapy doses they may go into opioid withdrawal and their tolerance to opioids may be reduced. During this time people may use other opioid drugs or CNS depressants such as alcohol or benzodiazepines. This places them at increased risk of overdose if the pharmacotherapy is reintroduced. To reduce these risks the following procedures are recommended.

Before recommencing dosing the prescriber should take into consideration:

- the reasons for failure to attend
- drug use during this period
- symptoms of opioid withdrawal
- evidence of withdrawal or intoxication on physical examination
- feedback from the dosing pharmacy.

### Reintroduction schedule for methadone and buprenorphine

The following schedule is considered safe and effective for recommencement of both methadone and buprenorphine. All patients should be reviewed on the following day and the dose adjusted accordingly.

*Table 12 Reintroduction Schedule for Methadone and Buprenorphine*

Doses/days missed*	Response
One	If no evidence of intoxication may be dosed as usual.
Two	
Three	Pharmacists must consult with prescriber or CAS before dosing. Approval to dispense treatment can be given to the pharmacist over the phone. The following advice may be given if the patient is not intoxicated. <b>Buprenorphine</b> – the patient may be dosed as usual if no evidence of intoxication <b>Methadone</b> – dose to be reduced by half.



**Table 12 Reintroduction Schedule for Methadone and Buprenorphine continued**

Doses/days missed*	Response
Four	<p>Withhold dose.</p> <p><b>Patient must be seen by the prescriber.</b></p> <p><b>Buprenorphine</b> – the prescriber may recommend the same or a reduced dose to be given after reviewing the patient, and provide a script for the altered dose to the pharmacy.</p> <p><b>Methadone</b> – the patient may be re-scripted and recommence on 40mg methadone or half the usual dose, whichever is the lower.</p>
Five or more	<p><b>Patient must be seen by the prescriber for re-induction of OST</b></p> <p><b>Buprenorphine rapid dose re-induction</b></p> <p>Day 1 4–8mg Day 2 8–12mg Day 3 12–16mg</p> <p><b>Methadone</b></p> <p>Re-introduction dosing for methadone should follow the recommended induction advice (i.e. starting dose 20–25mg with dose increments of 5mg methadone every 2–3 days subject to clinical assessment), with a total weekly dose increase not exceeding 20mg in the following weeks.</p>

\*refers to days equivalent if the patient is not dosing on a daily basis e.g. patients dosing on second daily buprenorphine who miss two doses will have missed 4 days.

### Missed doses are not a medical emergency

Missed doses are not a medical emergency and it is not appropriate for patients to seek or be prescribed methadone or buprenorphine from the emergency department of a hospital.

### Attendance on non-dosing days (buprenorphine)

Sometimes a patient prescribed an alternate-day or four-times-a-week buprenorphine dosing regime misses a usual dosing day, attending the pharmacy on a 'non-dosing' day. Where this occurs, **a lower dose of buprenorphine can be prescribed and dispensed** in order to tide the patient over until the next usual scheduled dose.

The following procedures should be followed:

- The pharmacist will contact the prescriber for advice. The buprenorphine dose prescribed should be sufficient to last until the next scheduled dose (if this is 24 hours, then prescribe a 24 hour dose).
- In circumstances where the pharmacist cannot contact the prescribing doctor, no buprenorphine can be dispensed by the pharmacist. When this situation arises, the pharmacist will contact CAS for advice.
- Patients who repeatedly miss doses should be reviewed by the prescriber to find out why and whether these issues can be addressed. Alternatively, consideration might be given to a more achievable dosing regime.



### 5.5.2 Frequently missed doses

The WA CPOP is a supervised dosing program requiring regular attendance. Methadone is administered on a daily basis; buprenorphine is administered daily or may be prescribed on a second daily basis.

Where a patient misses more than 2 attendances for dosing in any one month, the prescriber should be notified by the pharmacist. The prescriber should then review the patient with regard to treatment compliance, stability and ongoing management.

### 5.5.3 Lost or stolen doses

In the event that a patient reports that their takeaway doses have been lost, stolen or damaged, **they should not be replaced**. Consideration should however be given to the particular clinical safety of the patient in any situation (e.g. pregnancy).



Lost, stolen or damaged takeaway doses should not be replaced.

### 5.5.4 Vomited doses

#### Methadone

Vomiting after a dose of methadone creates uncertainty regarding the absorption of the dose. The following procedures are recommended.

*Table 13 Responding to Vomited Methadone Dose*

Situation	Response
Patient vomits <b>20 minutes or more after</b> consuming the dose.	Reassure the patient that the dose has been absorbed.
Patient who has been in treatment for more than two weeks is observed by dispensing staff to vomit <b>within 20 minutes</b> of the dose.	A half dose may be administered.
Patient is in the first two weeks of treatment or there is uncertainty about the event.	Review the patient 4–6 hours after initial dosing when plasma levels will be at their peak. If withdrawal signs are evident a dose supplement <b>up to half</b> the patient's usual dose may be prescribed.
Patient is pregnant	As withdrawal symptoms can produce foetal distress, review the patient 4–6 hours after initial dosing to ensure no signs of withdrawal. If dosing appears inadequate a further small dose may be considered. CAS consultation is recommended.



## Buprenorphine

Buprenorphine taken sublingually is rapidly absorbed through the oral mucosa and vomiting 5 minutes after administration will not affect its absorption.

The patient should be reassured that a sufficient amount of the dose will have been absorbed. No further dose should be given.

### 5.6 Takeaway doses

In general, treatment of opioid dependence with methadone or buprenorphine is based on daily, supervised dosing at a pharmacy. To enable daily supervised dosing, new patients should be placed with a **seven day pharmacy** wherever possible. Where the patient attends a six day pharmacy for regular dosing a second dispensing point may be used on the seventh day. No takeaway doses of methadone or buprenorphine should be considered **until the patient has been in continuous treatment for a minimum of 6 months, has dosed regularly for 2–3 months, and has no contraindications present.**

Supervised dosing provides:

- greater adherence to the medication regime, with less diversion to others and less misuse such as injecting of medication
- less risk of overdose with pre-dosing assessment
- daily structure and routine that can be important for patients.

Provision of unsupervised doses may:

- assist a patient's return to normal daily activities and work
- reduce the cost of treatment to patients
- reduce stigma associated with supervised dosing.

The criteria for prescribing takeaway doses are discussed below (item 5.6.1) and prescribers are advised to consider the balance between patient autonomy and risk management. A prescriber can make application to the CPOP Clinical Review Committee to vary the number of takeaways a patient can be issued where extenuating circumstances are thought to exist.

A small number of existing patients may be receiving takeaway doses outside the scope of this Manual. An *Application for authority to prescribe takeaway doses for an opioid dependent person* should be made to the CPOP Clinical Review Committee for consideration, detailing the circumstances and the basis for continuation of these takeaways.

#### 5.6.1 Indicators of stability

Supervised dispensing is an essential component of OST. In general, doses should be consumed under direct supervision of the pharmacist.

Once stability has been established over the approved period, takeaway doses may be considered for suitable patients. Takeaway doses can be prescribed in accordance with the WA schedule when, following risk assessment, the patient is assessed as stable and there are no contraindications present.

**Risk assessment to provide an indication of stability includes:**

- evidence that the patient is not engaging in unsanctioned or hazardous use of opioids, benzodiazepines, alcohol or psychostimulants. Evidence of hazardous use should be based on history, self report, examination of injection sites, observation for signs of intoxication, urine testing and feedback from others involved in the patient's care
- regular and reliable contact with prescriber and community pharmacy
- suitable accommodation (stable, adequate storage facilities)
- functional social behaviour (e.g. no violence or threats to staff or others, stable employment/ education)
- prior history of responsible use of takeaway doses where the patient has previously been prescribed takeaway doses.

**5.6.2 Contraindications for prescribing takeaway doses**

Contraindications for prescribing takeaway doses may include **any** of the following:

- diversion or attempted diversion in the last 6 months
- antisocial behaviour (e.g. violence/threats toward staff, others)
- injection of illicit drugs in the last 3 months
- unstable or acute psychiatric illness
- irregular contact with prescriber, pharmacist or other relevant worker
- current hazardous use of alcohol, benzodiazepines or other drugs (within the past 3 months)
- child protection concerns
- homelessness
- recent prison release
- intoxicated presentation in the last 3 months.

Risk assessment of stability and/or contraindications for takeaway doses must be recorded in the patient record. The *CPOP Takeaway Dose Application and Agreement* form is used to document the approval process.

**5.6.3 Prescribing takeaway doses**

The *CPOP Takeaway Dose Application and Agreement* must be completed for all patients requesting take-away (unsupervised) doses of methadone or buprenorphine. The patient is required to read and sign the agreement. This ensures that the patient is made aware of the dangers of misuse of takeaway doses and serves as a useful medico-legal record in the event of an adverse incident. This form should be kept in the patient's medical record, and a copy provided to the patient at the time of signing.



Patients receiving Subutex cannot be prescribed takeaway doses unless commenced on Subutex due to pregnancy/breastfeeding, have a known allergy to Suboxone (with ADRAC form forwarded and on record) or are undertaking a time-limited withdrawal from OST.



Where takeaway doses are prescribed on a regular basis the prescriber should be satisfied at each review that the patient continues to meet stability criteria. Should the patient's situation or risk assessment change such that contraindications are present, **the prescriber should stop or reduce the number of takeaway doses**. In this way patient safety and the role of takeaway doses in giving recognition to progress in treatment will be preserved.

Patients transferring between prescribers (including interstate transfers to WA), where there is no break in treatment, may continue to be prescribed takeaway doses where considered appropriate, **in numbers consistent with WA policy**. Where a patient's level of stability is uncertain, access to unsupervised doses may be suspended or restricted with gradual re-introduction.

 The prescriber and CPP should be notified of any diversion or adverse incidents. Where there is a report of diversion, no further takeaway doses should be issued by the pharmacist before the patient is appropriately reviewed by the prescriber.

#### 5.6.4 WA Schedule for takeaway doses

After 6 months in continuous treatment, where the patient is assessed as stable and no contraindications are present, takeaway doses can be prescribed according to the standard WA Schedule (see Table 14).

Length of methadone or buprenorphine treatment in hospital or prison is not considered when calculating the treatment period in order to determine the patient's eligibility for takeaway doses. Release from prison can be a very unsafe time for patients, who may require increased contact and support until stability can be properly established.

*Table 14 WA Takeaway Schedule*

Length of time in treatment	STANDARD SCHEDULE Number of takeaway (unsupervised) doses permitted per week where stability criteria are met		
	Methadone	Suboxone (daily dosing) or Subutex under special conditions	Less frequent dosing on Suboxone or Subutex under special conditions
Less than 6 months	Nil.	Nil.	Nil.
6 – 12 months	One	One	One single day dose
12 – 18 months	Two (non consecutive inclusive of pharmacy closures)	Two (non consecutive).	One second daily dose
18 – 24 months		Three single day doses No more than two consecutive inclusive of pharmacy closures.	One second daily dose and One single daily dose (nonconsecutive and inclusive of pharmacy closures)

Table 14 WA Takeaway Schedule continued

	STANDARD SCHEDULE Number of takeaway (unsupervised) doses permitted per week where stability criteria are met		
More than 24 months	Three (no more than two consecutive) includes cover for pharmacy closures.	Four No more than two consecutive inclusive of pharmacy closures.	Two second daily doses Nonconsecutive and inclusive of pharmacy closures.

Takeaway doses may be authorised in accordance with the above Schedule **when the patient is assessed by the prescriber as meeting stability criteria** and the appropriate takeaway application form has been completed and signed with agreement by the patient.

The patient should have a **minimum 2–3 month history of regular dosing with no contraindications present** prior to any unsupervised dose being prescribed. Where diversion has been previously confirmed, access to unsupervised doses should be withheld for 6 months.

Where second daily dosing is achieved, takeaway dose instructions must be clearly defined.



Assessment of ongoing patient stability should occur at every review appointment for takeaway doses to continue.

### 5.6.5 Takeaway doses and public holidays

Guidelines for prescribers to deal with public holidays are as follows:

- Where a patient is not yet eligible to receive takeaways, **temporary transfer arrangements to another pharmacy should be made**. CPP will assist where needed.
- Patients on one or two takeaway doses per week can be prescribed one additional takeaway dose to accommodate a public holiday **where the usual dosing pharmacy is closed and temporary transfer arrangements cannot be made**.
- Patients receiving three takeaway doses per week **should not be prescribed additional takeaway doses** for public holidays.

### 5.6.6 Authorisation of takeaway doses outside the WA Schedule

To prescribe more takeaway doses than the above amounts on a regular basis the *CPOP Takeaway Dose Application and Agreement* must be completed and faxed to CPP prior to prescribing. This is forwarded to the CPOP Clinical Review Committee, which meets on a regular basis to review all such applications received.

Prescribers can apply to the CPOP Clinical Review Committee to increase the number of regular takeaway doses of **methadone** and **Suboxone** or **Subutex** where **'exceptional circumstances'** exist. These circumstances will normally be health or work related.



For this to be considered:

- the patient must have a demonstrated history of appropriate use of takeaway doses
- risk assessment should indicate no obvious cause for concern relating to inappropriate use or diversion
- the exceptional circumstances must be clearly documented and **supporting evidence must be submitted with the application.**

Before prescribing additional regular takeaway doses the prescriber should:

- exclude the viability of other options (such as second daily dosing or alternative dispensing sites)
- undertake a random urine test of the patient which must be free of illicit drug use and show the presence of the pharmacotherapy
- complete the *CPOP Takeaway Dose Application and Agreement*, ensuring that patient and prescriber declarations are signed, and forward with supporting evidence (including urine test results) to CPP. Examples of supporting evidence may include a letter from the employer regarding work schedules, letters from medical specialists attesting to treatment needs etc.

Applications along with supporting evidence should be re-submitted annually for previously approved additional regular takeaway doses to be continued.

The CPOP Clinical Review Committee will review all such applications received at the earliest opportunity and provide their recommendation. Support may be given by the CPOP Clinical Review Committee for additional takeaway doses contingent upon further safety mechanisms being incorporated into the treatment plan. All approvals will be reviewed on at least an annual basis.

**To be eligible for additional regular takeaway doses**, patients must be on *doses of methadone not greater than 120mg and for buprenorphine not greater than 24mg per day.*

#### **Limitations to note when prescribing regular takeaway doses**

The prescriber should graduate the introduction of additional takeaway doses and monitor the patient for changes in risk status and level of stability. The increase in takeaway doses should generally be not more than one additional takeaway dose every 3–6 months. With each increase a new application must be submitted to the CPOP Clinical Review Committee.

#### **5.6.7 Review and monitoring requirements**

The prescriber must review the patient regularly when prescribing takeaway doses. Regular urine tests are a useful aid in monitoring stability. Additional takeaway doses **must be withdrawn if the patient at any time no longer meets the criteria upon which the support was based** (e.g. if the work situation changes). Ongoing eligibility must be assessed at each review.

### 5.6.8 One-off takeaway requests in emergencies and exceptional circumstances

Emergency and exceptional circumstances may arise for patients and give rise to takeaway requests that are outside the Schedule. The patient should be assessed as stable, the emergency verified and any travel documents sighted. The number of takeaway doses would generally not exceed 4 daily doses.

A *CPOP Takeaway Dose Application and Agreement* must be faxed to CPP to ensure that alternative dosing arrangements cannot be otherwise facilitated for the patient before travel.

### 5.6.9 One-off holiday takeaway requests

In general holidays should be managed within the standard takeaway schedule and by transfer to an alternative dosing site. CPP should be contacted for information and assistance where patients are intending to travel interstate or overseas well before travel plans are confirmed.

A one-off request for holiday takeaway doses outside the standard schedule can be considered by the prescriber where the following conditions apply:

- an alternative dispensing site is unavailable, inappropriate or unsuitable
- the patient has been in treatment for more than 2 years, has been receiving takeaway doses without incident and easily meets stability criteria
- the request is for 7 days or less
- documents confirming travel plans are provided.

Carriage of takeaway doses will need to be declared at customs for most travel destinations. Patients intending to travel overseas should access up-to-date information regarding importation and carriage of prescribed OST from the relevant Consulates.

A *CPOP Interstate/Overseas Travel Request* (see Appendix 8) should be completed and signed prior to travel and filed in the patient record. A copy should also be forwarded to CPP.



Patients who have one-off holiday takeaway requests approved must be advised that any future requests will again be subject to stringent review.

Holiday takeaway requests outside the above advice should be sent to the CPOP Clinical Review Committee for consideration and endorsement. Requests must include patient contact details, proposed itinerary and flight details.

Where in-flight fluid restrictions apply contact CPP or PSB for advice.

### 5.6.10 Child Protection/Safety

Consideration of the risk to a child's safety in the event of ingestion of methadone or buprenorphine is critical. Takeaway doses should be stored in a safe place which ideally should be locked and beyond the reach of children. **Takeaway doses should not be kept in a fridge.** Where there are concerns that doses may be accessed by children, no takeaway doses should be prescribed.



All patients receiving takeaway doses should be specifically counselled with regard to safe, secure storage and proper administration of all medications.

## 5.7 Transfer of treatment

### 5.7.1 Transfers within Western Australia

Patient transfers within WA can generally be arranged if dosing facilities are available, and an authorised prescriber can be located within a reasonable distance from the patient's new address. Transfers within WA are facilitated through CPP. There are many areas of WA where prescribing or dispensing is not available and hence participation in CPOP is not possible. Where patients seek to relocate into areas where there is no CPOP prescriber or dispenser, a planned withdrawal should be undertaken.

### 5.7.2 Patients requesting prescriber transfers

Patients can request to be transferred to a new prescriber. This can be facilitated through CPP. The new prescriber must apply for a new authorisation number, and the previous prescriber authority is thereafter terminated through completion of a *Termination of opioid substitution treatment*.

### 5.7.3 Prescribers requesting patient transfers

Patients with complex clinical, behavioural and other problems should be discussed with CPP/CAS. Transfer of patients to the Next Step Drug & Alcohol Service or an alternative prescriber can be arranged if appropriate.

### 5.7.4 Transfer of Pharmacy

When a patient is transferring to an alternative dispensing site, the prescribing doctor must:

1. provide a current endorsed photograph of the patient or a Next Step ID form and a prescription to the new dispensing pharmacy
2. fax the completed *CPOP Pharmacy Transfer Notification* form (see Appendix 12) to the current pharmacy, the new pharmacy and CPP as a matter of priority.

Both pharmacies must receive the information prior to the patient being transferred.



CPP can provide assistance to arrange or locate a new dispensing pharmacy if needed and must be advised of all pharmacy transfers.



### 5.7.5 Interstate transfers

The transfer of patients from one state to another must be arranged in accordance with the policies and procedures of each jurisdictional authority. The transfer process is guided by legislative requirements and agreed policies and procedures.

CPP coordinates interstate transfers into and out of WA.

Up to four weeks notice is advised to ensure that necessary arrangements can be made to find and arrange referral to an appropriately located prescriber and pharmacy if required. Patients should be advised not to confirm travel arrangements until continuation of treatment arrangements have been established.

As a minimum, for all patients intending to transfer, the prescriber should provide:

1. a referral letter giving all relevant history and details of current treatment
2. an endorsed photo ID of the patient.

As is the case in WA, OST is not available at all interstate destinations.

A *CPOP Interstate/Overseas Travel Request* (see Appendix 8) should be completed and kept with the patient record and copy faxed to CPP.

### 5.7.6 International travel

Some countries prohibit the importation of methadone and/or buprenorphine and do not have established OST programs. Travel to these areas may not be supported for clients of CPOP who may be advised to vary their destination or undertake withdrawal prior to travel. Patients need to source accurate information regarding the carriage of Schedule 8 medications into and through countries travelled from the relevant Consulate(s) well in advance of their travel plans.

Prescribing doctors should advise patients to contact CPP regarding intended international travel arrangements. CPP will assist patients, where possible, to access OST at the first international destination point. Patients will need to be provided with a letter to confirm their treatment and the number and details of takeaways being carried.

A completed *CPOP Interstate/Overseas Travel Request* (see Appendix 8) should be kept with the patient record and a copy faxed to CPP.



## 6. Completing Opioid Substitution Treatment

### 6.1 Duration of treatment

Treatment is a process which often involves a patient's engagement with different services, sometimes over many years. Evidence shows that entry into treatment has a positive impact on reduction of drug use and crime however improvement may not be sustained where the person is not retained in treatment.

Evidence indicates that post-treatment outcomes are improved with increased time in OST, and that patients who leave treatment *within the first year* are more likely to relapse than those who remain in treatment for longer than one year. Ideally OST should not be time-limited, however patient progress should be regularly reviewed and when appropriate, withdrawal from OST encouraged.

Patients withdrawing from OST may benefit from additional psychosocial support and counselling.

### 6.2 Planned and voluntary withdrawal

Factors that motivate patients to consider withdrawal include family, work and lifestyle issues, personal rewards from being opioid free, and perceptions and attitudes directed towards methadone/buprenorphine treatment. Evidence from methadone research suggests that long-term outcomes of treatment are enhanced by treatment episodes of more than 12 months.

A longer treatment episode allows the opportunity for patients to establish a lifestyle away from opioid and other drug use prior to withdrawing from OST. Premature withdrawal from OST (before the patient has achieved a degree of stability in social circumstances and drug use) is more likely to be associated with a relapse into dependent opioid use.

The likelihood of premature withdrawal from maintenance treatment is reduced if patients are well informed about how treatment works. A patient may wish to withdraw from OST for a range of reasons, (i.e. the need for interstate travel, concerns about side-effects or about remaining in treatment 'too long'). Clinicians should discuss issues regarding the duration of treatment and withdrawal early in the treatment Program and provide information regarding the process of withdrawal.

Literature is available regarding withdrawal from methadone/buprenorphine treatment, and patients should be well informed regarding the likely duration of withdrawal symptoms.

### 6.3 Management of withdrawal from Opioid Substitution Treatment

Before commencing a reduction in dose, the prescriber should assess the patient to determine their level of motivation, psychosocial stability, current alcohol and other drug use, expectations, sources of support, after care plans and concerns. A treatment plan for withdrawal should be developed, including the frequency of dose reduction. Information should also be provided to the patient about the nature and severity of the withdrawal symptoms.



Contraindications to dose reduction and withdrawal include:

- irregular attendance at the dispensing site for dosing
- non-attendance at review appointments
- significant current psychological problems, social instability or distress
- significant current opioid or other substance use (as indicated by self report or drug testing).

When abstinence is an immediate goal, outpatient withdrawal from OST can generally be achieved through gradual reduction of the buprenorphine or methadone dose. The rate of reduction will depend on the person's experience of withdrawal symptoms and objective monitoring, which should occur at regular intervals. Most patients can withdraw safely and effectively within the community and do not require admission to a withdrawal unit.

Dose reduction regimes can be planned to address variables such as starting dose, duration of time on OST, the timeframe and patient circumstances in order to minimise discomfort and maximise the likelihood of the person achieving their aims. The patient should be assured that the rate of reduction can be changed if experiencing difficulties such as intolerable withdrawal, unanticipated stressors, or resumption of regular opioid use.

Dose reductions should be made in consultation with the patient. Patients should be aware of their dose, except where an agreement has been reached between the patient and service provider for the administration of a 'blind dose'. A blind dose may be negotiated where a patient becomes anxious about anticipating a planned dose reduction. If withdrawal symptoms cause distress it may be appropriate to maintain the patient at a reduced dose for a prolonged period until the patient feels comfortable recommencing the reduction regime.

The aim of treatment is to ensure that the withdrawal process is completed with safety and comfort. Increased counselling support, as well as information and education, should be available for patients withdrawing from methadone or buprenorphine. There may be a role for other medication for symptomatic relief (e.g. clonidine). Caution should be applied regarding the use of potential drugs of abuse (e.g. benzodiazepines).

### 6.3.1 Methadone reduction regime

When a regime of reducing doses of methadone is used typically **signs and symptoms of opioid withdrawal will begin to increase as the methadone dose falls below 20mg/day**. Subsidence of the symptoms is slow with studies reporting withdrawal scores not falling below baseline until 10 to 20 days after the cessation of methadone, depending on the duration of the methadone taper.

Clonidine offers little benefit as an adjunct to a regime of reducing doses of methadone, primarily due to a high incidence of hypotensive side-effects when used in this way. However, clonidine can be given after cessation of methadone. While generally safe, at toxic doses it can cause serious cardiopulmonary instability and central nervous system depression. Caution should therefore be exercised when prescribing clonidine.



### Planned Withdrawal Schedule

- Reduce dose by 5mg/week to a level of 45mg/day, then 2.5mg/week. Rates of reduction should be negotiated with patients, and dose changes should occur no more frequently than once a week.
- Abrupt cessation of methadone can be considered from 20mg/day in conjunction with use of clonidine and symptomatic medications to manage withdrawal signs and symptoms.

### 6.3.2 The use of buprenorphine to assist withdrawal from methadone

Many patients on long-term methadone maintenance programs experience difficulties in conventional approaches to withdrawing from methadone, including a prolonged period of withdrawal discomfort with risk of relapse to opioid use. Consequently, there is considerable interest in finding alternative methods of withdrawing from methadone maintenance programs.

Patients may be assisted to withdraw from methadone maintenance by reducing the dose of methadone to 40mg or less, transferring to buprenorphine and subsequently tapering the withdrawal from buprenorphine (refer 4.2.11 this Section).

Protocols for switching high dose methadone maintained patients have been developed by individual services and practitioners; however there is little research available at this time to guide practice. This type of transfer is ideally undertaken within an inpatient setting where the patient can be closely monitored. Patients must be appropriately counselled and complete a *Consent to transfer to buprenorphine from a methadone dose greater than 40mg* form prior to the transfer. This consent form must accompany the application for authority to prescribe buprenorphine.

### 6.3.3 Buprenorphine reduction regime

Slow graduated reduction of buprenorphine over weeks results in less relapse to opioid use than rapid reductions. The following rates of dose-reduction are suggested, although reductions can occur more rapidly or more slowly.

**Table 15 Rates of Buprenorphine Dose Reduction**

Dose of buprenorphine	Reduction rate
Above 16mg	4mg per week or fortnight
8–16mg	2–4mg per week or fortnight
Below 8mg	≤ 2mg per week or fortnight

An increase or return to illicit or unsanctioned drug use, or a worsening of the patient's physical, psychological or social wellbeing may warrant a temporary pause of the reduction or an increase in dose.

Some patients may request dose reductions of less than 2mg. Due to manufacturing methods and regulatory requirements it is not recommended that buprenorphine tablets or film be broken or cut to create smaller dose sizes.



Low dose treatment with Subutex (under 6mg) allows for combinations of 0.4mg, and 2mg enabling more gradual reductions in dose. Reductions of 0.4mg or 0.8mg may then be appropriate, especially for those coming off long term treatment.

As 0.4mg strength Suboxone is not available, patients requesting to reduce in increments of less than 2mg will be required to transfer to Subutex. Patients must be on a dose of 6mg or less in order to qualify for Subutex for this purpose. Prescribers must complete an *Application for Authority to Prescribe* form and receive a new authority number before prescribing Subutex. A 6 month limited authority will be granted in these situations, and prescribers should ensure that the patient's withdrawal plan is managed within the 6 month time frame. An application to extend this term may be granted if supported by the CPOP Clinical Review Committee.

## 6.4 Transfer to naltrexone

### 6.4.1 From buprenorphine

Naltrexone maintenance treatment is most suitable for people who have withdrawn from opioids and have a high motivation, along with adequate supervision and support. To minimise the risk of withdrawal symptoms, naltrexone should be delayed for 5–7 days after the last buprenorphine dose. Doses of naltrexone taken earlier than this are likely to induce some withdrawal symptoms depending on the buprenorphine doses taken in the previous few weeks. Naltrexone taken within 1–3 days of the last buprenorphine dose of 2mg or more may induce a severe withdrawal syndrome.

The following procedures are recommended:

1. Use of naltrexone is not recommended within 5 days of last use of buprenorphine.
2. A urine drug screen should be conducted prior to commencing naltrexone to exclude recent opioid use.
3. Administer a test dose of naltrexone (1/4 tablet, 12.5mg orally). If tolerated, increase to 25mg Day 2, and 50mg Day 3. The patient should be monitored for up to 3 hours after the first dose of naltrexone for features of opioid withdrawal. If withdrawal symptoms develop, symptomatic treatment (clonidine and antiemetic) may be necessary. Clinical guidelines regarding the use of naltrexone should be consulted.
4. Symptomatic withdrawal medication should be available for the patient to use in the 12 hours after the first dose of naltrexone.

If transfer to naltrexone is required in four days or less, advice should be sought from CAS.

### 6.4.2 From methadone

Administration of naltrexone to a patient who is dependent on methadone will precipitate a severe withdrawal syndrome. Methadone maintenance patients being transferred to naltrexone should undergo methadone withdrawal followed by a 10 day drug free period prior to commencement of naltrexone. Seek specialist advice from CAS if it is not possible to follow this regime.



## 6.5 Risk of relapse

Relapse following cessation of OST is not uncommon. The likelihood of a patient maintaining abstinence after leaving treatment is increased for people who have established drug-free social supports, are in stable family situations, are productively employed, and have good coping skills. Structured after care, rather than assistance upon request, reduces the risk of relapse and should be offered for at least 6 months following cessation of OST. For recently discharged patients a fast track for readmission to treatment should be available if needed.

## 6.6 Involuntary discharge from treatment

It is sometimes necessary to discharge a patient from treatment for either their own safety or wellbeing, or that of other people. This may be the result of:

- violence or threat of violence against staff or other patients
- diversion of methadone/buprenorphine
- illegal activities such as theft, property damage or drug dealing in or near the service
- poor compliance with treatment
- continuing high risk poly drug use.

Interruption to treatment may also occur as the result of a change in the patient's situation such that they are no longer able to access a prescriber or dispensing site.

Patients being discharged must be informed of the availability of other treatment options and warned about the risks of illicit drug use.

*Table 16 Circumstances Resulting in Discharge from OST*

Circumstances	Methadone	Buprenorphine
Serious threat to safety of other people or staff	Rapid dose reduction.	Can be abruptly terminated without a graduated dose reduction.
Less serious breaches or other reasons	Withdraw according to the above voluntary withdrawal schedule with reductions every 5–7 days.	Faster reduction schedule of up to 4–8mg reductions every 3–4 days).

Cases where the prescriber is considering an involuntary withdrawal of treatment should be discussed with CAS as a matter of urgency.

## 6.7 Completion of exit procedures by a prescriber

Prescribers are required to complete exit procedures for a patient. This is a condition of the authority to prescribe within CPOP, and patients must be promptly exited by the service provider to ensure that further treatment is not blocked. Where a patient is exited due to non-payment of fees or services received, the service may pursue legal options available to recover any outstanding debt.

**CPP should be advised by the prescriber when a patient's participation in treatment is to be involuntarily terminated for any reason.**



## 7. Specific populations receiving Opioid Substitution Treatment

### 7.1 Patients under 18 years of age

Methadone/buprenorphine maintenance is generally not an appropriate treatment choice for young people who are unlikely to have:

- a history of long term opioid use
- significant tolerance
- opioid using problems that are not amenable to other forms of help and treatment.

Young users of opioid drugs tend to be poly-drug users, often with a history of erratic drug and alcohol use. Established long term dependence on opioids is uncommon. Methadone/buprenorphine should not be prescribed if opioids are only one of a number of drugs a young person is taking and there is no evidence to suggest they are physically dependent on opioids. It is important that counselling and rehabilitation options be encouraged and assistance provided. Treatments that pose least risk to the patient should be given preference.

Methadone is registered for use in patients aged 18 or over, with buprenorphine registered for administration to people aged 16 and over. Caution should always be exercised in prescribing a drug of dependence for anyone less than 18 years of age. Positive treatment outcomes can however be anticipated from the combination of buprenorphine and behavioural interventions for opioid-dependent adolescents.

Suitability for maintenance treatment for patients under the age of 18 and the type of pharmacotherapy prescribed will be determined by:

- the history of AOD use
- the physical and psychological assessment
- evidence of opioid dependency and current physical dependence
- prior treatment history and present reasons for seeking treatment
- parental or family support
- a comprehensive risk assessment (to include self harm/suicide, accommodation arrangements, ongoing chaotic drug use, etc.)
- the person's capacity to give informed consent to treatment. The young person must be deemed mature enough to understand the risks and consequences of the treatment.

All patients under 18 years of age must be referred to the integrated Drug and Alcohol Youth Service (DAYS) for a comprehensive, multi-disciplinary assessment if OST is considered appropriate. Patients under 16 years of age who are being considered for OST will require special approval from the Department of Health.

In cases where the prescriber, for reason of their remote area location, cannot easily refer their patient to the integrated Drug and Alcohol Youth Service, the Clinical Advisory Service (CAS) should be contacted to discuss alternative assessment and treatment options.



## 7.2 Pregnant and breastfeeding women

Pregnant women who are dependent on opioids are at high risk of complications, generally as a result of:

- inadequate antenatal care
- lifestyle factors including smoking, poor nutrition and high levels of stress
- the use of a range of substances (including alcohol, benzodiazepines, amphetamines, and tobacco)
- repeated cycles of intoxication and withdrawal which can harm the foetus or precipitate premature labour or miscarriage.

Substitution treatment is the preferred treatment option for opioid dependent pregnant women as it enables a stable condition to be achieved throughout pregnancy. Women with substance use disorders during pregnancy should be referred to a specialist multidisciplinary drug and alcohol antenatal clinic where available. Such a multidisciplinary team typically would include midwives, obstetricians, paediatricians, social workers, and addiction specialists. Engagement with a multidisciplinary team will ensure continuity of care through to the post-natal period and minimise post-birth consequences for both mother and baby.

Women who are in methadone treatment when they become pregnant are encouraged to continue. The second trimester of pregnancy is the most suitable period to accomplish dose reductions if required, and should be managed in consultation with CAS. The bioavailability of methadone is decreased in the later stages of pregnancy due to increased plasma volume, an increase in plasma proteins that bind methadone and placental metabolism of methadone. It may be necessary to divide the daily dose and possibly to increase the dose in the third trimester of pregnancy to avoid withdrawal symptoms and minimise any additional drug use. The dose should be reviewed post-delivery.

Methadone and buprenorphine are Category C drugs. The safety and effectiveness of buprenorphine during pregnancy and lactation is still to be established, and methadone remains the recommended treatment of choice. This position is currently under review, and it is likely that buprenorphine will also be recommended as a first-line treatment option in the near future.

The Australian Drug Evaluation Committee (ADEC) reported that this group of drugs “has caused, or may be suspected of causing, harmful effects on the human fetus or neonate without causing malformations. These effects may be reversible.” Opioid analgesics can cause respiratory depression in the neonate, and Neonatal Abstinence Syndrome (NAS) has been reported in cases of prolonged maternal use.

Respiratory depression is not a significant problem in babies born to opioid dependent mothers receiving methadone maintenance treatment; however, these babies may experience a withdrawal syndrome. The available evidence is unclear about the existence of a relationship between the severity of the neonatal withdrawal syndrome and maternal methadone dose at delivery. Its occurrence is unpredictable, and the benefits of methadone maintenance treatment for both the mother and the baby outweigh any risks from the neonatal withdrawal syndrome. Breastfeeding can be promoted with confidence.



Any woman seeking pharmacotherapy maintenance treatment who might become pregnant should be counselled and information presented to them in writing. Reliable forms of contraception should be recommended to women not wanting to become pregnant.

### **Patients who become pregnant while on buprenorphine**

The risks of buprenorphine treatment during pregnancy, while not yet accurately quantified, are unlikely (given the available evidence) to be greater than the risks associated with a return to opioid use. Women who have been stabilised on buprenorphine and who have ceased opioid use may risk a return to regular opioid use if destabilised during the transfer to methadone.

It is preferable for pregnant women who do not wish to transfer to methadone to be maintained on buprenorphine. Counselling must be provided regarding treatment options to ensure that each woman is fully informed of the known risks and benefits of buprenorphine during pregnancy and breastfeeding.

In these situations the mono preparation (Subutex) should be used. Application to prescribe Subutex must be faxed to CPP together with a signed *Patient Consent for Buprenorphine (Subutex) Treatment during Pregnancy and Breastfeeding* (see Appendix 9).

### **Principles in managing pregnancy in opioid dependent women**

1. Opioid using pregnant women not already in treatment warrant high priority for assessment for OST.
2. Treatment options should be discussed and informed consent obtained.
3. Pregnant women should be maintained on an adequate dose of OST to achieve stability and prevent relapse or continued illicit opioid drug use.
4. Women already receiving OST who become pregnant should be given information about risks and can be maintained on their current treatment.



Antenatal and postnatal care should be managed in collaboration with the WA Neonatal Drug & Alcohol Service (WANDAS) at King Edward Memorial Hospital.

### **Dose reductions or detoxification during pregnancy**

It is important that pregnant women are not exposed to opioid withdrawal during the first and third trimesters. Opioid withdrawal in the first trimester of pregnancy may be associated with an increased risk of miscarriage, and opioid withdrawal in the third trimester of pregnancy may be associated with foetal distress and foetal death.



If dose reductions or detoxification are to be undertaken during pregnancy they should be implemented in the second trimester and in consideration of the following:

1. Dose reductions should only occur if the pregnancy is stable.
2. The magnitude and rate of reduction needs to be flexible and responsive to the symptoms experienced by the woman concerned.
3. In most instances, methadone dose reductions of 2.5mg-5mg per week are considered safe.
4. Careful monitoring of the pregnancy and foetus should be undertaken during any dose reduction.
5. Withdrawal symptoms should be avoided as much as possible as they cause considerable distress to the foetus.

### **Methadone and breastfeeding**

Breast milk contains only small amounts of methadone and mothers can be encouraged to breastfeed provided they are not using other drugs of concern. Breastfeeding may reduce the severity of neonatal withdrawal syndrome in the neonate.

### **Buprenorphine and breastfeeding**

It is known that only small amounts of buprenorphine and buprenorphine-naloxone pass into breast milk and therefore absorption of buprenorphine from breast milk would be expected to be minimal.

Since Suboxone is contraindicated in pregnancy, breastfeeding patients should ideally be transferred to Subutex. Pregnant and breastfeeding women who wish to continue with buprenorphine should be appropriately counselled and sign a *Patient Consent for Buprenorphine (Subutex) Treatment during Pregnancy and Breastfeeding* (see Appendix 9), which should remain with the patient record.

Patients should be transferred to Suboxone when no longer pregnant or breastfeeding.

### **Neonatal Abstinence Syndrome (NAS)**

The occurrence and severity of neonatal withdrawal is unpredictable, and depends on what opioids were consumed by the pregnant opioid dependent woman. For example, the withdrawal syndrome with heroin occurs in the first 24 hours in the neonate, while with methadone it does not develop until after 48 hours post-delivery. Methadone causes a withdrawal syndrome in 60–80% of cases, and often requires pharmacological treatment.

All babies born to opioid dependent mothers should be observed for signs of withdrawal. It is recommended that a validated scale be used to assess the presence and severity of the withdrawal syndrome in the neonate.

**Table 17 Signs of Withdrawal in the Neonate**

Common signs include	Less common signs include
Irritability and sleep disturbances	Yawning
Sneezing	Vomiting
Fist sucking	Increased mucus production
A shrill cry	Increased response to sound
Watery stools	Convulsions (rare)
General hyperactivity	
Ineffectual sucking	
Poor weight gain	
Dislike of bright lights	
Tremors	
Increased respiration rate	

Withdrawal symptoms usually start within 48 hours of delivery but may be delayed if methadone was being used in conjunction with illicit benzodiazepines.

Supportive treatment involves minimising environmental stimuli and enhancing the baby's comfort which may include:

- soothing by holding close to the body or swaddling
- keeping nostrils and mouth clear of secretions
- use of a dummy to relieve increased sucking urge
- frequent small feeds.



Treatment of NAS is based on the severity of withdrawal signs. Advice on treatment should be obtained from the Neonatal Intensive Care Unit at King Edward Memorial Hospital.

### 7.3 Patients with blood-borne viruses

All patients should be offered testing for hepatitis A, B, C and HIV at assessment and periodically thereafter as appropriate.

#### 7.3.1 Hepatitis A, B & C

##### Hepatitis A and B

Hepatitis A vaccination and hepatitis B vaccination are recommended for all patients receiving OST who are found to have no immunity to the hepatitis A or B virus. Those patients found to be chronic carriers of hepatitis B should be appropriately assessed for stage of infection (e.g. ALT, viral load) to guide referral for treatment.



## Hepatitis C

A high percentage of patients entering OST programs will be hepatitis C antibody positive. Patients should be offered testing at assessment, and where diagnosed PCR+ve, treatment options discussed and referral for treatment encouraged. The Hepatitis Council offers support and counselling.

## Impaired liver function

Patients with chronic liver disease on long term methadone/buprenorphine treatment generally do not need dose alterations but abrupt changes in liver function may necessitate substantial dose adjustments.

### 7.3.2 Human Immunodeficiency Virus (HIV)

Treatment providers should ensure that HIV positive patients have access to specialist HIV medical care so that the patient's overall health may be monitored and appropriate treatment provided. In general, patients who are HIV positive can comply with the requirements and conditions of OST, however the medical, psychological and social implications of HIV infection may warrant the provision of additional services.

Methadone/buprenorphine doses must be monitored closely due to the potential for interaction with HIV medications and related illnesses.

Service providers may need to work with hospice services in managing OST and AIDS conditions.

Flexibility in dosing arrangements may be needed if patients are unable to attend for daily dosing due to illness. Alternative options should be considered by the CPOP Clinical Review Committee where special arrangements may be considered.

## 7.4 Patients with psychiatric comorbidity

Symptoms of psychiatric disorders such as depression, anxiety and psychosis are more the rule than the exception in patients who misuse substances. Both disorders may have to be treated concurrently, although improvement in one does not necessarily result in improvement in the other.

OST can reduce levels of psychiatric distress with improvement apparent within weeks of commencing treatment.

It is important to distinguish between substance-induced and substance-related psychiatric disorders. The order of onset of the psychiatric disorder and substance use, family history and effect of previous treatments for the co-occurring psychiatric disorder should be determined.

Depression has been found to predict poor psycho-social functioning and to increase the risk of relapse to opioid use. Generally mood will only improve in those with a significant depressive disorder and use of antidepressants should be restricted to this population.



Tricyclic antidepressants should be used with caution due to potentially serious interactions with substances, including cardio toxicity and death in overdose. Psychotherapy as an adjunct may be of benefit, and some patients may need referral to a psychiatrist.

Anxiety is a common symptom of substance use, and a comprehensive assessment is needed to determine the likelihood of an independent anxiety disorder. Assessment by a specialist addiction service is recommended prior to using a benzodiazepine to treat anxiety.

Caution should be exercised if considering also prescribing medications known to have a risk of arrhythmia or sedation to patients on OST.

## 7.5 Patients in custody

Patients held in a lockup should be taken by the police to the patient's usual pharmacy for dispensing. Takeaway doses **are not to be issued to police or other persons** on behalf of the patient.

Patients who are imprisoned can be maintained on OST within the corrections setting for a period of 1 month before a new authority number is required. Where the patient is detained in prison beyond the period of one month, a prison authority number must be obtained, treatment transfer initiated and the regular prescriber advised to terminate the authority number assigned to that patient.

Where a prison authority number has been activated, a new number must be applied for by the community prescriber after the patient's release and upon re-presentation.

## 7.6 Prisoners recently released

A key strategy to the success of the Prison Addiction Service (PAS) initiative is appropriate discharge management and re-entry planning for prisoners engaged in an OST program. A key objective is to ensure continuity of treatment and service access for prisoners nearing their date of release.

CPP works closely with the Department for Corrections to ensure that prisoners who are receiving OST while in prison have a smooth transition to the community and continuation of OST.

CPP facilitates all requests for continuation of treatment for prisoners engaged in OST prior to release. Prison referrals should attend for medical review with a prescriber within two weeks post-release. Where patients have been incarcerated for a short term only, prior arrangements may be re-activated where the prescriber and pharmacy are agreeable. A new authority number and/or pharmacy may be required.



Recently released prisoners with a history of opioid substitution treatment in prison are at risk of overdose and death if they return to high levels of opioid use upon release.



Prisoners who are released unexpectedly during the week are directed to contact CPP, who will facilitate dosing and medical review appointments. CPP will confirm details of the last dose upon the person's release.

Prisoners who are released unexpectedly across the weekend will be directed by the PAS nurse to present to the Next Step pharmacy (with approved ID documentation) for dosing until alternative arrangements can be made by CPP. Where necessary, CAS will provide an interim script to cover the post-release period until the person's scheduled appointment with the prescriber.

## 7.7 Patients admitted to hospital

In most situations methadone or buprenorphine treatment should continue when patients are admitted to hospital. The hospital doctor managing the patient should consult with the community prescribing doctor. When a prescribing doctor or pharmacist at a dosing location is contacted regarding inpatient treatment of a person on OST they should provide all possible assistance to the hospital doctor (information about the legal requirements for prescribing opioid treatment, patient history, and the significance of the patient's current dosing regime).

The pharmacist at the community dosing location should document that the patient has been admitted to hospital. Before recommencing dosing and to avoid double dosing the community pharmacist must receive confirmation that the person has been discharged and the date and time of the last dose.

When a prescribing doctor is contacted regarding treatment they must ensure that the dosing location has been notified of any change of situation.

### 7.7.1 Patients who are currently receiving methadone or buprenorphine through CPOP

Hospital staff are referred to the Operational Directive *Management of community program for opioid pharmacotherapy (CPOP) patients in a hospital setting*.

When patients of CPOP are admitted to hospital, the inpatient prescribing of methadone or buprenorphine becomes the responsibility of the hospital doctors in charge of their care. The patient's clinical information and prescription details should be directly confirmed with both the authorised prescriber and the dispensing pharmacy.

Continuation of treatment without interruption is advocated unless otherwise indicated or not possible. Continuation of OST requires confirmation of current dosing on a community prescription at the time of admission. Where the community script expires during the period of hospitalisation, renewal by the community prescriber is not required for the continuation of inpatient treatment.

Patients experiencing acute pain may require larger doses of analgesia to provide adequate pain relief due to tolerance to opioids. Care should be taken with the prescribing of other medications while in hospital and upon discharge which, when used in combination, have the potential to produce adverse outcomes.



All care should be taken regarding dispensing and supervised administration for OST medication to patients while in hospital in order to maximise bioavailability through effective dose delivery and to avoid dosing errors. Hospital dosing should be under direct and close observation to minimize diversion potential. Doses must not be left with patients to be taken at a later time.



Patients must not be provided with OST prescriptions or take-home OST medication upon discharge from hospital, or in the course of attendance at outpatient emergency departments or clinics.

### 7.7.2 Opioid dependent patients who are not on OST

Opioid dependence may be diagnosed when an inpatient reports a history of illicit opioid use during assessment or may be identified following the development of withdrawal symptoms. In these circumstances, the inpatient may be considered appropriate for referral and commencement on OST upon discharge.

CPP can be contacted for advice on treatment options that are available prior to a patient's discharge.

Where a patient is pregnant, referral should also be made to the WANDAS team at King Edward Memorial Hospital.

## 7.8 Patients requiring analgesia and anaesthesia

Patients on methadone or buprenorphine who need acute pain management in the hospital setting can be managed as for patients who are not opioid dependent, although doses of analgesic drugs may need to be higher.

Patients requiring surgery should advise their doctors that they are taking methadone or buprenorphine and discuss pain management options prior to surgery, and for the post operative period.

Patients needing methadone or buprenorphine for ongoing management of chronic pain need a comprehensive management plan. It is recommended that specialist advice be sought regarding such patients.

### 7.8.1 Analgesic and anaesthetic considerations for patients on methadone

Patients on methadone who are experiencing acute pain in hospital often receive inadequate doses of opioids for serious pain. Analgesia should be provided to patients on methadone in the same way as for other patients. This includes the use of injectable and patient controlled analgesia.

Patients taking methadone frequently require larger and more frequent doses of opioid analgesia to achieve adequate pain relief due to tolerance to opioids. **Partial agonists such as buprenorphine should be avoided as they may precipitate withdrawal symptoms.**



Cross-tolerance between methadone and anaesthetic agents suggest that patients on methadone may also require higher doses of anaesthetic agents if undergoing dental or surgical procedures.

### Management of acute pain in primary care settings

Patients on methadone or buprenorphine who need acute pain management can be administered Schedule 8 drugs in the surgery but due to regulatory requirements cannot be prescribed Schedule 8 medications unless specifically authorised by the Department of Health.

Non-opioid analgesics (NSAIDs or paracetamol) should be considered, and where parenteral analgesia is required, ketorolac (Toradol), or tramadol (Tramal) may be selected.



Consult CAS for advice on clinical management of patients with acute pain.

The Department of Health Pharmaceutical Services Branch should be contacted on (08) 9222 6612 to clarify any regulatory issues.

### 7.8.2 Analgesic and anaesthetic requirements for patients on buprenorphine

Patients maintained on buprenorphine will have a diminished response to opioids prescribed for analgesia. This is because of the opioid 'blocking' effect of buprenorphine. Consequently, people on buprenorphine who suffer severe or chronic pain will require considerably higher doses of opioid analgesia than individuals not on buprenorphine treatment.

Use simple analgesics where possible (such as aspirin, NSAIDS, paracetamol, tramadol).

In the hospital setting use:

- regional anaesthesia if appropriate
- ketamine infusion alone or in combination with other opioids.

Failing this, cease buprenorphine and transfer to a full opioid agonist.

- In the community, use methadone.
- In the hospital setting, use of shorter acting opioids will facilitate transfer back to buprenorphine.

Transfer back to buprenorphine is usually possible when pain has settled. To recommence buprenorphine, cease all other opioids and then recommence buprenorphine after early withdrawal symptoms appear (usually 24 hours after the last dose of opioid).



## 8. Complex management issues

### 8.1 Side-effects/adverse drug reactions

Adverse drug reactions may be predictable based on the known actions of the drug, or may be unpredictable (e.g. allergic drug responses, idiosyncratic drug reactions). Management of side-effects, depending on their nature and severity, should be negotiated between the patient and prescriber.

Conventional strategies should be adopted to manage opioid-related side-effects (e.g. constipation).

Many patients report less sedation on buprenorphine than on methadone, and it has been noted that buprenorphine has minimal effects on psychomotor performance and less affect than methadone or slow release oral morphine. Any effect is likely to be greatest during the early stages of treatment or following dose increases. At such times patients should be advised to exercise caution in driving or operating machinery.

Buprenorphine appears to have minimal effect on hepatic function, although there have been some reports of acute hepatitis following very high doses (>32mg IV).

#### **Precipitated withdrawal with buprenorphine**

Buprenorphine may precipitate opioid withdrawal symptoms between 1 and 4 hours after the first dose. Given its high affinity and low intrinsic activity, buprenorphine will displace other agonists such as methadone, morphine and heroin from the opioid receptors. Since it may not immediately produce sufficient agonist effects to compensate, precipitated opioid withdrawal may be experienced as the buprenorphine reaches its peak effects.

The phenomenon of precipitated withdrawal has particular clinical relevance during the induction of heroin users and methadone patients. This can largely be avoided by using appropriate dose induction procedures.

### 8.2 Incorrect dose administered

The prescribing doctor must be immediately advised of any dosing errors by the dispensing pharmacist. Where the prescriber is unable to be contacted in the first instance, CAS must be notified.

Patients who have been dispensed an overdose may require prolonged observation and referral to a hospital emergency department. All overdose events must be notified in writing to the prescriber and CPP as a matter of course by the dispenser.

#### **8.2.1 Methadone overdose**

Patients in the first 2 weeks of treatment with methadone who receive an excess dose of **any magnitude** require observation for a minimum of 4 hours and up to 12 hours if significant signs of intoxication or sedation occur. This level of observation is best achieved within an emergency department.



Overdose risk increases around the third or fourth day of methadone induction.

In all cases of dosing error the following procedures should be followed:

1. The pharmacist must advise the patient of the mistake, carefully explain the seriousness of the situation, and advise the client to wait in the pharmacy until discussion with the prescriber.
2. The Pharmacist will contact the prescriber for advice. If unavailable, CAS must be contacted.
3. If the patient has left the pharmacy before the mistake is realised, every attempt must be made to contact the patient. Police assistance should be obtained if necessary.

Prolonged observation at a hospital emergency department is advised in the following circumstances:

- patients who are sedated following the dose (for any reason)
- patients who are new to substitution treatment (within the first two weeks of treatment)
- if a patient's tolerance is uncertain (e.g. if patients are receiving regular takeaway doses or if they do not attend daily, or where the dose <40mg/day, or receiving treatment for <2months)
- patients who have other medical conditions that impact on respiratory drive
- patients with unstable mental health problems
- patients who use other depressant or sedative medications such as benzodiazepines and psychiatric medications.

Patients who have been on a dose of methadone >40mg/day consistently for two months will generally tolerate a dose which is double their usual dose without significant symptoms. These patients should be warned about the possible risk of intoxication and toxicity and advised to attend an emergency department if these symptoms emerge. The patient should be warned against any additional drug use and driving or operating machinery should be avoided for the rest of the day.

Patients who receive a dose of ***greater than double the usual daily dose should be referred to an emergency department for assessment and observation.***

A lower dose, or no dose, should be prescribed for the following day.

#### **Caution regarding inducing vomiting:**

Inducing vomiting may be dangerous and is contraindicated if the patient has any signs of CNS depression. Emesis more than 10 minutes after dosing is an unsatisfactory means of dealing with methadone overdose as it is impossible to determine how much of the dose has been eliminated. Where medical help is not readily available or the patient refuses medical care, induced vomiting within 5–10 minutes of ingesting the dose may be appropriate as a first aid measure only. Ipecac syrup is contraindicated as its action may be delayed.

When treating methadone overdose, naloxone promptly reverses opioid induced coma, and should be given as a prolonged infusion in a medical setting. A single dose of naloxone will wear off within one hour leaving patients at risk of relapse into coma due to the long lasting effects of methadone.



The patient should be reviewed by the prescriber prior to the next dose. It may be that a reduced dose is required the following day.

### 8.2.2 Buprenorphine overdose

The risk of lethal overdose of buprenorphine for an opioid-tolerant individual is less than that associated with the use of other opioid medications, such as methadone. This is due to the ceiling dose response effects of buprenorphine.

While overdose on buprenorphine is relatively uncommon, there is a greater risk when it is combined with other sedating drugs such as alcohol, benzodiazepines, barbiturates, tricyclic antidepressants and major tranquillisers. Several such deaths have been reported.

In the event of an incorrect dose being administered:

- The pharmacist must notify the patient of the error and warn of the likely consequences including increased sedation/drowsiness which may occur for several hours afterwards.
- The pharmacist should contact the prescriber for advice.
- Any additional drug use and driving or operating machinery should be avoided by the patient for the rest of the day.

If any of the following circumstances apply with buprenorphine overdose the patient should be monitored in an emergency department:

- the patient is sedated following the dose
- the patient is new to substitution treatment (within the first 2 days of treatment and the dose incorrectly administered is  $\geq 16$ )
- the regular daily buprenorphine dose is  $< 4\text{mg}$  and the patient was incorrectly administered a dose of  $\geq 16$
- where a buprenorphine dose of  $\geq 64\text{mg}$  was incorrectly administered.

A lower dose, or no dose, should be prescribed for the following day (in effect, a 2 or 3 day dose may have been administered).

Buprenorphine has a high affinity for  $\mu$ -opioid receptors, and is not easily displaced by the antagonist naloxone. ***Naloxone in high doses delivered by IV infusion under prolonged observation in a medical setting may be necessary to reverse the effects of buprenorphine toxicity.***

### 8.3 Continued high risk drug use and polydrug use

Polydrug use is prevalent among opioid users. One in five people seeking OST are also likely to be dependent on benzodiazepines and 5% are likely to be alcohol dependent. A high percentage of these people are likely to be using alcohol or benzodiazepines at hazardous or harmful levels.



Continued high risk polydrug use is evidenced by:

- frequent presentations when intoxicated or with signs of benzodiazepine or alcohol withdrawal
- overdose (fatal and non-fatal)
- chaotic behaviour
- doctor shopping or forging prescriptions
- deteriorating general health or mental state.



It is recommended that specialist advice be sought when treating patients at high risk from polydrug use, especially when sedatives are involved.

Continued drug use can affect patient stability and treatment progress and place the person at risk of:

- relationship, social and employment problems
- contracting infectious diseases
- involvement in crime
- overdose and death.

Attempts to stabilise such patients should include a review of:

- psychosocial interventions and supports
- precipitants to continued drug use
- medication regimes
- methadone or buprenorphine dose increases may be helpful if considered safe by the prescriber
- the risks versus benefits of continuing OST when other drugs are also used. Where risks outweigh benefits the patient should be gradually withdrawn from treatment.

### 8.3.1 Use of benzodiazepines

Benzodiazepine users exhibit overall patterns of increased risk and poorer psychological functioning than other people. Patients should be advised about the interactions of benzodiazepines and methadone or buprenorphine. Overdose deaths of patients on OST almost invariably involve benzodiazepine abuse. Benzodiazepine injecting is also associated with vascular damage.

Benzodiazepine prescribing at the time of induction is extremely high risk and **consultation with CAS is advised prior to the prescribing of benzodiazepines.**

Great caution should be exercised in prescribing benzodiazepines for patients on OST. Many patients can cease their use of benzodiazepines without specific treatment. If a patient is considered appropriate for benzodiazepine prescribing when stabilised on OST, the goal of treatment should be a gradual managed withdrawal. The preferred benzodiazepine for withdrawal treatment is diazepam. **Short acting benzodiazepines known to be commonly abused by illicit drug users such as alprazolam should not be prescribed.**



The supervision of patients receiving benzodiazepines must generally be of the same high standard as for methadone or buprenorphine maintenance treatment. In general, daily dispensing of prescribed benzodiazepines is recommended for high risk patients, with half the daily dose being taken under the direct supervision of a pharmacist. Patients should not be dispensed full quantities of benzodiazepines.

Use of formalised agreements should be considered to reduce access to medications from multiple sources. Good communication between prescribers and dispensers regarding use of other prescription medications is strongly encouraged.

### 8.3.2 The Prescription Shopping Program (PSP)

This Program helps to protect the integrity of the Pharmaceutical Benefits Scheme (PBS) and is available to registered prescribers 24hrs per day, 7 days per week to provide information on the prescription history of people identified by the Program. Information is accurate up to the previous 48hrs. PSP is an important point of contact to elicit prescription information where possible doctor shopping may be occurring.

**The Prescription Shopping Information Service (PSIS)** operates as an information service to assist doctors in prescribing decisions. The prescriber can request information about the patient and does not need that person's permission to call the PSIS if there are reasonable grounds for suspicion that they may be accessing more medicine than they medically need.

If you suspect a person of accessing more medicine than they need, you can call the PSIS on **1800 631 181**.

#### **The PSIS can:**

- tell you if the patient has been identified under the PSP
- tell you the number of prescribers who have prescribed
- provide information on the amount and type of PBS medicine recently supplied to that patient.

#### **Each time you contact the PSIS you will need to provide your:**

- prescriber number
- full name
- answer to a personal validation question
- patient's Medicare number
- patient's date of birth
- patient's full name.

If you are not already registered for the PSIS you can complete a Registration Form, which can be located on the Medicare website.



### **Pharmaceutical Services Branch (PSB), Department of Health**

Prescription and authorisation information regarding Schedule 8 medicines is available to medical practitioners through the Department of Health. The PSB can be contacted on 9222 6812 regarding any Schedule 8 concerns about a patient. The Department may notify a prescriber when an OST patient obtains a Schedule 8 medicine from a prescriber without authority. A copy of this letter is provided to the treating OST prescriber who in this circumstance should review the adequacy of the patient's current dose of methadone or buprenorphine and consider the appropriateness of any currently approved takeaways.

## **8.4 Managing challenging behaviours**

It is important that, prior to commencing treatment, patients have a clear understanding of expected conduct within the Program. Specifically, patients must be advised that physical and verbal aggression will not be tolerated, and such incidents may compromise their continuation in treatment.

Challenging behaviours exhibited by patients may indicate poor communication skills or emotional dysregulation. Identifying and managing these behaviours when present is an important skill for service providers to develop.

### **8.4.1 Aggression and threatening behaviour**

Any behaviour which causes a person to feel intimidated, fearful or offended can be perceived as aggressive. This may be directed at an individual, a group, or property and can be expressed in a range of ways.

#### **Responding to aggressive behaviour**

Patients of CPOP who make verbal threats or display aggressive behaviour are in breach of the CPOP Agreement.

Such behaviours must be addressed with the patient at the earliest opportunity. Patients should in the first instance be counselled as to the unacceptable behaviour. The incident should be discussed and details, including proposed actions, documented in the clinical record.

Generally it is recommended that the following sequence of actions be undertaken with patients who fail to comply with reasonable behaviour expectations:

1. A *CPOP Formal Warning* (see Appendix 10) to be given and a Behaviour Management Plan activated.
2. A change in conditions of treatment which may include removal of takeaway doses and the requirement to attend more frequently for review.
3. Transfer to a more suitable treatment setting or alternative treatment program.
4. Withdrawal from the Program if behaviour continues.



Should a formal warning be appropriate, a Behaviour Management Plan should be activated, clearly stating any behaviour deemed to be unacceptable along with clearly stated consequences should the behaviour continue.

If a situation escalates to the point of posing a physical threat to a person or property, police should be called. Staff involved in any threatening or aggressive incident should be provided with debriefing, all incidents documented and appropriately investigated.

CPP should be advised when a formal warning is given, or when police have become involved. Training and support in dealing with difficult behaviours can be provided by CPP.



## 9. Drug Dependent Behaviours

### 9.1 Therapeutic dependence

Therapeutic opioid dependence may develop following the use of prescribed opioids for the treatment of pain and can become an additional problem complicating the original medical condition.

Determining whether a patient's presenting issue is one of severe pain or opioid dependence can be difficult. The treatment of therapeutic opioid dependence in association with persisting pain is also complex. Sound clinical management usually requires a range of psychosocial, biological and medical interventions. To ensure a comprehensive patient management plan, a clinical team consisting of GP, Addiction Medicine Specialist, Pain Management Specialist and allied health (e.g. psychologist) is often required.

Patients with therapeutic dependence may be recommended for specialist addiction assessment prior to S8 prescribing authorisation by the Department of Health. This can occur when a person has a prior history of illicit drug dependence or when recent prescription drug monitoring indicates the possibility of aberrant drug seeking behaviour.

Where a GP is advised to cease prescribing opioid medication for a particular patient, they should seek advice from CAS to develop a management plan for submission to the Department of Health while awaiting a referral appointment to Next Step or other recommended specialist service.



Patients with therapeutic opioid dependence are often resistant to change of treatment and reluctant to engage with AOD services as they do not identify themselves as drug users.

Clinicians should be sensitive to the patient's perceptions and experience of being referred to an alcohol and drug service. Education in relation to effective pain management and opioid dependence can assist the patient's understanding of their situation and help to facilitate a shift in understanding about treatment.

### 9.2 Minimising risk for therapeutic dependence

The management of patients who have developed an opioid dependence due to the management of chronic pain poses a particular challenge for doctors and others involved in their care. The issues are complex and there are considerable psychosocial factors that impact upon the patient's situation.

#### 9.2.1 Guide for use of opioids in chronic non-malignant pain

Opioid therapy for chronic non-malignant pain may provide analgesic benefit for some patients. Generally however, improvement of function is limited and only a minority of patients with chronic non-cancer pain will gain lasting benefit from long-term opioid medication.

The decision to prescribe opioids for an extended period of time should be made in consultation with a pain management specialist.



**Opioids should be prescribed only after a full assessment process has been undertaken which includes:**

- a pain diagnosis
- assessment of mental health, alcohol and other dependency issues
- a trial of non-opioid analgesia and non-drug treatments
- a corroborating history from other health professionals.

Only then should a trial of opioid medication be initiated. Patients should sign a treatment contract that sets out the goals of treatment and the dose and quantity of medication to be provided.



Where a patient is receiving OST, it is not appropriate to prescribe additional opioids.

### 9.3 Drug seeking

Doctors need to recognise and manage people who present seeking drugs for non-medical purposes, and those who are misusing prescription medications.

Patients may ask for inappropriate types and quantities of drugs for illicit purposes. The most common requests are for benzodiazepine or opioid drugs. Other less common prescription drugs such as antipsychotics, psychostimulants and non-benzodiazepine sedatives may also be sought and misused.

Behaviours that may raise suspicion of drug seeking include the following:

- arriving after regular hours or wanting an appointment toward the end of office hours
- exaggerating or feigning medical problems
- providing a convincing textbook description of symptoms but a vague medical history
- providing old clinical reports or x-rays in support of their request
- being unwilling to provide the name or contact details of their regular doctor
- claiming to have lost their prescription or saying that medication has been lost or stolen
- showing a detailed knowledge about opioids
- stating that specific non opioid medications are ineffective or that they are allergic to them
- stating that a specific opioid or benzodiazepine is the only one that works for them
- pressuring the doctor by eliciting sympathy, guilt or threats.



These patients present a challenge to GPs with persuasive stories, urgent requests and sometimes an intimidating demeanor.



Under no circumstances should these people be prescribed full PBS quantities of the requested medication or be given medication samples to take away. The basic strategies available to GPs in this situation are to either say no to the request, or to try to engage the person into a structured treatment plan. The Prescription Shopping Information Service (PSIS) can be contacted on 1800 631 181 and the Pharmaceutical Services Branch (PSB) on 9222 6812.

## 9.4 Intoxicated patients

Patients who present to the pharmacy and appear intoxicated may be instructed by the pharmacist to return later in the day for dosing when they are no longer intoxicated.

The prescription provided by the prescriber authorises the supply of a medication; however, the pharmacist carries his or her duty of care obligations and therefore must make the final decision about whether to dose the patient.

Where a pharmacist is unsure about the safety of providing a dose to a patient, support and advice should be elicited from the person's prescriber or from CAS. The person should not be dosed or provided with takeaways until the pharmacist has assessed them as safe to receive medication. The risk of overdose or death to a person who is not safe to be dosed outweighs the discomfort of withdrawal experienced from delaying or missing a dose.

Patients with a history of intoxicated presentations should be reviewed more frequently, and takeaway doses withheld or removed until the patient is assessed as stable. Where continuing polydrug use and intoxication is noted, **a review of the patient's treatment plan is necessary and an alternative treatment program may be recommended.**



Safety is the key consideration in responding to patients who present for dosing while intoxicated. All intoxicated presentations should be notified to the prescriber as a matter of routine.

## 9.5 Diversion of methadone/buprenorphine and non-adherence to dosing instructions

Diversion and non-adherence issues occur when methadone and buprenorphine are not used as intended. Diversion may include selling, trading or giving medication to others, removing doses from the dosing point, and secreting doses for on-selling. The diversion of both supervised doses and takeaway doses of methadone and buprenorphine to the illicit drug market or to a user for whom the drug was not intended is a serious issue for the Program, with implications for patient and public safety as well as the reputation of the Program. The use of diverted medications can have serious and potentially fatal consequences. Non-adherence, where the medication is not taken exactly as directed, undermines the therapeutic rationale and effectiveness of treatment. This may include removing all or part of the supervised dose from the dosing site for personal use, stockpiling doses, and injecting doses.



While most patients do not divert their medication, the potential for some to attempt to divert their medications is always a risk. When considering management options where diversion has occurred, the value of keeping patients in treatment must be weighted against other options.

### 9.5.1 Minimising the risk for diversion

To minimise the risk for diversion it is important that patients are:

- carefully assessed by the prescriber for risk of diversion
- appropriately supervised at the dosing point
- supplied takeaway doses only in accordance with the WA Schedule
- appropriately managed if found to be diverting.

Concerns about suspicion of diversion may arise from observations of patient behaviour, or information from other sources such as other service providers, friends or family members of the patient. Prescribers will need to make a judgment as to the credibility of third party reports.



All patients should be informed about the consequences of diversion or attempted diversion of their OST at the commencement of treatment.

Service providers may wish to seek advice from CPP or to enlist the Opioid Replacement Program Advocacy and Complaints Service (ORPACS ph: 9321 2877) to assist in communicating with patients to positively resolve any problems.

### 9.5.2 Responding to diversion or attempted diversion

Discussion should occur with the patient regarding their behaviour in all situations and full consideration given to the appropriate course of action before any changes to treatment are recommended or made.

Where a pharmacist suspects that the patient is diverting or attempting to divert their medication, the pharmacist should discuss the concerns with the patient in the first instance. Both the prescriber and CPP should be notified via a Pharmacy Incident Report (see Appendix 13), and the concern documented in the patient record.

Where there is direct observation by pharmacy staff or other conclusive evidence of diversion or diversion attempts the prescriber and CPP should be advised and the patient referred back to the prescriber. The following action should be implemented by the prescriber.



**Table 18 Management of Diversion**

	<b>Recommended action</b>
Diversion of takeaway dose(s)	Provide an official warning to the patient. Immediate cessation of takeaway doses and daily supervised dosing implemented for a minimum period of 6 months.
Diversion of supervised buprenorphine	Provide an official warning to the patient. No further takeaway doses for a minimum of 6 months. Consider transfer to methadone. Review of dosing arrangements and suitability for continuation of treatment.
Diversion of supervised methadone dose	Doses should be made up to 200mL with water or cordial and the dose should be administered in 50mL aliquots with no takeaway doses for a minimum period of 6 months.

For subsequent diversion incidents occurring within a 12 month period

The incident should be discussed with CAS and a management plan developed.

Referral to a specialist service may be appropriate.

\* Consideration should be given to the particular clinical situation of the patient (e.g. pregnancy) when deciding on the appropriateness of any action to change methadone or buprenorphine treatment.

**All diversion episodes and actions should be recorded on the patient record and CPP advised in writing.**

### 9.6 Theft of methadone/buprenorphine from the pharmacy

Theft of methadone or buprenorphine from a pharmacy by a CPOP patient will be notified to the prescriber and to CPP. It is the role of the pharmacy to also advise the police and the Department of Health.



## 10. Fraudulent Access to S8 Medicines and other Scheduled Medicines

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When a patient seeks fraudulent access to S8 and other Scheduled medicines consideration needs to be given to the appropriateness of the current opioid substitution treatment including the risk of overdose. The goals of treatment and the treatment plan need to be revisited. Suspension of all takeaway doses would be appropriate.

### 10.1 Forged documentation to obtain medicines including S8 medicines

When a prescriber becomes aware that documentation relating to the patient's medical treatment has been altered/forged or copied in some way to gain access to Scheduled medicines a report should be made to the police and to the Pharmaceutical Service Branch. CPP should also be advised.

### 10.2 Forged prescriptions to obtain medicines including S8 medicines

When a prescriber becomes aware that a patient has altered/forged a prescription to gain access to Scheduled medicines, a report should be made to the police, and to PSB. Where this involves a prescription for methadone or buprenorphine, CPP should also be advised.

### 10.3 Fraudulent use of another person's identity to obtain scheduled medicines including S8 medicines

When a prescriber becomes aware that another person's identification details, generally a stolen Medicare card, have been used to gain access to Scheduled medicines including S8s, report to the police and PSB. Where this involves methadone or buprenorphine, CPP should also be advised.

## 11. Unexpected Death of Patient Receiving Opioid Substitution Treatment

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Where a CPOP patient dies unexpectedly while receiving OST, CPP is to be advised by the prescriber at the earliest opportunity.



## 12. Prescriber Departure from CPOP

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### 12.1 Notifications and exit administration requirements

Where an authorised prescriber intends to leave CPOP, they should at the earliest opportunity advise CPP and the Department of Health of the planned exit date. The prescriber may request a list of all currently authorised patients from the Department and provide a copy to CPP. Patients should be advised well before the prescriber's exit wherever possible and transfer of management plan formulated.

All patients currently inactive and authorised to the prescriber should have a *Termination of Opioid Substitution Treatment* form completed and forwarded to the Department.

### 12.2 Patient transfer arrangements

Patients engaged in treatment should be advised to seek assistance through CPP to find an alternative OST prescriber if needed. The prescriber should provide to CPP a summary of the patient's treatment and participation prior to leaving the Program. This will assist CPP to facilitate safe and timely transfer of CPOP patients to a new treatment provider where possible.

There may be some instances where an alternative prescriber is not available. Where this is the situation, CPP should be contacted for advice.

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Pharmacist guide



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## 1. Regulatory Requirements

### 1.1 Approved methadone/buprenorphine dispensing pharmacies

Pharmacies participating in the dispensing of methadone and buprenorphine for opioid dependence must be authorised by the Department of Health Chief Executive Officer.

- The pharmacy licence holder is required to complete an *Application for a pharmacy to participate in the Community Program for Opioid Pharmacotherapy*.
- The licence holder must ensure that all pharmacists dispensing an opioid pharmacotherapy have the competencies required by the **WA Clinical Policies and Procedures for the Use of Methadone and Buprenorphine in the Treatment of Opioid Dependence**. Details on accessing the on-line Pharmacist Training Program are provided as part of the start-up pack when new pharmacies apply for CPOP authorisation.
- The Department issues an authorisation to the pharmacy for participation in the dispensing of methadone/buprenorphine, and notifies the nominated wholesaler that the pharmacy is participating in CPOP. The pharmacy is eligible for methadone and buprenorphine free of charge; however a recording fee is charged to the pharmacy by the wholesaler.

All relevant forms can be accessed on the Department of Health website by entering [www.health.wa.gov.au/cpop](http://www.health.wa.gov.au/cpop) and following the link.

#### 1.1.1 Client numbers per approved pharmacy

Pharmacies participating in CPOP are authorised to dispense to a maximum of 50 clients per day.

Authority to dispense to more than the equivalent of 50 clients per day **requires written approval from the CPOP Management Committee**.

The pharmacy may make application by completing a self-report using the *Application for a pharmacy to increase client numbers* which is submitted to the Pharmaceutical Services Branch of the Department of Health, and then forwarded to the CPOP Management Committee for consideration. In assessing the application, the Committee will consider the record of the pharmacy in complying with CPOP policies and procedures, the ability of the pharmacy to maintain appropriate levels of client care for managing more than 50 clients, and any other information considered to be relevant.

In the event of concerns emerging about public amenity due to a large number of clients attending a particular pharmacy, the matter may be reviewed by the CPOP Management Committee who may require changes to the maximum number of clients.

Where a number of CPOP pharmacies operate within a locality and there is a notable difference in client numbers dosing at each pharmacy, recommendations may be made regarding client allocation.



## 1.2 Role of the dispensing pharmacist

Pharmacists play a key role in the delivery of methadone and buprenorphine treatment. The pharmacist's role includes:

- checking that the prescription satisfies the legal requirements, including endorsement with an authorisation number
- ensuring positive identification of the client before administration of any dose
- checking the prescriber's instructions (use of a daybook or diary is recommended)
- explaining any side-effects of medication when appropriate
- assessing the client for intoxication and contacting the prescriber if necessary
- ensuring the dose is correct
- supervising the consumption of each dose
- dispensing any takeaway doses in accordance with the script
- providing any relevant information regarding the client's progress, including missed doses, dose diversion, intoxicated presentations and other issues of concern to the prescriber and other health workers involved in treatment management
- supporting the client and encouraging a healthy lifestyle
- ensuring that client information is kept confidential
- ensuring all pharmacy staff (including locum pharmacists) are appropriately trained and informed of CPOP requirements
- reporting incidents to the prescriber and CPP
- ensuring that methadone and buprenorphine are stored and recorded in compliance with the Poisons Regulations.

## 1.3 Drugs of dependence recording requirements

Regulation 47 of the Poisons Regulations 1965 states that records are to be retained for not less than 7 years from the date of the last entry, to be made available on demand. This regulation pertains to "all records, registers, dosing record sheets, prescription books, invoices and other documents relating to drugs of addiction and transactions in regard thereto..."



Regulation 47 includes dosing record sheets, which may be requested within the given 7 year period.

### 1.3.1 Drugs of Addiction Register

Pursuant to the Poisons Regulations 1965 all transactions involving methadone and buprenorphine for CPOP are to be entered into an approved register on the day of transaction. These registers are either bound books (HA 212 or HA 176, available from the wholesaler) or an approved electronic register.

These registers are to be kept separate from non CPOP registers. Methadone for use outside of CPOP is to be purchased and recorded separately from CPOP with a separate running balance.



These register entries are accurate records of the movement of OST medicines to and from the approved secure storage area or safe. Entries will detail client doses, incoming and outgoing stock, stock destruction or stock spillage/wastage. These entries can also contain footnotes. Pharmacists must clearly annotate details of takeaway (unsupervised) doses and unusual but noteworthy events.

### 1.3.2 Dose administration records

In addition to the legal requirement to maintain a register of OST medicine transactions, separate entries into a client's individual dose record is also required. This record documents the client's dosing history and is an aid in reviewing client compliance (e.g. monitoring missed doses, intoxicated presentations) and also enables easier completion of the monthly transaction reports. This form can be accessed on the Department of Health website by entering [www.health.wa.gov.au/cpop](http://www.health.wa.gov.au/cpop) and following the link.

### 1.3.3 Pharmacy Report

The *Pharmacy monthly report Methadone-Suboxone-Subutex* must be completed and can be emailed to [poisons@health.wa.gov.au](mailto:poisons@health.wa.gov.au) with the *Schedule 8 Monthly Transaction Report* to the Department of Health before the seventh day of the following month.

The Pharmacy monthly report requires the following details for each client administered or supplied with methadone or buprenorphine:

- indicate with M, B or X whether the drug is Methadone (M), Subutex (B) or Suboxone (X)
- the client's name in full
- the Department of Health authorisation number as endorsed by the prescriber on the prescription
- the last dose (in milligrams) administered or supplied that month
- the number of takeaway doses supplied
- the number of missed doses
- indication of clients who commenced or ceased dosing at the pharmacy that month.

## 1.4 Storage

Methadone and buprenorphine must be stored in accordance with Regulations 56, 56A, 56E and Appendix M of the WA Poisons Regulations 1965. Methadone and buprenorphine must be stored in a locked safe. If a pharmacist is on the premises then they can be stored in a locked cupboard or drawer and the key kept in the possession of the pharmacist. At no time should methadone or buprenorphine be left unattended. When receiving stock, methadone and buprenorphine must be transferred to the storage area promptly. When dosing, methadone and buprenorphine must be removed from the approved area **only at the time of dosing** and returned promptly. Pre-preparing doses for clients prior to their arrival is not supported due to the increased risk for dosing errors.



## 2. Orientating and Commencing New Clients

### 2.1 The client interview and agreement

Pharmacies are under no obligation to accept any client for dispensing. It is recommended that the pharmacist interview the person before agreeing to act as their dispenser. If the pharmacist agrees to accept them as a client it is also recommended that a *CPOP Pharmacy/Client Agreement* (see Appendix 11) should be completed outlining the conditions under which the dispensing is to occur.

Discussion should include:

- the cost of daily dosing and payment procedures
- opening times and dosing hours
- the code of conduct and acceptable behaviour
- supervised dosing procedures
- the consequences of diversion or attempted diversion
- procedures for takeaway doses (\*if appropriate)
- consequences of theft from the pharmacy.

#### Client behaviour

Retention in treatment is known to improve outcomes for clients in OST programs. It is important for clients to understand and follow a code of conduct when attending services for treatment and dosing to ensure trouble free access. Before a pharmacy accepts a client for dosing, it is recommended that clients be asked to discuss and sign a pharmacy agreement detailing what action will be taken by the pharmacy should the contract be breached. The contract should be renewed annually with the client.

The *CPOP Pharmacy/Client Agreement* provided as Appendix 11, may be used as is or amended for individual pharmacy requirements. It is recommended that the client be asked to sign each point of the agreement to ensure their understanding of the agreement. The client should also receive a copy for their record.

#### 2.1.1 Dispensing fees

Community pharmacies charge clients a fee to cover the professional costs of dispensing methadone and buprenorphine. Pharmacies are free to determine their dispensing fees. The individual dispensing fee is part of the contract between the pharmacy and the client and is the responsibility of the client.

Accumulation of debt causes clients anxiety, and may lead to an alteration of dosing routines, potentially compromising a client's stability in treatment. Pharmacists may consider offering discount payments for early pre-payment, or may negotiate payments through Centrelink (Centrepay).

**A policy of no payment no dose is recommended and pharmacists are advised to request payment before doses are dispensed.** This reduces the risk for possible restrictions to dosing due to an excessive accumulation of debt at the pharmacy.



The pharmacy has the right to refuse dosing if the client does not pay the agreed fee and accumulates a debt. Where this occurs the client can:

- look for an alternative dosing site
- attend the prescriber for planned withdrawal
- commence detoxification.

### 2.1.2 Client Identification

The prescribing doctor must provide the pharmacy with appropriate client identification. This must include either a recent photo of the client endorsed by the prescribing doctor in hard copy or digital format, or a *SIMS Client Identification Details* form issued by Next Step.

Where the appropriate client identification is not provided by the prescriber (e.g. due to unscheduled or temporary transfer of the client, or the faxed identification is unclear) the pharmacy may confirm the client's identity upon production of approved ID documentation. The ID requirement can be met with the following:

#### Category A – One document required

- Current driving licence issued by an Australian state or territory (with photo)
- Current Australian Passport
- WA Proof of Age Card (with photo)
- Current firearms licence issued by an Australian state or territory (with photo)

***If Category A documentation is not available then two documents from Category B may be provided***

#### Category B – Two documents required

- Medicare card issued by the Health Insurance Commission
- Centrelink card issued by Centrelink
- Health Care Card
- Department of Veterans' Affairs (DVA) card issued by DVA
- Credit or debit card or account issued by a financial institution in Australia
- Department of Immigration and Multicultural Affairs (DIMA) certificate of evidence of residence status
- Citizenship certificate
- Current overseas passport with current Australian entry permit
- DIMA immigration papers
- Photo identification issued by a Government Authority (e.g. prison ID)
- Original birth certificate

***If Category A or B documentation is not available then three documents from Category C may be provided (All documents presented from category C must be not more than 12 months old and show current residential address)***

**Category C – three documents required**

- Motor vehicle registration or insurance papers
- Property rates notice
- Property lease agreement
- Home insurance papers
- Utilities bills (e.g. telephone, electricity or gas)
- Bank or credit card statements
- Trade certificate
- School certificate

## 2.2 Maintaining the client record

**Paper records**

It is recommended that each CPOP client dosing at the pharmacy has a separate folder that is kept in a secure place and is accessible only by the pharmacist. The folder should contain the following:

- an identification sheet with photo ID
- a notes sheet
- a current prescription
- dosing administration charts
- a copy of the *CPOP Pharmacy/Client Agreement*.

Colour coding the folders with a different colour for each of the pharmacotherapy preparations can help to prevent dosing errors and improve dosing efficiency.

**Electronic recording systems**

There are a number of electronic recording systems available for use in CPOP. Whilst commercial software packages vary in complexity and features, they provide many advantages over a paper based systems. These programs may have some or all of the following features:

- They provide additional checking processes for pharmacists.
- They store photo ID.
- They alert the pharmacist when the prescription is due to expire.
- They provide a daily dosing record for each drug that can be printed.
- They reduce the time spent recording doses in a paper-based register and in the client record.

All computer systems in use must have an adequate backup system in order to ensure the safety and security of the electronic records.

Computer based systems used for the purpose of a Drugs of Addiction Register in CPOP must be authorised and approved by the WA Department of Health. The Department ensures that the approved systems meet all required standards of compliance for use as a recording system for methadone syrup/solution and buprenorphine as Subutex and Suboxone sublingual film in CPOP. The Department can provide advice regarding systems available for this purpose.

All records must be kept for a minimum of 7 years.



## 3. Administration of Opioid Substitution Treatment

### 3.1 The dosing environment

When considering the pharmacy environment for dosing clients with methadone and buprenorphine attention needs to be given to issues of both security and confidentiality. The dosing area should be set up taking into account the security of staff and medication, along with the discretion and comfort of clients. Dosing areas should be suitably private for respectful dosing and confidential discussion with clients while still ensuring security of the pharmacotherapies and pharmacy staff. The layout of the dosing area should ensure that the pharmacist can adequately supervise the consumption of the dose of opioid pharmacotherapy to reduce the potential for dose diversion.

The physical environment ideally should separate the client from the dispensary and ensure that dispensing staff have adequate security in the event that a client becomes aggressive. Many pharmacies have designed specific dosing areas that promote both security and confidentiality. The CPP team can assist pharmacies who are setting up dosing areas with ideas and suggestions for improving security and confidentiality.

### 3.2 Prescriptions

Prescriptions should be checked and verified as authentic and unaltered upon receipt at the pharmacy.

The prescription must include:

- the client's full name, address and date of birth
- date of prescription
- the client's authorisation number
- the drug to be administered\*
- the date of administration of first dose\*
- the finish date\*
- the daily dose expressed in milligrams, written in both numbers and words\*
- any variations to daily dosing to be written in milligrams and words\*
- number of takeaway doses allowed (refer to WA Schedule)\*
- the pharmacy/dispensing point at which the script is valid\*
- the signature of the prescriber\*
- the name and practice address of the prescriber.

\* To be in the authorised prescriber's own handwriting.

Pharmacists must only dispense OST medication in accordance with a valid prescription received from an authorised CPOP prescriber. If a pharmacist receives an OST prescription from a prescriber unknown to them, CPP should be contacted for confirmation of authorisation status.

Clients should be advised within the week prior to the script expiring of the need for prescriber review where an appointment date is not known. Expired scripts are not valid and should not be dispensed.



The pharmacist should contact the prescriber for advice when a script has expired. Contact CAS or CPP for advice when the prescriber is not available.

If a pharmacy receives a prescription from an authorised prescriber which is incomplete, unclear or ambiguous, the prescriber must be contacted to clarify the instruction.



Instructions and/or information must not be passed to the pharmacist by the client.

Should situations arise where a client advises that a prescriber has approved a variation from the script currently held at the pharmacy, **the prescriber must be contacted for a verbal instruction** before making any adjustment. **Takeaway doses that have not been prescribed are not to be issued.**

Takeaway methadone doses must be made up to 100mL with water unless otherwise specified on the prescription. In the case of suspected/proven diversion, it is advised that the supervised dose be made up to 200mL with water and dispensed as 50mL aliquots.

### 3.2.1 Other prescriptions

A combination of opioid and sedative medication may be potentially hazardous and requires close liaison between the prescriber and the dispenser. Pharmacists may be requested to provide limited dispensing of benzodiazepine medication by the prescriber in order to reduce the potential for abuse by clients of CPOP. If clients present a prescription for sedative medication from another physician and there is concern at the dose, then the pharmacist should contact the prescribing physician to discuss safety concerns. The CPOP prescriber should also be contacted where appropriate.

## 3.3 Dosing

Dosing of CPOP clients should be in accordance with this Manual, and as directed by the prescriber. Correct dosing technique is important to ensure the client receives the full benefit of their dose. Where the instruction for dosing does not comply with these policies and procedures, the pharmacist is advised to contact the prescriber if the pharmacist has concern regarding the instruction. CAS or CPP can also be contacted to assist if needed.

Pharmacists should note that conical measures are not accurate for measuring methadone. The use of syringes or suitably sized cylindrical measures is recommended. Pumps and syringe units are available to ensure accurate measuring.



### 3.3.1 Correct supervision of dosing

All supervision of opioid pharmacotherapy must be provided by the pharmacist. Clients are expected to adhere to requests made by the pharmacist regarding dosing procedures.

Clients in the induction phase of treatment should be dosed at approximately the same time each day, and a divergence of more than 12 hours from the usual scheduled time should be avoided.

Before attending the pharmacy, clients should be advised that:

- only the client can pick up their dose where takeaways are prescribed
- no bags or containers are allowed in the dosing area
- the client's hands and mouth must be visible at all times
- the dose must be consumed in direct view of the pharmacist with no turning of the head
- the dose must be consumed directly from the spoon or the cup
- for buprenorphine tablets, the dose must be placed under the tongue and the client must remain in full view of the pharmacist until the crushed tablets are completely dissolved
- clients are not allowed to handle tablets
- for buprenorphine film, the dose must be placed under the tongue or buccal mucosa, taking care not to overlap and ensuring a minimum of 1 minute direct supervision
- the empty cup or spoon must be shown to the pharmacist before being disposed of
- clients must speak to the pharmacist, open their mouth and have a drink of water or cordial after dosing if asked to do so
- clients should not provide their own drink container
- clients must not loiter in the pharmacy after dosing.

Diversion of supervised doses can be minimised when the following procedures are followed:

#### **For both methadone and buprenorphine:**

- dose one client at a time
- do not allow other people (including children where possible) in the dosing area while a client is being dosed
- do not allow bags, drinks or other containers in the dosing area
- ensure the client throws away (into a designated bin) or hands back any items used during dosing
- observe the client throughout the dosing process, especially when the dose is placed in the mouth and immediately after
- once the dose is placed in the mouth ensure that the client's hands are kept away from their mouth
- CCTV monitoring is useful for monitoring inappropriate behaviour and modifying people's behaviour accordingly
- containers issued for takeaway (unsupervised) doses should not be re-used.

#### **For methadone:**

- use an individual disposable cup for each client
- do not pour methadone into another drink container
- empty methadone bottles should be rinsed with water and the label defaced before discarding.

**For buprenorphine:**

- ask clients to remove anything from their mouth prior to dosing (e.g. chewing gum)
- ask the client where possible to remove dentures while still maintaining the dignity of the client
- for tablets, roughly crumble the dose to large granule size. Avoid powdering the dose and place under the tongue, keeping the client in full view until the tablets are dissolved
- for film, the dose must be placed under the tongue taking care not to overlap multiple films
- clients should be supervised for at least 1 min to ensure film has adhered to the mucous membrane
- film should not be cut
- dispense the dose in a clear plastic cup or disposable spoon
- view and inspect the mouth cavity after the client reports that the dose has been absorbed.

### 3.4 Induction doses

Clients should be monitored very carefully during the first 2 weeks of treatment. Clients who present with any signs of intoxication should not be dosed and must be referred to the prescriber for review. If a client reports sedation after dosing or snoring at night the prescriber should be advised.

Where a client is commencing induction to OST, a gradual dose increase is generally prescribed for the first 1–2 weeks. Where pre-determined dose increases are prescribed it is essential that the client attends on a regular daily basis for supervised dosing.

**If the client fails to attend for a single dose within the induction period the prescriber must be contacted and advised before any further dose is provided.** A single non-attendance may warrant a review of the scheduled dose increase during the induction period and a new script to be issued.

It is preferable that clients do not take benzodiazepines during the induction period. If a client presents with a benzodiazepine prescription written by a doctor other than the authorised prescriber, the authorised prescriber should be contacted. The pharmacist should also contact the prescriber if there are concerns about the quantities of benzodiazepines being prescribed and dispensed to clients.

The patient's doctor should be contacted if any of the following occur during induction:

- the client presents intoxicated prior to dosing
- the client reports sleeping 4–5 hours after dosing
- the client reports heavy snoring when sleeping
- the client presents a prescription for benzodiazepines or other sedatives, opioid or psychiatric medication from another doctor
- the client misses a dose.



### 3.5 Changes to dose

Any variation to the dose prescribed requires a valid script written by the prescriber or a specialist CAS prescriber, with clear instruction as to the preparation and dose to be administered. Where this information is telephoned or faxed to the pharmacist, an original prescription confirming the instruction must be provided within 72 hours.

### 3.6 Blind dosing

Some prescribers may request for a client to be dosed without the client's awareness of the dose amount that they are receiving. This dosing regime is negotiated by the GP with the client's consent and participation, and clear dose instructions should be written on the script for administration by the pharmacist. Blind dosing is occasionally implemented when a client is seeking to reduce their dose however experiences anticipatory anxiety prior to any planned dose reduction.

### 3.7 Changes to dosing location

Where a client requires dosing at an alternative pharmacy temporarily (e.g. due to work/travel arrangements) or permanently, a *CPOP Pharmacy Transfer Notification* form should be completed (see Appendix 12).

Where a client's change of dosing location is necessary due to an incident at a pharmacy, the prescriber should be advised, and a *CPOP Pharmacy Incident Report* also provided to CPP (see Appendix 13).

### 3.8 Dual dispensing locations

A client will require two dispensing pharmacies where their usual pharmacy is closed on Sundays and on public holidays, and they are not eligible for a takeaway dose to cover that period. The following instruction reduces the risk for dosing errors relating to missed doses and double dosing.

Where clients are dosing at a six-day a week pharmacy (the primary pharmacy) and attending for Sunday dosing at a secondary pharmacy:

1. The primary pharmacy must inform the secondary pharmacy of any doses missed by the client during the week prior to the Sunday closure.
2. If the client has missed more than two consecutive doses immediately prior to their Sunday dose the secondary pharmacy must contact CAS for instruction prior to dispensing (\*See Missed Doses).
3. Where a client does not attend for the Sunday dose, the primary pharmacy must be advised by the secondary pharmacy upon opening on the Monday morning.

### 3.9 Increasing CPOP client numbers

Refer to **Client numbers per approved pharmacy** within this Manual for details of the process by which pharmacies may make application to increase client numbers.



## 4. Missed Doses

Pharmacists are referred to Table 19 when determining their responsibility for dosing clients who have missed methadone or buprenorphine doses.

**IMPORTANT NOTE:** If a client fails to attend for a single dose of methadone or buprenorphine during the induction period, the prescriber must be contacted and advised before any subsequent dose is provided to the client.

*Table 19 Pharmacist Actions Following Missed Doses*

Equivalent of daily doses missed	Response
1 or 2 days dosing missed	If no evidence of intoxication dose as usual.
3 days dosing missed	Pharmacists <b>must consult with the prescriber or CAS</b> before dosing. Approval to dispense treatment can be given over the phone, however the prescriber may decide to authorise a reduced dose if tolerance is thought to be reduced.
4 or more days dosing missed	Withhold dose. <b>Client must be seen by the prescriber.</b>

### 4.1 Frequently missed doses

Methadone and buprenorphine are generally provided as a daily dose for clients of CPOP, requiring daily attendance at the pharmacy to ensure optimal engagement and treatment compliance. There may be an occasion where a client fails to attend as expected, resulting in a single missed dose.

The prescriber or case manager should be advised **when a client fails to attend for dosing on more than two occasions in any month** at the earliest opportunity. Non-attendance for dosing may warrant an early review of the client.

### 4.2 Attendance on non-dosing days (buprenorphine)

The following procedures should be followed where a client attends for buprenorphine dosing on a non-dosing day, or where takeaway doses have previously been provided to cover that dosing period:

1. No buprenorphine can be dispensed (since there is no valid prescription).
2. The pharmacist should contact the prescriber for advice.
3. In circumstances where the pharmacist cannot contact the prescribing doctor, CAS should be contacted.
4. Clients who repeatedly miss doses under these circumstances should be appropriately reviewed by their prescribing doctor.



### 4.3 Hospitalised clients

Generally methadone or buprenorphine treatment will be continued when clients are admitted to hospital. If the pharmacy is contacted by hospital medical staff regarding treatment details, assistance should be provided to ensure accurate and safe continuation of treatment. This includes information about the client's history and the client's current dosing regime. The pharmacist should record that the client has been hospitalised as an inpatient and is being dosed continuously elsewhere.

To avoid double dosing upon discharge, the pharmacist should obtain confirmation of discharge and the date the client received the last dose from the hospital before recommencing dosing.

### 4.4 Lost or stolen doses

Lost or stolen doses should not be replaced by the pharmacist without a valid prescription and should be reported by the client to both the prescriber and the police.

### 4.5 Vomited doses

Vomiting after a dose of methadone creates uncertainty about the amount of dose absorbed. If the vomiting occurs 20mins or more after the dose is given, reassurance can be given that the entire dose has been absorbed. Where less than 20mins after dosing has elapsed, contact the prescriber or CAS for advice and further instruction.



## 5. Intoxicated Clients Presenting for Dosing

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Client safety is the key consideration in responding to those who present for methadone or buprenorphine dosing when intoxicated with opioids, alcohol, benzodiazepines or other drugs. Intoxicated clients should not be dosed, and the following advice followed.

- Clients must be assessed for intoxication by the person dispensing the dose (nurse or pharmacist) before any dose is given.
- The assessor should be satisfied that the client is not showing evidence of intoxication due to opioids, alcohol, benzodiazepines or other drugs (see Appendix 5 for *Assessment of Acute Intoxication*).
- Clients who appear intoxicated should not be given their usual methadone or buprenorphine dose or any takeaway doses at that time.
- Clients who present early in the day for dosing and are assessed as being mildly intoxicated should be advised to re-attend the pharmacy 3 hours later for reassessment and dose review. Where the client presents too late in the day to re-present at the specified time, the prescriber or CAS must be contacted for advice. Generally in these situations, the client will not be dosed and will instead be advised to return early the following day to re-commence dosing.

### 5.1 Repeated intoxicated pharmacy presentations

Prescribers must be notified of any client with a history of repeated intoxicated presentations. It is recommended that no takeaway doses be issued until the client has been reviewed. Pharmacists can contact CAS or CPP to discuss any concerns.



## 6. Takeaway Doses

Takeaway doses **may only be provided to the client for whom they are prescribed** and can only be dispensed in accordance with instructions on a valid prescription.

If a prescriber authorises a takeaway dose verbally to the pharmacist, the prescriber must dispatch written confirmation of the verbal instruction within 24 hours clearly indicating that it is in confirmation of the direction given.

Where the script has not been received by the dispenser within 72hrs it must be immediately reported to Pharmaceutical Services (as per Poisons Regulations 1965. 53(2)).

Takeaway dose(s) must be given directly to the client on the day(s) before the scheduled day(s) of absence from the usual dispensing location. **Takeaway doses must not be provided to a third party on behalf of any client without the written approval of the CPOP Clinical Review Committee.**

Pharmacists should advise and then again remind clients regarding the secure storage of takeaway doses in an appropriate place, not in the refrigerator, and safe from the reach of children.

Clients are solely responsible for the care and proper consumption of each takeaway dose once they have taken possession of it. Clients should be reminded to remove the labels and rinse single use takeaway methadone containers after use and before disposal.



Lost, stolen or damaged takeaway doses cannot be replaced by the dispenser without the authorisation of the prescriber.

### 6.1 Dilution of methadone takeaway doses

Each takeaway dose of methadone is to be made up to 100mL with water.

### 6.2 Requests for additional takeaway doses

Additional takeaway doses may be authorised by the prescriber for emergency and one-off use as described within this Manual. All additional takeaway doses authorised for dispensing must be written on a valid script with clear instruction provided by the prescriber.

All regular takeaway doses outside the WA Schedule must be approved by the CPOP Clinical Review Committee.

### 6.3 Labelling and containers

Takeaway doses must be dispensed in accordance with the following instructions.

#### **Methadone**

All takeaway doses of methadone are to be made up to 100mL with water.



Individually dispense each day's takeaway dose in a **single use plastic container** with child resistant cap, ensuring that the label contains the following information:

Keep Out of Reach of Children  
Methadone Hydrochloride  
This bottle contains \_\_\_\_\_ mg of methadone hydrochloride diluted to 100mL with water.  
Take the contents of this bottle as a single dose on *(date to be consumed)* *(name of client)*  
*(Rx No 00000)* *(Date of dispensing)*  
Pharmacy name and address

Attach an Appendix K label.

### **Buprenorphine**

Takeaway doses of buprenorphine as Subutex and buprenorphine/naloxone as Suboxone **must** be dispensed in their original packaging. Tablets must not be crushed, and should remain in their original blister pack. Film should not be cut.

Each daily dose may include more than one dose strength, should be retained in its original packaging and individually dispensed in a box or bottle labelled as per the following example:

Keep Out of Reach of Children  
Buprenorphine/naloxone Sublingual Film (Suboxone) (or Buprenorphine as Subutex)  
This container contains \_\_\_\_\_ mg of buprenorphine hydrochloride.  
Take the contents of this container as a single dose dissolved under the tongue  
on *(date to be consumed)* *(name of client)*  
*(Rx No 00000)* *(Date of dispensing)*  
Pharmacy name and address

Attach an Appendix K label.

## **7. Urgent Prescriptions Due to Unforeseen Circumstances**

There may be occasion when clients require a prescription to receive a dose at a location other than their usual dosing site. Where a client's authorised prescriber is contactable it is advised that any changes or extensions to a client's prescription be undertaken by that prescriber. If the client's prescriber cannot be contacted and an alternate prescriber within the practice is not available, contact CAS for advice.



## 8. Diversion

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Diversion within the context of this Manual refers to the non-approved removal of all or part of a prescribed dose by the client.

Diversion of supervised doses and takeaway doses of both methadone and buprenorphine does occur. While most clients do not divert their medication the potential for some clients to attempt to divert their medications, for a range of reasons, always remains a risk and is treated very seriously.

### 8.1 Identifying diversion

It is difficult to provide absolute indicators, therefore the following **must be assessed in the context in which they occur and with regard to the dispenser's/prescriber's knowledge of the client**. Video surveillance is highly recommended.

To minimise the risks of diversion, clients should be provided with clear guidance on how and why medication is given, and how they should present during the observed consumption of the dose in order to avoid unnecessary suspicion of diversion. Some behaviours that may give rise to suspicion of diversion include:

- receptacles in the mouth such as plastic caps, glad wrap
- not wanting to stay for the supervision period
- causing distractions
- reading books, magazines etc. close to face
- touching mouth with hand or sleeve
- browsing the shop
- spitting, coughing, sneezing
- out of character behaviour, nervousness, being 'overly-nice', watching the pharmacist closely
- suspicious interaction with other clients or acquaintances after dosing.

### 8.2 Management of diversion

In all situations discussion should occur with the client regarding their behaviour, and full consideration given to the appropriate course of action before any changes to dispensing are applied.

#### **Confirmed incidents of diversion or attempted diversion**

Where there is a direct observation by pharmacy staff or other conclusive evidence of diversion or diversion attempts, the prescriber and CPP should be advised in the first instance and the client should be referred back to the prescriber. A *Pharmacy Incident Report* should be completed and forwarded to CPP (see Appendix 13).



Where diversion has occurred, stability regarding takeaway doses should be re-assessed by the prescriber who may consider the following actions:

- Removal of takeaways.
- Where clients have diverted methadone, it is recommended that subsequent doses be made up to 200mL with water or cordial and the dose administered in 50mL aliquots (to be stated on the prescription).
- Where clients have diverted Subutex tablets the prescriber may prescribe transfer to methadone.
- Where clients have diverted Suboxone film the prescriber may prescribe transfer to methadone.

Consideration should be given to the particular clinical situation of the client (e.g. pregnancy) when deciding on the appropriateness of any action to change methadone or buprenorphine treatment.

### **Suspected diversion**

Where the pharmacist suspects the client of diverting or attempting to divert their medication, the pharmacist should discuss their concerns with the client. This may clarify any misunderstandings regarding the dosing requirements. If required, a formal first warning should then be given to the client by the pharmacist outlining the concerns and consequences of further diversion attempts. The prescriber and CPP should also be notified.



Indications or evidence of subsequent diversion incidents should result in the pharmacist referring the client back to the prescriber where the above actions are recommended as per confirmed diversion.

### **8.2.1 Client complaints mechanism**

Clients who do not agree with decisions made by pharmacists or prescribers under this policy may make a complaint using the mechanism appropriate to their service provider.



## 9. Public Safety Issues

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The issue of public safety and amenity is an important concern for the Program. In the event of concerns emerging about public amenity due to a large number of clients attending a particular service, the matter may be considered by the CPOP Management Committee which may recommend changes to the maximum number of clients who can be treated at that service.

### 9.1 Needle and Syringe Program (NSP)

Clients of CPOP may on occasion attend a pharmacy for the dual purpose of receiving OST and the purchase of needles and syringes. CPOP clients may associate with current injecting drug users and can facilitate access to sterile injecting equipment for others.

The provision of sterile injecting equipment is an important harm minimisation initiative which has significantly reduced the spread of blood-borne viruses. CPOP clients requesting fitpacks should be provided with sterile injecting equipment as per normal procedures within the pharmacy.

Pharmacists who have concerns regarding a CPOP client's ongoing illicit drug use or the injecting of takeaway doses should report their concerns directly to the prescribing doctor who may review the client's progress and stability on the Program.

### 9.2 Forged prescriptions to obtain medicines including S8 medicines

When a pharmacist identifies a forged prescription, a report must be made to the police and the PSB.

### 9.3 Fraudulent use of another person's identity to obtain scheduled medicines including S8 medicines

When a pharmacist becomes aware that another person's identification details, generally a stolen Medicare card, have been used to gain access to Scheduled medicines including S8s, report to the police and the PSB.

### 9.4 Theft of methadone/buprenorphine from the pharmacy

When a pharmacist is aware of a burglary or individual incident involving the theft of S8 medicines, the matter must be reported to the police and to the PSB.



## 9.5 Responding to threats/aggressive behaviour

CPOP clients who make verbal threats or display aggressive behaviour are in breach of the *CPOP Client/Pharmacy Agreement* (see Appendix 11) which can result in restriction or cancellation of dispensing, and possible termination of treatment.

When encountering such behaviour pharmacy staff should act calmly, examine the reasons why the client is responding in such a manner (such as intoxication, misunderstandings or complaints regarding treatment) and respond in a manner which will de-escalate the situation and avoid the potential for violence.

Should a situation escalate to the point of posing a physical threat to a person or property **police should be called**. Staff involved in any threatening or aggressive incident should be provided with debriefing and incidents investigated to identify possible changes that may be made to reduce the potential for repeated occurrences.

Training and support in dealing with difficult behaviours can be provided by CPP. When disputes with the pharmacy cannot be resolved between the client and the service provider the client can be referred to the Opioid Replacement Pharmacotherapy Advocacy and Complaints Service (ORPACS) for assistance.

Incidents should be reported by the pharmacist to the prescribing doctor and CPP using the *Pharmacy Incident Report* form.



## 10. Dosing Errors

It is essential to the safety and effective working of CPOP that all pharmacists, including locums and part time staff, are familiar with CPOP requirements. All prescriptions, client identification records and other information should be readily accessible.

A basic check prior to administration of doses should include:

- signs of intoxication
- a current script with clearly written instructions
- dosing history (\*missed doses)
- correct OST preparation
- correct OST formulation
- correct client
- correct day
- correct dose.

It is recommended that the following procedures be adopted to reduce the possibility of dosing errors:

1. Use a day book, diary or computerized dosing system, to record and communicate important information to other pharmacists who practice at the premises. This book should be inspected by staff daily.
2. Check the treatment dates for validity period. Indicate the date of script expiry on the client's dose administration record.
3. All clients must have a photograph signed by the prescriber attached to their record card to establish identity.
4. Prescriptions for methadone should only be written in milligrams. **Do not confuse millilitres (mL) with milligrams (mg) of methadone as this may result in a fivefold error.**
5. If the dose is written in **millilitres** check the dose with the prescriber.
6. Take extra care to elicit information from all new clients about the effect of the dose to monitor the toxicity of the dose being administered.
7. If there is more than one client with the same surname attach a cautionary note to the client's record card alerting staff to this.
8. Check that telephone contact details for clients are kept up-to-date monthly.

### 10.1 Methadone overdose

To prevent accidental methadone overdose, procedures should be established for easy and accurate identification of clients to minimise the risk of inappropriate dosing.



A client who receives a methadone dose in excess of that prescribed is at risk of overdose.

In all cases of dosing error the following procedures should be followed and a **Pharmacy Incident Report form completed and forwarded to CPP (see Appendix 13).**



1. Advise the client of the mistake and carefully explain the possible seriousness of the consequences. Ask the client to wait in the pharmacy until the situation is discussed with the prescriber.
2. Contact the prescribing doctor immediately to obtain advice. If the client's prescriber (or another prescriber within the same practice) is not able to be contacted, consult with CAS.
3. If it is decided by the prescriber or CAS doctor that hospitalisation is required, the reasons should be explained to the client and they should be accompanied to the hospital to ensure admitting staff receive clear information on the circumstances.
4. If the client has left before the mistake is realised, every attempt must be made to contact the client. This may warrant a welfare check conducted by the police.

#### **Caution regarding inducing vomiting:**

Inducing vomiting may be dangerous and is contraindicated if the client has any signs of CNS depression. Emesis more than ten minutes after dosing is an unsatisfactory means of dealing with methadone overdose as it is impossible to determine if the entire dose has been eliminated.

In circumstances where medical help is not readily available or the client refuses medical care, induction of vomiting (by mechanical stimulation of the pharynx) within 5–10 minutes of ingesting the dose may be appropriate as a first aid measure only. Ipecac syrup is contraindicated as its action may be delayed.

## 10.2 Buprenorphine overdose

The risks associated with an incorrect dose of buprenorphine are not as severe as with other opioid medications.

In the event of an incorrect dose being administered:

1. Advise the client of the mistake and carefully explain the seriousness of the consequences. Ask the client to wait in the pharmacy until the situation is discussed with the prescriber.
2. If the prescriber cannot be contacted then consult with CAS. Complete a *Pharmacy Incident Report* (see Appendix 13) and fax to the prescribing doctor and to CPP.
3. If the client has left before the mistake is realised, every attempt must be made to contact the client. This may warrant a welfare check conducted by the police.

A lower dose, or no dose will be prescribed for the following day as in effect, a 2 or 3 day dose may have been administered.

## 10.3 Documentation

For all dosing errors:

1. Complete the form *Pharmacy Dosing Errors – Recommended Action Plan* (see Appendix 14).
2. **Contact PDL** (ph. 1300 854 838); PDL website <http://www.pdl.org.au/incident>.
3. Complete a *Pharmacy Incident Report* (see Appendix 13) and forward to CPP and to the prescribing doctor.



## 11. Closure of pharmacy

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### 11.1 Planned closures

When planning closure of an authorised pharmacy with CPOP clients for any period, the following must be observed to ensure that there is no interruption to any client's treatment:

1. The licence holder must advise PSB and CPP in writing at least two weeks prior to the planned closure. This will enable PSB and CPP to facilitate client transfers for the period where necessary.
2. Clients must be advised of the intended closure, along with the arrangements that will be in place to ensure continuation of their treatment.

### 11.2 Unplanned closures/emergency situations

There may be times when a CPOP pharmacy is unable to provide its usual service to clients due to emergency or disaster. In these circumstances, the following must be observed at the earliest opportunity:

1. The licence holder must advise PSB and CPP of the situation.
2. Dosing information should be provided to CPP where possible to assist with treatment transfer.
3. A notice must be placed in a prominent position at the pharmacy location advising clients to contact CPP for further treatment assistance.
4. The license holder of the pharmacy must provide CPP with a current mobile contact phone number, and maintain communication with regard to any changes in the situation.

CPP will advise clients when it is considered appropriate to return to the pharmacy, upon advice from the license holder.

### 11.3 Next Step Pharmacy support in emergency situations

Where an unplanned pharmacy closure occurs due to an unprecedented event, clients may be directed by CPP to attend the Next Step Pharmacy for supervised dosing.



## 12. Pharmacy Withdrawal from CPOP

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### 12.1 Notifications and exit administration requirements

It is essential that sufficient notice is provided by pharmacies wishing to withdraw part or all of their services from CPOP in order to ensure continued access to OST for clients.

When an authorised pharmacy with clients wishes to no longer participate in the Program:

1. The licence holder must advise PSB and CPP in writing at least one month prior to cessation of involvement with the Program. This will enable CPP to facilitate client transfers where necessary, and PSB to advise the wholesalers.
2. Ensure stock levels of methadone, Subutex and Suboxone in the pharmacy are minimal at the time of withdrawal from CPOP.
3. Contact PSB if advice regarding disposal of stock is required.

### 12.2 Client transfer arrangements

- Advise all clients to make arrangements to attend a new dosing pharmacy. Clients should then contact their CPOP prescriber to make the necessary administrative arrangements for transfer to the new pharmacy.
- Where a client is unable to locate a suitable alternative dosing site, they should be advised to contact CPP for advice.





## APPENDICES



<p><b>CPOP</b></p> <p><b>Patient Contract to Receive Opioid Substitution Treatment</b></p>	Name _____ Address _____ _____ Suburb _____ DOB _____
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I \_\_\_\_\_ (Name) consent to medication assisted treatment for opioid dependence. This involves treatment with methadone or buprenorphine, which will occur in consultation with my treating doctor and/or treatment team throughout the duration of my participation in the Community Program for Opioid Pharmacotherapy (CPOP).

**Objectives of Treatment**

The objectives of opioid substitution treatment are to:

- bring to an end or significantly reduce my opioid dependence
- reduce my risk of overdose
- reduce my risk of contracting and transmitting blood borne virus infections
- improve my physical, psychological and social wellbeing.

**Cautionary notes**

I understand the following:

- Treatment involves the use of a drug that causes physical dependence and can result in withdrawal symptoms if I stop or reduce my dose.
- There is a cost associated with daily dispensing, to be paid by me before each dose.
- There is a need to attend a pharmacy **each day for supervised dosing**, and the restrictions that this can impose on my life such as having the freedom to travel and work in certain locations.
- Providing my opioid medicine to others is illegal and could be dangerous to them.
- My details will be recorded as a Drug Dependent Person and included on the Register.

**I have received written information about the potential side-effects of these drug treatments and discussed the conditions associated with receiving this treatment.** I understand that it is my responsibility to advise my prescriber of any side-effects of treatment, and to inform any other doctor that I might attend that I am a client of CPOP. This will affect my access to prescription opioids without Health Department approval.

I have read and understood the treatment requirements, and understand it is my responsibility to be aware of the drug and alcohol policy of my employer.

I understand that my capacity to drive, operate machinery or work at heights during the early stages of treatment or following dose adjustments may be affected and that I am required to refrain from these activities at these times in treatment.

I understand that it is dangerous to combine methadone and buprenorphine with sedating drugs or medications such as other opioids, benzodiazepines, antipsychotics and alcohol. I understand that there is a risk of overdose from the combined effects that may result in death.

**Pregnancy**

I have been informed that there are risks associated with pharmacotherapy treatment during pregnancy so that in the event of planning or becoming pregnant, I must advise my prescribing doctor as soon as possible so that treatment options can be discussed and an appropriate treatment plan developed.

**Pharmacy Information**

I understand that I will need to find and attend a community pharmacy who will agree to provide supervised daily dosing *prior to commencement* of treatment. I understand that not all pharmacies participate in the Program and that I will be charged a dispensing fee for daily dosing, the cost of which is my responsibility.

Patient: \_\_\_\_\_ Date \_\_\_/\_\_\_/\_\_\_ Prescriber \_\_\_\_\_ Date \_\_\_/\_\_\_/\_\_\_

\* Copy to patient and original document filed with the clinical record.

## CPOP Patient Contract to Receive Opioid Substitution Treatment

### Why do I need to sign a treatment contract?

Both you and your doctor are subject to strict regulations when an opioid substitution treatment is prescribed.

Your doctor needs to get special approval from the Department of Health in order to prescribe opioid substitution medication. A treatment contract ensures that you understand what is expected from you when you take this type of medication and that you consent to the requirements described in this contract.

There needs to be good communication between you, your doctor, your dispenser and others involved in your opioid substitution treatment.

The doctor that prescribes your opioid substitution treatment is expected to:

- Comply with the *Western Australian Clinical Policies and Procedures for the use of Methadone and Buprenorphine in the Treatment of Opioid Dependence* as per the Poisons Regulations 1965.
- Prescribe the medicine safely and effectively.
- Arrange your appointments and prescriptions so that you do not run out of your medication.
- Regularly review your treatment plan with you.

In order to participate in CPOP it is expected that you will sign a treatment contract with both your doctor and your pharmacist. These contracts will list some important conditions that you will need to accept.

CPOP

Clinical Opiate Withdrawal Scale (COWS)

**Flow-sheet for measuring symptoms over a period of time during OST induction.**

For each item, write in the number that best describes the patient's signs or symptom. Rate on just the apparent relationship to opiate withdrawal. For example, if heart rate is increased because the patient was jogging just prior to assessment, the increase pulse rate would not add to the score.

Patient's Name: _____ Date: _____				
OST induction:				
Enter scores at time zero, 30min after first dose, 2hrs after first dose, etc.				
Times: _____				
<p><b>Resting Pulse Rate:</b> (record beats per minute)  <i>Measured after patient is sitting or lying for one minute</i>  <b>0</b> pulse rate 80 or below  <b>1</b> pulse rate 81–100  <b>2</b> pulse rate 101–120  <b>4</b> pulse rate greater than 120</p>				
<p><b>Sweating:</b> <i>over past ½ hour not accounted for by room temperature or patient activity.</i>  <b>0</b> no report of chills or flushing  <b>1</b> subjective report of chills or flushing  <b>2</b> flushed or observable moistness on face  <b>3</b> beads of sweat on brow or face  <b>4</b> sweat streaming off face</p>				
<p><b>Restlessness</b> <i>Observation during assessment</i>  <b>0</b> able to sit still  <b>1</b> reports difficulty sitting still, but is able to do so  <b>3</b> frequent shifting or extraneous movements of legs/arms  <b>5</b> Unable to sit still for more than a few seconds</p>				
<p><b>Pupil size</b>  <b>0</b> pupils pinned or normal size for room light  <b>1</b> pupils possibly larger than normal for room light  <b>2</b> pupils moderately dilated  <b>5</b> pupils so dilated that only the rim of the iris is visible</p>				
<p><b>Bone or Joint aches</b> <i>If patient was having pain previously, only the additional component attributed to opiates withdrawal is scored</i>  <b>0</b> not present  <b>1</b> mild diffuse discomfort  <b>2</b> patient reports severe diffuse aching of joints/muscles  <b>4</b> patient is rubbing joints or muscles and is unable to sit still because of discomfort</p>				

<p><b>Runny nose or tearing</b> <i>Not accounted for by cold symptoms or allergies</i></p> <p><b>0</b> not present</p> <p><b>1</b> nasal stuffiness or unusually moist eyes</p> <p><b>2</b> nose running or tearing</p> <p><b>4</b> nose constantly running or tears streaming down cheeks</p>				
<p><b>GI Upset:</b> <i>over last 1/2 hour</i></p> <p><b>0</b> no GI symptoms</p> <p><b>1</b> stomach cramps</p> <p><b>2</b> nausea or loose stool</p> <p><b>3</b> vomiting or diarrhea</p> <p><b>5</b> Multiple episodes of diarrhea or vomiting</p>				
<p><b>Tremor</b> <i>observation of outstretched hands</i></p> <p><b>0</b> No tremor</p> <p><b>1</b> tremor can be felt, but not observed</p> <p><b>2</b> slight tremor observable</p> <p><b>4</b> gross tremor or muscle twitching</p>				
<p><b>Yawning</b> <i>Observation during assessment</i></p> <p><b>0</b> no yawning</p> <p><b>1</b> yawning once or twice during assessment</p> <p><b>2</b> yawning three or more times during assessment</p> <p><b>4</b> yawning several times/minute</p>				
<p><b>Anxiety or Irritability</b></p> <p><b>0</b> none</p> <p><b>1</b> patient reports increasing irritability or anxiousness</p> <p><b>2</b> patient obviously irritable anxious</p> <p><b>4</b> patient so irritable or anxious that participation in the assessment is difficult</p>				
<p><b>Gooseflesh skin</b></p> <p><b>0</b> skin is smooth</p> <p><b>3</b> piloerection of skin can be felt or hairs standing up on arms</p> <p><b>5</b> prominent piloerection</p>				
<p><b>Total scores</b> <b>with observer's initials</b></p>				

**Score:**

**5–12 = mild;**

**13–24 = moderate;**

**25–36 = moderately severe;**

**more than 36 = severe withdrawal**

### Objective Opioid Withdrawal Scale (OOWS)

Name \_\_\_\_\_

Date \_\_\_\_\_ Time \_\_\_\_\_

**OBSERVE THE PATIENT DURING A  
5 MINUTE OBSERVATION PERIOD  
THEN INDICATE A SCORE FOR EACH OF THE OPIOID WITHDRAWAL SIGNS  
LISTED BELOW (ITEMS 1–13). ADD THE SCORES FOR EACH ITEM TO OBTAIN  
THE TOTAL SCORE**

	<b>SIGN</b>		<b>MEASURES</b>	<b>SCORE</b>
1	Yawning	0 = no yawns	1 = $\geq 1$ yawn	
2	Rhinorrhoea	0 = $< 3$ sniffs	1 = $\geq 3$ sniffs	
3	Piloerection (observe arm)	0 = absent	1 = present	
4	Perspiration	0 = absent	1 = present	
5	Lacrimation	0 = absent	1 = present	
6	Tremor (hands)	0 = absent	1 = present	
7	Mydriasis	0 = absent	1 = $\geq 3$ mm	
8	Hot and Cold flushes	0 = absent	1 = shivering/huddling for warmth	
9	Restlessness	0 = absent	1 = frequent shifts of position	
10	Vomiting	0 = absent	1 = present	
11	Muscle twitches	0 = absent	1 = present	
12	Abdominal cramps	0 = absent	1 = Holding stomach	
13	Anxiety	0 = absent	1 = mild – severe	
<b>TOTAL SCORE</b>				

Range 0–13

Handelsman, L., Cochrane, K.J., Aronson, M.J. et al. (1987) Two New Rating Scales for Opiate Withdrawal, *American Journal of Alcohol Abuse*, 13, 293-308.



### Subjective Opioid Withdrawal Scale (SOWS)

Name \_\_\_\_\_

Date \_\_\_\_\_ Time \_\_\_\_\_

		PLEASE SCORE EACH OF THE 16 ITEMS BELOW ACCORDING TO HOW YOU FEEL <b>NOW</b> (CIRCLE ONE NUMBER)					
	SYMPTOM	A LITTLE	NOT AT ALL	MODER- ATELY	QUITE A BIT	EXTREMELY	SCORE
1	I feel anxious	0	1	2	3	4	
2	I feel like yawning	0	1	2	3	4	
3	I am perspiring	0	1	2	3	4	
4	My eyes are teary	0	1	2	3	4	
5	My nose is running	0	1	2	3	4	
6	I have goosebumps	0	1	2	3	4	
7	I am shaking	0	1	2	3	4	
8	I have hot flushes	0	1	2	3	4	
9	I have cold flushes	0	1	2	3	4	
10	My bones and muscles ache	0	1	2	3	4	
11	I feel restless	0	1	2	3	4	
12	I feel nauseous	0	1	2	3	4	
13	I feel like vomiting	0	1	2	3	4	
14	My muscles twitch	0	1	2	3	4	
15	I have stomach cramps	0	1	2	3	4	
16	I feel like using now	0	1	2	3	4	
<b>TOTAL</b>							

Range 0–64. Handelsman, L., Cochrane, K.J., Aronson, M.J. et al. (1987)

Two New Rating Scales for Opiate Withdrawal, *American Journal of Alcohol Abuse*, 13, 293-308.



### Assessment of Acute Intoxication

Class of Drug	Intoxication	Overdose
<b>Opioids</b> (e.g. methadone, heroin, morphine)	Constriction of pupils Itching/scratching Sedation/somnolence Lowered blood pressure Slowed pulse Hypoventilation	Loss of consciousness Respiratory depression Pinpoint pupils Hypotension Bradycardia Pulmonary oedema
<b>Alcohol</b>	Relaxation Disinhibition Impaired coordination Impaired judgement Poor concentration Slurred speech Unsteady gait Vomiting	Nausea and vomiting Disorientation/confusion Respiratory depression Loss of consciousness Loss of bladder control
<b>Benzodiazepines</b> (e.g. diazepam, oxazepam, flunitrazepam)	Disinhibition Sedation Drooling Impaired coordination Slurred Speech Lowered blood pressure Unsteady gait	Stupor/coma Ataxia Confusion/disorientation Respiratory depression
<b>Stimulants</b> (e.g. amphetamines, cocaine)	Hyperactivity Restlessness Agitation Anxiety/nervousness Dilation of pupils Elevated blood pressure Increased pulse Raised temperature Sweating Tremor	Headache Panic attacks Acute paranoid psychosis Seizures Cardiac arrhythmias Myocardial ischaemia Hypertensive crisis Cerebrovascular accidents Hyperpyrexia Dehydration
<b>Cannabis</b>	Relaxation Poor concentration Impaired psychomotor performance Unsteady gait Red conjunctivitis	Paranoid psychosis Confusion Agitation Anxiety/panic attacks Hallucinations

### Signs and symptoms to look for/enquire about

Intoxication		Toxicity	
Slurred speech Unsteady gait Sedation Pupil constriction/dilation Conjunctival injection	Alcoholic foetor Disinhibition Drooling Restlessness Itching/scratching	Drowsiness Shallow breathing Poor circulation Increased temperature Slow or rapid pulse	Nausea and vomiting Headache Confusion Tremor Agitation Sweating

From NSW Methadone Maintenance Treatment Clinical Practice Guidelines. Used with permission.



### Patient consent to transfer to Buprenorphine from a Methadone dose greater than 40mg

I, \_\_\_\_\_ (full name) \_\_\_\_/\_\_\_\_/\_\_\_\_ (DOB) wish to undertake a transfer from methadone to buprenorphine treatment.

I have been taking \_\_\_\_\_ mg methadone since \_\_\_\_\_ (date of commencement of current dose).

In making this decision, I understand that:

- the procedure for transferring to buprenorphine from doses of methadone higher than 40mg is experimental
- there are risks associated with undertaking this transfer including the likelihood that I may experience significant withdrawal symptoms

I have chosen to undertake this transfer with \_\_\_\_\_ (name of prescribing doctor).

- The procedure for making the transfer and the risks associated with this procedure have been fully explained to me.
- I have been provided with written information about buprenorphine.

My last dose of methadone was \_\_\_\_\_ mg on \_\_\_\_\_ (date) at \_\_\_\_ : \_\_\_\_ am/pm at \_\_\_\_\_ (pharmacy).

My first dose of buprenorphine will be \_\_\_\_\_ mg on \_\_\_\_\_ (date) at \_\_\_\_ : \_\_\_\_ am/pm at \_\_\_\_\_ (pharmacy).

Client signature: \_\_\_\_\_ Date: \_\_\_\_ / \_\_\_\_ / \_\_\_\_  
Prescriber signature: \_\_\_\_\_ Date: \_\_\_\_ / \_\_\_\_ / \_\_\_\_  
Prescriber name: \_\_\_\_\_

(PLEASE USE BLOCK LETTERS)

**Attach completed form to the *Application to prescribe opioid substitution treatment* and fax to CPP on 94710444.**



## CPOP Pharmacotherapy Review Form

(To be completed 6 monthly as a minimum and filed with the patient record)

Date of Completion \_\_\_\_\_

### 1. Client Details

Surname \_\_\_\_\_ Given names \_\_\_\_\_

Address \_\_\_\_\_ P/code \_\_\_\_\_

Client contact no. \_\_\_\_\_

### 2. Consultation for this review with

- Pharmacist
- Counsellor/Case Manager
- Other \_\_\_\_\_

- Missed doses
- Presenting intoxicated
- Suspected/established diversion
- Payment issues
- Other concerns

### 3. Current Treatment

Methadone \_\_\_\_\_ mg  Suboxone \_\_\_\_\_ mg  Subutex \_\_\_\_\_ mg  Daily  2nd daily

- a) Current Pharmacy \_\_\_\_\_
- b) Length of time in continuous treatment \_\_\_\_\_
- c) Number of takeaway doses per week \_\_\_\_\_
- d) Prescribed and OTC medications \_\_\_\_\_  
\_\_\_\_\_
- e) Urine screen \_\_\_\_\_

### 4. Describe changes in:

- a) Physical health and mental wellbeing \_\_\_\_\_  
\_\_\_\_\_
- b) Use of opioid and other drugs (including alcohol) \_\_\_\_\_  
\_\_\_\_\_
- \*\*Use of illicit opioids reported in the past 4 week period?  Yes  No
- c) Hepatitis status/immunisation status \_\_\_\_\_
- d) Psychosocial situation \_\_\_\_\_  
\_\_\_\_\_
- e) Legal status \_\_\_\_\_  
\_\_\_\_\_
- f) Contraception/Pregnancy/Breastfeeding \_\_\_\_\_  
\_\_\_\_\_

**Review Summary**

Surname \_\_\_\_\_ Given names \_\_\_\_\_

Problem/Issue	Goals (e.g. Reduce symptoms, improve functioning)	Agreed actions/tasks for review period (e.g. Medication, referral to psychologist and/or psychologist)
1.		
2.		
3.		
4.		

**Proposed Treatment Plan**

*withdrawal = dose reduction to zero and termination of opioid substitution treatment*

- a) Client plans to continue maintenance treatment
- b) Client plans to commence withdrawal in the next 6 months
- c) Client has commenced a planned withdrawal

Referral to \_\_\_\_\_

Completed by \_\_\_\_\_ Designation \_\_\_\_\_

Date \_\_\_\_\_

Client signature \_\_\_\_\_ Date \_\_\_\_\_

(Provide copy to patient)

### CPOP Interstate/Overseas Travel Request

**CLIENT TO COMPLETE. (copy to client and to CPP for Client record)**

I, (Name) \_\_\_\_\_ DOB \_\_\_\_\_

of \_\_\_\_\_

am a client of the WA Community Program for Opioid Pharmacotherapy (CPOP). I am planning to transfer/travel to (*interstate/overseas destinations*) \_\_\_\_\_

\_\_\_\_\_

departing on \_\_\_\_\_ and returning to WA on \_\_\_\_\_.

***\*\*Attach copy of travel documents and itinerary.***

I am seeking the assistance of the Community Pharmacotherapy Program (CPP) in support of these travel arrangements, and understand that all assistance provided to me is offered in good faith. I understand that the Community Pharmacotherapy Program has no pre-existing arrangement or agreement with any overseas jurisdiction and provides no guarantee that arrangements will be successful.

I understand that it is my responsibility

- To contact the relevant consulate/s of the country/countries I intend to visit to ensure that it is legal to import prescribed opioid containing medications for my personal use.
- To comply with all customs and immigration requirements both in Australia and overseas.
- To comply with fluid restrictions on international flights to/from and within Australia.
- To obtain a letter/supporting documentation from my doctor attesting to my treatment.
- To provide accurate and up-to-date information about my travel plans.

The Community Pharmacotherapy Program does not accept responsibility for issues arising before, during or after the course of my travel. I understand that some overseas countries do not allow the importation of any prescribed opioid containing medications.

Applicant Signature \_\_\_\_\_ Date \_\_\_\_\_

Witness Signature \_\_\_\_\_ Date \_\_\_\_\_

Name of Witness \_\_\_\_\_ Designation \_\_\_\_\_



## Patient Consent for Buprenorphine (Subutex) Treatment During Pregnancy and Breastfeeding

I, (Name) \_\_\_\_\_ DOB \_\_\_\_\_

(Please tick the appropriate box)

**am** currently regularly taking buprenorphine for the management of my opioid dependence, and wish to continue treatment with buprenorphine during my pregnancy/period of breastfeeding, rather than:

- transfer to methadone, or
- withdraw from buprenorphine

**am not** currently receiving opioid substitution treatment. I wish to start treatment with buprenorphine for the management of my opioid dependence, rather than have treatment with methadone.

The risks and benefits of taking buprenorphine during pregnancy or when breastfeeding have been explained to me by my prescribing doctor.

In making this decision, I understand that:

- methadone is the recommended first-line opioid substitution treatment for opioid dependence in pregnancy/when breastfeeding
- the safety of buprenorphine during pregnancy or breastfeeding remains uncertain at this stage
- pregnancy and breastfeeding are currently listed as contraindications for the use of buprenorphine in Australia by the Therapeutic Goods Administration
- I will need to attend regularly (and as directed) for antenatal care at \_\_\_\_\_ Hospital
- I will need to attend regular appointments with my treatment team/prescribing doctor
- I give permission for my prescribing doctor to be notified of my outcome Yes  No
- I have been provided with written information about buprenorphine and my questions have been answered.

Patient's Signature: \_\_\_\_\_

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

Prescriber's Name: \_\_\_\_\_

(BLOCK LETTERS)

Prescriber's Signature: \_\_\_\_\_

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



Client Name \_\_\_\_\_ DOB \_\_\_\_\_

**CPOP Formal Warning**

Dear \_\_\_\_\_

This warning notice is issued further to the incident that occurred on (date) \_\_\_\_\_ at (location) \_\_\_\_\_.

**Notes regarding incident**

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**Management Plan**

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

You are advised that the above management plan has been activated, and you will be expected to comply with this plan as per the conditions of your continuing treatment at this Service.

Any future incidents that you are involved in while in treatment with this Service will result in a change in the conditions of your treatment. This may involve transfer to a more suitable treatment setting, an alternative treatment program or withdrawal from the Program.

If you have any questions regarding this notice, please discuss with me.

Yours faithfully

\_\_\_\_\_ Date \_\_\_\_\_

- Copies to: Client   
Client record   
CPP



### CPOP Pharmacy/Client Agreement

The following Agreement details the conditions associated with receiving Opioid Substitution Treatment at this dispensing site. Please initial the box against each point to ensure that you have read and understood each part of the Agreement.

- 1 Each dose of methadone or buprenorphine must be consumed under the pharmacist's supervision as per Program policy and prescription instructions. It is your responsibility to satisfy the pharmacist that the dose has been properly consumed before leaving the pharmacy. The pharmacist may request that you remain in full view and follow all instructions to satisfy them that you have taken the medication in the appropriate manner. The pharmacist can provide you with information on how to best take your medication to achieve maximum benefit.
- 2 Diversion of your **methadone or buprenorphine will result in restriction or cancellation** of dispensing and possible termination of treatment.
- 3 Medication will not be dispensed to you if the pharmacist believes that you may be under the influence of alcohol and/or drugs.
- 4 Vomited doses of **methadone or buprenorphine** will not be replaced unless the pharmacist has **seen** you vomit **and your prescriber authorises a replacement dose**.
- 5 You must attend for dosing at the **times nominated** by this dispensing site. If you present outside of these times you will not be dosed.
- 6 You can only be dosed at this site on the **days/dates** arranged by the prescriber in accordance with a **valid prescription**. It is important to **keep appointments** as scheduled by your prescriber. It is your responsibility to be aware of the dates and times of these appointments to continue dosing here.
- 7 If you miss more than two consecutive doses of your medication you cannot be dosed without the approval of your prescriber.
- 8 Takeaway doses can only be provided in accordance with WA CPOP policy and where a valid prescription authorises takeaway doses. Takeaway doses that are reportedly lost or stolen will not be replaced by the pharmacist.
- 9 Dispensing fees apply at this dispensing site. Accurate records of fee payments will be kept and the pharmacist can refuse to provide doses where fees cannot be paid. The pharmacist reserves the right to amend the charges relating to the provision of this service with 30 days notice being provided to you.

10 Rudeness, theft, disruptive or threatening behaviour **will result in restriction or cancellation** of dispensing and possible termination of treatment.

11 Any acts of violence, suspicion of **drug dealing or other criminal activity** on or within the vicinity of these premises will result in the police being called.

12 Should this dispensing site refuse to continue dosing you it is your responsibility to find another dispensing site, and to arrange for a new prescription from your prescriber. If you are unable to find another community dispensing site you will be required to commence a **withdrawal** [reduction] regime.

13 Prescriptions may be **faxed** to this dispensing outlet however the pharmacist requires the original prescription in order to dispense.

14 The pharmacist, prescriber, case manager (or other authorised health practitioner), the Department of Health and the Community Pharmacotherapy Program have authority to exchange information concerning my medical history, social wellbeing and/or any other relevant information related to my participation in this treatment Program.

**The pharmacist will endeavour to provide this service in a prompt and efficient manner and provide ongoing staff training to ensure the efficient provision of the CPOP service to you. If you are have any concerns or are experiencing any difficulties with your treatment please discuss these with your pharmacist, prescriber, staff at Community Pharmacotherapy Program (9219 1907) or the ORPACS worker at WASUA (9321 2877).**

The daily supervised dispensing fee for methadone/buprenorphine is \$ \_\_\_\_\_

The dispensing fee per supervised dose for alternate day dosing is \$ \_\_\_\_\_

The fee for takeaway doses of methadone/buprenorphine is \$ \_\_\_\_\_

SPECIAL TIMES/CONDITIONS AND/OR CHARGES RELATING TO THIS PHARMACY/DISPENSING SITE:

\_\_\_\_\_

\_\_\_\_\_

Client Signature \_\_\_\_\_ Date \_\_\_\_/\_\_\_\_/\_\_\_\_

Pharmacist Signature \_\_\_\_\_ Date \_\_\_\_/\_\_\_\_/\_\_\_\_

**A copy of this Agreement should be retained by both the pharmacist and the client.**

Date for review \_\_\_\_/\_\_\_\_/\_\_\_\_

<b>CPOP Pharmacy Transfer Notification</b>		Surname .....
		First Name .....
		Dob ...../...../..... Gender .....
<b>Prescriber Details</b>		
Name:		
Phone:		
Fax:		
<b>Pharmacy Details</b>		
Pharmacy Name:		
Phone:		
Fax:		
Reason for Transfer:		
Date of Last Dose:		Date Resuming Dose:
Current Script Cancelled		Y <input type="checkbox"/> N <input type="checkbox"/>
<b>New Pharmacy</b>		<b>Temporary</b> <input type="checkbox"/> <b>Permanent</b> <input type="checkbox"/>
Pharmacy Name:		
Phone:		
Fax:		
Date of First Dose:		Date of Last Dose:
Please Provide Photo ID for New Pharmacy		
<b>Fax to</b>		
Current Pharmacy		<input type="checkbox"/>
New Pharmacy		<input type="checkbox"/>
CPP		<input type="checkbox"/>
Prescriber Signature:		Date:
<b>Community Pharmacotherapy Program</b>		<b>Phone: 9219 1907 Fax: 9471 0444</b>
CPP Office Use Only	Fax DoH <input type="checkbox"/>	Database Updated <input type="checkbox"/>



<b>PHARMACY INCIDENT REPORT</b>  PHARMACY.....	CLIENT SURNAME .....
	FIRST NAME .....
	DOB ...../...../..... GENDER .....

**PHARMACY DETAILS**

Name \_\_\_\_\_

Pharmacy Address \_\_\_\_\_

Suburb \_\_\_\_\_ Postcode \_\_\_\_\_

Phone \_\_\_\_\_ Fax \_\_\_\_\_ Email \_\_\_\_\_

**DOSING DETAILS**

Pharmacotherapy \_\_\_\_\_ Dose \_\_\_\_\_

Prescribing GP \_\_\_\_\_ HDWA \_\_\_\_\_

**DATE OF INCIDENT** \_\_\_\_\_

Please be advised that the above client:

- |  |  |
|--|--|
| <input type="checkbox"/> is suspected of diversion             | <input type="checkbox"/> is suspected of stealing                          |
| <input type="checkbox"/> has been caught diverting             | <input type="checkbox"/> has been caught stealing                          |
| <input type="checkbox"/> has been verbally/physically abusive  | <input type="checkbox"/> has missed >2 daily doses in the past month       |
| <input type="checkbox"/> has presented in an intoxicated state | <input type="checkbox"/> has demonstrated behaviour indicating instability |
| <input type="checkbox"/> has payment issues at this pharmacy   | <input type="checkbox"/> <b>has been dosed in error</b>                    |

**OUTCOME**

- has been referred to the prescriber for review
- has been given a warning
- may no longer dose at the above pharmacy
- police called
- is banned from being on the premises of the above pharmacy (provide details below)
- Recommended Action Plan Guide** completed for all errors of medication

**DETAILS**

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

Pharmacist Name \_\_\_\_\_ Pharmacist Signature \_\_\_\_\_ Date of Report \_\_\_\_\_

**Fax a copy** of this Incident Report to CPP on (08) 9471 0444 **and Fax a copy** to the prescriber  
**Retain original in client record**



**Pharmacy Dosing Errors – Recommended Action Plan**

PHARMACY NAME \_\_\_\_\_ Phone \_\_\_\_\_ Fax \_\_\_\_\_  
 Contact Pharmacist (re incident) \_\_\_\_\_

CLIENT NAME \_\_\_\_\_  
 OST: Methadone/buprenorphine Auth/reg no: \_\_\_\_\_  
 Address \_\_\_\_\_ Phone \_\_\_\_\_  
 DOCTOR \_\_\_\_\_ Phone \_\_\_\_\_

DETAILS OF ERROR Dose prescribed: \_\_\_mg \_\_\_mL Dose dispensed: \_\_\_mg \_\_\_mL  
 Time client first dosed: \_\_\_\_\_ am/pm Second dosed (if double dosed): \_\_\_\_\_ am/pm  
 Time became aware of the error: \_\_\_\_\_ am/pm  
 Approx. 80% of methadone is absorbed after 15mins and peaks 4 hours after oral dosing.  
 Pharmacist supervising dosing \_\_\_\_\_  
 Staff present (for backup or support) \_\_\_\_\_

**ACTION GUIDE** Notify prescribing doctor/CAS yes/no \_\_\_\_\_  
**Action recommended by doctor** \_\_\_\_\_  
 Phone client directly if possible. Inform of situation and recommend client seeks medical attention by visiting the prescribing doctor or a hospital A&E service. Advise to stay in the company of others able to monitor any changes.  
**Time/s phoned:** \_\_\_\_\_ am/pm \_\_\_\_\_ am/pm \_\_\_\_\_ am/pm \_\_\_\_\_ am/pm other \_\_\_\_\_  
**Outcome:** \_\_\_\_\_  
**No phone:** Check current address. If practicable (with respect to time/distance/known habits), have a staff member visit.  
**Outcome:** \_\_\_\_\_  
**No phone/no fixed abode:** Contact any known close friends or relatives who will know the client's whereabouts \_\_\_\_\_  
**Police:** There may be some reluctance to involve the law, however the police are best placed to access information quickly (leading to a person's whereabouts), not usually available to the average citizen.  
 Station/Officer contacted: \_\_\_\_\_

**OUTCOME:** \_\_\_\_\_  
 \_\_\_\_\_

- CONTACT: CAS** on **9442 5042** if you are unsure how to manage the incident or have further concerns.  
 In **ANY cases of error:** PDL 1300 854 838
- FILE** this completed Action Plan with the client record.
- COMPLETE:** A Pharmacy Incident form **and Fax to:** CPP  the prescribing doctor



## Additional Service Contacts

### **Clinical Advisory Service (CAS)**

Telephone: 9442 5042

Toll Free: 1800 688 847

Fax: 9471 0444 (\*CPP)

Provides 24 hour support and advice on the management of community based methadone and buprenorphine clients.

### **Community Pharmacotherapy Program (CPP)**

Telephone: 9219 1907 or 9219 1913

Fax: 9471 0444

Provides telephone support, information and advice to clients, pharmacists and medical practitioners involved in methadone and buprenorphine treatment across metropolitan and regional WA. The Program offers information and advice to locate services, access treatment, and transfer between states and overseas. The Program also provides training and resources to medical practitioners and pharmacists who are, or who wish to become authorised to provide methadone and buprenorphine treatment in WA.

### **Alcohol and Drug Information Service (ADIS)**

Telephone: 9442 5000

Toll Free: 1800 198 024

The Alcohol and Drug Information Service (ADIS) is a 24-hour state-wide telephone service that provides counselling, information and referral for those concerned with their own or another person's misuse of alcohol and other drugs. ADIS also provides information and referral support to health professionals.

### **Parent Drug Information Service (PDIS)**

Telephone: 9442 5050

Toll Free: 1800 653 203

PDIS is a 24-hour state-wide telephone service that provides counselling, information and referral for parents and friends concerned with their own or another person's misuse of alcohol or other drugs. Support is offered to parents by trained parent volunteers who have had the experience of drug use in their own families.

### **Hepatitis WA**

Hepatitis WA (Inc) is a non-profit community-based organisation providing free services to the community. Hepatitis WA aims to assist in obtaining the best possible care and support for people affected by hepatitis, reducing discrimination and stigma directed at people living with viral hepatitis and raising community awareness in relation to hepatitis.

Office Telephone: (08) 9227 9800

Hepatitis Helpline: (08) 9328 8538 (Metro)  
1800 800 070 (Country)

Address: 187 Beaufort Street  
Northbridge. WA

Postal address: PO Box 8435  
Perth Business Centre. WA 6849

### Women and Newborn Drug and Alcohol Services (WANDAS)

WANDAS is a specialist team based at King Edward Memorial Hospital (KEMH), dedicated to caring for women experiencing drug and alcohol issues during pregnancy. The WANDAS team is made up of a number of health professionals including doctors, midwives, social workers, dieticians and mental health professionals.

Address: King Edward Memorial Hospital, 374 Bagot Road, Subiaco, WA 6008

Phone: (08) 9340 1582 or mobile 0414 892 753

### Next Step Specialist Drug and Alcohol Services

Provides specialist medical services to individuals through outpatient clinics located in Warwick, East Perth, Thornlie, Midland, Fremantle, and Rockingham.

#### East Metro Community Drug Service

Address: 32 Moore Street,

**East Perth, WA 6004**

Phone: (08) 9219 1919

#### North Metro Community Drug Service

Address: 26 Dugdale Street,

**Warwick, WA (main office) 6024**

PO Box 2587

Warwick WA 6024 (postal address)

Phone: (08) 9246 6767

Address: Lotteries House, 70 Davidson Terrace,

**Joondalup, WA 6027**

Phone: (08) 9246 6767

#### North East Metro Community Drug Service

Address: 4 Stafford St

**Midland, WA 6056**

Phone: (08) 9274 7055

#### South East Metro Community Drug Service

Address: 312 Spencer Road,

**Thornlie WA 6108**

Phone: (08) 9262 4000

#### South Metro Community Drug Service

Address: Level 3, 22 Queen Street,

**Fremantle, WA 6160**

Phone: (08) 9430 5966

Address: 22 Tuckey Street,

**Mandurah, WA 6210**

Phone: (08) 9581 4010

Address: Unit 3, 3 Goddard Street,

**Rockingham, WA 6168**

Phone: (08) 9529 2500

#### Drug and Alcohol Youth Service (DAYS)

Address: 129 Hill Street,

**East Perth, WA 6004**

Phone: (08) 9222 6300

**Medically supervised detoxification** from alcohol, heroin and other opioids is provided through the Inpatient Withdrawal Unit (IPWU) located at the East Perth site. Non-government service partnerships enable the planned transfer of detoxified patients to residential rehabilitation programs when needed.

### Western Australian Substance Users Association Inc. (WASUA)

Telephone: 9321 2877

Fax: 9321 4877

Address: 519 Murray St  
Perth. WA 6005

### **Opiate Replacement Pharmacotherapy Advocacy and Complaints Service (ORPACS)**

A service offered through WASUA to assist people on a pharmacotherapy with any concerns they have about their treatment.

Telephone: 9321 2877

### **Pharmaceutical Services Branch**

The Pharmaceutical Services Branch of the WA Department of Health provides advice, develops policy and administers regulatory controls for medicines including drugs of dependence (Schedule 8 medicines), therapeutic goods and poisons in Western Australia. The Pharmaceutical Services branch is responsible for the administration of the Poisons Act 1964 and the Poisons Regulations 1965.

### **CPOP Management**

Telephone: 9222 6812

### **Drugs of Dependence Health Professionals Contact Line** – Telephone: 9222 4424

Address: PO Box 8172, Perth Business Centre, Perth, WA, 6849

### **Prescription Shopping Information Service (PSIS)**

Medicare Australia offers access (24 hours a day/7 days a week) to information and advice through the Prescription Shopping Information Service.

To meet strict privacy conditions, individual medical practitioners must register before they may use the service.

PSIS – Telephone: 1800 631 181



## Websites

### Adverse Drug reporting form (ADRAC) and information

<http://www.tga.gov.au/pdf/forms/problem-medicine-forms-bluecard.pdf>

### Australian Health Practitioner Regulation Agency (AHPRA)

<http://www.ahpra.gov.au>

### Department of Health

<http://www.health.wa.gov.au>

### Pharmaceutical Services Branch

[http://www.public.health.wa.gov.au/2/1084/2/community\\_program\\_for\\_opioid\\_pharmacotherapy\\_cpop.pm](http://www.public.health.wa.gov.au/2/1084/2/community_program_for_opioid_pharmacotherapy_cpop.pm)

- WA Poisons Act 1964
- WA Regulations 1965
- WA CPOP Policies and Procedures

## Forms

- Application to be authorised as a Community Program for Opioid Pharmacotherapy (CPOP) Prescriber
- Application to Prescribe Opioid Substitution Treatment
- Application for a Pharmacy to Participate in the Community Program for Opioid Pharmacotherapy (CPOP)
- Application to prescribe high dose opioid substitution treatment
- Termination of Opioid Substitution Treatment

### Drug and Alcohol Office

<http://www.dao.health.wa.gov.au>

### Community Pharmacotherapy Program

<http://www.dao.health.wa.gov.au/Home/Professionals/CommunityPharmacotherapyProgram.aspx>

- WA CPOP Policies and Procedures
- CPOP Interstate/Overseas Travel Disclaimer Form
- CPOP Takeaway Dose Application and Agreement
- Consent form for transfer of treatment from high dose methadone dose greater than 40mg to buprenorphine
- Client Dosing Sheet

### Hepatitis WA

<http://www.hepatitiswa.com.au/>

### Pharmacy Guild of WA

[http://www.guild.org.au/WA\\_Branch](http://www.guild.org.au/WA_Branch)

### Pharmacy Society

<http://www.pswa.org.au>

### Western Australian Substance Users Association Inc. (WASUA)

<http://www.wasua.com.au/>



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