

Tasmanian Opioid Pharmacotherapy Program

Policy and Clinical Practice Standards

Title:	Tasmanian Opioid Pharmacotherapy Program, Policy and Clinical Practice Standards
Summary:	To provide contemporary policy and clinical practice standards for the delivery of opioid pharmacotherapy for the treatment of opioid dependence in Tasmania.
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- Department of Health, Western Australia Government and the Drug and Alcohol Office, (2006). Clinical policies and procedures for the use of methadone and Buprenorphine in the treatment of opioid dependence.
- Department of Human Services, Victoria, Drugs Policy and Services Branch, (2006). Policy for Maintenance Pharmacotherapy for Opioid Dependence.
- Queensland Health, (2008). Queensland Opioid Treatment Program Clinical Guidelines.
- The New South Wales (NSW) Department of Health, (2006). NSW Opioid Treatment Program, Clinical guidelines for methadone and buprenorphine treatment of opioid dependence.
- Workplace Instructions, Alcohol Tobacco and Other Drug Service, Gold Coast Health Services District, Queensland Health.
- Department of Health and Ageing, (1997). National Methadone Policy.
- Department of Health and Ageing, (2001). National Buprenorphine Policy.

The policy and clinical practice standards have been developed based upon evidence from the research literature, consultation with clinicians, the alcohol and other drug sector; peak bodies; advocacy groups (including individuals and their families receiving treatment); and independent overseeing bodies.

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CONTENTS

1	Epidemiology of opioid use in Tasmania	11
1.1	Overview	12
1.2	The Tasmanian perspective	13
2	Clinical features of opioid dependence, withdrawal and overdose	15
2.1	Definition of opioid dependence	16
2.2	Signs and symptoms of opioid withdrawal, intoxication and overdose	17
2.3	Definition of opioid withdrawal	17
2.4	Opioid intoxication and overdose	18
2.5	Implications for the current guidelines	19
3	Policy framework	21
3.1	Principles of harm minimisation	22
3.2	Biopsychosocial approach	22
3.3	Psychosocial interventions	23
3.4	Case management	24
3.5	Client self-determination	24
3.6	Evidence based practice	24
3.7	Risk management	25
3.8	Rationale for opioid pharmacotherapy	25
3.9	Aims of opioid pharmacotherapy treatment	26
3.10	Priority access	26
3.11	Evidence for effectiveness of various opioid pharmacotherapies	27
3.12	Key principles for effective treatment	27
3.13	Effective treating teams	28
3.14	Collaborative practice	29
3.15	How opioid pharmacotherapy is provided in Tasmania	29
3.16	Shared care model	30
3.17	Tasmanian shared care model	31
4	Clinical pharmacology	33
4.1	Basic opioid pharmacology	34
4.2	Methadone	35
4.3	Buprenorphine	39
4.4	Indication for opioid pharmacotherapy	44
4.5	General contraindications and precautions for opioid pharmacotherapy	44
4.6	Comparing treatment options	46
4.7	Gateway Model – Buprenorphine as induction agent of choice	50
5	Assessment for entry into the Opioid Pharmacotherapy Program	51
5.1	Assessment	52
5.2	Patient examination guidelines	52

5.3	Initial assessment	53
5.4	Substance use history	54
5.5	Past medical history	55
5.6	Psychological and psychiatric history	56
5.7	Social history	56
5.8	Family history	57
5.9	Pregnancy and breastfeeding	58
5.10	Allergies	58
5.11	Clinical examination	58
5.12	Investigations	59
5.13	Urine drug screening (UDS) during assessment	59
5.14	Collateral information	60
5.15	Summary and formulation	60
5.16	Additional consideration – harm reduction advice	61
6	Entry into opioid pharmacotherapy	63
6.1	Preparing the patient	64
6.2	Request for second opinion	68
6.3	Requirements for entry into treatment: administrative procedures	69
6.4	Alcohol and drug services treatment agreement	74
6.5	Creating a patient file	74
6.6	Information pack	74
7	Safe treatment induction	75
7.1	Induction to opioid treatment	76
7.2	Induction to methadone pharmacotherapy	77
7.3	Induction to buprenorphine pharmacotherapy	81
7.4	Alternative treatment options	84
7.5	Patient reviews	84
7.6	Dosing location	85
7.7	Methadone and buprenorphine dosing procedure	85
7.8	Moving to maintenance	86
8	Maintenance treatment	87
8.1	Methadone	89
8.2	Buprenorphine	90
8.3	Adjustments to prescriptions	90
8.4	Ongoing review	91
8.5	Urine drug screening during maintenance	91
8.6	Takeaway doses: general considerations	92
8.7	Methadone takeaway doses	95
8.8	Buprenorphine dosing schedules and takeaway doses	97
8.9	Missed doses	101
8.10	Lost or stolen doses	106

8.11	Vomited doses	107
8.12	Continued use of other drugs	107
8.13	Transferring between treatment agents	108
9	Completing treatment	III
9.1	Planned and voluntary withdrawal from opioid pharmacotherapy	112
9.2	Withdrawal from treatment plan	112
9.3	Rapid withdrawal from opioid pharmacotherapy	116
9.4	Avoiding secondary problems with alcohol, sedative or hypnotic drugs	117
9.5	Exiting patients	117
10	Psychosocial interventions in opioid pharmacotherapy	119
10.1	Psychosocial and social issues in substance use	120
10.2	Benefits of including psychosocial interventions	121
10.3	Types of psychosocial interventions in opioid pharmacotherapy	121
10.4	Case management	124
10.5	Other psychosocial interventions	126
10.6	Applying psychosocial interventions across the pharmacotherapy treatment spectrum	126
10.7	Providing psychosocial interventions	128
II	Specific population groups	129
II.1	Comorbid mental health disorders	130
II.2	Cognitive impairment	133
II.3	Working with families and significant others	133
II.4	Female clients	134
II.5	Pregnancy	134
II.6	Management of neonatal care	139
II.7	Blood-borne viruses	141
II.8	Culturally sensitive practice	142
II.9	Young people	144
II.10	Recently released prisoners	145
II.11	Older persons	146
12	Managing complex presentations	147
12.1	Consultation and liaison services	149
12.2	Managing hospitalised clients with opioid dependence	149
12.3	Persistent pain	152
12.4	Therapeutic dependence	153
12.5	Section 59E: addiction medicine review	154
12.6	Sudden cessation of opioid pharmacotherapy	156
12.7	Managing aggression and threatening behaviour	156
12.8	Continued high risk drug use and polysubstance use	158
12.9	Drug dependent behaviours	160
12.10	Involuntary discharge from the opioid pharmacotherapy program	164

12.11	Public safety issues	165
12.12	Managing overdose	167
12.13	Boundary violation and boundary crossing	167
12.14	Professional reporting	168
13	Transfers	169
13.1	Prescribing across Australian jurisdictions	170
13.2	Unsanctioned transfers	170
13.3	Clients travelling to Tasmania	171
13.4	Intrastate transfers of Tasmanian opioid pharmacotherapy clients	174
13.5	Interstate transfers of Tasmanian opioid pharmacotherapy clients	176
13.6	Overseas travel	179
13.7	Transfer of dosing location	180
14	Legislative requirements	183
14.1	<i>Poisons Act 1971</i>	184
14.2	<i>Alcohol and Drug Dependence Act 1968</i>	185
14.3	<i>Mental Health Act 1996</i>	185
14.4	<i>Misuse of Drugs Act 2001</i>	186
14.5	<i>Guardianship Administration Act 1995</i>	186
14.6	<i>Children, Young Persons and Their Families Act 1997</i>	187
14.7	<i>Family Violence Act 2004</i>	188
14.8	<i>Personal Information Protection Act 2004</i>	188
14.9	<i>Right to Information Act 2010</i>	189
14.10	<i>Firearms Act 1996</i>	190
14.11	<i>Vehicle and Traffic Act 1999</i>	191
14.12	<i>Health Practitioners Regulation National Law (Tasmania) Act 2010</i>	191
15	Prescriber training and authorisation	193
15.1	Process of prescriber authorisation	194
15.2	Regulations relating to pharmacotherapy prescribing	195
16	Pharmacy instructions	199
16.1	Approval and accreditation to dose	201
16.2	Patient orientation to a community pharmacy	203
16.3	Dosing procedure	203
16.4	Regulatory requirements	209
16.5	Dosing errors	211
16.6	Dosing challenges	212
16.7	Financial considerations	218
16.8	Documentation	219
Acronyms		221
References		223

Figures

Figure 3.1	Biopsychosocial theoretical model (Engel, 1977)	23
Figure 4.1	Opiate agonist effects of full agonists, partial agonists and antagonists	34
Figure 4.2	Methadone molecule	35
Figure 4.3	Buprenorphine molecule	40
Figure 7.1	Plasma concentration after a single dose of oral methadone	79
Figure 7.2	Plasma concentration after three daily doses on oral methadone	80
Figure 7.3	Plasma concentration once steady state achieved on oral methadone	80
Figure 8.1	Three day recovery to steady state from missed dose at day 10	101
Figure 10.1	Tasmanian alcohol & drug service pharmacotherapy services delivery model: phases of opioid pharmacotherapy	126
Figure 12.1	Section 59E Model	155
Figure 15.1	Prescribing S8 opioids and drugs of dependence quick reference guide	196
Figure 16.1	Example of takeaway dose label	207

Tables

Table 2.1	Signs and symptoms of opioid withdrawal, intoxication and overdose	17
Table 4.1	Summary of Methadone Pharmacokinetics	36
Table 4.2	Effects of methadone	37
Table 4.3	Summary of buprenorphine pharmacokinetics	40
Table 4.4	Summary of the pharmacological and clinical properties of buprenorphine	42
Table 4.5	Pharmacological comparisons between methadone and buprenorphine	46
Table 8.1	Guidelines for methadone dosing and authorisation at various doses	89
Table 8.2	Guidelines for the provision of methadone takeaway doses	96
Table 8.3	Guidelines for buprenorphine takeaway doses for patients on daily dosing schedules	99
Table 9.1	Recommended methadone dose reductions	114
Table 9.2	Recommended buprenorphine dose reductions	114
Table 9.3	Suggested dosing regimen for rapid withdrawal from methadone	116
Table 9.4	Suggested dosing regimen for rapid withdrawal from buprenorphine	117

Appendices

Appendix 1	Possible Drug Interactions with Methadone	237
Appendix 2	Medications Metabolised by Cytochrome	241
Appendix 3	Possible Drug Interactions with Buprenorphine or Buprenorphine-Naloxone	242
Appendix 4	ADS Clients Rights and Responsibilities Brochure	243
Appendix 5	ADS Pharmacotherapy Treatment Agreement	245
Appendix 6	ADS Opioid Pharmacotherapy Program Confidential Client Identification Form	247
Appendix 7	ADS Clinical Opiate Withdrawal Scale (COWS)	249
Appendix 8	ADS Pharmacotherapy Takeaway Dose Risk Assessment Plan	250
Appendix 9	ADS Takeaway Medication Agreement	252
Appendix 10	Fact Sheet: Naltrexone	253
Appendix 11	Neonatal Withdrawal Scoring Instrument (Finnegan Scale)	254
Appendix 12	ADS Benzodiazepine Reduction Agreement	255
Appendix 13	Notice of Drug Dependency and Application for an Authority to Administer, Prescribe or Supply Buprenorphine/Methadone for Opioid Pharmacotherapy - Under Section 59E Poisons Act 1971	256
Appendix 14	Notice of Termination of Methadone/ Buprenorphine/Suboxone/Subutex Prescribing	257
Appendix 15	Pharmacy – Client Contract	258
Appendix 16	Assessment of Acute Intoxication	260
Appendix 17	Withdrawal States from Commonly Used Drugs	262
Appendix 18	ADS Opioid Pharmacotherapy Did Not Dose Form	263



FOREWORD



For many individuals and their families in Tasmania, opioid dependence and illicit opioid use has had a very significant impact on their quality of life. The health, social and economic costs for individuals, families and the community are wide-ranging and include overdose deaths, family breakdown, blood borne viruses, psychological distress, workplace absenteeism, and the costs associated with law enforcement and drug related crime. It is well established that opioid pharmacotherapy treatment is effective in reducing drug use and the physical, emotional and social harms associated with opioid dependence use.

Access to opioid pharmacotherapy assists individuals to stabilise their lives, to improve their physical and mental health, and their social functioning and relationships. The regulatory structures of this treatment program allow for the re-establishment of routine activities of daily living. Over time, and with continued participation in treatment, individuals are able to re-establish control over their lives and to make meaningful contributions to the community. This important document will ensure that individuals and their families affected by opioid dependence will receive high quality, contemporary, safe and effective treatment that will assist them to improve their quality of life.

A great deal has changed in Tasmania since 2000 when the Tasmanian Methadone Policy 2000 was published and nationally, in terms of the nature of drug use and drug-related harms. In addition, there is a large body of evidence to guide the delivery of treatment for opioid dependence.

The introduction of buprenorphine has expanded the range of opioid pharmacotherapy treatment options available and treatment has evolved in relation to the way in which it can most safely and efficaciously be delivered. The clinical intersection between opioid dependence and persistent pain has had a significant impact on drug use and on the scope of practice of those working in the alcohol and other drugs field.

The development of closer working relationships between clinicians working in the specialties of addiction and pain has been necessary. While the need for a close clinical intersection with mental health services is well recognised, there is growing recognition that comorbidity among people presenting to alcohol and drug services extends beyond the purview of mental health services to include emergency medicine, internal medicine, obstetrics, paediatrics, surgery, rehabilitation medicine, public health, population health and most importantly, primary health care.

The Tasmanian Opioid Pharmacotherapy Program, Policy and Clinical Practice Standards 2012 (TOPP) inform the treatment of opioid dependence with methadone and buprenorphine. This document has been developed based on contemporary evidence and national and jurisdictional clinical policies and guidelines for the use of methadone, buprenorphine and naltrexone in the treatment of opioid dependence. The TOPP focuses on both methadone and buprenorphine pharmacotherapies. Buprenorphine includes Subutex® and both formulations of Suboxone® (sublingual film and tablet).

The TOPP's development has taken into account the local circumstances and needs of Tasmanians including epidemiological data, the patterns and types of opioid drug use in Tasmania, documented public health and clinical safety issues, and legislative, regulatory, and administrative requirements.



This document provides the policy framework and clinical practice standards for the treatment of opioid dependence in Tasmania. Alcohol and Drug Services and private practitioners offering opioid pharmacotherapy should provide this treatment in a manner consistent with the Tasmanian Opioid Pharmacotherapy Program, Policy and Clinical Practice Standards (2012).

While this document provides detailed clinical standards for the delivery of treatment, it cannot address every clinical situation. To assist in the management of complex clinical issues, it is strongly recommended that clinicians seek specialist advice from the Alcohol and Drug Service. Individual clinicians (i.e. medical practitioners, pharmacists, nurses and allied health professionals) are responsible for the safety and effectiveness of treatment provided for each patient.

In reviewing the TOPP the reader should be aware of the use of certain terms and concepts that are specific to this document. The terms 'patient' and 'client' are used interchangeably throughout this document, in recognition of the multidisciplinary approach to the delivery of opioid pharmacotherapy. The term patient is used in sections that relate primarily to the medical aspects of opioid pharmacotherapy treatment and the term client is used in those sections that reflect psychosocial interventions and approaches.

As a consequence of a number of significant public and clinical safety issues that have been identified in Tasmania, this document has an emphasis on the identification and management of clinical risks. As a result, the clinical and policy approach of the TOPP is necessarily conservative.

In some sections of the TOPP the emphasis on the management of clinical risks may be construed by some readers as the adoption of an abstinence model in the treatment of opioid dependence. However, this emphasis on risk management does not negate harm reduction as the fundamental construct that underpins the TOPP. The document incorporates both harm reduction and risk management approaches. The term 'harm reduction' for the purpose of this document refers to specific strategies for reducing drug related harm, particularly for patients of the Tasmania Opioid Pharmacotherapy Program, or patients receiving opioids from their physicians. In this instance harm reduction does not exclude the reduction or cessation of use of drugs of concern as a potential outcome of therapeutic strategies.



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SECTION: I

Epidemiology of opioid use in Tasmania

In this section you will...

- Gain an overview of opioid use and the associated risks to individuals and the community;
- Obtain specific Tasmanian statistics in relation to opioid use and prescription rates; and
- Acquire information on mortality related to the use of pharmaceutical opioids in Tasmania.

I	Epidemiology of opioid use in Tasmania	I2
I.1	Overview	I2
I.2	The Tasmanian perspective	I3
I.2.1	Prescription dispensing rates	I3
I.2.2	Mortality related to use of pharmaceutical opioids	I4

Section: I

I Epidemiology of opioid use in Tasmania

I.1 Overview

Long acting oral forms of opioid analgesics have been increasingly used in Australia since the early 1990s for the treatment of persistent non-malignant pain, such as back pain (The Royal Australian College of Physicians, 2009). Examples of these analgesics include morphine, oxycodone, Phseptone, and methadone syrup. Persistent pain is very common in the community and prescriptions for opioid analgesics have increased substantially since 1992, both nationally and in Tasmania (RACP, 2009). In Australia between 1990 and 2006 there was a 40 fold increase in oral morphine supply; and between 1990 and 2003, a 4 fold increase in oxycodone supply (RACP, 2009). More detailed discussion and contemporary data may be found in the Tasmanian Review of Opioid Prescribing (conducted by National Drug and Alcohol Research Centre (NDARC), University of New South Wales: www.ndarc.med.unsw.edu.au) and the National Pharmaceutical Drug Misuse Strategy conducted by the Natinoal Centre for Education and Training on Addiction (NCETA): www.nceta.flinders.edu.au) both these reports are due for release in 2012.

While these increases in prescription rates have contributed to better management of pain, prescription opioid analgesics are highly addictive and can lead to opioid dependence (RACP, 2009). Opioid dependence is a persistent, relapsing condition, requiring substantial and costly treatment (van den Brink & Hassen, 2006).

Opioid dependence is a persistent, relapsing condition, requiring substantial and costly treatment.

Furthermore, the risks associated with opioid dependence can significantly impact on the biological, psychological, and social health of individual patients, their family, and the community.

Some of the widely documented risks associated with opioid dependence include:

- premature death in comparison to non using peers, including:
 - death through intentional or unintentional overdose;
 - death through intentional or unintentional combination with other drugs;
 - death due to inappropriate mode of administration;
- damage to, or loss of limbs due to complications arising from intravenous administration of oral preparations;
- transmission of blood-borne viruses such as HIV, Hepatitis B and C;
- localised and systemic infections, such as septicaemia, due to non-sterile injection practices;
- motor vehicle, domestic, and workplace accidents;
- diversion of prescription opioids to the illicit market;
- unemployment;
- forensic issues; and
- socio-economic disadvantage.

The risks associated with opioid dependence can significantly impact on the biological, psychological, and social health of individual patients, their family, and the community.

Finally, alcohol and benzodiazepines are often implicated in opioid related deaths, making the combination of alcohol and prescription or illicit opioids a particularly risky behaviour.

1.2 The Tasmanian perspective

Traditionally, very little heroin use has been reported in Tasmania. The 1998 to 2007 National Drug Strategy Household Surveys (NDSHS) (AIHW, 1999, 2002a & b, 2005a & b & 2008a & b) reported between 0.1% and 0.5% of the Tasmanian population had used heroin in the 12 months preceding the interview, compared with between 0.2% and 0.8% of the national population that had used heroin.

Amongst participants in the Illicit Drug Reporting System (IDRS), an annual study monitoring drug use trends amongst people who inject drugs (PWID), heroin use in Tasmania was uncommon. Between 2004 and 2010, 5% to 19% of the samples reported use of heroin in the six months preceding the interview, compared with 56% to 69% nationally. In addition, data from the Tasmanian Needle and Syringe Program (NSP) show 0.4% to 1.1% of transactions between 2003/04 and 2009/10 were for heroin (de Graaff & Bruno, 2011). Treatment episodes in Tasmania noting heroin as the principal drug of concern also remained very low over this period, with less than 1% reported between 2003/04 and 2008/09; notably lower than the national rate of 10.3% in 2008/09 (Australian Institute of Health and Welfare, 2004-2010).

Higher rates of pharmaceutical opioid use have been reported in jurisdictions such as Tasmania and the Northern Territory where there has been an extended period of low availability of heroin (Degenhardt et al., 2006). According to the 2001 to 2007 NDSHS reports (AIHW, 2002a & b, 2005c & 2008 a & b), between 0.4% and 0.7% of the Tasmanian population reported use of a pharmaceutical opioid in the preceding 12 months (excluding heroin and methadone), whilst nationally, this rate was between 0.2% and 0.3% of the population. In the 2004 to 2010 IDRS surveys, the rates of Tasmanian participants reporting use of pharmaceutical opioids such as morphine and oxycodone

were higher than reported for the national samples of these studies (Stafford & Burns, 2011). In addition, in 2008/09, 6.4% of treatment episodes noted morphine as the principal drug of concern, whereas nationally this rate was just 1.4% (AIHW, 2010).

Multiple data sources indicate that use of heroin in Tasmania is relatively uncommon, whilst use of pharmaceutical opioids is more widely reported. Therefore, this document will focus on issues associated with pharmaceutical opioids. While much of the information regarding diagnosis and treatment of heroin and pharmaceutical opioids will overlap, further information regarding treatment and management of heroin dependence can be found in O'Brien (2004).

The use of heroin in Tasmania is relatively uncommon, whilst use of pharmaceutical opioids is more widely reported.

This document will focus on issues associated with pharmaceutical opioids.

1.2.1 Prescription dispensing rates

In this section the term 'prescriptions' refers to dispensed prescriptions, and the data presented is consumption data based on prescriptions actually filled and then calculated per 1,000 persons. Increases in rates of dispensed prescriptions (in this section the term 'prescriptions' refers to dispensed prescriptions, the data presented is consumption data based on prescriptions actually filled and then calculated per 1,000 persons) for pharmaceutical opioids have been noted in both Tasmania and Australia, however, there has been considerable variability. The rate of Tasmanian consumption of morphine per 1,000 persons was consistently 110% or more of the national average between 1991 and 2007. In 2008 and 2009, the Tasmanian consumption rate decreased, resulting in the local rate matching the national rate (de Graaff & Bruno, 2011).



Both national and Tasmanian prescription rates for oxycodone have increased substantially since 2000. This increase has been particularly rapid in Tasmania, with an eight-fold increase occurring between 2000 and 2009. In 2009, consumption of oxycodone in Tasmania was similar to the national rate (109% of the national average) (de Graaff & Bruno, 2011).

Tasmanian prescription rates per 1,000 persons for methadone syrup have been consistently below the national rate (with the exception of 2003), however prescription rates for the tablet form of methadone (Physeptone) have been consistently above 200% that of the national average since 1995. In 2006, prescribing rates for Physeptone reached a peak of 278% (de Graaff & Bruno, 2011). Evidence from the PSB and ADS clinical reviews suggests that methadone tablets are regularly prescribed to patients under the PSB who would be more appropriately managed on the Tasmanian Opioid Pharmacotherapy Program (OPP).

When combining trends for both forms of methadone, consumption per 1,000 persons in Tasmania remained above that of the Australian rate between 2003 and 2007. In the subsequent two years this trend was reversed and in 2009 the Tasmanian rate was 87.86% of the national rate (de Graaff & Bruno, 2011). One explanation for this is the marked increase in consumption of buprenorphine (all forms) in Tasmania from 2008.

It is important to note that in 2009 Tasmanian population rates for the consumption of methadone syrup stabilised and were 72% of the national average. However, the rates for Physeptone were still high at 243% of the national average (de Graaff & Bruno, 2011).

1.2.2 Mortality related to use of pharmaceutical opioids

The number of opioid-related deaths in Tasmania is of particular concern. In 2007, the Pharmaceutical Benefits Scheme identified 33 deaths associated with opioid use or misuse. A review conducted by McKeown (2005) identified 86 prescription opioid-related deaths between 2001 and 2005 in Tasmania. The average age of death was 38.6 years; thus many of these people died well before experiencing significant age-related health factors. The Tasmanian Coroner confirmed concurrent use of benzodiazepines in many of these cases, with factors associated with drug-seeking behaviour or drug dependence (including alcohol) present in all of the deaths.

While many patients appropriately access opioids through their prescribing doctors, there is clinical and anecdotal evidence, from the IDRS and reports to ADS staff in Tasmania, that many pharmaceutical drugs are also being diverted and traded illicitly. According to anecdotal evidence provided to ADS staff, some of these drugs are being sourced from patients' primary GPs. This creates dilemmas for doctors when deciding which patients are suitable for, and may benefit from, prescription opioids, and which patients are at risk of diverting or using these opioids in a manner for which they were not prescribed. While this dilemma is not unique to the prescription of opioids, it does indicate that thorough guidelines and recommendations for the prescription of opioids are required. This includes policy and clinical practice standards for the delivery of opioid pharmacotherapies.



SECTION: 2

Clinical features of opioid dependence, withdrawal and overdose

In this section you will:

- Gain an understanding of opioid dependence, withdrawal, intoxication and overdose; and
- Learn the implications for the Tasmanian Opioid Pharmacotherapy Program.

2	Clinical features of opioid dependence	16
2.1	Definition of opioid dependence	16
2.2	Signs and symptoms of opioid withdrawal, intoxication and overdose	17
2.3	Definition of opioid withdrawal	17
2.4	Opioid intoxication and overdose	18
2.5	Implications for the current guidelines	19

Section: 2

2 Clinical features of opioid dependence

This section will outline the diagnostic criteria and key clinical features of opioid dependence and withdrawal, intoxication and the risks associated with misuse of pharmaceutical opioids.

2.1 Definition of opioid dependence

According to the fourth edition of the Diagnostic and Statistical Manual of Mental Disorders (DSM-IV-TR, 2000), substance dependence occurs when an individual continues using a substance despite it having a significantly negative effect on his or her life, including functional impairment and emotional distress.

Diagnosis occurs when at least three of the following physiological, cognitive, or behavioural symptoms are present within a 12 month period (DSM-IV-TR (2000, p. 179):

- (1) Tolerance, as defined by either of the following:
 - (a) a need for markedly increased amounts of the substance to achieve intoxication or desired effect;
 - (b) markedly diminished effect with continued use of the same amount of substance.
- (2) Withdrawal, as manifested by either of the following:
 - (a) a characteristic withdrawal syndrome for the substance; or
 - (b) the same (or closely related) substance is taken to relieve or avoid withdrawal symptoms.
- (3) The substance is often taken in larger amounts over a longer period than was intended;
- (4) There is a persistent desire or unsuccessful efforts to cut down or control substance use;

- (5) A great deal of time is spent in activities necessary to obtain the substance, use the substance, or recover from its effects;
- (6) Important social, occupational, or recreational activities are given up or reduced because of substance use; or
- (7) The substance use is continued despite knowledge of having had a persistent or recurrent physical or psychological problem that is likely to have been caused or exacerbated by the substance.

Substance dependence occurs when an individual continues using a substance despite it having a significantly negative effect on his or her life, including functional impairment and emotional distress.

While the official definition of opioid dependence, referenced above, is the same as for all other classes of substance dependence, opioid dependence is frequently associated with rapidly developed and significant levels of tolerance, making it a highly addictive class of drugs. Drugs in this category include prescription opioids such as morphine, codeine, oxycodone, methadone, and buprenorphine; and illicit opioids, such as heroin. Thus, due to the addictive qualities of opioids, combined with the definition of substance dependence, a core clinical feature of opioid dependence is the impairment of control over use of the drug.

2.2 Signs and symptoms of opioid withdrawal, intoxication and overdose

Other significant opioid related disorders include opioid withdrawal, opioid intoxication and overdose refer Table 2.1: Signs and symptoms of opioid withdrawal, intoxication and overdose.

Table 2.1: Signs and symptoms of opioid withdrawal, intoxication and overdose

Withdrawal	Intoxication	Overdose
Dilation of pupils	Constriction of pupils	Pinpoint pupils
Anxiety	Itching and scratching	Loss of consciousness
Muscle and bone ache	Sedation and somnolence	Respiratory depression: respiratory rate less than 12 breaths per minute
Muscle cramps	Lowered blood pressure	Hypotension
Sleep disturbance	Slowed pulse	Bradycardia
Sweating	Hypoventilation	
Hot and cold flushes		
Piloerection ('gooseflesh')		
Yawning		
Lacrimation		
Rhinorrhoea		
Abdominal cramps		
Nausea		
Vomiting		
Diarrhoea		
Palpitations		
Rapid pulse		
Raised blood pressure		
Flight & fight reaction		

Note: Adapted from Department of Health, Western Australia Government and the Drug and Alcohol Office, (2006). Clinical policies and procedures for the use of methadone and buprenorphine in the treatment of opioid dependence (p.19).

2.3 Definition of opioid withdrawal

The symptoms of opioid withdrawal are often experienced as extremely unpleasant and uncomfortable, they are rarely life threatening. According to the DSM-IV-TR (2000, p. 273), the criteria for diagnosis of opioid withdrawal are:

- A. Either of the following:
 - (1) cessation of (or reduction in) opioid use that has been heavy and prolonged (several weeks or longer); or
 - (2) administration of an opioid antagonist after a heavy period of opioid use.
- B. Three (or more) of the following, developing within minutes to several days after cessation or reduction of opioid use that has been heavy and prolonged (Section A):
 - (1) dysphoric mood;
 - (2) nausea and vomiting;
 - (3) muscle aches;
 - (4) lacrimation;
 - (5) pupillary dilation, piloerection, or sweating;
 - (6) diarrhoea;
 - (7) yawning;
 - (8) fever; or
 - (9) insomnia.

- 
- C. The symptoms in Criterion B cause clinically significant distress or impairment in social, occupational, or other important areas of functioning; and
 - D. The symptoms are not due to a general medical condition and are not better accounted for by another medical disorder.

As well as the DSM-IV-TR (2000) diagnostic criteria, the International Statistical Classification of Diseases and Related Health Problems (ICD-10) (World Health Organisation, 1992) provides additional clinical signs of opioid withdrawal:

- anxiety;
- craving for the drug;
- restlessness;
- muscular and abdominal cramps or pain;
- piloerection, or recurrent chills;
- tiredness and fatigue;
- rhinorrhea and sneezing; and
- tachycardia or hypertension.

The intensity and severity of the withdrawal syndrome can vary according to several factors, including:

- duration of opioid use;
- polysubstance use;
- general physical health;
- psychological factors (e.g. mental state, anxiety, fear of withdrawal, low self confidence); and
- drug pharmacology factors (e.g. half life, dose).

This last factor, in particular, explains why some opioids are reported as more difficult to withdraw from than others. The onset and duration of opioid withdrawal symptoms is associated with the half-life of the drug the patient is dependent on. Withdrawal symptoms for short-acting opioids such as morphine and heroin occur more rapidly than for opioids with longer half-lives, such as methadone (Kenny, et al., 2009).

Withdrawal usually occurs in two phases. The first or acute phase of withdrawal, as discussed above, may be followed by a period of protracted, though less dramatic, withdrawal symptoms. The second phase, or protracted syndrome, is characterised by a general feeling of reduced physical and psychological well-being (NSW Department of Health, 2008). During this period, strong cravings for opioids may be experienced episodically. The pharmacological properties of specific opioids that can cause these symptoms of withdrawal, specifically, methadone and buprenorphine, will be discussed in detail in Section 4.

2.4 Opioid intoxication and overdose

Opioid intoxication is caused by use of opioid drugs, which include morphine, heroin and oxycodone. Opioid intoxication generally occurs during or shortly after opioid use. The extent of intoxication is related to the dose consumed and the characteristics of the individual, for example tolerance, rate of absorption and regularity of use (see Section 4 for specific details).

The criteria for diagnosis of opioid intoxication in the DSM-IV-TR (2000, p. 272) are:

- A. Recent use of an opioid.
- B. Clinically significant maladaptive behavioural or psychological changes (e.g., initial euphoria followed by apathy, dysphoria, psychomotor agitation or retardation, impaired judgment, or impaired social or occupational functioning) that developed during, or shortly after, opioid use.
- C. Pupillary constriction (or pupillary dilation due to anoxia from severe overdose) and one (or more) of the following signs, developing during, or shortly after, opioid use:
 - (1) drowsiness or coma
 - (2) slurred speech
 - (3) impairment in attention or memory.

- D. The symptoms are not due to a general medical condition and are not better accounted for by another mental disorder.

Specify if:

With Perceptual Disturbances.

Symptoms of intoxication can last for several hours depending on the half-life of the opioid used (see Section 3).

Opioid overdose is potentially dangerous and can result in respiratory depression, unconsciousness and death (see Section 12); particularly if used in combination with other central nervous system sedatives such as alcohol and benzodiazepines. Emergency treatment should be accessed immediately.

2.5 Implications for the current guidelines

Considering the nature of opioid dependence and withdrawal, and the current opioid trends in Tasmania (Section 1), strategies are required to improve the selection processes for the prescription of opioid medications to Tasmanian patients. Furthermore, clear guidelines are required to determine which patients are suitable for the Tasmanian Opioid Pharmacotherapy Program (TOPP) and which patients are suitable for receiving opioids on the PBS. This necessitates a comprehensive understanding of opioid medications, combined with thorough assessments and formulations about each patient's history and current situation, that includes the patient's physical, psychological and social wellbeing.

In order to improve patient safety and ensure the appropriate prescription and use of opioids, the Tasmanian Opioid Pharmacotherapy Program is conservative. There is a deliberate focus on the assessment and management of clinical risk and community safety in this policy document along with the establishment of clinical practice standards to inform the delivery of the program in Tasmania. The remainder of this document will outline the theoretical and policy framework on which the Tasmanian OPP is based, as well as provide specific instructions on the appropriate delivery of services for clinicians working in the program.

There is a focus on the assessment and management of clinical risk and community safety in this policy document along with the establishment of clinical practice standards to inform the delivery of the program in Tasmania.



SECTION: 3

Policy framework

In this section you will...

- Gain an understanding of harm minimisation, biopsychosocial approaches and evidence based practices as they relate to opioid pharmacotherapy treatment;
- Understand the rationale for and the aim of opioid pharmacotherapy treatment;
- Discover who will be given priority access to treatment; and
- Acquire an insight into how opioid pharmacotherapy treatment is provided in Tasmania.

3	Policy framework	22
3.1	Principles of harm minimisation	22
3.2	Biopsychosocial approach	22
3.3	Psychosocial interventions	23
3.4	Case management	24
3.5	Client self-determination	24
3.6	Evidence based practice	24
3.7	Risk management	25
3.8	Rationale for opioid pharmacotherapy	25
3.9	Aims of opioid pharmacotherapy treatment	26
3.10	Priority access	26
3.11	Evidence for effectiveness of various opioid pharmacotherapies	27
3.12	Key principles for effective treatment	27
3.13	Effective treating teams	28
3.14	Collaborative practice	29
3.15	How opioid pharmacotherapy is provided in Tasmania	29
3.16	Shared care model	30
3.17	Tasmanian shared care model	31
3.17.1	Specialist services	31
3.17.2	Primary care services	32
3.17.3	Specialist-primary care interface	32

Section: 3

3 Policy framework

3.1 Principles of harm minimisation

Harm minimisation is the fundamental concept underpinning the management of people with alcohol, tobacco and other drug problems in Australia. This concept was central in Australia's National Campaign Against Drug Abuse (NCADA), first launched in 1986, and has remained a core principle of the current National Drug Strategy (2010 – 2015).

The harm minimisation approach aims to reduce the harm associated with substance use by providing an overarching framework that supports a range of interventions. It recognises the impact of substance use on the individual, their immediate family and social networks, and the community as a whole, while at the same time acknowledging that the eradication of psychoactive substance use is not possible (see also Hamilton & Rumbold, 2004).

Harm minimisation is a core principle driving the Australian National Drug Strategy and the Tasmanian Opioid Pharmacotherapy Program.

The aim is to reduce harms associated with substance use by providing an overarching framework that supports a range of interventions.

The term 'harm minimisation' is regularly used in conjunction with, or interchanged with, the term 'harm reduction'. While the exact definitions of the two terms vary widely, Room (2004) observes that the term 'harm reduction' is often used when referring to specific interventions or strategies used for influencing drug related harm, for example, needle exchange programs and supervised injecting rooms. The core feature of these harm reduction strategies is that they do not necessarily advocate abstinence from drug use.

Hence, for this document, the term 'harm reduction' will be used when referring to specific strategies for reducing drug related harm, particularly for individual patients of the Tasmanian Opioid Pharmacotherapy Program (OPP), or patients receiving prescription opioids from their physicians. Therefore, potential outcomes of the therapeutic strategies may range from reduction to cessation of the drug/s of concern. This would be consistent with the goal of the program, that is, to reduce the harm associated with inappropriate use of prescription opioids (or heroin) by replacing them with appropriate use of a controlled and less harmful substance.

Clinicians have a duty of care to address and manage identified risks and clinical safety issues for their patient's substance use. If reducing or abstaining from substance use is identified as an achievable and appropriate goal, it should be explored by the clinician and patient as a potential treatment goal, along with other harm reduction strategies. This is particularly important if it facilitates the patient's retention in opioid pharmacotherapy treatment.

For a more detailed discussion on harm minimisation and harm reduction, see Room, 2004.

3.2 Biopsychosocial approach

A number of factors can influence both the aetiology of substance abuse and the effectiveness of subsequent treatment. In Tasmania, Alcohol and Drug Services (ADS) provide a range of treatment programs that are informed by the biopsychosocial approach.

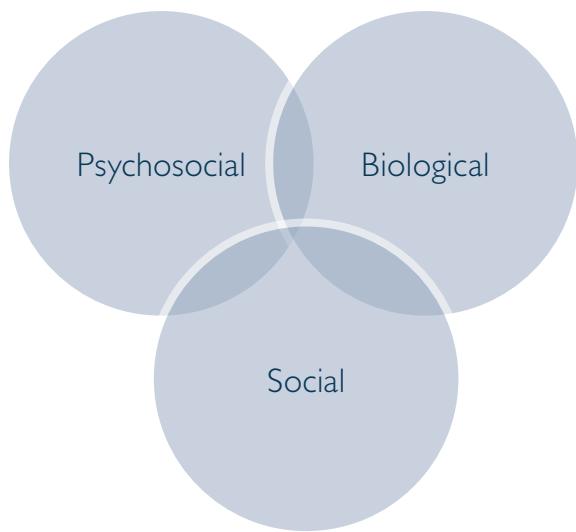


Figure 3.1: Biopsychosocial theoretical model (Engel, 1977)

The biopsychosocial model, as represented in Figure 3.1, is commonly adopted by health services as a guide to service delivery (Engel, 1977 & 1980). This holistic approach specifies that three main factors contribute to an individual's overall functioning and health outcomes: biological, psychological, and social factors.

In applying this model to the treatment of alcohol and other drug use issues, factors influencing substance use, abuse and dependence can be specified as follows:

- psychological (e.g. mental health, trauma, response to stressors, coping styles);
- social (e.g. family relationships, peer groups, social support, socio-economic factors, geographical location, education, lifestyle, health beliefs, cultural influences); and
- biological (e.g. physical health, blood-borne viruses, genetic/environmental predisposition to dependence, neuroadaptation).

As highlighted throughout this document, all aspects of opioid pharmacotherapy in Tasmania, including assessment and risk management, treatment delivery, and recommendations regarding psychosocial interventions, will be informed by the biopsychosocial model of health.

3.3 Psychosocial interventions

In addition, the TOPP introduces the importance of psychosocial interventions in opioid pharmacotherapy. Section 10, Psychosocial Interventions in Opioid Pharmacotherapy, provides an introduction and overview of the types of psychosocial interventions that are effective in treating opioid dependence. This section is not intended to provide a comprehensive review of the psychosocial literature. Rather, the emphasis is on establishing psychosocial interventions as valid and necessary in treating opioid dependence and enhancing the effectiveness of opioid pharmacotherapy.

This is consistent with the international literature (specifically the release of Guidelines for the Psychosocially Assisted Pharmacological Treatment of Opioid Dependence, WHO, 2009) and advances clinical treatment approaches beyond the provision of opioid substitution, to address psychosocial factors that influence the development, maintenance, and recovery from opioid dependence. The TOPP is the first national policy to emphasise the value of psychosocial interventions in opioid maintenance treatment and to establish practice standards that actively promote the need for clinicians to facilitate access to these interventions.

In Tasmania the alcohol and drug sector is made up of both public and community sector organisations. There are a range of programs and services offered by the sector, with the majority of community sector organisations providing specialist individual, family and youth psychosocial interventions. It is recognised that private practitioners may be limited in their capacity to deliver psychosocial interventions. In this instance the TOPP recommends that the prescriber regularly reviews and monitors the client's circumstances and facilitates access to these interventions/services as required.

3.4 Case management

In response to the TOPP risk management and biopsychosocial policy framework, and the emphasis on access to psychosocial interventions, the ADS will provide case management. There are many case management models including brokerage/generalist, strengths based, assertive community treatment, intensive case management, and clinical case management (Jenner, Devaney and Lee, 2009). The case management framework adopted by the ADS (see Section 10.2) is based upon the clinical case management model which combines brokerage and treatment (Jenner et. al. 2009). In adopting this model it is recognised that clinical case managers provide specialist interventions and facilitate access to resources.

Case management is a collaborative process between the case manager and the client. It is a direct client service (Case Management Society of Australia 2009). The focus of case management is to help clients to identify goals, actively participate in their treatment, and overcome gaps and obstacles within the service system (Addy et.al., 2000).

It is expected that the intensity of case management required will change over time. This will vary depending upon the client's needs and risk status. As the client progresses and clinical risks resolve, the key functions of case management may focus more on monitoring and care coordination, rather than direct clinical interventions.

It is anticipated that the increased level of care provided through case management will not only assist in assertively managing risk, it will facilitate access to psychosocial interventions, enhance the effectiveness of opioid pharmacotherapy and overall positive outcomes.

3.5 Client self-determination

Members of the treating team should be aware of the principle of self-determination which recognises the right of clients to make their own choices and decisions (Connolly & Roeg, 2004). Working within legal, practice and organisational constraints, clinicians have a responsibility to create a working relationship with clients in which choice can be exercised. This approach seeks to enhance the client's capacity and opportunity to change and address their own needs. However it is important that clients also understand their shared responsibility for maintaining personal safety and the safety of the community. This means that clinicians will need to balance autonomy and self-determination with evidence based clinical practice and risk management. As a result there may be occasions where a client's preferences cannot be met due to clinical safety issues.

3.6 Evidence based practice

The current guidelines are based on evidence based practice (EBP). EBP is a decision making model designed to assist clinicians in making the most appropriate recommendations for their patients. EBP involves three components: best available evidence, clinical expertise, and patient values and preferences (Sackett, et al., 2000). According to this model, clinicians need to be up-to-date with the best available, most current, and relevant research evidence.

However, decisions cannot be based on research evidence alone. While evidence may suggest that a particular therapy or treatment is suitable for most patients, the evidence based intervention cannot always be applied uniformly. Therefore, clinicians need to also be aware of the patient's circumstances, preferences, and values. Finally, while patients may indicate preferences, their choices may not always be the most clinically appropriate. Therefore, clinical expertise and specialist knowledge is required to make decisions, with consideration of clinical risk and safety issues. According to EBP, none of these components can operate in isolation. It is also important to highlight that EBP does not always imply that the most cost effective

treatments are best practice. The fit between the evidence, patient values, and clinical judgment, help inform which treatment options are most suitable and facilitates the decision making process between the clinician and patient, about the safest and most efficacious treatment.

Current evidence from national and international research will be cited throughout this document. Furthermore, guidelines for how to make the most appropriate decision for each patient are also included. For example, Section 5 outlines how to assess a patient's opioid use and their suitability for opioid pharmacotherapy.

3.7 Risk management

As a consequence of a number of significant public and clinical safety issues that have been identified in Tasmania, this document has an emphasis on the identification and management of clinical risk. Risk management is integral to contemporary health care service delivery and is embedded in organisational clinical governance frameworks. The delivery of opioid pharmacotherapy requires the careful consideration of all potential risks and protective factors (see Section 5).

Consideration of risk should be an integral component of every assessment, review and should inform ongoing management of the patient (Reith, 1998). As part of the assessment of risk the clinician should also identify any protective factors that the patient may have that mitigate risks and facilitate or support treatment interventions (Reith, 1998). Clinicians should always consider both risk and protective factors.

Considering risk and protective factors when assessing patients and developing treatment plans is considered to be a 'strengths based' approach. Such models are commonly used in other health areas, such as mental health. In adopting and applying this framework, in the TOPP it is expected that clinical safety will be enhanced.

It is important to note that risk factors do not necessarily preclude the patient from accessing opioid pharmacotherapy, but may indicate the need for risk management strategies such as closer monitoring, second opinions, specialist interventions to strengthen protective factors and caution around dosing practices (e.g. precluding them from takeaway doses). Risk factors may also have implications on longer-term treatment planning and referral, consultation or communication with other treatment services.

3.8 Rationale for opioid pharmacotherapy

Opioid dependence is characterised by a cluster of symptoms (as discussed in Section 2), including increased preoccupation with, and time spent, obtaining and using the drug. Furthermore, impairment of control over use of the drug is a key clinical feature of dependence (see Section 2 for the full diagnostic criteria). Other potential consequences of opioid use and/or dependence include fatal and non-fatal overdose, transmission of blood-borne viruses, and negative impacts on a range of aspects of social functioning, including family relationships, housing, crime and family disruptions (Chalmers, et al., 2009). In addition, many opioid dependent people who attempt to withdraw rapidly often relapse to opioid use or dependence, particularly if unsupported in their attempts to withdraw (Kenny, et al., 2009). Thus, opioid dependence can negatively impact on a range of biopsychosocial health factors.

For opioid dependent people, replacing heroin or other unsanctioned opioid use with maintenance therapies, such as methadone and buprenorphine treatment, is recommended (Mattick, et al., 2009; National Pharmacotherapy Policy, 2007). Clinical research in Australia and internationally indicates a range of benefits of these treatments, resulting in overall improved biopsychosocial functioning for individuals.

Specifically, placing opioid dependent people on supervised oral pharmacotherapy has been shown to:

- reduce the risks associated with unsanctioned opioid use and dependence, including reduced risk of premature death;
- reduce rates of spread of blood borne viruses from intravenous administration;
- reduce crime rates; and
- decreased use of unsanctioned opioids (Gowing et al., 2008; Mattick, et al., 2001; Teesson et al., 2008).

The benefits of pharmacotherapy treatments are associated with the pharmacological properties of the maintenance drugs (see Section 4 for further information). In brief, both methadone and buprenorphine are long acting oral medications and, when taken daily, blood levels of the medications remain constant after an initial stabilisation phase. Hence, patients become tolerant to the effects, and are less likely to display symptoms of opioid intoxication and withdrawal and experience an overall reduction in drug seeking behaviours, than when using heroin or other unsanctioned opioids (Mattick, et al., 2001). This increases the likelihood that individuals will be able to focus on improving various other aspects of their health, as well as maintaining stable employment, and re-engaging in social activities. Engagement in treatment programs often results in increased and improved access to various health, welfare and support services for an often marginalised group of individuals. These benefits have been shown to be improved over longer periods of treatment (Simpson & Sells, 1982).

3.9 Aims of opioid pharmacotherapy treatment

The overall aims of opioid pharmacotherapy treatment are to:

- assist opioid dependent individuals to reduce or cease the use of illicit or unsanctioned opioids by replacing them with safer maintenance medication;
- improve the biopsychosocial health and overall functioning of the opioid dependent individual; and

- reduce the risks and harms associated with illicit and unsanctioned opioid use to the individual, his or her family and social networks, and the community as a whole.

In order to provide comprehensive and holistic care to the individual in treatment, a range of ancillary services, such as counselling, employment support, care coordination, and housing support, should be accessible. In Tasmania, treating teams will facilitate access to such services when appropriate, particularly if limited resources prevent these services from being directly provided by the opioid pharmacotherapy treating team.

Since patient outcomes are improved over longer periods of treatment, the provision of opioid pharmacotherapy should not be time limited.

Opioid pharmacotherapy is suitable for opioid dependent individuals.

Opioid pharmacotherapy should not be time limited.

3.10 Priority access

Opioid pharmacotherapy should be accessible to all patients seeking treatment for opioid dependence. When there is a delay in access to treatment, patients most at risk of deterioration in health outcomes if treatment is not available, should be provided with priority access to the Tasmanian (OPP). These include:

- pregnant women and their opioid dependent partners;
- people with HIV and carriers of Hepatitis B and their opioid dependent partners; and
- opioid dependent people recently released from prison and at risk of overdose or those maintained on opioid pharmacotherapy whilst in prison (see Section 11.10 Recently Released Prisoners).

Priority access to pharmacotherapy treatment should be provided to:

- **pregnant women and their opioid dependent partners;**
- **people with HIV and carriers of Hepatitis B and their opioid dependent partners; and**
- **opioid dependent people recently released from prison.**

These factors should be taken into consideration during the assessment phase. Clinical judgment will guide the allocation of priority services.

3.11 Evidence for effectiveness of various opioid pharmacotherapies

The effectiveness of opioid replacement therapies has been widely researched and documented over many years (Ward, Mattick and Hall, 1998). In 2001, the Australian National Council on Drugs (ANCD) released a report rating the evidence for the effectiveness of methadone as strong, and moderate for buprenorphine. This report also noted that the evidence for the efficacy of naltrexone in relapse prevention treatment is limited (Gowing et al., 2001, Tucker, et al, 2004).

The National Evaluation of Pharmacotherapies for Opioid Dependence (NEPOD) study was a multi-centre, randomised clinical trial that compared the clinical effectiveness, clinical safety, and cost effectiveness of a range of opioid pharmacotherapies. In a comparison of methadone, buprenorphine, and naltrexone, the authors found that methadone maintenance was the most cost effective treatment for opioid dependence in Australia (Mattick et al., 2001). They also found that retention rates in treatment – a highly important indicator of treatment success – at six months was 44% in the groups treated with methadone and buprenorphine, in comparison to a retention rate of 4% for those treated with naltrexone.

As a result of the findings from the NEPOD study, the Commonwealth government was prompted to fund a wider range of opioid pharmacotherapy treatment options.

Since evidence indicates that methadone and buprenorphine pharmacotherapy treatments are current best practice in the treatment of opioid dependence, they will be the focus of these TOPP guidelines. However, while methadone remains the most cost effective treatment for opioid dependence in Australia, the pharmacological properties of buprenorphine (outlined in Section 4) indicate that it is a clinically safer medication than methadone. This decision for clinicians between the safer medication and the most cost effective medication remains challenging (see Mattick et al., 2008 and Gray, 2007 for discussions on this topic).

This document will provide information and guidelines for medical practitioners and pharmacotherapy treatment teams to identify the most appropriate medication for each patient.

3.12 Key principles for effective treatment

This section describes the qualities required for an ‘ideal’ opioid pharmacotherapy treatment setting. When developing a service, or providing opioid pharmacotherapy, clinical safety for the patient and clinicians, as well as public safety, are the most important considerations in decision making. Constraints and limitations on resources will affect the viability of providing all the recommended components of an ideal pharmacotherapy service.

The key principles for effective pharmacotherapy treatment include:

- **Availability** – where a need for opioid treatment services exists, these services should be made available;
- **Accessibility** – services should be located at appropriate sites, affordable to patients, and open during hours that optimise service utilisation;

- **Acceptability** – the operation of opioid treatment services should be acceptable to major stakeholders including patients, service providers and the local community;
 - **Equity** – treatment services should be planned and operated to reduce inequities in access to and quality of services between target groups.
 - **Quality of Care** – treatment services must be of a high standard. Doses should be provided to suppress opioid withdrawal and adjusted in accordance with a continuous assessment of clinical safety;
 - **Accountability to key stakeholders** should be maintained through ongoing review processes of clinical practices and treatment outcomes;
 - **Length of time in treatment** – opioid pharmacotherapy should not be time limited. Current evidence indicates that post-treatment outcomes are improved with increased time in pharmacotherapy (Simpson & Sells, 1982), and that people who drop out of treatment within the first year are much more likely to relapse than those who remain in treatment for longer than one year (Teesson, et al., 2008; Greenfield & Fountain, 2000);
 - **Voluntary** – all patients must be receiving opioid pharmacotherapy treatment voluntarily. In Tasmania, patients referred via Court Mandated Diversion still have a choice in whether they participate in the pharmacotherapy treatment program.;
 - **Quality of the therapeutic relationship** – attitudes of the treating team can influence the quality of opioid treatment programs. Evidence shows that when patients have a good relationship with at least one treatment team member, program effectiveness is positively influenced (Gjersing, et al., 2010). A non-judgmental attitude among clinicians is important in fostering good clinical relationships;
 - **Negotiated goal setting for client centred outcomes** – Connolly and Roeg (2004 p.34) identify that best practice constitutes a ‘collaborative determination with the client of the most effective treatment plan’.
- Individuals are more likely to be motivated, engaged and achieve treatment goals if these goals are determined in collaboration. This approach fosters the development of personal strengths, self efficacy and commitment to the treatment plan.;
- **Holistic care** – patients should have access to a range of ancillary services to help improve all aspects of their biopsychosocial health, including psychosocial interventions such as counselling services (McLellan et al., 1993; Drummond & Perryman (2007)). If such services are not immediately available, referrals should be made when appropriate. (For more details regarding psychosocial interventions and case management, see Section 10);
 - **High staff morale** – the maintenance of high staff morale is critical to the delivery of effective opioid pharmacotherapy services. Staff should be appropriately trained to deliver pharmacotherapy services, and require ongoing workforce development and training, recognition and acknowledgment of skilful clinical practice, as well as support in managing complex patients; and
 - **Staff and clinical safety and risk management** – staff and other patients must feel safe at all times and appropriate security measures should be available. Decisions regarding patient care should be made with awareness of and attention to clinical risk factors, above all other considerations. This includes close supervision of the consumption of liquid, tablet and film medications to reduce the risk of overdose, accidental poisoning, and diversion.

3.13 Effective treating teams

Opioid pharmacotherapy in Tasmania is currently provided through either public opioid treatment clinics, that is, specialist Alcohol or Drug Services (ADS), or community based medical practitioners. Opioid pharmacotherapy is usually delivered by a treating team that includes a prescriber, pharmacist and ideally, a case manager. Regardless of whether the client receives their treatment from a private prescriber or public clinic, the pharmacist

(whether a community pharmacist or ADS specialist pharmacist) is an integral part of the treating team.

Regular communication between members of the treating team is essential to ensure safe and coordinated care. The private prescriber and community pharmacist should ideally communicate at least once a month to monitor and review the client's progress. During the induction phase, times of increased vulnerability, or when high risk factors are identified, more frequent and timely communication should occur to ensure client safety.

Regular brief contact builds a strong working relationship, however when changes in the client's care are made, verbal instructions must also be provided to the pharmacist in writing. Clients should be made aware that the pharmacist and doctor will be sharing information on a regular basis to ensure that the care they receive is safe and effective and meets regulatory requirements.

Regular communication between members of the treating team is essential to ensure safe and coordinated care.

3.14 Collaborative practice

There are often a wide range of issues faced by clients who access alcohol and other drug services, many of which require interventions and involvement from a range of other agencies. It is important for prescribers and case managers involved in the delivery of opioid pharmacotherapy to be aware of other services that may be involved in their client's care. This may in effect broaden the treating team to include key services and clinicians and community sector organisations. In these circumstances it will be important to ensure: the client is aware of the involvement of other agencies; determine the lead agency; and clarify responsibility for actions in the negotiated goal plan.

A strong collaborative working relationship between health professional and across agencies ensures that services are integrated, meet the needs of the client and are effective (Jenner, Devaney & Lee, 2009). Strategies that facilitate collaborative practice include streamlined referral processes; integrated treatment planning, case conferencing, case review and joint clinical practice. Ideally, there should be good communication and regular sharing of information between key services and health professionals (Mills, et al., 2010). At an organisational level, joint training, professional development and workplace placements/rotations also build strong collaborative practice.

Collaborative practice not only ensures that services to clients are coordinated; it contributes to enhanced health outcomes, and can reduce risk (this is particularly important for clients that are high risk). For this reason, collaborative practice underpins the provision of opioid pharmacotherapy and is essential for the delivery of services to clients with comorbid issues and multiple and complex needs.

Collaborative practice underpins the provision of opioid pharmacotherapy and is essential for the delivery of services to clients with comorbid issues and multiple and complex needs.

3.15 How opioid pharmacotherapy is provided in Tasmania

The delivery of opioid pharmacotherapy in Tasmania provides many challenges to both public specialist services and other non-specialist community based services. Although many services often experience funding restrictions, the delivery of Tasmania's specialist drug services is further limited by geographical accessibility. That is, 48.7% of Tasmania's population lives in rural and remote areas (Australian Bureau of Statistics, 2001), with little or no access to public transport. Hence, managing the requirements of accessibility to services and maintaining high standards for the management of clinical

and other risks can often result in competing demands on policy.

The specialist public clinics are staffed by treating teams comprising prescribing doctors, specialist nurse case managers, pharmacists (Hobart ADS only) and allied health professionals, who provide a range of services such as assessment, counselling, psychotherapy, and access and referral to medical care, psychiatric treatment, and community services.

Case management is undertaken by designated opioid pharmacotherapy program staff or (in the private sector) by the patient's prescribing doctor. It is acknowledged that the intensity and frequency of the case management role will vary across the clinical setting according to the client's needs eg. GP prescribers are more likely to provide a care coordination function rather than the level of case management provided by the ADS treating team.

Reviews are undertaken by the treatment team, usually the allocated case manager or treating doctor, during the induction phase into pharmacotherapy treatment. Dosing usually occurs onsite at the Specialist Pharmacotherapy Pharmacy in the South, and community dispensing pharmacies in the North and North West. Once patients are stabilised, they are dosed at a convenient community or hospital pharmacy.

Community based medical practitioners (usually authorised general practitioners and specialist medical practitioners) also provide opioid pharmacotherapy treatment, as well as performing a case management role with their patients. These patients usually attend community pharmacies to receive their methadone or buprenorphine.

It is not compulsory for pharmacies to provide dosing for clients receiving opioid pharmacotherapy. The recruitment and retention of pharmacists to the program is reliant upon their goodwill and individual preferences.

Hospital pharmacies are an important avenue for delivering opioid pharmacotherapy in Tasmania. In some rural settings, multipurpose

health centres or community hospital pharmacies may be the only dispensing options available.

Difficulties are experienced in both types of service delivery models. The combination of the location of specialist clinics, funding restrictions, limitations on outreach work, and safety considerations, may contribute to specialist services being less accessible to some patients. In addition, specialist clinics can, at times, experience difficulty meeting the demand for their services, primarily due to periodic increases in demand from consumers for these services, and an ongoing shortfall in the number of specialist clinicians.

Community based medical practitioners and community pharmacies can often be overwhelmed by the complexity of opioid dependent patients, can feel unsupported in the management of these patients, and may lack specialist knowledge in this area. Safety concerns are also a limitation to providing opioid pharmacotherapy in many smaller medical clinics.

In order to improve the availability and quality of opioid pharmacotherapy services in Tasmania, a model of service delivery that supports close collaboration between primary care (i.e. community based medical practitioners) and specialty care (specialist drug services) services is required. Tasmania will adopt and move towards the full implementation of a shared care model of service delivery for its opioid pharmacotherapy program. This model will be implemented over time, as the capacity of the specialist alcohol and other drug sector develops in Tasmania.

3.16 Shared care model

Shared care models for the management of chronic health conditions have been adopted in many countries. These can vary widely from formalised referral and discharge pathways to regular contact and collaboration between treating services in the ongoing management of patients (Keene, et al., 2004).

In this document, the shared care model will be broadly defined as 'a structured system in which primary and specialty clinicians collaborate over an extended period in order to provide high quality care to patients with chronic disease' (Smith et al., 2008 p. 214.).

While there are numerous documents outlining, describing, and evaluating the benefits and challenges of shared care arrangements, the availability of high quality randomised control studies (RCT) is limited. For example, in a review of over 4,000 documents on shared care, Smith and colleagues (2008) found that only 20 studies met the criteria for inclusion in a systematic review. The authors found positive results for the benefits of shared care in improving mental health, improving quality of life and wellbeing, reducing functional impairment, reducing hospital admissions and inpatient days, and improving appropriateness of prescribing practices (Smith et al., 2008).

Various other investigations specific to opioid treatment programs have found that well defined shared care models can assist in maintaining prescribing practices within specified guidelines, allow drug users to feel normalised by accessing help through the primary care setting, and provide a holistic approach to patient care (Felice & Kouimtsidis, 2008; Smith & Mistral, 2003). Furthermore, shared care models are more likely to attract the participation of primary care providers if they feel well supported, for example, through the support of their specialist colleagues or a liaison officer (Dey et al., 2002; Felice & Kouimtsidis, 2008; Keene et al., 2004).

Finally, there are indicators that the outcomes of opioid pharmacotherapy – specifically, buprenorphine – are equivalent when provided by either specialist services or well supported specialist primary physicians (Gibson, et al., 2003). All these indicators, combined with the limitations of the current opioid pharmacotherapy program in Tasmania, indicate that a shared care model will be both beneficial for patients, as well as progress the quality and accessibility of services.

3.17 Tasmanian shared care model

The Tasmanian ADS will facilitate the development and support the implementation of the shared care model of opioid pharmacotherapy in Tasmania. The ADS recognises the need to provide support and supervision for primary care physicians currently providing, or demonstrating potential to provide, pharmacotherapy services. As the capacity of the specialist services improves, increased opportunity for support, education and professional development will be established. Despite current service limitations, if a primary care physician cannot provide a safe treatment service within the current guidelines, then no opioid treatment should be provided.

If safe treatment cannot be provided, no treatment should be provided.

The Tasmanian shared care model will have the following characteristics:

3.17.1 Specialist services

The Tasmanian ADS Opioid Pharmacotherapy Program (OPP) will:

- accredit pharmacists and doctors to prescribe and dispense pharmacotherapies (refer Sections 15 & 16);
- be responsible for the initial assessment of a large proportion of Tasmanian patients for their suitability for registration on the opioid pharmacotherapy program (excluding patients with access to authorised GPs, see 3.11.2):
- induct patients into the OPP;
- oversee the dosing of patients;
- provide or facilitate access to other services as required;
- transfer patient care to a community based general practitioner if:
 - (a) a suitable practitioner and pharmacist is available;
 - (b) the practitioner agrees to take the patient; and
 - (c) the patient is stable and safely managed by a primary care service.

In addition, the Tasmanian ADS will:

- manage the care of complex, non-compliant or moderate to high risk patients;
- provide care for patients being managed in primary care services who have begun to display moderate to high risk including non compliance;
- provide support for primary care physicians and dosing pharmacies;
- provide case management services; and
- provide access to multidisciplinary reviews for integrated care planning and specialist intervention.

3.17.2 Primary care services

Primary care physicians may assess, induct, and stabilise opioid pharmacotherapy patients if:

- they are approved to do so by the Clinical Director, ADS;
- they have in place an authority to prescribe for each patient from Pharmaceutical Services Branch;
- they are experienced in providing opioid pharmacotherapy;
- the treatment provided is consistent with the current Tasmanian Opioid Pharmacotherapy Program, Policy and Clinical Practice Standards;
- the patient is generally compliant and low risk; and
- the offer or provision of services does not place the patient, the community, or clinicians at risk.

Primary care practitioner's roles also include:

- providing generalist medical services to opioid pharmacotherapy patients, including the management of blood borne viruses;
- providing referrals to external health services when appropriate; and
- consulting with or referring to ADS when managed pharmacotherapy clients display moderate to high risk behaviours, or become non compliant.

3.17.3 Specialist-primary care interface

To improve the quality of opioid pharmacotherapy services provided to Tasmanian patients, ADS will engage in the following strategies.

- ADS will provide to primary care physicians involved in the provision of opioid pharmacotherapy services with:
 - teaching;
 - clinical supervision;
 - clinical mentoring; and
 - consultation and liaison services.
- ADS will improve strategies for:
 - increasing the number of medical practitioners able to provide opioid pharmacotherapy, particularly in remote communities;
 - ensuring efficient referral pathways and communications with specialist services;
 - engaging primary care physicians in generalist care of opioid pharmacotherapy patients prior to discharge from specialist services;
 - consulting with primary care clinicians; and
 - PSB (DHHS) in further developing and recruiting dispensing pharmacies to support Tasmania's shared care model of opioid pharmacotherapy.



SECTION: 4

Clinical pharmacology

In this section you will...

- Gain an overview of opioid pharmacology and the actions and potential side effects associated with methadone and buprenorphine;
- Be provided with a comparison of treatment options; and
- Understand the Gateway Model.

4	Clinical pharmacology	34
4.1	Basic opioid pharmacology	34
4.2	Methadone	35
4.2.1	Methadone formulations	35
4.2.2	Methadone pharmacokinetics	36
4.2.3	Methadone actions and side effects	37
4.2.4	Methadone and dental health	38
4.2.5	Drug interactions with methadone	38
4.3	Buprenorphine	39
4.3.1	Buprenorphine pharmacokinetics	40
4.3.2	Buprenorphine formulations for opioid dependence	40
4.3.3	Buprenorphine formulations for pain management	41
4.3.4	Buprenorphine actions and side effects	41
4.3.5	Drug interactions with buprenorphine	43
4.3.6	Clinical policy on buprenorphine in pregnancy and breastfeeding	43
4.4	Indication for opioid pharmacotherapy	44
4.5	General contraindications and precautions for opioid pharmacotherapy	44
4.6	Comparing treatment options	46
4.6.1	Pharmacology	46
4.6.2	Safety	47
4.6.3	Abuse potential	48
4.6.4	Accessibility	49
4.6.5	Administration	49
4.6.6	Evidence	49
4.6.7	Effects	49
4.6.8	Withdrawal	49
4.6.9	Switching treatment options	49
4.7	Gateway Model – Buprenorphine as induction agent of choice	50

Section: 4

4 Clinical pharmacology

4.1 Basic opioid pharmacology

The term opioid is used to describe drugs whose actions resemble morphine but whose chemical structures are different from natural opiates derived from the opium poppy. The term describes all of the compounds that interact with stereospecific μ (μ)-opioid receptors in the central and peripheral nervous systems, including natural and synthetic compounds, as well as endogenous peptides. The principal effects of opioids are analgesia, sedation, respiratory depression and euphoria. Opioids have varying potency, bioavailability, speed of onset and duration of effect.

Opioids produce their effects by acting on a range of receptors at the molecular level of the nervous system. Figure 4.1 below demonstrates opioid effects according to dose. Opioid compounds can be classified into four groups: pure agonists, partial agonists, mixed agonist-antagonists and antagonists, which will be referred to when describing specific opioids later in this section.

- **A pure agonist** is a drug that has affinity for and binds to receptors to induce changes in the cell that stimulate physiological activity. The potency of a μ -opioid receptor agonist can be described by a dose-response relationship. This relationship is influenced by the drug's pharmacokinetic characteristics (absorption, distribution, metabolism and elimination), affinity for the receptor, and the level of intrinsic activity at the receptor level. Morphine, methadone, pethidine, hydrocodone, oxycodone and heroin are examples of opioid agonists.

- A **partial agonist** is a drug that binds to a receptor but does not produce maximum stimulation. Because it occupies the receptor, it can prevent a concurrently administered agonist with weaker receptor affinity from attaching to -opioid receptors and producing its full agonist effect. Buprenorphine is a partial agonist at the μ -opioid receptor.
- **Mixed agonist-antagonists** are drugs that have a mixed μ -opioid receptor action, stimulating one receptor type while antagonising another. Buprenorphine, pentazocine, butorphanol and nalbuphine are examples of agonist-antagonist opioids.
- **Antagonist** opioids have no intrinsic pharmacological action on -opioid receptors but can block the action of an agonist; thus they can reverse the effects of μ -opioid agonists. They are often used therapeutically to reverse the effects of opioid overdose. Naloxone and naltrexone are opioid receptor antagonists that can reverse the effects of agonists such as morphine and methadone.

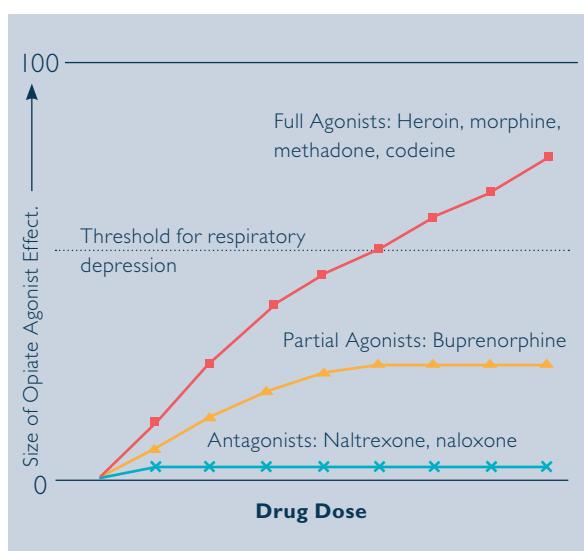


Figure 4.1: Opiate agonist effects of full agonists, partial agonists and antagonists

Note: Reproduced from *Induction into buprenorphine treatment*. Dr Nicholas Lintzeris. Presentation at Conference Safer options, Hamburg 19-21 April 2005.

4.2 Methadone

Methadone is a synthetic μ -opioid receptor agonist used to treat opioid dependence. In Tasmania its medical use is regulated under the *Poisons Act 1971*, as a 'controlled (S8) drug'. The effects of methadone are qualitatively similar to morphine and other pure agonist opioids. The clinical pharmacology of methadone makes it a very good agent for the treatment of opioid dependence (Vazquez, et al., 2006, Gowing et al., 2001).

The chemical name for methadone hydrochloride is: 6-dimethylamino-4,4-diphenyl-3-heptone hydrochloride and is represented in Figure 4.2 below.

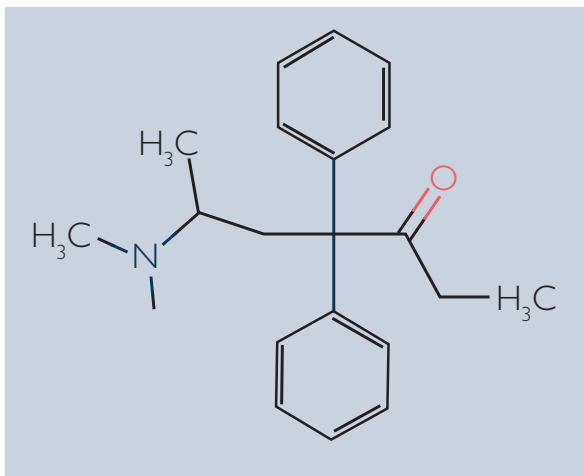


Figure 4.2: Methadone molecule

Note: Adapted from *Sigma Methadone Syrup, Product Information, 2008*. TGA Product and Consumer Medicine, 2003. Retrieved September 22, 2011, from <https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/PICMI?OpenForm&t=&q=buprenorphine&r=/>

There appear to be two separate active sites in the molecule:

- the nitrogen atom with the hydrochloride bonded to it at one end – thought to act on the peripheral nervous system; and
- the 2 phenyl 'rings' – thought to be necessary for its opiate-like action on the central nervous system.

4.2.1 Methadone formulations

In the context of this document, the general term 'methadone' will be used when describing information that applies to both of the available methadone preparations for opioid dependence in Australia. These preparations are:

- (a) **Methadone Syrup®**. This formulation contains 5mg/mL methadone hydrochloride, sorbitol, glycerol, ethanol (4.75%), caramel, flavouring, and sodium benzoate; and
- (b) **Biodone Forte Syrup®**. This formulation contains 5mg/mL methadone hydrochloride and permicrol-red colouring.

The two formulations are of equal strength and bioavailability. While community pharmacies can choose to dispense either one, or both of these formulations, Alcohol and Drug Services (Tasmania) recommend Biodone® for the following reasons:

- it is safer than the syrup if inappropriately injected by the patient;
- Biodone does not contain sorbitol and does not cause gastrointestinal problems;
- the aftertaste of Biodone® is easier to remove than the aftertaste of the syrup;
- it contains no alcohol;
- it is easier for pharmacists to use as it is less viscous; and
- it is easier to clean equipment after dispensing Biodone®.

Biodone® is the preferred agent for commencement and stabilisation of patients in Tasmania.

4.2.2 Methadone pharmacokinetics

There is wide individual variability in the pharmacokinetics of methadone, however, in general blood levels rise for three to four hours following ingestion of oral methadone and then begin to fall. Methadone is rapidly absorbed from the gastrointestinal tract, with measurable concentrations in plasma within 30 minutes of oral administration, and a long half-life. The apparent half-life of a single first dose is 12 – 18 hours, with a mean half-life of 15 hours. With ongoing dosing, the half-life of methadone is extended to between 14 and 58 hours with a mean of 24 hours (Lugo, et al., 2005 and Eap, et al., 1999).

This prolonged half-life contributes to the fact that methadone blood levels continue to rise during the first week of daily dosing and fall relatively slowly between doses. The clinical implication is that missing one day's dose is not usually associated with significant withdrawal symptoms.

Table 4.1: Summary of Methadone Pharmacokinetics

Onset of effects	30 minutes
Peak effects	Approx. 2-4 hours
Half life (in MMT)	14-58 hours
Time to steady state	5-10 days
Withdrawal onset	36-48 hours Peak intensity 5-7 days

Note: Adapted from Department of Health, Western Australia Government and the Drug and Alcohol Office, (2006). Clinical policies and procedures for the use of methadone and Buprenorphine in the treatment of opioid dependence, (p.11).

Sometimes patients report withdrawal symptoms if they are a few hours late for dosing. However, due to the long half-life of methadone, they are unlikely to be in withdrawal and their discomfort is more likely to be due to their anxiety about not receiving the dose on time. However, if a dose is missed, near steady state methadone blood levels may not be re-attained for a number of days following resumption of daily dosing.

Methadone reaches steady state in the body (where drug elimination equals the rate of drug administration) after a period equivalent to four to five half-lives or approximately three to ten days. Steady state does not automatically imply clinical stability of the patient.

Steady state refers to a point where the methadone plasma level has reached equilibrium.

Once steady state has been achieved, variations in blood concentration levels are relatively small, and good suppression of withdrawal is achieved (Lugo, et al., 2005). For some, however, fluctuations in methadone concentrations may lead to withdrawal in the latter part of the inter-dosing interval. A dose increase or split dosing may prevent this; however, constrained pharmacy resources, and clinical safety considerations, mean that split dosing cannot be made available in Tasmania. In such circumstances, a switch to buprenorphine should be considered providing there are no identifiable contraindications.

Methadone is fat soluble 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. Because of its good oral absorption and long half-life, methadone is taken in an oral daily dose.

Methadone is primarily broken down in the liver via the Cytochrome P450 3A4 enzyme system. Approximately 10% of methadone administered orally is eliminated unchanged. The rest is metabolised and the (mainly inactive) metabolites are eliminated in the urine and faeces. Methadone is also secreted in sweat and saliva.

Signs and symptoms of opioid withdrawal (see Section 2 for a definition and Section 5 for assessment) usually begin two to three half-lives (i.e. 36-48 hours) after the last dose of methadone.

4.2.3 Methadone actions and side effects

Most people who have used heroin will experience few side effects from methadone. Once on a stable dose, tolerance develops until cognitive skills and attention are not impaired (Gruber, et al., 2006). This may not be the case at very high doses or when other depressant drugs, including alcohol and benzodiazepines, are used. Symptoms including constipation, sexual dysfunction, and increased sweating, can continue to be troubling for the duration of methadone maintenance treatment. Table 4.2 contains a summary of the overall effects of methadone.

Table 4.2: Effects of methadone

Main actions	Analgesia Sedation Respiratory depression Euphoria (oral methadone causes less euphoria than intravenous heroin)
Skin actions	Histamine release – may cause itching
Other physiological effects	Decreased blood pressure Constricted pupil Gastrointestinal tract actions, including: Reduced gastric emptying Reduced mobility Elevated tone of Sphincter of Oddi, which can result in biliary spasm Suppression of immune function
Endocrine actions	Reduced Luteinising Hormone Elevated Prolactin Reduced Adreno-Cortico-Trophic Hormone (ACTH) Elevated Anti Diuretic Hormone (ADH) Reduced testosterone (endocrine function may return to normal after 2-10 months).
Side effects	Headaches Sleep disturbances Nausea, vomiting and constipation Lethargy Dry mouth and reduced salivary flow Increased sweating Vasodilatation and itching Menstrual irregularities in women Gynaecomastia in males Sexual dysfunction including impotence in males Fluid retention and weight gain

Note: Adapted from Queensland Health, (2008). *Queensland Opioid Treatment Program Clinical Guidelines*. (p.8).

4.2.4 Methadone and dental health

Large proportions of opioid pharmacotherapy program patients report dental problems such as decayed teeth and periodontal disease (Graham & Meechan, 2005 and Nathwani & Gallagher, 2008). In the past, methadone syrup contained sugar, which was associated with tooth decay and dental caries. In 1993, the sugar in methadone syrup was replaced by sorbitol, a non-cariogenic sweetening agent.

More recently, Biodone®, another methadone formulation containing no additives apart from colourant (as required by the Commonwealth Government's Therapeutic Goods Administration), has been introduced and is commonly used. Nevertheless, dental problems may still occur in opioid pharmacotherapy patients for the following reasons:

- the acidic nature of methadone syrup can cause direct corrosion of the enamel;
- opioids, including methadone and buprenorphine, inhibit saliva production. Saliva is a natural defence against plaque;
- pre-existing dental problems;
- a high sugar diet;
- a history of poor dental hygiene during periods of dependent drug use;
- the analgesic effects of opioids, which can mask the existence of a tooth ache; and
- use of other drugs/route of use (eg. rubbing cocaine on the gums).

Researchers have noticed similar prevalence of dental problems in intravenous heroin users who are not on methadone (Laslett, et al., 2008 and Picozzi et al., 1972). This supports the conclusion that poor dental health is endemic among opioid users and that, in some instances, methadone may be exacerbating pre-existing problems rather than causing new ones.

A few simple countermeasures may assist in the management of dental health of opioid treatment program patients:

- examine the mouth and gums in the initial and subsequent physical examinations, and develop a management plan for any problems identified;

- if xerostomia (abnormal dryness of the mouth) is identified as a problem, recommend sugar-free gum or sugar-free candy to stimulate saliva production;
- recommend non-cariogenic diluents for takeaway doses;
- provide information about low sugar diet and oral hygiene when appropriate;
- recommend treatment at community dental clinics for concession card holders, or by private dentists in other cases;
- recommend the use of aqueous-based, sugar-free methadone, especially in long-term methadone treatment;
- explain and encourage good dental hygiene;
- encourage regular check-ups;
- encourage regular brushing of teeth; and
- suggest rinsing the mouth immediately after taking methadone.

4.2.5 Drug interactions with methadone

Toxicity and death have resulted from interactions between methadone and other drugs. The following are a list of cautions and contraindications for prescribing and administering methadone maintenance treatment.

- **Sedatives:** including other opioids, alcohol, benzodiazepines, tricyclic antidepressants, anti psychotics, and sedating antihistamines. Combined with methadone, these drugs can lead to accidents, depression of respiratory drive, and fatal and non-fatal overdose;
- **Benzodiazepines:** in addition to the risks mentioned above, benzodiazepines combined with methadone are associated with impairment of memory (Barker et al., 2004).
- **Other opioid agonists:** combined with methadone increase the risk of overdose and death;
- **Naltrexone and Naloxone** (μ -opioid receptor antagonists) reverse or inhibit the effects of methadone;
- **Buprenorphine** (agonist/antagonist) can precipitate withdrawal symptoms in people taking methadone;

- **Interferon-alpha and ribavirin:** used in the management of hepatitis B and C and other conditions. Side effects of these medications may mimic opioid withdrawal symptoms. Methadone is metabolised by the cytochrome P450 3A4 enzyme system in the liver. Drugs that induce this system can accelerate the metabolism of methadone and precipitate withdrawal. Inhibitors of cytochrome P450 can slow the metabolism of methadone and increase risk of opioid toxicity, particularly in the presence of other CNS depressant drugs. Specialist advice and caution are required if medications affecting cytochrome P450 are to be prescribed to patients receiving methadone;
- **Highly active antiretroviral therapy (HAART).** Drugs used in the treatment of HIV infection alter methadone pharmacokinetics and caution must be exercised in patients receiving HAART (Neuman, 2006)). HIV anti-viral drugs are usually strong inhibitors of the Cytochrome P450 3A3,5,7 enzymes leading to delayed metabolism of methadone and the possibility of opioid toxicity if the dose is not adjusted in accordance with careful clinical assessment and review.

A full list of possible drugs interactions with methadone is presented in Appendix I.

4.3 Buprenorphine

Buprenorphine is a synthetic opioid used to treat opioid dependence. In Tasmania its medical use is regulated under the *Poisons Act 1971*, as a 'controlled (S8) drug'. Buprenorphine is derived from the morphine alkaloid thebaine, and is a partial μ -opioid receptor agonist at the μ -opioid receptors in the nervous system (Lintzeris, 2008).

Although buprenorphine is a relatively potent μ -opioid receptor agonist at low doses, there appears to be a ceiling on its maximal opioid activity. Buprenorphine diminishes cravings for heroin and other unsanctioned opioids such as morphine, and prevents or alleviates opioid withdrawal in dependent opioid users. Therefore, it is suitable for opioid

maintenance or withdrawal treatment.

Buprenorphine has a higher affinity for μ -opioid receptors than all full μ -opioid receptor agonists. Initial research suggest that, naltrexone and naloxone have a similar receptor affinity for the μ -opioid receptors (Schmidt et al., 1985). Because of this, buprenorphine can block the effects of other opioid agonists in a dose-dependent fashion. At a dose of 16mg, most or all of the μ -opioid receptors are occupied by buprenorphine (Greenwald et al., 2003). Through this dual effect of reducing craving and attenuating the response to administered heroin and other μ -opioid receptor agonists, buprenorphine assists in reducing use of heroin and other unsanctioned opioids.

Methadone, a full μ -opioid receptor agonist, also reduces the impact of additional μ -opioid receptor agonist use, but the effect of methadone is achieved primarily through its pharmacological action of inducing cross-tolerance to other opioids. This cross-tolerance is dose dependent. In contrast, at doses approaching 16mg daily, buprenorphine achieves its effect primarily through its prolonged occupancy of a high proportion of μ -opioid receptors, blocking the action of other opioid agonists.

Unlike methadone, the effect of buprenorphine on respiratory depression reaches a ceiling at doses of between 8 and 16mg (Greenwald et al., 2003). Higher doses are not associated with increasing respiratory depression to any significant degree. Hence, buprenorphine is much safer than methadone and is associated with fewer deaths from overdose. However, if buprenorphine is used in combination with other central nervous system depressants such as alcohol or benzodiazepines, the combined effect on respiration can be life threatening. While respiratory depression from buprenorphine overdose is less likely than methadone, intravenous use of buprenorphine can be fatal due to complications caused by mode of administration (e.g. rapid increase in blood levels reaching the brain after injection).

Buprenorphine also exhibits antagonist effects at the kappa (k) opioid receptor. The role of these

receptors in humans is still poorly understood. Thus, buprenorphine acts as an agonist/antagonist.

Chemically, buprenorphine is 17-(cyclopropylmethyl)- α -(1,1-dimethylethyl)-4,5-epoxy-18,19-dihydro-3-hydroxy-6-methoxy- α -methyl-6,14-ethenomorphinan-7-methanol, hydrochloride [5 α ,7 α (S)]. Buprenorphine hydrochloride has the molecular formula C₂₉H₄₁NO₄ HCl and the molecular weight is 504.10 (Figure 4.3).

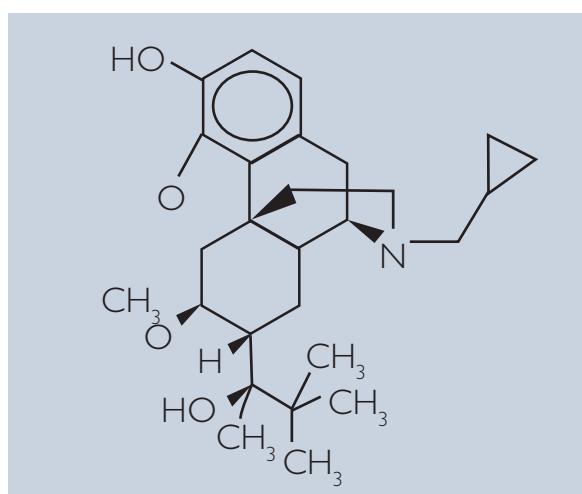


Figure 4.3: Buprenorphine molecule

Note: Adapted from Subutex, Product Information, TGA Product and Consumer Medicine, 2003. Retrieved September 22, 2011, from <https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/PICMI?OpenForm&t=&q=methadone&r=/>

4.3.1 Buprenorphine pharmacokinetics

Peak plasma concentrations are achieved one to two hours after sublingual administration of buprenorphine. Buprenorphine undergoes extensive first pass metabolism when swallowed. The major metabolite, norbuprenorphine, has some opioid activity but the extent of its contribution to the pharmacological effects of buprenorphine is unknown.

Buprenorphine is principally metabolised by two hepatic pathways: conjugation with glucuronic acid and N-de-alkylation, mediated by the cytochrome P450 3A4 iso-enzyme. The metabolites are excreted in 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 terminal elimination half-life of 24-37 hours. Peak clinical effects occur one to four hours after sublingual administration. Typically, effects will continue to be experienced for up to 12 hours at low doses (2mg), but as long as 24-72 hours at higher doses (16 – 32mg). The prolonged duration of effect at high doses enables alternate-day (double), and even 3-days-a-week (triple) dispensing regimes.

Table 4.3: Summary of buprenorphine pharmacokinetics

Onset of effects	30-60 minutes
Peak effects	1-4 hours
Half life (in MMT)	mean 35 hours range 20-73
Duration of effects	8-12 hours at low dose (<2mg) 24-72 hours at high dose (>16mg)
Time to steady state	7-10 days
Withdrawal onset	3-5 hours, symptoms generally milder than withdrawal from other opioids.

Note: Adapted from Department of Health, Western Australia Government and the Drug and Alcohol Office, (2006). Clinical policies and procedures for the use of methadone and Buprenorphine in the treatment of opioid dependence, (p.16).

4.3.2 Buprenorphine formulations for opioid dependence

In the context of this document, the general term 'buprenorphine' will be used when discussing both of the available buprenorphine preparations for opioid dependence in Australia. These preparations are:

- Subutex®:** a mono product containing buprenorphine hydrochloride in 0.4, 2, and 8mg tablets; and
- Suboxone®:** a sublingual combination product containing buprenorphine hydrochloride and naloxone hydrochloride in a 4:1 ratio. Available in 2mg and 8mg

sublingual tablets and in 2mg and 8mg sublingual film.

Both preparations have approximately 30-50% of the bioavailability of intravenous buprenorphine preparations. The bioavailability of sublingual buprenorphine is largely dependent on the amount of time the drug is in contact with the oral mucosa.

Partly in response to the mono preparation of buprenorphine being easier to divert than methadone liquid, the combination product containing naloxone was developed. The naloxone is poorly absorbed via the sublingual route, however, if injected it will cause opioid withdrawal symptoms in a person who is neuro-adapted. It was expected that the combination product would be less likely to be diverted or injected than the mono preparation. However experience has shown that diversion still does occur. In Tasmania, Suboxone® is the preferred preparation of buprenorphine.

In Tasmania, Suboxone® is the preferred preparation of buprenorphine.

Exceptions are:

- patients with a known sensitivity of naloxone (rare);
- pregnant and breastfeeding women; and,
- patients prescribed small daily doses or doses requiring the use of the 0.4mg strength that is presently available as Subutex® but not Suboxone®.

The Suboxone® sublingual film was introduced in September 2011 and is an alternative preparation that may overcome the disadvantages of sublingual tablets.

The sublingual film formulation of buprenorphine with naloxone is intended to make dosing easier. Buprenorphine sublingual tablets take approximately 2–10 minutes to dissolve and this can make supervision of dosing difficult, particularly in community pharmacies. As the film rapidly adheres to the oral mucosa, this makes it difficult to remove. The sublingual film dissolves faster under the tongue than sublingual tablets, and is difficult to remove (after 30 seconds: <16mg; 1 minute >16mg)

and therefore requires less supervision time.

It is anticipated that this may deter removal of the product and reduce the potential for diversion. The introduction of this preparation into clinical practice will assist in determining if the film has a lower rate of abuse than the combination sublingual tablet or than methadone syrup.

Doctors must be trained and authorised to prescribe Subutex® and Suboxone® for opioid dependence; these two preparations are not available to pain medicine specialists or other doctors for the treatment of persistent pain alone. However, if an opioid dependent patient has a comorbid, chronic non-malignant pain condition, Subutex® and Suboxone® can be effective in treating both conditions.

4.3.3 Buprenorphine formulations for pain management

Two buprenorphine preparations are available for treatment of pain in Australia:

- (a) **Temgesic®** available in 0.2mg sublingual tablet and ampoules for intramuscular injection for the relief of short-term pain (up to 7 days). The usual dose is 1-2 tablets, 3-4 times daily; and
- (b) **Norspan®** available as a low dose weekly patch in 5, 10, and 20 (maximum dose) mcg/hr doses for the relief of persistent pain (up to 7 days).

These two buprenorphine preparations are used for persistent non-malignant pain management and are not suitable for the management of opioid dependence because the doses are generally too low to suppress opioid craving and opioid withdrawal. For further information on pain, see Section 12.

4.3.4 Buprenorphine actions and side effects

Many patients report less sedation on buprenorphine than on methadone (Soyka, et al., 2008). Research evidence suggests that buprenorphine has minimal effect on psychomotor performance; less than methadone or slow release oral morphine (Lintzeris, 2008). Any effect on psychomotor performance is likely to be greatest during the

early stages of treatment or following dose increases. During this time, patients should be advised to exercise caution in driving or operating machinery. The increased alertness commonly described by patients treated with buprenorphine may make it a more suitable pharmacotherapy than methadone for people who are working, studying or looking after young children.

Buprenorphine appears to have minimal impact on hepatic function, although there have been some reports of acute hepatitis following very high doses (>32 mg IV) (Hervé, et al., 2004). It should be noted however that there are some adverse side effects that have been observed with the sublingual film. These include a redness of the mouth, sore tongue and numb mouth. These symptoms are not reported for the sublingual tablet.

Because of its lower intrinsic activity and higher affinity with μ -opioid receptors than other opioids, when presently treated with full μ -opioid receptor agonists, buprenorphine may precipitate opioid withdrawal symptoms one to

four hours after the first dose. It may do so by displacing the agonist opioid medication from μ -opioid receptors. In the short term, newly introduced buprenorphine may not produce sufficient agonist effects to compensate for the displaced methadone, morphine or heroin, producing opioid withdrawal as it reaches its peak effects (approximately 1-4 hours after initial administration).

The phenomenon of precipitated withdrawal has particular clinical relevance during the induction of persons taking full agonist opioids, such as morphine, oxycodone and methadone. If precipitated withdrawal does occur, it is not life threatening and usually settles quite rapidly. This may nevertheless be distressing for patients and require treatment with clonidine 150 μ g Stat.

Buprenorphine has similar actions and side effects to methadone, however, the sedative and euphoric effects of buprenorphine are not as pronounced as methadone.

A summary of the pharmacological and clinical properties of buprenorphine are included in Table 4.4.

Table 4.4: Summary of the pharmacological and clinical properties of buprenorphine

Property	Clinical implication
Produces opioid effects	Reduces cravings for heroin and enhances treatment retention.
Prevents or alleviates heroin withdrawal symptoms	Can be used for maintenance or withdrawal treatment.
Diminishes the effects of additional opioid use (e.g. heroin)	Diminishes psychological reinforcement of continued opioid use. May complicate attempts at analgesia with opioid agonists (e.g. morphine).
Long duration of action	Allows for once a day dosing up to three times a week.
Ceiling on dose response effect	Less sedating than full agonists (heroin, morphine or methadone). Buprenorphine doses have 12mg/day may not increase the opioid agonist effects, but will prolong the duration of action. Safer in overdose, as high doses in isolation rarely result in fatal respiratory depression.
Sublingual preparation	Safer in accidental overdose (e.g. in children) as poorly absorbed orally. More time involved in supervised dispensing.
Modified withdrawal precipitated by opioid antagonists	Treatment with naltrexone can be commenced within 5-7 days of buprenorphine. May complicate management of opioid overdose requiring high naloxone doses.
Side effect profile or similar to other opioids	Generally well tolerated with most side effects transient.

Note: Reproduced from the Queensland Health (2008), Queensland Opioid Treatment Program Clinical Guidelines. Brisbane: Queensland Health.

4.3.5 Drug interactions with buprenorphine

The principal drug interactions with buprenorphine relate to its opioid activity. Drugs which interact with buprenorphine that are more likely to be observed in the opioid pharmacotherapy setting include:

- **Sedatives:** including opioids, alcohol, benzodiazepines, tricyclic antidepressants, antipsychotics, and sedating antihistamines, combined with buprenorphine, can lead to additive sedative effects, respiratory and CNS depression;
- **Opioid antagonists:** naloxone and naltrexone, can precipitate a withdrawal reaction in patients on buprenorphine, although the effect may be delayed by between 2 to 4 hours;
- **Opioid agonists:** effects can be blocked by buprenorphine, complicating the use of additional opioids for analgesia. Furthermore, the initial dose of buprenorphine can precipitate opioid withdrawal in patients who have recently used an opioid drug; and
- **Hepatic enzyme inducers and inhibitors:** buprenorphine metabolism can be influenced by the presence of drugs and other compounds that are metabolised by, or affect the activity of the Cytochrome system. Patients who are concurrently prescribed or using inhibitors of Cytochrome P450 3A4 may have increased buprenorphine blood concentrations, and those taking inducers may have decreased blood concentrations. To date, the identified clinically important CYP3A4 inhibitors mainly include macrolide antibiotics (e.g., clarithromycin, and erythromycin), anti-HIV agents (e.g., ritonavir and delavirdine), antidepressants (e.g. fluoxetine and fluvoxamine), calcium channel blockers (e.g. verapamil and diltiazem), steroids and their modulators (e.g., gestodene and mifepristone), and several herbal and dietary components. Such interactions are unlikely to be clinically significant, but precaution should still be exercised (see Appendix 2).

A full list of possible drug interactions with buprenorphine is presented in Appendix 3.

4.3.6 Clinical policy on buprenorphine in pregnancy and breastfeeding

At the time of writing, the Therapeutic Goods Administration (TGA) had not approved the use of buprenorphine pharmacotherapy during pregnancy and breastfeeding due to insufficient scientific support. Consequentially, previous recommendations were to switch female patients who became pregnant while on buprenorphine to methadone. However, (Vester & Buning, 2005) found that switching a patient from buprenorphine to methadone can cause opioid withdrawal in both mother and unborn baby. Therefore, the TOPP does not recommend switching female patients from buprenorphine to methadone if they become pregnant while in the program.

The Tasmanian Opioid Pharmacotherapy Policy and Clinical Guidelines do not recommend switching female patients from buprenorphine to methadone if they become pregnant while on the program.

This does not apply to the combination product, Suboxone®, which is absolutely contraindicated in pregnancy. Furthermore, pregnant patients cannot be inducted into the program on either buprenorphine preparation due to risks of precipitated opioid withdrawal, which can potentially lead to premature labour.

Therefore, the guidelines regarding buprenorphine and pregnancy are as follows:

For patients who become pregnant while receiving opioid pharmacotherapy

- if on Subutex®, continue on Subutex®; or
- if on Suboxone®, switch to equivalent dose of Subutex®.

For pregnant patients being inducted onto opioid pharmacotherapy

- DO NOT induct on either buprenorphine preparation; and
- induct on methadone only.

For patients who are breastfeeding:

- DO NOT induct on either buprenorphine preparation;
- induct on methadone only;
- if on methadone, continue breastfeeding; and
- if buprenorphine is the only viable treatment option, inform the mother of the limited research regarding the safety and effects on development of breastfed babies exposed to buprenorphine.

For a more detailed discussion on management of pregnancy and breastfeeding and buprenorphine, see Section 11.

4.4 Indication for opioid pharmacotherapy

Patients are suitable for opioid pharmacotherapy with either methadone or buprenorphine if they are opioid dependent and have been using opioids for an extended period time. Section 2 contains more detailed information about the criteria for opioid dependence.

For patients with an opioid use history of less than 6 months duration, the advice of an ADS Addiction Medicine Specialist must be sought to review the possibility of other treatment options prior to commencing opioid maintenance treatment.

4.5 General contraindications and precautions for opioid pharmacotherapy

There are several situations in which opioid pharmacotherapy may not be appropriate, require additional caution, or require approval through additional procedures. These include:

(1) When there are concerns about informed consent:

- (a) **Patients aged 16–17 years:** A second opinion by an Addiction Medicine Specialist in support of treatment must be obtained and fully documented before commencing pharmacotherapy. Buprenorphine may be preferred over methadone due to its lower risk of harm

in overdose and less severe withdrawal syndrome;

(b) **Patients aged less than 16 years:** Opioid pharmacotherapy treatment is generally contraindicated. If wanting to commence treatment, the prescriber must request an exemption in writing from the Clinical Director, Alcohol and Drug Services. The request for an exemption should include a second opinion from an ADS Addiction Medicine Specialist. Alternative dosing times may need to be considered for this special patient group so they are kept separate from adults in treatment;

(c) **Patients with reduced capacity to provide consent:** These include patients with an impaired mental state and reduced cognitive capacity. A second opinion from an Addiction Medicine Specialist is required to ensure legal requirements for consent are met.

(2) When there is a comorbid mental illness:

If the patient has a serious mental illness (e.g. schizophrenia or severe mood disturbance including mood instability), the general priority is to treat the mental illness; caution is required when prescribing opioid pharmacotherapy. A second opinion from an Addiction Medicine Specialist is required to authorise unsupervised dosing when the patient has a history of impulsive self-harm, a current risk of suicide or deliberate self-harm or thought disorder. In such cases, ongoing assessment of mental state is required to ensure that the patient can safely manage takeaway doses. If there is any reason for concern takeaway doses should not be provided.

(3) When there is polysubstance use:

If the patient is using other drugs, especially sedatives including alcohol and benzodiazepines, caution should be exercised. **All drug use, (prescribed, licit or illicit), can impact on the effectiveness of opioid pharmacotherapy.** For this reason all polysubstance use must be carefully assessed and strategies negotiated with the patient to reduce the risks and impact

of polysubstance use. **Regardless of the type of drug** (cannabis, amphetamines or over the counter medications) continued polysubstance use exposes the patient to a range of significant risks. These include social environments, networks and situations that may compromise their compliance with opioid pharmacotherapy; increased risk of relapse to unsanctioned drug use; and ambivalence about engagement in treatment. **Polysubstance use will also impact on the patient's eligibility for unsupervised dosing.**

- (4) Particular emphasis should be given to assessing the level of physical dependence on opioids, the likelihood of continued use of other sedative or psychoactive drugs, and the risk of overdose. Patients should be advised that commencing opioid pharmacotherapy is contingent on the patient's agreement to address other drug use. This may be through supervised daily dosing where appropriate (e.g. benzodiazepine dependence) and selective withdrawal management. Admission to the Inpatient Withdrawal Unit (ADS, Hobart) may be appropriate to facilitate safe induction and selective withdrawal management of other substances.
- (5) **When there is persistent pain:** Patients with persistent pain require specialist assessment and management. In the presence of co-occurring opioid dependence and persistent pain, safe and effective management of the pain is not possible unless and until the dependence is brought under control. Such patients are best managed by an Addiction Medicine specialist in consultation with a Pain Medicine specialist and a Multi-disciplinary Pain Unit team (See section 12.4).
- (6) **When there is allergy or hypersensitivity:** If the patient has a known hypersensitivity or allergy to the proposed drug formulation, an alternative preparation needs to be prescribed.
- (7) **Certain medical conditions:** Some medical conditions and associated treatments can affect the pharmacokinetics of

both methadone and buprenorphine. For example, in patients with advanced liver disease, doses of either medication may need to be significantly reduced. In cases of progressive liver disease, such as that seen in patients with Hepatitis C, previously tolerated doses may need to be reduced. Patients with respiratory disease may also be at increased risk of respiratory depression. In all these cases, and in patients with: acute alcohol dependence, head injury and raised intracranial pressure, ulcerative colitis, biliary and renal tract spasm, and for patients receiving monoamine oxidase inhibitors or within 14 days of stopping such treatment, caution is required. Seeking advice from an Addiction Medicine Specialist is recommended.

(8) When there is no neuroadaptation: Opioid pharmacotherapy is usually only suitable for individuals with opioid dependence accompanied with neuroadaptation: that is, patients who have developed tolerance and experience withdrawal symptoms when reducing or ceasing opioid use. However, some individuals with a long history of opioid dependence may benefit from opioid pharmacotherapy as a preventative measure following a long period of abstinence, for example, following incarceration. In such individuals, treatment induction must be cautious and a second opinion is recommended if treatment suitability is unclear. Such patients should be inducted as follows:

- Start with 5-10mg methadone and increase to no more than 20mg per day by the end of the first two weeks (unless the patient is showing signs of sedation. If so dose should be reduced); or
- Start with 2-4mg buprenorphine and increase to no more than 8mg by the end of the first two weeks (unless the patient is showing signs of sedation. If so dose should be reduced).

Section 6 outlines guidelines for safe treatment induction.

4.6 Comparing treatment options

With the availability of two major opioid pharmacotherapy treatment options, medical practitioners and their patients need to consider many factors when deciding on the most appropriate treatment. A thorough assessment will help clinicians identify risk and lifestyle factors that will influence the choice of pharmacotherapy for their patients, thus improving clinicians' ability to match treatment to assessment. It is important to remember that, despite the associated risks of both maintenance therapies, appropriate prescription and use of the medications is unlikely to lead to adverse consequences. The following section will offer comparisons between methadone and buprenorphine opioid pharmacotherapy on a variety of factors.

4.6.1 Pharmacology

A summary of the pharmacological comparisons is presented in Table 4.5 below.

Table 4.5: Pharmacological comparisons between methadone and buprenorphine

	Methadone	Buprenorphine
Classification	Full μ -opioid receptor agonist Used for maintenance treatment	Partial μ agonist Used for maintenance or withdrawal treatment
Substitutes for heroin	+++ Reduces cravings for heroin	+++ Reduces cravings for heroin
Blocks effects of heroin	++ At high doses (e.g. >60mg)	++++ At low doses (e.g. >4mg)
Side effects	Opiate like	Less sedating Can precipitate withdrawal
Withdrawal on cessation	+++ Described as severe and prolonged	++ Less severe
Onset of effects	30-60 minutes	30-60 minutes
Peak effects	2-6 hours	1-4 hours
Duration of clinical effects	16-30 hours	2-3 days
Metabolism	Hepatic MES +++ affected by liver metabolism	Hepatic MES and conjugation Less clinical impact on liver metabolism
Mode of administration	Oral	Sublingual
Drug interactions	Sedatives, μ -opioid receptor antagonists, inducers/inhibitors MES	Sedatives, μ -opioid receptor agonists and antagonists

Note: Reproduced from Queensland Health, (2008). Queensland Opioid Treatment Program Clinical Guidelines, (p.27).

4.6.2 Safety

Diversion

Both buprenorphine preparations are easier to divert than methadone liquid since they are in tablet form. However, Suboxone® is less likely to be diverted than Subutex® because the naloxone can precipitate withdrawal if injected (as discussed earlier). The recently released Suboxone® sublingual film may assist in reducing diversion.

Crushing the Subutex® tablets has been shown to have equal bioavailability to non-crushed tablets (Simojoki, et al., 2010) and is recommended to reduce the likelihood of diversion.

Injection of buprenorphine tablets is more likely to cause serious vascular damage and infection leading to the loss of limbs or digits than diverted methadone, which is already in a liquid form.

Polysubstance use

All drug use, prescribed, licit or illicit), can impact on the effectiveness of opioid pharmacotherapy. **For this reason all polysubstance use must be carefully assessed and strategies negotiated with the patient to reduce the risks and impact of polysubstance use.** Regardless of the type of drug (**cannabis, amphetamines or over the counter medications**) continued polydrug use exposes the patient to a range of significant risks. These include social environments, networks and situations that may compromise their compliance with opioid pharmacotherapy; increased risk of relapse to unsanctioned drug use; and ambivalence about engagement in treatment. Polysubstance use will also impact on the patient's eligibility for unsupervised dosing.

While polysubstance use is a risk factor for methadone and buprenorphine treatments, buprenorphine is generally safer when combined with other substances than methadone.

However, buprenorphine combined with benzodiazepines or alcohol, particularly in a non-opioid tolerant individual, can lead to fatal respiratory depression. Because of this risk,

Gibson and Degenhardt (2005) recommend patients receiving the buprenorphine-naloxone combination should be warned of toxicity when the medication is combined with alcohol and benzodiazepines. The authors conclude that people dependent on alcohol or benzodiazepines should not receive unsupervised administration of buprenorphine.

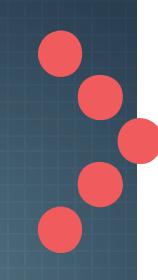
Toxicity and respiratory depression

Dose response studies show that high buprenorphine doses (>16mg daily) do not result in substantially greater peak opioid effects than lower doses (8 – 12mg) (Walsh et al., 1995). Because buprenorphine is a partial μ -opioid receptor agonist, doses many times greater than normal therapeutic doses appear to be well tolerated in most individuals, 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.

Methadone, however, is a full μ -opioid receptor agonist. Therefore, increasing the dose causes progressive depression of respiration and consciousness, which contributes to a higher risk-profile for methadone than buprenorphine.

Overdose

Either directly experiencing or witnessing an overdose is a common occurrence for many opioid dependent people. Route of administration, variable drug purity, variable tolerance, polysubstance use, and poor general health, all contribute to the risk of accidental overdose. Furthermore, the mortality rate for opioid users who are recently released from prison and not in an opioid pharmacotherapy program is up to fifty times greater than that for age-matched comparison groups (Kamina, et al., 2007; and Krinsky, et al., 2009). High levels of psychiatric comorbidity in opioid users mean that the risk of intentional overdose is high. Takeaway doses should be suspended immediately following any episode of attempted suicide, or when there is suicidal ideation to ensure the safety of the patient.



Experience of a non-fatal overdose can be a traumatic experience for patients. Clinicians should attempt to improve patient engagement with treatment services following an overdose. It is important to establish the causes of the overdose: deliberate attempt at self-harm may require psychiatric assessment, potentially leading to scheduling the patient under the *Mental Health Act 1996*.

Since buprenorphine is safer than methadone in overdose, it is the preferred treatment option, particularly in patients at risk of overdose or in situations in which children may accidentally consume stored or diverted medication. In the event of a high dose buprenorphine overdose higher doses of naloxone may be required (in conjunction with other medical interventions) in order to resuscitate the patient in comparison to overdose on methadone or other opioids with lower μ -opioid receptor affinity.

Mortality

A number of factors have been associated with death during the induction phase of methadone. These factors include:

- concurrent use of other drugs;
- inadequate assessment of tolerance;
- commencement dose too high;
- dose increase too rapid;
- inadequate understanding of cumulative effects of methadone;
- poor supervision during dosing; and,
- individual variation in the metabolism of methadone.

Furthermore, mortality rates associated with methadone treatment are higher than rates associated with buprenorphine treatment (Bell, et al., 2009a). Indeed, over one-fifth of all methadone deaths occur during the first week of treatment induction whereas international literature has recorded only two deaths during buprenorphine induction (Bell, et al., 2009b, Gibson & Degenhardt, 2005). More specifically, Australian research by Gibson and Degenhardt (2005) has shown that buprenorphine is associated with lower mortality (0.02/1,000 treatment episodes) than methadone (2.7/1,000 treatment episodes) and naltrexone

(10.1/1,000 treatment episodes). In other words, on the basis of this study, the risk of death per treatment episode is 135 times greater for methadone compared to buprenorphine, and 500 times greater for naltrexone compared to buprenorphine.

There are some concerns in the literature that buprenorphine deaths may be under-represented in Australian coronial databases (Gibson & Degenhardt, 2005); however, many of the deaths that have occurred in association with buprenorphine treatment outside of Australia have largely been due to patient's unsanctioned use of opioid drugs. Overall, however, when administered appropriately (with supervision), buprenorphine is safer during both the induction and the maintenance phases of opioid pharmacotherapy.

4.6.3 Abuse potential

Although all opioids have abuse potential, people who are frequent users of heroin, methadone, or other μ -opioid receptor agonists which bind less tightly to opioid receptors than buprenorphine (Jones et al., 1999). This particularly applies if patients are aware that this may cause precipitated withdrawal.

The effects of buprenorphine (taken sublingually or by intravenous injection) in people on naltrexone maintenance treatment remains unclear. It is salient to note once again that naltrexone has a higher affinity for the μ -opioid receptor. Administration of buprenorphine to this population may result in an attenuated agonist effect, particularly with low doses of naltrexone, as is generally the case with implanted preparations of naltrexone.

4.6.4 Accessibility

Both methadone and buprenorphine are available to patients and subsidised by the Pharmaceutical Benefits Scheme (PBS – Section 100).

Patients can be dosed on buprenorphine every second to third day once stabilised, whereas methadone must be dosed daily. Since there are very few 7 day dosing pharmacies in Tasmania, buprenorphine is usually the most convenient option for patients.

4.6.5 Administration

Methadone liquid is immediately consumable, whereas buprenorphine sublingual tablets take between 4-10 minutes to be absorbed sublingually. The buprenorphine sublingual film takes less time than this to be absorbed and need only be supervised for 30 seconds (up to 16mg) or one minute if greater than 16mg. Although the rate of dissolution of buprenorphine can be increased (if the patient is given a lemon drink before the medication is placed under the tongue and the tablets rough crumbled), time taken to complete the procedure remains lengthier than the administering of methadone.

4.6.6 Evidence

Current evidence indicates that both methadone and buprenorphine are the most effective opioid pharmacotherapy treatment options and significantly reduce illicit opioid use and associated risks. Furthermore, they are both similarly effective on several measures (Gowing et al., 2001 and Mattick et al., 2004). Although many patients report preferring buprenorphine in comparison to methadone due to its subjective effects, some evidence indicates that treatment retention is better for methadone (Gowing et al., 2001 and Mattick et al., 2004). This may in part arise from the observation that when patients miss one or more doses of buprenorphine the withdrawal symptoms tend to be less severe compared to when methadone doses are missed. It is important to acknowledge that despite the documented benefits of buprenorphine, methadone has been available to practitioners for much longer;

hence, methadone may be a more familiar option to both practitioners and patients.

4.6.7 Effects

The patient's personal and psychosocial circumstances will influence whether they prefer the effects of methadone or buprenorphine. It has been reported that patients generally prefer buprenorphine as it has fewer side effects and patients experience less sedation and often report feeling more energetic when receiving buprenorphine treatment in comparison to methadone (Pinto, Rumball & Holland, 2008). However, some patients with psychosocial problems may prefer the sedating effects of methadone, while others who are more active or have more responsibilities may prefer buprenorphine (White, et al., 2007). Finally, some patients wishing to continue unsanctioned opioids may prefer methadone as it is less likely to block the effects of unsanctioned opioid use than buprenorphine at higher doses.

4.6.8 Withdrawal

During induction onto buprenorphine, there is a risk of precipitated withdrawal occurring (particularly if continuing to use full agonist opioids) as the buprenorphine displaces other agonist opioids from μ -opioid receptors (see section 4.3.4). Patients and clinicians may sometimes misinterpret this as an allergy or adverse event.

However, buprenorphine withdrawal is generally less severe than withdrawal from methadone – both in the severity of the symptoms and the duration of withdrawal. Buprenorphine is now favoured as the pharmacological agent of choice for opioid withdrawal management. A more rapid withdrawal from buprenorphine can be achieved than with methadone. It is also possible to immediately cease buprenorphine if necessary.

4.6.9 Switching treatment options

It is relatively easy to transfer from buprenorphine to methadone, but more complex transferring from methadone to buprenorphine, as this can precipitate withdrawal. (See section 8.12 for guidelines for switching).



4.7 Gateway Model – Buprenorphine as induction agent of choice

As evidenced when comparing buprenorphine and methadone on a variety of outcomes, buprenorphine is safer (particularly during induction) and overcomes access issues, and patients can engage in treatment more readily. It also has a more favourable side-effect profile than methadone. This, combined with the availability of 7 day dosing pharmacies in Tasmania, make it the most desirable induction agent of choice.

Therefore, Tasmanian Alcohol and Drug Services adopt and support a 'Gateway Model' for opioid pharmacotherapy induction. More specifically, the preferred agent for commencement and stabilisation of patients onto the Tasmanian Opioid Pharmacotherapy Program is the buprenorphine-naloxone preparation Suboxone®. Considerations and exclusions from this model of treatment induction are:

- pregnant females;
- patients currently on methadone being transferred from another clinic;
- patients with a known allergy or hypersensitivity to buprenorphine (and its available preparations);
- patients for whom a clinical evidence indicates methadone would be the most appropriate induction agent and where this is considered safe; and
- patients with clinically significant respiratory or hepatic insufficiency. For these clients both buprenorphine and methadone may pose significant risks, and specialist opinion should be sought.

Suboxone® is the preferred agent for commencement and stabilisation of patients in Tasmania.

Patients should be trialled on buprenorphine for a minimum of two weeks. If the patient is experiencing clearly observable and clinically significant side-effects from the buprenorphine they may be switched to methadone at any stage. Where there is any doubt about a patient's side effects from buprenorphine, advice from an ADS Addiction Medicine Specialist should be sought.

It is important to ensure that all patients entering opioid pharmacotherapy are thoroughly assessed prior to commencement of treatment. Ongoing review will ensure that the appropriate treatment is provided, remembering that clinical safety considerations will guide treatment decision making. The following section describes how to conduct a thorough assessment prior entry into pharmacotherapy.



SECTION: 5

Assessment for entry into the Opioid Pharmacotherapy Program

In this section you will...

- Develop a comprehensive understanding of the assessment requirements for entry into the Opioid Pharmacotherapy Program.

5	Assessment for entry into the Opioid Pharmacotherapy Program	52
5.1	Assessment	52
5.2	Patient examination guidelines	52
5.3	Initial assessment	53
5.3.1	Risk and protective factors	53
5.3.2	Contraindications	54
5.4	Substance use history	54
5.4.1	Opioid use history	54
5.4.2	Other drug use history	54
5.4.3	Risk factors	54
5.4.4	Protective factors	55
5.4.5	Prescribed medication history	55
5.5	Past medical history	55
5.5.1	Risk factors	55
5.5.2	Protective factors	55
5.6	Psychological and psychiatric history	56
5.6.1	Risk factors	56
5.6.2	Protective factors	56
5.7	Social history	56
5.7.1	Risk factors	57
5.7.2	Protective factors	57
5.8	Family history	57
5.8.1	Risk factors	57
5.8.2	Protective factors	57
5.9	Pregnancy and breastfeeding	58
5.9.1	Risk factors	58
5.9.2	Protective factors	58
5.10	Allergies	58
5.11	Clinical examination	58
5.11.1	Additional considerations	59
5.12	Investigations	59
5.13	Urine drug screening (UDS) during assessment	59
5.14	Collateral information	60
5.15	Summary and formulation	60
5.16	Additional consideration – harm reduction advice	61



Section: 5

5 Assessment for entry into the Opioid Pharmacotherapy Program

5.1 Assessment

The foundation of every treatment plan and intervention is a comprehensive assessment. It determines the clinical pathway for access to specialist programs and interventions, as well as informing the treatment plan.

Assessment of alcohol and other drug use is a complex and continuous process that occurs both at the commencement of, and throughout treatment (Sobell, 1988). Continuous assessment allows the clinician to identify changes that occur in the patient's life, and determine how these changes may impact on their risk status and treatment planning (Addy et al., 2000).

A carefully conducted alcohol and drug assessment should also be patient focussed and fulfil the following functions:

- to support the development of a therapeutic and trusting relationship;
- to assist patients to evaluate and consider their own drug use and motivation for change;
- to assist patients to make linkages between their drug use and current difficulties that they may be experiencing in their lives;
- to assist the patient to review their past and current circumstances and to make linkages between these and current drug use; and,
- to assist the patient to review the choices that they have made and the consequences of their drug use behaviour (Helfgott, 1997).

The Alcohol and Drug Service (Department of Health and Human Services, Tasmania) has developed a suite of standardised assessment tools and guidelines to inform service delivery. These include The Clinical Assessment Tool (CAT) and the Medical Examination. These tools are routinely used by ADS staff

involved in the delivery of clinical services and can be accessed by contacting 1300 139 641.

5.2 Patient examination guidelines

The Australian Medical Association (AMA) has developed and endorsed the AMA Patient Examination Guidelines (1996). These guidelines (presented below) assist clinicians when seeking permission to conduct a physical examination. They are based upon the premise that communication is critical to the therapeutic relationship and that clinicians have a responsibility to behave in a professional, considerate and ethical manner (AMA 1996).

Whilst some procedures or examinations may be a simple or routine matter for clinicians, they may not be seen as such by the patient. When conducting a physical examination of a patient who may have a history of physical or sexual abuse or trauma, or if you observe increased anxiety or agitation, you should ask the patient if they would like a support person to be present. This would usually be another staff member of the same sex as the patient.

I. Physical examination

- the patient should be examined in privacy
- the patient should be provided with a sheet, a gown or some other garment to preserve modesty as appropriate.
- the patient's modesty should be preserved in undressing and redressing before and after the physical examination eg:
- the provision of a screen behind which the patient can undress.
- the clinician excusing themselves from the consulting room whilst the patient is undressing.
- the clinician turning away while the patient is disrobing.
- consideration of whether the presence of a third person is required.

2. Explanation to the patient

prior to the physical examination commencing, the clinician should explain:

- what part(s) of the body is/are to be examined.
- why the examination is being conducted.
- what the examination entails, including the extent to which any disrobing may be required (AMA, 1996).

5.3 Initial assessment

The aim of the initial assessment is to establish the patient's suitability for opioid pharmacotherapy with either methadone or buprenorphine. Suitability is established when there is clear evidence that the patient:

- is opioid dependent;
- meets the DSM-IV-TR criteria for opioid dependence; and,
- has been using opioids for an extended period of time.

If the patient has been using opioids for less than 6 months, treatment other than opioid pharmacotherapy should be considered.

This can include inpatient detoxification followed by intensive psychosocial intervention or residential rehabilitation. Inpatient detoxification without follow-up is not recommended due to the risk of overdose or death if opioid use is recommenced after treatment.

Furthermore, the clinician must ensure that there is objective information to support the patient's opioid use, since commencing a non-opioid dependent patient on opioid pharmacotherapy can place the patient at risk of overdose or death.

The initial assessment should also provide opportunity for:

- establishing a therapeutic relationship with the patient;
- the patient to make an informed decision about treatment;
- documenting an initial treatment plan; and
- meeting legislative requirements (e.g. gaining authority to prescribe for the patient).

In some settings the initial assessment may

be conducted by practitioners from different professional backgrounds. However, all initial assessments must include a medical examination conducted by the prescribing doctor.

All initial assessments must include a medical examination conducted by the prescribing doctor.

The process of the initial assessment includes history taking, examination and investigations. Specific content areas required for the initial assessment include:

- substance use history;
- social history;
- family history;
- prescribed medication history;
- past medical history ;
- psychological and psychiatric history;
- allergies; and
- clinical examination and investigations.

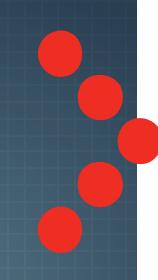
5.3.1 Risk and protective factors

Consideration of risk should be an integral component of every assessment and ongoing management of the patient (Reith, 1998). Patients accessing alcohol and other drug treatments often have comorbid mental health disorders, chaotic and unstable lives and are frequently at greater risk of suicide (Maloney et al 2007).

However, patients may also have protective factors that mitigate risks and facilitate or support treatment interventions (Reith, 1998). When reviewing each of the initial assessment content areas (listed above), clinicians should consider both risk and protective factors.

The key risk and protective factors will be highlighted throughout this section.

It is important to note that risk factors do not necessarily preclude the patient from accessing opioid pharmacotherapy, but may indicate the need for closer monitoring, second opinions, risk management strategies or caution around dosing practices (e.g. precluding them from takeaway doses). Risk factors may also have



implications on longer-term treatment planning and referral, consultation or communication with other treatment services. Risk factors for specific issues, such as drug use, medical and psychiatric histories, are discussed in the following subsections.

Considering risk and protective factors when assessing patients and developing treatment plans is a strengths based approach. Such models are commonly used in other health areas, such as mental health. In adopting and applying this framework to Tasmanian ADS patients, it is expected that clinical safety will be enhanced.

5.3.2 Contraindications

Clinicians are referred to Section 4 which contains a list of treatment contraindications and circumstances under which a second opinion is either recommended or required.

5.4 Substance use history

It is essential that a comprehensive substance use history is carried out for new patients. This assessment should focus on all current and lifetime drug use – both prescribed and illicit.

5.4.1 Opioid use history

Obtaining a thorough assessment of a patient's opioid use history is essential at the commencement of treatment. This includes assessing opioid dependence, withdrawal and neuroadaptation. Definitions (including the characteristics) for opioid dependence and withdrawal are discussed in Section 2. Critical information in establishing evidence of neuroadaptation includes:

- age when first used opioids and relevant circumstances;
- age when first dependent on opioids;
- duration, route, frequency and pattern of use;
- duration of current episode of dependence on opioids;
- cues for drug use;
- type of drug used (i.e. heroin; oxycodone);
- date and time of last use of opioids;

- needle sharing and equipment cleaning practices;
- previous treatment history, particularly opioid pharmacotherapy or opioid withdrawal;
- history of overdose and severity;
- any other previous complications of injecting drug use; and
- longest opioid free period and how this was achieved.

5.4.2 Other drug use history

Critical in establishing the patient's safety on the program will be accurate knowledge about the patient's non-opioid drug use history. Key information includes:

- age when first used alcohol and other drugs and relevant circumstances;
- all current drug use, including alcohol, tobacco and cannabis;
- duration, route, frequency and pattern of use;
- duration of current episode of dependence on other drug/s;
- type of drug used;
- date and time of last use of other drugs;
- number of drug free periods and how these were achieved;
- cues for alcohol and other drug use;
- previous treatment history, particularly detoxification or rehabilitation;
- history of overdose and severity; and
- any other previous/current complications of substance use.

5.4.3 Risk factors

When assessing for the above factors, it is important to consider the behaviours associated with the opioid and other substance use. Some behaviours that might indicate increased risk on the program include:

- 'doctor shopping';
- accessing substances from multiple sources;
- over-the-counter drug seeking from pharmacies;
- concurrent use of multiple opioids;

- reporting of lost, stolen, or misplaced medications and/or prescriptions within the last 12 months;
- history of drug overdose;
- unsafe injecting practices;
- history of diversion;
- polysubstance use that increases the risk of multiple drug toxicity;
- hazardous or harmful other drug use
- using up prescription medication ahead of time;
- benzodiazepine dependence and concurrent use with opioids;
- daily or most daily alcohol use and/or binge drinking;
- complications associated with withdrawal; and
- poor compliance or removal from previous treatment programs.

5.4.4 Protective factors

Protective factors in this category are those behaviours that mitigate the risks involved with unsanctioned opioid and/or other drug use, for example:

- use of harm reduction strategies around drug use;
- skills developed through previous alcohol and drug treatment interventions;
- positive engagement with previous treatment services;
- compliance with previous treatment programs;
- adherence with recommendations regarding prescription medications;
- absence of risky polysubstance use; and
- successful periods of abstinence.

5.4.5 Prescribed medication history

The patient's current and past medication history is required. Some medications used to treat infectious or other diseases are contraindicated, or may affect the choice of pharmacotherapy agent. The reader is referred to Section 4 on clinical pharmacology.

5.5 Past medical history

A medical history should gather information on:

- physical symptoms;
- history of withdrawal-related problems;
- childhood illnesses;
- surgery and hospital admissions;
- accidents, including head trauma;
- infectious diseases including viral hepatitis, HIV and tuberculosis;
- current medications;
- history/experience of pain related conditions; and
- chronic diseases.

5.5.1 Risk factors

A good medical history assists in identifying contraindications (refer to Section 4) for opioid pharmacotherapy treatment as well as informing the selection of an appropriate treatment agent. Inaccurate reporting of medical history by the patient, or restrictions on sharing of information by key health professionals is a significant risk when assessing the patient's suitability for pharmacotherapy.

Diagnosis of HIV and HBV also gives patients priority access to the program (see Section 3).

The presence of non malignant persistent pain or reluctance to follow through on referrals to specialist pain treatment services can be an indicator that the patient is drug seeking and not using prescription pain medications as prescribed.

5.5.2 Protective factors

Overall, good health and the absence of other medical conditions provide a good foundation for entry into opioid pharmacotherapy maintenance treatment. Active engagement and appropriate management of ongoing physical conditions by other relevant providers can also be a protective factor. Transparency, accurate reporting and information sharing about ongoing medical conditions are also likely to reduce risks associated with these conditions.

5.6 Psychological and psychiatric history

The patient's psychological wellbeing, attitude towards pharmacotherapy and stage of change are important to assess. Further areas for assessment include:

- mental state, including self-harm, suicidal or homicidal ideation;
- past and present mental health diagnoses and interventions;
- mental health related hospital admissions;
- involvement of mental health support agencies or clinicians;
- cognitive functioning; and
- motivation for change and goals of treatment.

5.6.1 Risk factors

Psychological and psychiatric risk factors include:

- a recent deterioration in mental state or psychiatric admission;
- untreated serious mental illness;
- poor compliance with medication and other interventions for the treatment of mental illness;
- poor insight into mental health problems;
- loss of volition;
- inability to understand and consent to pharmacotherapy treatment due to mental state or cognitive impairment;
- history of risk taking or impulsive behaviour;
- absence of problem solving skills and adaptive coping strategies;
- current self-harm, suicidal or homicidal ideation;
- history of self-harm, suicide attempts, or violence towards others, particularly in the past year; and
- high vulnerability to stressors.

Prescribed treatment with multiple psychoactive drugs such as antipsychotics, anti-depressants, benzodiazepines, and mood stabilisers may increase the patient's risk on the pharmacotherapy program. Regardless of whether medications are prescribed or obtained illicitly, the risk of combining drugs with respiratory depressant activity with opioid pharmacotherapy is the same.

5.6.2 Protective factors

Psychological and psychiatric protective factors include:

- stable mental state;
- active engagement in treatment for serious mental illness;
- high motivation for change;
- self awareness of strengths and weaknesses;
- stable affect and emotional regulation skills;
- past success in making cognitive and behavioural changes;
- ability to learn from and to make linkages to past experiences;
- realistic goals for treatment outcomes;
- positive thinking style;
- insight and awareness into problems; and
- well developed problem solving and coping skills.

5.7 Social history

This includes information about the patient's:

- employment history (including home duties);
- education history and qualifications;
- forensic history;
- personal interests and hobbies;
- peer groups and social networks;
- accommodation arrangements – location and co-habitants;
- intimate relationships;
- major life events including trauma, grief, loss, and history of abuse; and
- barriers to change.

5.7.1 Risk factors

Within this category, factors that may increase risk include:

- insecure or unstable housing – which may exclude the patient from receiving takeaway doses;
- presence of problematic alcohol and other drug use in the living environment;
- engagement in criminal activities;
- forensic history involving violent or abusive behaviour, prescription pad theft or forgery;
- problematic alcohol and/or drug use, or a drug seeking partner and peers;
- relationship breakdown;
- unsafe sexual practices (increasing risk of exposure to blood borne viruses);
- ongoing exposure to threatening, aggressive and violent behaviour;
- peer pressure to use or supply drugs;
- social isolation; and
- recent release from prison.

5.7.2 Protective factors

The following factors are likely to positively influence the patient's success on the program:

- stable employment;
- stable relationships;
- reliable transport and access to services;
- community ties;
- hobbies and interests;
- supportive social networks and partner;
- non drug seeking social network and partner;
- stable and secure housing ; and
- absence of legal issues.

5.8 Family history

Important information in this section includes:

- a genogram;
- family of origin;
- current marital status;
- quality of family relationships, family supports, and current custody and care arrangements of children; and
- substance use, medical and mental health history of the family.

5.8.1 Risk factors

Risk factors in this section include:

- poor health and wellbeing (including special needs) of children in the patient's care, which may involve mandatory reporting or liaison with family services;
- family history of substance use and abuse;
- family history of significant mental health issues;
- family history of poor coping skills, vulnerability, and crises;
- dysfunctional or disrupted family relationships, including abuse, neglect and involvement with the child protection system; and
- family relocation.

5.8.2 Protective factors

Protective factors in this category include:

- stable family relationships;
- secure, nurturing, and appropriate attachments;
- positive family role models;
- well developed and functional coping skills of family;
- appropriate family engagement in the patient's treatment; and
- appropriate interpersonal boundaries within the family unit.

5.9 Pregnancy and breastfeeding

As stated in Section 3, pregnant women are a priority group for entry into opioid pharmacotherapy. Chaotic drug use and withdrawal states can place the mother and foetus at risk and may result in miscarriage.

For female patients, it is important to establish their pregnancy and breastfeeding status, as well as their plans or intention to get pregnant, as this will influence the choice of opioid pharmacotherapy treatment agent. Reported pregnancy should be confirmed with a blood test. Section 11.5 outlines the management of the pregnant patient in opioid pharmacotherapy.

Female patients often cease ovulation during periods of unsanctioned and chaotic opioid use. Commencing patients on opioid pharmacotherapy may stabilise their ovulation, hence increasing the risk of unplanned pregnancy if contraception is not used. For this reason it is important to assess and discuss with patients their current use of contraception.

5.9.1 Risk factors

Pregnancy itself is not a risk factor to preclude female patients from accessing opioid pharmacotherapy. However, there is a significant risk of miscarriage if a pregnant patient misses a number of consecutive doses or abruptly ceases opioid maintenance treatment. Therefore, it is essential that this is clearly explained to the patient upon assessment.

Another risk factor to consider is reluctance to engage with antenatal services and a general practitioner or obstetrician. This may compromise the health and well being of the baby and mother, and also affect the ability to develop an integrated antenatal and postnatal care plan for the mother and baby.

5.9.2 Protective factors

If the mother is focused on the health and wellbeing of her baby, this can be a motivating factor for positive engagement and compliance with opioid pharmacotherapy treatment. Regular and transparent communication between the treating team and antenatal services is likely to result in more positive outcomes for mother and baby.

5.10 Allergies

It is important to establish and clarify if the patient has any allergies or has had previous adverse affects associated with prescribed or non-prescribed medications. This includes clarifying allergies from drug interaction effects.

Patients may sometimes report an allergy to one of the treatment agents in order to access the alternative or their preferred treatment agent. In this instance, it is important to confirm this information through the use of, for example, discharge summaries and medical notes.

5.11 Clinical examination

This section of the initial assessment identifies clinical signs related to drug use, including intoxication and withdrawal, injection sites, and symptoms related to any other significant medical condition. (See Section 5.1 Patient Examination Guidelines; Physical Examination and Explanation to the patient).

Examining for signs and symptoms of opioid withdrawal, intoxication and overdose (see Section 2) are an important component of the physical examination.

The examination should also thoroughly assess for:

- injecting sites, with a particular emphasis on arms, legs, feet, neck and the groin area;
- bruising, phlebitis and puncture marks; and
- skin disorders and cellulitis.

A general physical examination should also include a systems review, with a focus on organs that may have been damaged as a result of substance use. This should include checking for:

- heart murmurs;
- signs of liver damage or disease;
- signs of haematological disorder;
- neurological impairment; and
- skin disorders and cellulitis.

5.11.1 Additional considerations

When conducting a physical examination of a patient who may have a history of physical or sexual abuse or trauma, or if you observe increased anxiety or agitation, the clinician should ask the patient if they would like a support person to be present. This would usually be another staff member of the same sex as the patient.

The clinician may elect to have another staff member present when there is a history of resistance, reluctance to engage in treatment, a lack of awareness and insight into problematic drug use, or a history of medico-legal complaints.

5.12 Investigations

A series of routine investigations should be performed to determine the general health status of the patient. Mandatory investigations include:

- full blood count and ESR;
- biochemical screen (electrolytes, hepatic and renal function);
- BBV screen;
- urine toxicology;
- breath alcohol test; and
- thyroid function.

Secondary investigations (not mandatory) include:

- chest x-ray;
- sexual health screen;
- Mantoux test; and
- others as indicated by the history and examination.

If a patient presents with signs of alcohol intoxication or has a history of alcohol abuse, they should be breathalysed as part of a routine and thorough clinical assessment.

5.13 Urine drug screening (UDS) during assessment

Commencing a patient who is not opioid dependent on opioid pharmacotherapy presents a significant risk of overdose or death. Consequently, a supervised UDS that confirms the presence of opioid metabolites is required prior to commencing treatment. A supervised urine drug screen is compulsory for assessing suitability for treatment.

A supervised urine drug screen is compulsory for assessing suitability for treatment.

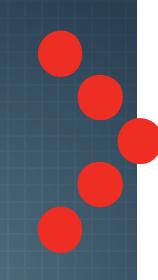
While there are limitations in the sensitivity and specificity of each method of analysis, urine drug testing provides important objective evidence of drug use. This not only corroborates evidence of opioid use, it also establishes the test as a legitimate and integral element of opioid pharmacotherapy. Patients need to be aware that a UDS is required in order to commence treatment,

Supervised UDS

A supervised UDS involves monitoring and co-ordinating the process for obtaining a urine specimen, thus maximising the likelihood that the sample provided is that of the patient's. The specimen should also be warm and of normal depth and colour (not diluted).

Specifically, it involves:

- confirming the identity of the patient;
- escorting the patient to the designated area;
- providing the patient with the necessary equipment for obtaining the sample;
- receiving the specimen directly from the patient; and
- limiting or removing other items that they are allowed to take into the room (e.g. bags and coats).



In the general practice setting, the practice nurse may assist in obtaining a supervised UDS. Alternatively, a supervised UDS can be requested from the local laboratory service.

Directly Observed UDS

A directly observed UDS requires the clinician to directly observe the urine leave the body into the container. This process is intrusive and, hence, should only be used where there are significant clinical risks or clear evidence that previously supplied urine samples were tampered with or not that of the patient's.

If the patient is unable to immediately provide a urine sample, provide the patient with 500ml of water to consume and repeat the UDS process again in 20-30 minutes time. If the patient is still unsuccessful in providing a specimen, they should be asked to re-present later in the day or early the next morning to repeat the procedure. It is important to note that the UDS procedures detailed above are based on the Australian/New Zealand Standard Procedures for the Collection, Detection and Quantification of Drugs of Abuse in Urine. However, they do not meet the standards required for the provision of samples as evidence for legal proceedings.

Directly Observed UDS are recommended when:

- there is concern about the accuracy of clinical information provided;
- there is an established history of tampering with UDS;
- there is poor compliance with UDS procedures and requirements;
- there is a need for reliable and objective clinical information; and
- there are concerns about clinical and public safety.

Obtaining a specimen for a UDS is by nature an intrusive process that can be intimidating, embarrassing and distressing for patients. Demonstrating a pleasant and professional approach will assist in minimising the patient's discomfort. If a patient has a history of abuse or trauma (or increased anxiety or agitation is observed), it may be helpful to enquire if

the patient would like a support person to be present. This would usually be another staff member of the same sex as the patient.

5.14 Collateral information

Collateral information can inform a thorough assessment and aid in developing a formulation. If possible, collateral information should be collected from the following sources with the patient's consent:

- previous and current medical practitioners;
- dispensing pharmacists;
- family (with patient's consent); and
- Medicare Australia.

The sharing of information is critical to the delivery of good clinical care and is essential to inform the clinical decision making process. It is appropriate to delay the start of treatment until all the necessary information is available, in order to make an informed decision about suitability for treatment. For this reason it is important to talk to the client about the need to obtain consent.

The sharing of information is critical to the delivery of good clinical care and is essential to inform the clinical decision making process.

5.15 Summary and formulation

A summary or formulation outlines the patient's key issues and factors that may influence treatment outcomes. Informed clinical decision making is based upon the evaluation of subjective and objective information collected through the assessment process. The provision of opioid pharmacotherapy treatment requires careful consideration of risks to ensure patient safety.

In determining a patient's suitability for pharmacotherapy, the clinician should consider the identified risk and protective factors, and determine whether risk factors are manageable within the treatment program. If a patient does not wish to address a co-occurring alcohol or other drug use issue (that will have

a direct impact on the effectiveness and clinical safety of opioid pharmacotherapy treatment) consideration needs to be given to whether treatment with pharmacotherapy is indicated.

If there are multiple or significant clinical risks that cannot be managed in the practice setting, a second opinion and clinical review (within the ADS, a multidisciplinary team case review or discussion with the Clinical Director) should be requested from the Alcohol and Drug Service.

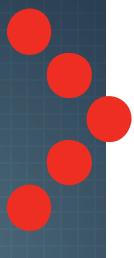
If there are multiple or significant clinical risks that cannot be managed in the practice setting, a second opinion and clinical review should be requested from the Alcohol and Drug Service.

- information about the risks associated with polysubstance use;
- the heightened risks of overdose associated with use of respiratory depressant drugs, such as benzodiazepines and alcohol, in combination with methadone or buprenorphine;
- using a 'taste test', i.e. use of a small amount of a drug before using the intended amount; and
- how to respond to overdose; including calling an ambulance and reassuring the patient (if conscious) or others present that calling an ambulance does not involve police.

5.16 Additional consideration – harm reduction advice

The initial assessment can also be an opportunity to provide harm reduction advice and information. Such information may reduce the risks associated with drug use. This advice may include:

- using safe injecting practices including sterile injecting equipment (e.g. needles and syringes, water for injection);
- not sharing injecting paraphernalia, including needles and syringes, winged-infusion sets ('butterflies'), spoons, filters, water and tourniquets;
- referral to the local needle and syringe program;
- advice about mode of administration, for example, that oral administration is safer than intravenous use;
- using in the company of others in case of overdose;
- the risk of rapidly diminishing tolerance to opioids following cessation of use, and the risks of overdose on resumption of use if at levels close to those previously used;
- information and strategies for low risk alcohol use;





SECTION: 6

Entry into opioid pharmacotherapy

In this section you will...

- Develop an understanding of the requirements of both patients and the treating agency when a patient commences opioid pharmacotherapy treatment.

6	Entry into opioid pharmacotherapy	64
6.1	Preparing the patient	64
6.1.1	Developing rapport	64
6.1.2	Treatment planning	64
6.1.3	Treatment education	65
6.1.4	Special warnings	65
6.1.5	Pregnancy and contraception	67
6.1.6	Rights and responsibilities	67
6.2	Request for second opinion	68
6.3	Requirements for entry into treatment: administrative procedures	69
6.3.1	Providing adequate identification	69
6.3.2	Informed consent	69
6.3.3	Arranging transport	70
6.3.4	Securing a dosing site	70
6.3.5	Confidentiality and release of information	71
6.3.6	Health Insurance Commission Medicare Prescription Shopping Program	72
6.3.7	Complaints and appeals procedures	73
6.4	Alcohol and drug services treatment agreement	74
6.5	Creating a patient file	74
6.6	Information pack	74



Section: 6

6 Entry into opioid pharmacotherapy

Once a thorough assessment is complete, the clinician (or pharmacotherapy team) is able to determine whether the patient is safe and suitable for registration into the pharmacotherapy program. An important part of this process is ensuring that the patient has comprehensive knowledge about the program and the ability to consent to treatment.

This section outlines both the information required from patients, and the information that should be provided to them prior to the commencement of opioid pharmacotherapy treatment.

6.1 Preparing the patient

6.1.1 Developing rapport

Developing rapport with the patient is essential, especially considering that the therapeutic relationship has been shown to be highly important in influencing positive treatment outcomes (Simpson et al., 1997). An empathic, respectful, and non judgmental approach to the patient from the very beginning of treatment is likely to facilitate an open and trusting therapeutic relationship. Clinicians should discuss the importance of a strong therapeutic alliance with the patient, particularly in reference to the therapeutic goals of entering the program.

An open and honest relationship is the basis of a strong therapeutic alliance. The emphasis is on collaboration which facilitates the client's sense of mastery, competence, ownership and involvement in the process (March & Dale, 2006). For clients receiving opioid pharmacotherapy a secure therapeutic relationship can provide structure and containment in times of chaos.

It is essential that clinicians explain to clients the ground rules of the therapeutic relationship including:

- the need for open and honest communication and sharing of information;

- the clinician's responsibility to ensure clinical and community safety;
- what will occur in the event of relapse including the implementation of clinical safeguards such as immediate removal of takeaways and increased case management reviews for a period of time until stability is achieved; and
- that clinicians can only support treatment goals that are appropriate, safe, and for the benefit of the client.

Having a good therapeutic relationship with the patient does not imply liberal prescribing or agreeing to unsafe clinical practices to support the relationship. Rather, clinicians should inform patients that the goal of the therapeutic alliance is to maximise clinical improvement while managing the safety of both the patient and the community.

6.1.2 Treatment planning

The initial assessment will have identified some of the patient's treatment goals. The patient's opioid treatment goals should be confirmed prior to commencement of treatment.

For example, the patient may want to achieve total abstinence following the program, or perhaps, long-term opioid maintenance. The latter is more likely to be a realistic option for many opioid pharmacotherapy patients. Regardless of the exact goal, it is important that the patient and treating team are working towards an identified and shared goal and that this goal is documented in the patient file.

At this initial stage, the following should be clearly documented:

- starting date and dose of methadone or buprenorphine;
- dosing arrangements and requirements;
- early monitoring arrangements;
- initial harm reduction actions and advice; and
- case management arrangements.

Some patients may be better able to identify steps towards achieving their opioid management and general psychosocial goals once they have been stabilised in treatment, are in a more stable mental and physical state, and have established a working rapport with their treating team. Therefore, treatment goals and management plans can be reviewed at any time, as long as changes are made in collaboration with the patient and documented in the patient file.

The treatment plan may include a range of harm reduction goals including the reduction and/or cessation of other drug/s of concern. For example ceasing (when safe) or commencing an alcohol or benzodiazepine reduction program prior to the commencement opioid pharmacotherapy. Clinicians have a duty of care to address and manage identified risks and clinical safety issues related to their patient's substance use.

If reducing or abstaining from substance use is identified as an achievable and appropriate goal, then this should be explored by the clinician and patient as a potential treatment goal, along with other harm reduction strategies. This is particularly the important if this facilitates the patient's access to or retention in opioid pharmacotherapy treatment.

6.1.3 Treatment education

Patients should be well informed about their treatment options. Treating teams should discuss the rationale for treatment and the choice of medication with their patients. Before patients can consent to treatment, the treating team should provide information on:

- the aims and expected outcomes of opioid pharmacotherapy, including limitations;
- program policies, including the "Gateway Model" for buprenorphine as an induction agent of choice (see end of Section 4.7) for patients placed on opioid pharmacotherapy;
- when there are other drugs that may impact on the effectiveness of opioid pharmacotherapy, patients should be made aware of need to reduce off these drugs, the risk they pose to treatment and the regimen or plan for achieving this change;

- the expected or recommended duration of treatment;
- side effects and risks associated with the prescribed medication;
- the requirement for regular urine drug screening;
- only the patient can pick up their dose;
- the ongoing requirement to travel to pharmacy regularly for dosing as part participation on the program;
- operational functioning of the clinic, including dosing arrangements and pharmacy schedule; and
- how to obtain further information.

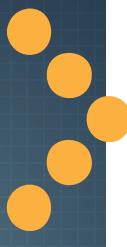
6.1.4 Special warnings

As well as receiving information about the treatment, patients must be informed about the specific risks associated with opioid pharmacotherapy. The following is a list of special warnings about treatment which patients must be informed.

Risk of overdose

Patients must be well informed about the risks of overdose associated with both methadone and buprenorphine, and that these risks are dramatically increased in the following circumstances:

- following a withdrawal period when the patient has less physical tolerance to opioids;
- when consumed by a non-opioid tolerant individual, e.g. other family members who have never used opioids, particularly children;
- when the medications are combined with other central nervous system depressants, such as, alcohol, benzodiazepines, and other prescription and illicit drugs;
- when the medications are taken against medical advice, e.g. escalation of dose; and
- when the medications are changed or administered via an alternative route leading to rapid absorption, e.g. intravenous or intranasal administration.



Both patients and clinicians should be aware of the clinical signs of overdose, which may include:

- slow respiration;
- reduced body temperature;
- miosis;
- cyanosis;
- weak pulse;
- bradycardia;
- decreased consciousness; and
- muscle twitching.

Patients should be provided with a management strategy if they begin to experience the above signs of overdose or if they experience unexpected effects from the medications. Where possible, carers and the patient's peers should also be informed of the management plan. The Tasmanian Opioid Pharmacotherapy Policy (TOPP) recommends all patients should have a basic overdose management plan including phoning 000 for an ambulance. Patients should also be informed that they will not get 'in trouble' for use of illicit substances when an ambulance is called, as this is a common fear among patients and their peers. All discussions and advice regarding managing overdose should be documented in the patient file. It is also recommended patients receive written information about their management plan including visual cues allowing quick and easy identification of emergency contact information.

Fitness to Drive and Drowsiness

Both methadone and buprenorphine opioid pharmacotherapy treatment can affect the patient's ability to drive, operate machinery, work at heights, and participate in active sports, particularly:

- during the first 7-10 days of commencing treatment;
- for 3-4 days after a dose increase; and
- when combined with other sedatives and depressant medications such as benzodiazepines and alcohol.

Patients must be advised that they may have to restrict or cease driving, operating machinery, working at heights, and participating in active sports during these periods. Ability to engage

in these activities is unlikely to be affected once the patient is stabilised in treatment or stabilised after a dose increase. If a patient is unfit to drive due to impaired mental state or a medical condition, they have a responsibility to cease driving and notify the licensing authority in Tasmania. However, this often does not occur.

Health professionals in the program still have a duty of care to the patient and the community relating to fitness to drive. Therefore, if a clinician observes that a patient is unfit to drive due to a known impairment and is, subsequently, a risk to road safety, the TOPP recommends the following actions:

- advise the patient not to drive, operate machinery, or work at heights;
- advise the patient that they need to arrange alternative transport for their children during these times;
- encourage the patient to report themselves to the vehicle licensing authority;
- advise the patient of your duty to contact the vehicle (or other appropriate) licensing authority;
- take measures to prevent the patient from driving or operating machinery if safe to do so. This may include, for example, requesting the patient to temporarily hand over their car keys until the risk is resolved;
- if the patient proceeds to drive or expresses intentions to continue driving (or operate machinery) against clinical advice, contact the appropriate authorities. This may include the Tasmanian Police to assist in preventing the patient from driving, particularly if there are children in the vehicle; and
- document the processes undertaken to fulfil duty of care obligations in the patient file.

For ADS clinicians:

- advise management or senior staff of the actions taken; and
- finally, always seek further advice from senior staff or management if unsure of the appropriate management strategy.

Patients should receive this information about driving and operating machinery when in opioid pharmacotherapy treatment, both verbally and in written form, prior to commencing treatment.

The clinicians handbook 'Assessing Fitness to Drive: 3rd Edition' (2006) is available at <http://www.austroads.com.au/aftd/>

Further information regarding vehicle licensing regulations in Tasmania is available at www.thelaw.tas.gov.au (specifically, the *Vehicle and Traffic Act 1999*) and www.tas.gov.au.

Possession of Firearms

If a patient has a firearms licence, the prescriber must notify the Commissioner of Police in writing of the patient's treatment with opioid pharmacotherapy. If the clinician identifies any impairment that is a result of opioid pharmacotherapy treatment or other alcohol or drug use, the prescriber must notify the Commissioner of police in writing of the patients inability to operate a firearm (*Tasmanian Firearms Act, 1996*). For further information, refer to the Section 14.9.

If a patient has experienced or witnessed the effects of an unintentional overdose, it can be a powerful clinical tool to engage them in developing a more detailed risk management plan specific to him or her. A risk management plan can be created at any stage of treatment.

6.1.5 Pregnancy and contraception

Female patients should be informed that ovulation patterns are likely to stabilise once on the opioid pharmacotherapy program, particularly if they were engaged in uncontrolled drug use prior to entering the program. This means their risk of unplanned pregnancy is increased.

Female patients not wanting to become pregnant during opioid pharmacotherapy treatment should be encouraged to speak with their GP about reliable contraception. Encourage female patients to speak with their treating team if they become pregnant or are planning to become pregnant, since this is likely to affect their treatment plan.

6.1.6 Rights and responsibilities

Both clinician/s and patients have shared obligations towards ensuring that treatment is ethical and safe for the patient and community (see the Tasmanian charter of Health Rights and Responsibilities: <http://www.healthcomplaints.tas.gov.au>). To help make their treatment as effective as possible, patients should be encouraged to assume a role in planning their care by being well informed, participating in treatment decisions, and communicating openly with members of their treatment team. The Alcohol and Drug Service has developed a client rights and responsibilities brochure (Appendix 4) which should be provided to patients.

Client rights

Persons receiving alcohol and drug services have a right to:

- be treated with respect and dignity;
- receive the best care that can be provided;
- discuss options for their care in terms and language that can be easily understood;
- have their personal health information protected and treated appropriately; and
- express concerns to their treatment team/ health care provider without fear of their care being affected.

Client responsibilities

In order to provide the best possible treatment, patients are required to:

- respect the rights, safety and privacy of others;
- treat others with respect, dignity and courtesy;
- respect the diversity of the treatment team other health service staff, and clients;
- provide accurate information;
- identify their needs and communicate them to the treating team;
- ask questions if the information given is unclear;
- actively participate in their care and discharge planning; and
- keep appointments, or notify in advance if unable to do so.

Keeping appointment times

Patients are required to attend appointment times as agreed or notify their treating team if they cannot attend. Limited opening hours of some services and the busy schedules of doctors and case managers means that attendance outside of scheduled times may have implications for the efficiency and effectiveness of treatment.

Failure to attend appointments compromises clinical safety and can result in the suspension of prescribing, and doses being withheld. Clinicians should clearly explain to clients that prescriptions cannot be provided without a recent medical review. Ongoing dosing is contingent upon regular nursing and case management reviews.

It is understood that many clients receiving opioid pharmacotherapy will have children in their care and may have no option but to bring to their appointments. In order to get the most out of their appointments clients should be encouraged to make alternative arrangements or bring a support person who can care for the children. This is particularly important during the first week of induction because of the need for frequent reviews and careful assessment.

Polysubstance Use

Patients are encouraged to report the use of other drugs to their case manager or prescribing doctor, as this is likely to affect the safety and success of their treatment. Clinicians are required to monitor the use of other drug use, both prescribed and illicit, and manage patient and community safety accordingly.

Urine drug screens

Patients are required to provide a random supervised urine drug screen upon request by the treating team. As in sports, drug-testing and Random Breath Testing (RBT) for drink-driving, refusal to provide a urine sample request will necessarily be treated as a positive result during the maintenance phase. This will consequently affect their treatment status, and potentially affect future treatment decisions, such as excluding them for eligibility for takeaway doses for a period of time. Further information about

urine drug screening is contained in Sections 5 and 7.

Non-compliance

Patients should be informed that one of the best indicators of successful treatment outcomes is treatment compliance. If patients are experiencing difficulties with their treatment, they should be encouraged to speak with their treating team to resolve these. This is particularly important if the patient is receiving takeaway doses, as non compliance and other drug use in combination with takeaway doses can increase the risk of overdose or death.

Patients should be assured that any changes to their treatment plan as a result of reporting non-compliance is not meant as punishment, but rather, to ensure their safety on the program. Indeed, reporting non-compliance is likely to improve the therapeutic alliance and improve outcomes in the long term. If a patient abruptly ceases pharmacotherapy treatment, a full blown relapse to hazardous and harmful drug use is likely to occur.

Involuntary discharge

Although the goal of the Tasmanian Opioid Pharmacotherapy (OPP) is to maintain long term therapeutic alliances with patients, there are certain circumstances under which patients may be automatically and involuntarily discharged. Issues of individual and public safety, public confidence in, and support for, the program, and treatment engagement are essential for an effective pharmacotherapy program. Activities or circumstances that may compromise these requirements (outlined in the ADS Pharmacotherapy Treatment Agreement (Appendix 5) should be clearly explained to the patient, including the potential for involuntary discharge.

6.2 Request for second opinion

Clients receiving services from Alcohol and Drug Services may seek a second opinion to clarify concerns about their diagnosis and/or treatment. A second opinion can provide reassurance and information, thereby providing the client with an optimum level of involvement

in decisions about their treatment. Requests for a second opinion must be made by the client, or next of kin/responsible person, with the client's written consent. In circumstances where complex clinical or organisational issues require clarification, the treating clinician may also request a second opinion after gaining the client's consent.

It is important for the client to communicate this request (and the concerns that they require clarification about) to their prescriber or case manager. In most circumstances the prescriber or case manager may be able to assist with this referral, or provide information about suitable specialist to provide a second opinion.

Prior to processing a request for a second opinion, clinicians should attempt to resolve any underlying issues such as lack of understanding about treatment, service quality, or difficulties between the client and treating clinician. Requests for second opinions are determined by the Area Manager or Clinical Director, after consideration of clinical, legislative and privacy considerations. Further information is contained in the SMHS policy on Second Opinions, in draft at time of writing.

6.3 Requirements for entry into treatment: administrative procedures

Opioid pharmacotherapy involves treatment with a Schedule 8 drug. Consequently, treatment is subject to jurisdictional regulations. In Tasmania, pharmacotherapy prescribers must be approved by the Clinical Director ADS. Prior to commencing treatment, the authorised prescriber must obtain authority to treat each patient from the Pharmaceutical Services Branch (PSB) (Section 59E of the *Poisons Act, 1971*).

No patient will be given a prescription or dosed with methadone or buprenorphine until PSB has been contacted and an authorisation number has been provided.

Figure 15.1 (see Section 15.2.1) presents a flowchart for the Prescribing of S8 Opioids and Drugs of Dependence in Tasmania.

An application must be forwarded to the PSB for approval to prescribe opioid pharmacotherapy. Applications are available online at <http://www.dhhs.tas.gov.au/data/assets/pdffile/0019/47026/S59Eapplication.pdf>. The prescriber is also required to arrange cancellation of any other existing S59E authorisations and notify the previous prescriber.

6.3.1 Providing adequate identification

A patient's identity must be verified before they can be admitted to the Tasmanian OPP. For clinical safety and legal reasons, if the prescriber is not satisfied with the identification provided, the patient cannot be registered on the opioid pharmacotherapy program. Appendix 6 contains a list of forms of identification the Tasmanian ADS accepts for registration onto the program. In addition, a photograph of the patient is required to be kept in the clinical file, and the application to prescribe must include a photograph of the patient.

6.3.2 Informed consent

Informed consent refers to the patient's agreement to undergo treatment where the agreement is made voluntarily and based on adequate information. Ethically, informed consent represents respect for the patient's autonomy and self determination (see Section 3), which are paramount to their journey to recovery.

Informed consent can only be given by capable, competent or legally fit individuals. Hence, additional precautions are required when ability to provide consent is unclear. Language and cultural barriers also need to be considered when obtaining informed consent. Refer to Section 4 for more details about treatment contraindications and precautions related to ability to provide consent.

There are two variations to the concept of informed consent, namely implied consent and presumed consent. Implied consent refers to individuals who are capable of providing informed consent but are not asked for consent on every occasion/event. This usually applies to low risk and routine processes (e.g.



case discussion of patient care with clinical colleagues). Presumed consent applies when an emergency treatment is required but the patient is temporarily incapacitated and unable to give consent.

As a general rule, informed consent should be discussed with patients from the outset, including the benefits and risks of engaging in treatment. Informed consent should always be sought prior to the disclosure of sensitive information, unless under duty of care obligations (see section 6.3.5). Treatment agreements and consent forms should also be signed and dated by the patient.

If a patient is on a guardianship order, clinicians are required to follow procedures as specified in the order to obtain consent.

A person under the age of 18 has legal capacity to consent where they are capable of:

- understanding the issues related to giving consent;
- forming views based on reasoned judgments about the issues associated with treatment; and
- communicating consent or refusal to consent.

When assessing a patient's capacity to consent, professionals must consider the ability of the young person to comprehend the issues and circumstances, their maturity and degree of autonomy, and the type and sensitivity of the information to be disclosed.

Further, it should be noted that parents and guardians are not automatically entitled to access all health information relating to a child in their care, if the child is competent to give informed consent.

6.3.3 Arranging transport

Due to the impact of opioid pharmacotherapy on patients' fitness to drive (section 6.1.4) patients will need to arrange suitable transport to their appointments and dosing facilities during stabilisation and following changes in their dose. It is important for clinicians to discuss with clients any barriers associated with attending appointments. Where possible the clinician/

prescriber may be able to refer them to support services eg. community transport options.

Patients should also be made aware that there will be an ongoing requirement for them to travel to appointments and to their pharmacy for dosing. It is important to clearly explain to the patient that they will need to regularly travel to the pharmacy for dosing (even after stabilisation) and that frequent case management review appointments will be required (with the prescriber and case manager) as part of their participation in the program. If transport is identified as a potential barrier to access or participation to the program (ideally this would be identified during the assessment for suitability) options should be explored to assist the patient in overcoming this barrier.

Patients should be made aware that there will be an ongoing requirement for them to travel to appointments and to their pharmacy for dosing.

6.3.4 Securing a dosing site

As part of the treatment planning process, it is important to ensure that an appropriate dosing facility has been located and a position secured for the patient. Most community pharmacies will have limited numbers of patients that they are able to accept for dosing at any one time. Hence, the decision to commence opioid pharmacotherapy must include a consideration of availability of a suitable dosing site. During stabilisation, daily observed dosing is the standard: therefore, a 7 day dosing facility is preferred.

The Tasmanian Opioid Pharmacotherapy Program, Policy and Clinical Practice Standards recommend that pharmacies do not allow patients to accumulate debts for dosing. Patients should be advised that they are required to make payment prior to dosing (see Section 16 for further information on the roles and responsibilities of pharmacists).

The Tasmanian Opioid Pharmacotherapy Program, Policy and Clinical Practice Standards recommend that pharmacies do not allow patients to accumulate debts for dosing.

Prescribers will also need to check that the pharmacy dispenses the opioid pharmacotherapy preparation required, as some pharmacies do not dispense all preparations of buprenorphine and methadone. Notify the PSB of the dosing point for the patient and verbally confirm the authorisation if the patient needs to be commenced immediately.

Once the dosing site has been secured, a letter of introduction including patient identification and personal details should be forwarded to the pharmacist. Arrangements should also be made for the direct transfer of the prescription from the prescriber to the dispensing site. If prescriptions are stolen, lost, misplaced, forged, traded, modified or sold, they can pose significant risk to the community if misused (See Section 12). Therefore, patients should never be given a prescription for opioid pharmacotherapy.

Patients should never be given a prescription for opioid pharmacotherapy.

6.3.5 Confidentiality and release of information

The Tasmanian Opioid Pharmacotherapy Policy (TOPP) stipulates confidentiality for patients on the program, as guided by the *Personal Information Protection Act 2004 (PIP Act 2004)* and the *National Privacy Act 1998*. It is a requirement of the TOPP that all patients are provided with written information regarding their rights to confidentiality and circumstances in which confidentiality may not be protected.

The sharing of information is critical to the delivery of good clinical care and is essential to inform the clinical decision making process. For this reason it is important to talk with the client about the need to obtain consent, and to clearly explain with whom the information will be shared, and why it is important to obtain

information from others involved in their care (see Section 5.14).

Within government services, patients should be advised that the information staff record about them, and the contact they have with staff, is stored securely safeguarded and kept confidential within the Department of Health and Human Services (DHHS). Access to information – that can either identify a patient, is regarded as clinically significant, or is of a sensitive nature – is restricted to those people with a duty of care to the patient, or are involved in the provision of a clinical service to them. For the ADS pharmacotherapy service, this includes staff within the service as well as the dispensing pharmacy. It is important to explain to clients that the pharmacists are part of the treatment team, and to ensure clinical safety, information will be shared between the pharmacist, case manager, and prescriber.

It is important to explain to clients that the pharmacists are part of the treatment team, and to ensure clinical safety, information will be shared between the pharmacist, case manager, and prescriber.

Patients wishing to access their personal records should discuss their request with their case manager/ prescriber who will provide information regarding the process for accessing records based on the information being sought.

Due to privacy requirements, patient information obtained from, or provided to agencies or individuals external to DHHS, must be done so with the patient's written consent (this excludes information provided under duty of care requirements, discussed below). Written consent must be obtained prior to releasing and obtaining information about the patient's clinical care. This is especially important for communicating with other service providers (including GPs), facilitating shared care partnerships and progressing the patient's treatment and case management plans. Clinicians can, however, contact relevant parties when there are risk issues as listed below.

Duty of care

In addition to clinicians having an obligation to maintain confidentiality, they also have a duty of care to the patient and the community. Hence, according to the *PIP Act (2004)* and the *National Privacy Act (1998)*, confidentiality cannot be guaranteed when:

- there is a risk of harm to the patient's life;
- there is a risk of harm to others (including children); or
- the patient's records are subpoenaed by court.

Information released under duty of care should be limited and relevant to the risk identified. Where possible, patients should be involved in the clinician's decision to release information under duty of care obligations. Ideally, if a potential risk can be anticipated, clinicians should identify a management plan ahead of time that is agreed upon between the clinician and patient, documented in the patient file, and signed by both parties.

Release of Schedule 8 Drug Information

Additional to duty of care requirements, the collection of information on Schedule 8 drugs is a statutory requirement in Tasmania. This information is consequently exempt from the provisions of the *PIP Act, 2004*. Prescribers are encouraged to contact the Pharmaceutical Services Branch for relevant information. Details are available at www.dhhs.tas.gov.au/psbtas.

6.3.6 Health Insurance Commission Medicare Prescription Shopping Program

Some patients are known to seek medication from multiple prescribers. This can be particularly risky for patients being prescribed Schedule 8 medications (e.g. methadone and buprenorphine).

It is therefore recommended that the prescribing doctor contacts Medicare Australia's Prescription Shopping Information Service prior to commencing treatment for the patient. The doctor will need to register – complete and sign the Registration Form and fax it to

(02) 6124 7820. Medicare Australia will provide confirmation of registration by fax within two business days or by mail if a fax number is not provided.

Once registered, a doctor can call the Information Service 24 hours a day, seven days a week on 1800 631 181 to:

- find out if their patient has been identified under the Prescription Shopping Program; and
- receive information on the amount and type of PBS medicine recently supplied to that patient.

When a doctor contacts the Information Service, they will need to provide their:

- prescriber number;
- full name;
- answer a personal validation question;
- patient's Medicare number;
- patient's date of birth; and
- patient's full name.

Prescribers should be aware that there are some limitations in the reporting of the prescribing of low cost benzodiazepines by pharmacist under this scheme. Further information and registration paperwork can be accessed at: <http://www.medicareaustralia.gov.au/provider/pbs/prescription-shopping/index.jsp>

Wherever possible, the clinician should inform the patient that they are authorised to access this information, and the reasons for doing so. In the near future, a system for real-time reporting, currently being trialled by the PSB, will be available across Tasmania. For further information, contact **132 290**.

6.3.7 Complaints and appeals procedures

Patients have the right to be engaged in their treatment decisions and appeal these decisions if they have concerns. The following principles apply to patient complaints:

- legally competent patients have a common law right to make their own decisions about medical treatment and a right to grant, withhold or withdraw consent before or during treatment;
- clinicians have a duty of care to their patients to only offer treatment which is assessed as clinically safe and appropriate;
- patients should not request or expect treatment that, in the opinion of the prescriber or treating team, does not satisfy duty of care principles;
- patients have the right of access to procedures established to resolve conflicts between themselves and those responsible for their treatment;
- patients should be informed of avenues to register a complaint and the procedures for doing so at the time of admission into pharmacotherapy treatment;
- patients who cannot read should have information about their rights and obligations read to them at the time they enter the program; and
- In the case of a dispute, patients should be retained on their current treatment, subject to safety considerations, pending the resolution of the dispute.

Patients should be informed of the various avenues for appealing their treatment decisions described below.

For patients receiving treatment from government Alcohol and Drug Services (ADS, DHHS).

Discussion with treating team

Encourage patients to discuss their concerns with their treating team, which can include the prescriber, case manager, pharmacist, or manager of that team. Often matters can be resolved at this level.

Complaint to manager of service region

If unable to resolve the matter within the treating team, the patient can make a complaint to the manager of the service area. For southern regions, this is the Manager of ADS South.

For the north and north western regions, this is the Manager of ADS North/North West. The manager can confer with the statewide Clinical Director of ADS and State Manager of ADS. Both the manager and Clinical Director can seek further clarification of the facts relating to the complaint. They will seek to resolve the matter promptly.

Complaint to the Director of Statewide and Mental Health Services

If the matter cannot be resolved, patients can seek a determination from the Director of State Specialist Services, Department of Health and Human Services (DHHS). Patients and/or carers can also complete a Client Carer Feedback Form which is available online or at Alcohol and Drug Service offices.

For patients receiving treatment from private prescribers

Discussion with treating team

Encourage patients to discuss their concerns with their prescriber or pharmacist.

Obtain second opinion from ADS

If unable to resolve the matter, the prescriber may refer to the ADS for a review and second opinion related to the complaint.

For ALL patients

Advocacy services

All Tasmanian Alcohol and Other Drug patients have access to advocacy for their rights via Advocacy Tasmania Inc (ATI), beginning in January 2010. Advocacy can be accessed at any time. ATI will be involved in providing a wide variety of services, including (but not limited to):

- being an independent body to support consumers in making complaints about services;
- providing advice to patients regarding their rights and responsibilities within ATOD services;

- improving patients' ability to access information about ATOD services;
- assisting in developing patients' understanding of ATOD referral services; and
- advocating for consumers who are experiencing difficulties in accessing ATOD services.

Health Complaints Commissioner

Finally, if none of the above steps resolve the complaint, patients can contact the Office of the Health Complaints Commissioner, which has been established under legislation to investigate health complaints. An independent statutory Commissioner heads this office. Officers of the Commissioner assist consumers and providers to resolve and/or investigate complaints. As a general rule they will raise the concern with the service providers concerned as a first step.

6.4 Alcohol and drug services treatment agreement

Prior to commencing pharmacotherapy treatment at ADS Pharmacotherapy, all patients must sign the ADS Treatment Agreement (Appendix 5). This treatment agreement contains information about patient responsibilities and indicates formal acceptance of these conditions.

6.5 Creating a patient file

It is essential that all treatment entry information provided to the patient, including the signed treatment agreement and consent form, are documented and lodged in the appropriate section of the patient file.

6.6 Information pack

While it is necessary to provide the information outlined in this section verbally to patients, many may be in a distressed or disorganised state when they are entering the program. Hence, an information pack containing written handouts should also be provided to all patients, and, where appropriate, their carer. The pack should also contain more detailed information regarding treatment, including:

- Patient information booklets for buprenorphine and methadone (as produced by the drug manufacturer);
- Information about the Gateway Model;
- Information on managing a drug overdose;
- Harm reduction advice (such as safe injecting practices);
- Your Kid's Safety leaflet (produced by DHHS);
- DHHS signed Treatment Agreement; and
- Copy of forms including consent to release or obtain information and treatment agreements and plans.



SECTION: 7

Safe treatment induction

In this section you will...

- Gain knowledge on how to safely induct a patient to opioid treatment;
- Be provided with an overview of the process for patient reviews; and
- Develop an understanding of dosing procedures.

7	Safe treatment induction	76
7.1	Induction to opioid treatment	76
7.1.1	Induction agent of choice	77
7.2	Induction to methadone pharmacotherapy	77
7.2.1	Access to 7 day dosing	78
7.2.2	Determining starting dose	78
7.2.3	Minimum starting dose	78
7.2.4	Maximum starting dose	78
7.2.5	Test dose	78
7.2.6	Supplementary doses	78
7.2.7	Methadone effects	78
7.2.8	Short opioid use history	79
7.2.9	Complicated presentation	79
7.2.10	Comparing strengths of different opioids	79
7.2.11	Reaching a steady state	79
7.2.12	Dose increases during induction	81
7.2.13	Dose decreases during induction	81
7.3	Induction to buprenorphine pharmacotherapy	81
7.3.1	Access to 7 day dosing	82
7.3.2	Starting dose	82
7.3.3	Test dose	82
7.3.4	Supplementary dose	82
7.3.5	Dose increases during induction	83
7.3.6	Dose reductions during induction	83
7.3.7	Managing precipitated withdrawal	83
7.3.8	Missed doses during induction	83
7.3.9	Prescriptions of methadone and buprenorphine	83
7.4	Alternative treatment options	84
7.5	Patient reviews	84
7.6	Dosing location	85
7.7	Methadone and buprenorphine dosing procedure	85
7.8	Moving to maintenance	86



Section: 7

7 Safe treatment induction

7.1 Induction to opioid treatment

Patients need to begin opioid treatment in a well supervised setting to ensure frequent monitoring. In Tasmania, this will usually be either in the ADS pharmacotherapy clinic or another community setting; it may be also be in a hospital ward or in a general practitioner's rooms. Induction into treatment takes a minimum of 2 weeks for methadone and 1-2 weeks for buprenorphine. No patient will be given a prescription or dosed with methadone or buprenorphine until Pharmaceutical Services Branch (PSB) has been contacted and an authorisation number has been provided.

Induction into treatment takes a minimum of 2 weeks for methadone and 1-2 weeks for buprenorphine.

The chief objectives during induction are to:

- safely induct a patient into opioid pharmacotherapy within recommended timeframes;
- retain the patient in treatment by minimising the discomfort of withdrawal and ensuring appropriate maintenance dosage; and
- attain a maintenance dosage as quickly and safely as possible.

Induction into opioid pharmacotherapy treatment involves two processes, both of which decrease the patient's need to use unsanctioned opioids:

- Stabilisation – abolishing fluctuations between intoxication; and
- Tolerance – reducing the response to additional unsanctioned opioids (methadone) and or blocking the action of other opioids (buprenorphine).

Induction into opioid pharmacotherapy, particularly on methadone, is a period of increased risk for opioid toxicity and can even be fatal. Strategies for improving safe induction into opioid pharmacotherapy (methadone and buprenorphine) include:

- developing a collaborative treatment plan that is documented in the patient file;
- providing a thorough explanation of intoxicating effects of opioid pharmacotherapy;
- providing a thorough explanation of withdrawal effects;
- reminding patients of the risks of taking other contraindicated drugs, prescribed or illicit, during treatment;
- practicing cautious initial dosing and dose titration;
- when clinically indicated, observing patients for intoxication or withdrawal 3-4 hours after their commencement dose;
- the treating team reviewing the patient daily for the first 3-4 days of dosing;
- repeated daily observation of patients is for at least 2 weeks;
- commencing a patient on the program (for the ADS on a Monday, and no later than Wednesday) to allow maximum time to for daily review the patient and to ensure clinical safety during stabilisation; and
- maintaining good communication and rapport with the patient throughout all phases of treatment.

The Tasmanian Opioid Pharmacotherapy Program, Policy and Clinical Practice Standards recommends commencing a new patient on a Monday, and no later than Wednesday.

The initial dose prescribed (either methadone or buprenorphine) will be contingent on the patient's tolerance to opioids and severity of opioid withdrawal observed. Information from the assessment will provide an estimation of the patient's tolerance. This information includes:

- frequency of use;
- quantity of use;
- time since last use;
- route of administration;
- severity of withdrawal syndrome;
- urine drug screen results and a presence of opioids and other drug use;
- findings on medical examination including clinical observation; and
- other corroborative information and history.

If there is doubt about the degree of tolerance, a review of the patient when withdrawal symptoms are being experienced may help to resolve uncertainty about a safe starting dose.

Other factors that will influence the decision about first dose include:

- dosing location;
- availability of staff to observe the patient before and after dosing;
- the concurrent use of benzodiazepines or other psychoactive substances;
- signs of intoxication with substances other than opioids; and
- the risk of overdose, particularly from substances other than opioids.

The patient should be seen immediately before administering the first dose. If the patient is intoxicated, particularly with alcohol and benzodiazepines, the first dose will be delayed. If not intoxicated, the patient can go directly to the pharmacy for dosing.

As discussed in Section 3, patients will usually only be eligible for the program if there is evidence of opioid dependence with neuroadaptation, unless they have a long history of opioid dependence and are at high risk of relapse following a period of abstinence. Consequently, most patients will be experiencing withdrawal prior to induction into the program.

7.1.1 Induction agent of choice

Please refer to Section 3, which outlines the rationale for having buprenorphine as an induction agent of choice, and Suboxone® as the preferred preparation of buprenorphine.

7.2 Induction to methadone pharmacotherapy

Since most patients will already be withdrawing from opioid use before treatment commences, inadequate dosing on methadone may fail to relieve patients' withdrawal symptoms. This increases the likelihood that they will seek to 'top up' their prescribed dose with other opioids. This can have fatal consequences.

Conversely, dosing too high can cause toxicity, sedation, and death. These risks are more immediate than the risk of dosing too low. Furthermore, a low dose can be increased if the patient continues to experience significant withdrawal symptoms. Therefore, the TOPP supports a 'start low and go slow' dosing induction approach to methadone.

The Tasmanian Opioid Pharmacotherapy Program, Policy and Clinical Practice Standards supports a 'start low and go slow' dosing induction approach to methadone.

This means starting patients on the lowest dose suitable for their needs within the range specified in this document (see 7.2.2). If a dose is too low, it can be slowly titrated up to achieve stabilisation.

Due to the pharmacological properties of methadone and the time it takes to reach a steady state (see 7.2.11), induction into methadone pharmacotherapy takes a minimum of two weeks.

Induction into methadone pharmacotherapy takes a minimum of 2 weeks.

7.2.1 Access to 7 day dosing

Patients are not eligible for methadone takeaway doses during the induction phase, and hence, will need to access supervised dosing at a 7 day dosing pharmacy during this phase. Detailed guidelines for takeaway doses are available in Section 7.

Patients will need access to a 7 day dosing pharmacy during methadone induction.

7.2.2 Determining starting dose

A thorough assessment will provide an insight into the extent of the patient's opioid use history and dependence. If there are difficulties determining a commencement dose, particularly when over the counter analgesia is being used (e.g. codeine), then the advice of an Addiction Medicine Specialist should be sought.

7.2.3 Minimum starting dose

Deaths during induction onto methadone have been associated with doses between 25-100mg per day, with most deaths occurring between 40-60mg (Drummer et al., 1992 and Caplehorn, 1998). Indeed, 21% of deaths associated with methadone occur during induction (Zador & Sunjic, 2000).

Therefore the initial dose, particularly for new patients or patients with compromised liver function, should be between 5-20mg. In fact, a dose of 20mg for a 70kg patient is generally safe even in opioid naïve individuals.

7.2.4 Maximum starting dose

A starting dose of 25mg is suitable for patients who:

- show evidence of significant opioid dependence;
- demonstrate signs of moderate to severe opioid withdrawal;
- are using large amounts of heroin and/or other opioid medication; and
- if using heroin, have been using heroin at least twice a day in the last two weeks.

The maximum commencement dose of methadone is 25mg on the first day of methadone treatment.

7.2.5 Test dose

Local experience indicates that for some patients a test dose (5-10mg) may be appropriate. This allows time for observation of the patient's reaction to the drug prior to giving them the full initial dose.

7.2.6 Supplementary doses

Sometimes patients will continue to experience withdrawal symptoms on the first day after the administration of an initial dose. Since peak serum methadone levels are usually not attained until three to four hours after oral administration, such persons may be considered for a supplementary dose after that period of time, following careful clinical assessment by the prescribing doctor.

If the patient is experiencing persistent and observable withdrawal signs four hours after the first dose, a supplementary dose of 5mg (10mg in exceptional circumstances) can be considered. However, the initial dose plus the supplementary dose must not exceed 25mg on the first day of methadone treatment. When a supplementary dose is provided the subsequent dosages should be equivalent to the initial dose plus the supplementary dose.

If a supplementary dose is provided, the maximum dose of 25mg of methadone on the first day of treatment still applies.

7.2.7 Methadone effects

Methadone takes 4-5 days of dosing to achieve its full clinical effect. It is particularly important to clearly explain to patients that induction into maintenance treatment takes time, and that they will experience increasing effects from treatment over the first few days even if the dose is not increased. Furthermore, slow onset of action and long half-life mean that the

toxic effects of methadone can become life threatening long after ingestion if the dose is increased too rapidly, hence, the minimum 2 week induction period.

7.2.8 Short opioid use history

For patients with an opioid use history of less than 6 months in duration, the advice of an ADS Addiction Medicine Specialist must be sought to review the possibility of other treatment options prior to commencing opioid maintenance treatment.

7.2.9 Complicated presentation

Advice from an ADS Addiction Medicine Specialist should be sought for patients requiring a high commencement dose (25mg), but whose presentation is complicated by significantly high levels of alcohol dependence or polysubstance use.

7.2.10 Comparing strengths of different opioids

Comparative strengths of opioids listed in pharmacology textbooks are approximations only, and, since consumption of the prescribed opioids are often not supervised, it is not possible to be sure that the patient is consuming

all of the quantity reported. Ayonrinde & Bridge (2000) report that in the chronic dosing situation, oral methadone can be up to twenty times as potent as oral morphine on a mg for mg basis. For these reasons, estimating an equivalent starting dose of methadone from these comparative tables should not be attempted. Rather, the induction procedure and maximum starting dose should be the same as that outlined in Section 7.2.4.

7.2.11 Reaching a steady state

For most patients, methadone does not reach a steady state until three to four days of daily dosing. For a small percentage of patients, this can be up to 10 days (Drummer et al., 1992). Thus, patients should be seen daily by the treating team for at least the first four days to stabilise them on an adequate dose of methadone. Careful assessment and monitoring each day is necessary as the dose is titrated against the patient's clinical state. The following series of figures shows the pattern of methadone levels in plasma after one and three days of daily dosing, and once a steady state is achieved.

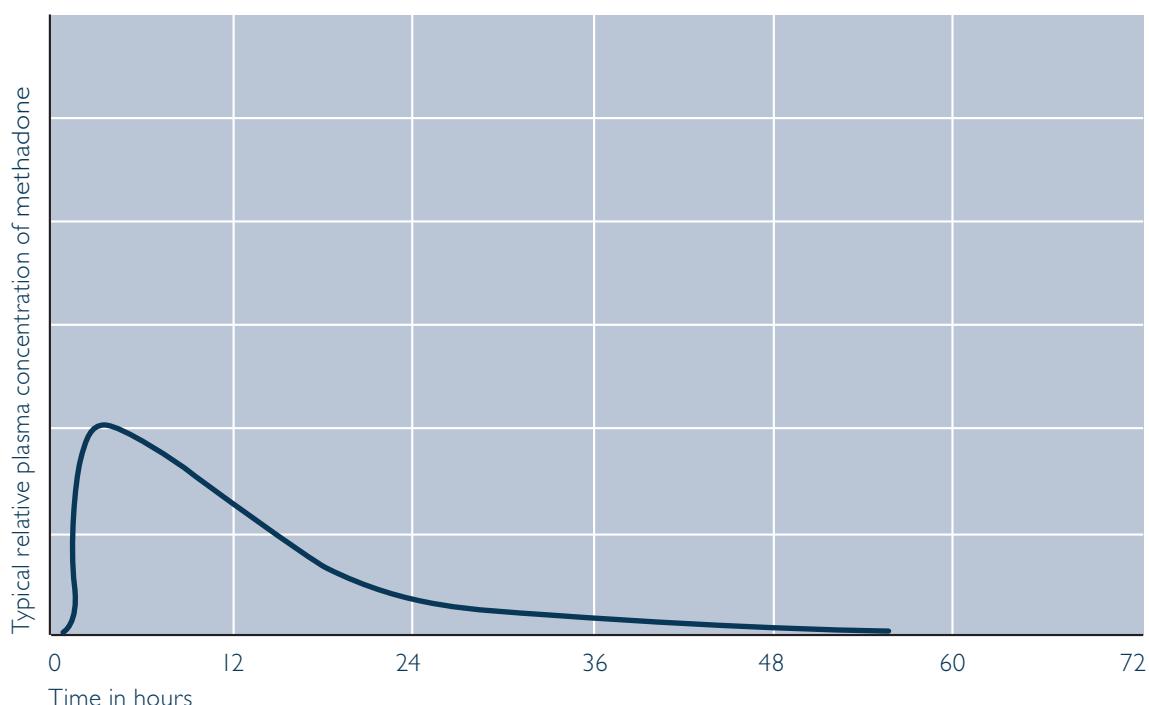


Figure 7.1: Plasma concentration after a single dose of oral methadone

Note: Reproduced from *The Methadone Briefing: An easy to use reference guide to methadone and methadone prescribing: for health and other professionals*, by Preston (1996) p. 52. Andrew Preston: London.

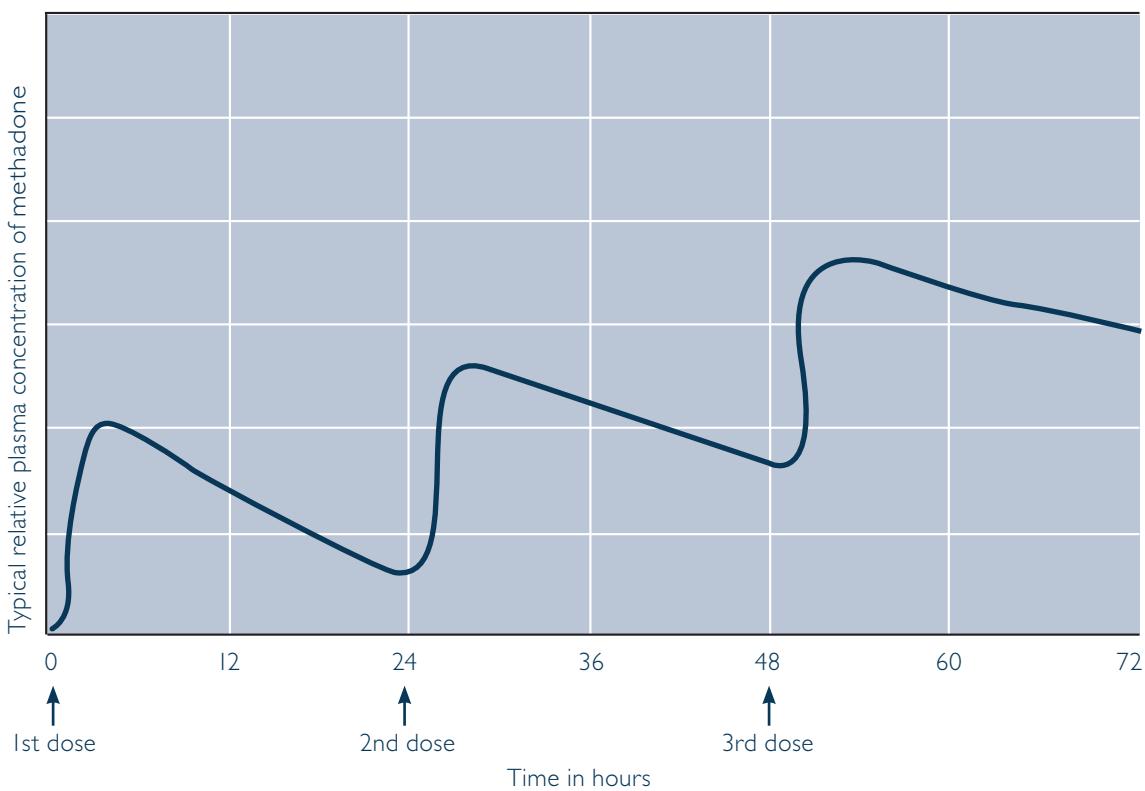


Figure 7.2: Plasma concentration after three daily doses on oral methadone

Note: Reproduced from *The Methadone Briefing. An easy to use reference guide to methadone and methadone prescribing: for health and other professionals*, by Preston (1996) p. 53. Andrew Preston: London.

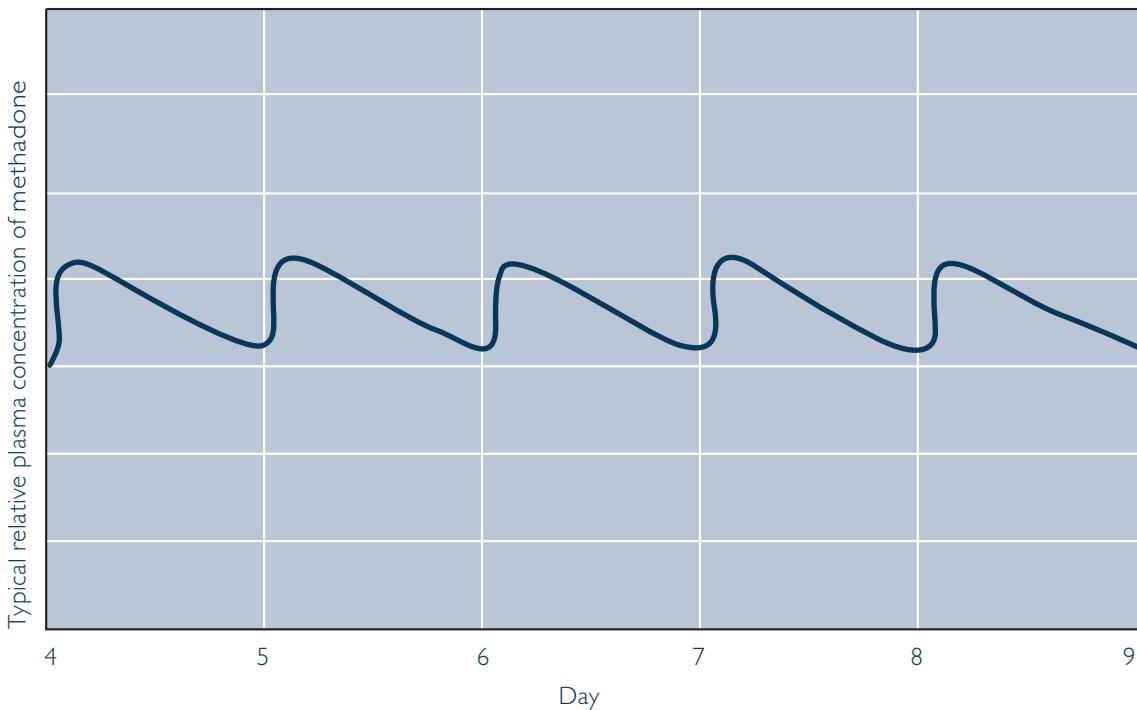


Figure 7.3: Plasma concentration once steady state achieved on oral methadone

Note: Reproduced from *The Methadone Briefing. An easy to use reference guide to methadone and methadone prescribing: for health and other professionals*, by Preston (1996) p. 54. Andrew Preston: London.

Steady state does not automatically imply clinical stability of the patient.

7.2.12 Dose increases during induction

Following a dose increase, serum levels can take up to five days (or more) to reach a steady state. Hence, rapid dose increases can exceed the patient's level of tolerance and increase the risk of over-sedation and have toxic or fatal consequences. The following limits apply to dose increases during induction.

Week One:

- Increase the dose by **5-10mg** every 3 days, subject to assessment;
- Do not increase the dose by more than **20mg** in the first 7 day period; and
- The maximum dose after the first week is **40mg**.

Week Two:

- Increase the dose by a **maximum of 10mg** during the second week; and
- The maximum dose after the second week is **50mg**.

Subsequent Weeks:

- The maximum dose increase in any subsequent week is **10mg**.

If clinical evidence indicates a need for more rapid dose increases during induction, the Tasmanian Opioid Pharmacotherapy Program, Policy and Clinical Practice Standards recommends seeking advice from an Addiction Medicine Specialist, ADS.

7.2.13 Dose decreases during induction

Decrease the dose if there are features of opioid intoxication three to four hours after dosing or if the patient experiences intolerable side effects. A reduction of 5-10mg or to the previous day's dose may be sufficient.

Continue monitoring the patient: clinical judgment will determine if the dose should be decreased further.

7.3 Induction to buprenorphine pharmacotherapy

Buprenorphine differs from methadone in that it displaces other opioids from opioid receptors but has less intrinsic opioid activity, thus precipitating withdrawal symptoms if given while other opioids are still active. Hence, buprenorphine treatment should not be commenced until the patient is in mild to moderate withdrawal. A Clinical Opioid Withdrawal Scale (COWS) (Appendix 7) score of at least eight (representing the mid-point of the COWS scale) is a good indicator of the patient's readiness to receive their first dose. If no opioid withdrawal signs are present, the patient may be asked to return later in the day or the next day so that withdrawal signs are present before the first dose is given.

As a further guide to avoiding precipitated withdrawal, buprenorphine should not be administered until at least:

- 6-12 hours after the last dose of short acting opioid agent (e.g. heroin or injectable morphine);
- 24 hours after the last dose of slow release morphine or oxycodone; or
- 24-36 hours after the last dose of methadone.

There is considerably less risk of death during induction to buprenorphine treatment in comparison to methadone induction, however, caution is still essential, particularly if the patient may be using other drugs with a sedative effect (e.g., alcohol or benzodiazepines). Nonetheless, contrary to methadone, it is usually safe to achieve rapid induction onto an effective maintenance dose of buprenorphine. Therefore, induction into buprenorphine pharmacotherapy takes a minimum of one week, but can often take up to 2 weeks.

Induction into buprenorphine pharmacotherapy takes a minimum of one week, and can often take up to two weeks.

7.3.1 Access to 7 day dosing

Patients are not eligible for takeaway buprenorphine doses during the induction phase. The preference is for patients to present daily for supervised dosing during buprenorphine induction. However, for patients living in rural and remote areas or with no access to a 7 day dosing pharmacy, a double dose on the first Saturday is permitted, with the advice of an ADS Addiction Medicine Specialist. See Section 8 for a more detailed explanation of double dosing for buprenorphine.

Patients without access to a 7 day dosing pharmacy may be double dosed from the first Saturday of buprenorphine induction – with the advice of an ADS Addiction Medicine Specialist.

7.3.2 Starting dose

Minimum starting dose

A minimum starting dose of **2-4mg** per day is suitable if:

- there are only mild signs and symptoms of opioid withdrawal;
- the patient has a low degree of neuroadaptation to opioids;
- there are concerns about concurrent use of alcohol, sedatives (e.g. benzodiazepines) or other illicit opioids;
- there is uncertainty about the timing of recent opioid use; or
- there is a concurrent medical condition, particularly compromised liver functioning.

Maximum starting dose

A starting dose of **4-8mg** per day is well tolerated by most patients and will lead to rapid stabilisation on an effective maintenance dose and increased retention in treatment.

The maximum commencement dose of buprenorphine is 8mg on the first day of treatment.

An initial starting dose of 6-8mg per day is suitable if:

- there are considerable signs and symptoms of opioid withdrawal; and
- the patient has a high degree of neuroadaptation to opioids.

The maximum commencement dose of buprenorphine is 8mg on the first day of treatment.

7.3.3 Test dose

Local experience indicates that for some patients a test dose (0.2-0.4mg) may be appropriate. This allows time for observation of the patient's reaction to the drug prior to giving them the full initial dose. This is particularly useful if there are concerns about the patient's potential to experience precipitated withdrawal or other clinical safety concerns.

7.3.4 Supplementary dose

The patient should be reviewed approximately four hours after the first dose. If the patient is feeling worsening symptoms of opioid withdrawal, this may be a sign of precipitated withdrawal (see Section 7.3.7) and no further doses should be given. If the patient is feeling better but there are still observable signs of withdrawal, a supplementary dose of **2-6mg can be given.**

However, the initial dose plus the supplementary dose must not exceed 8mg on the first day of buprenorphine treatment.

If a supplementary dose is provided, the maximum dose of 8mg of buprenorphine on the first day of treatment still applies.

7.3.5 Dose increases during induction

Rapid, higher dose induction with buprenorphine is both safe and effective, and is generally recommended to increase therapeutic effect and retention in treatment. The target dose is between **12-16mg** by the end of the first week. Induction into buprenorphine treatment is usually complete by the end of the first week, but can take up to 2 weeks, particularly if the patient requires a higher dose.

After the commencement dose, assess features of intoxication or withdrawal and the patient's perception of dose adequacy. If intoxication is not observed and the dose is not adequate, then the dose may be increased by **2-4mg** per day up to a maximum of:

- **16mg** by the end of the first week; and
- **24mg** by the end of the second week.

7.3.6 Dose reductions during induction

Decrease the dose if there are intolerable side effects or features of intoxication four hours after administration. A reduction to the previous day's dose may be sufficient. Continue monitoring the patient: clinical judgment will determine if the dose should be decreased further. All changes to prescriptions and the rationale for these changes must be noted in the client's clinical record.

7.3.7 Managing precipitated withdrawal

The precipitated withdrawal sometimes experienced in buprenorphine induction is reportedly not as severe as withdrawal from opioids such as methadone and heroin. However, patients should be provided with information and advice about how to manage precipitated withdrawal if it occurs.

Nevertheless, if the patient is experiencing highly unpleasant precipitated withdrawal, a single dose of 50-150mcg of clonidine may be provided. Due to the risk of hypotension and abuse potential of clonidine, clonidine should not be provided on an ongoing basis. A prescription must not be given to the patient.

To manage precipitated withdrawal a single dose of clonidine 50mcg may be administered under supervision.

Patients should be advised that, because of buprenorphine's competitive affinity for opioid receptors, continuing to use other opioids once they have started to take buprenorphine is likely to make stabilisation difficult and is unlikely to reduce their withdrawal symptoms Lintzeris et al., 2006.

7.3.8 Missed doses during induction

Regular dosing during stabilisation is essential for reaching steady state. Due to the time it takes to reach steady state for both methadone and buprenorphine, missed doses have a significant impact on stabilisation. Therefore, if doses are missed during stabilisation, the patient and their dose should be re-assessed. Patients may need to be recommenced on the initial starting dose.

7.3.9 Prescriptions of methadone and buprenorphine

Both methadone and buprenorphine are Schedule 8 drugs. Therefore prescriptions cannot be generated using only electronic software. The following information must be handwritten:

- the name of the drug;
- the strength of the drug;
- dispensing instructions;
- nominated days for takeaway doses; and
- double dosing arrangements (relevant for maintenance treatment): these instructions should include the dosage for each day;

Prescriptions for methadone and buprenorphine should never be given directly to patients.

7.4 Alternative treatment options

Although most patients in Tasmania will be able to access either methadone or buprenorphine induction and treatment, there will be some exceptional cases in which the patient:

- has a genuine clinical contraindication to both buprenorphine preparations; and
- cannot access a 7 day dosing pharmacy for the methadone induction period.

In this circumstance, prescribers are encouraged to consult with an ADS Addiction Medicine Specialist about an appropriate management plan. The advantages of an inpatient admission for withdrawal, the increased risk of overdose post admission, and the risks of not receiving pharmacological treatment should all be discussed.

One option for such patients is to consider referral to the ADS withdrawal unit. Some patients report that the benefits from inpatient management for withdrawal from unsanctioned opioid use can motivate ongoing commitment to opioid pharmacotherapy or other forms of treatment. However, there is a well documented increased risk of overdose and death if a patient returns to previous levels of unsanctioned drug use following their inpatient treatment (Strang et al., 2003).

Therefore, patients will only be considered for opioid withdrawal in this context as a pathway to longer term treatment options that include ongoing care: for example, residential rehabilitation treatment for addiction or a multidisciplinary pain treatment service for patients with persistent non-malignant pain.

7.5 Patient reviews

Medical reviews are required for the prescription of opioid pharmacotherapy. In the public system, specially trained nurses and/or allied health professionals conduct the majority of clinical reviews, in consultation with the prescribing doctor. In the private system, however, the prescribing doctor will usually be solely responsible for patient reviews.

Please note that only medical practitioners can conduct medical examinations and medical reviews (see Section 5 on assessment).

For the first four days treatment, daily clinical reviews by the treating team are required to:

- titrate the patient's optimal doses of methadone or buprenorphine;
- develop a comprehensive assessment of the treatment plan;
- communicate with the pharmacist about missed doses or other indicators of poor treatment compliance; and
- discuss future treatment plans.

As treatment progresses, the treating team should review the patient two to three times a week until stabilised to:

- establish adequacy of dose;
- enquire about withdrawal symptoms or side-effects; and
- monitor unsanctioned drug use and review the treatment plan to ensure clinical safety.

Once stabilised on a therapeutic dose, the treating team should review the patient weekly for a further four to six weeks to:

- monitor progress; and
- monitor effectiveness of the treatment plan.

Once stabilisation is complete and maintenance has commenced, patient reviews can be tapered to fortnightly for a further 6-8 weeks. After this period, Medical and/or case management reviews can be conducted more frequently at the request of any member of the treating team which includes the patient, case manager (within ADS), allied health professional, pharmacist or doctor. Any changes in medical management must be authorised by the prescribing doctor.

Within ADS, case management reviews should be conducted at least 6-8 weekly.

A comprehensive case management review (using the Pharmacotherapy Case Management Review template) is required at minimum 3 monthly intervals.

Once stabilisation of the patient is complete, medical reviews can occur fortnightly for 6-8 weeks. After this period, medical reviews are required at 3 monthly intervals.

7.6 Dosing location

In accordance with the Tasmanian Shared Care Model (Section 3.10), ADS will be responsible for inducting many of the patients commencing opioid pharmacotherapy in Tasmania. During the induction phase, dosing for most of these patients will occur in a pharmacy linked to the ADS pharmacotherapy program in the patient's area.

Patients who adhere to their treatment agreements may be referred to, and be dosed at, an alternative community pharmacy following the induction phase.

Doctors and pharmacists in the private setting inducting low risk patients to the program are encouraged to maintain regular communication with each other to determine the patient's ongoing suitability for the community dosing arrangements.

7.7 Methadone and buprenorphine dosing procedure

Patients must satisfy the pharmacist's requirements that the dose is being taken appropriately and that doses are not being diverted. Furthermore, the patient should always be assessed for signs of intoxication (on alcohol or other drugs) prior to dosing (a list of symptoms of withdrawal, intoxication and overdose is included in Section 5).

Some patients may even disclose their alcohol and other drug use.

Patients who present intoxicated should never be dosed. In these situations the patient must be advised that they cannot be dosed and asked to return to the pharmacy several hours later for review and possible dosing.

Patients who present intoxicated should never be dosed.

Prior to attending the pharmacy, patients should be advised of the following dosing procedures:

- only the patient can pick up their dose;
- the patient must enter the pharmacy alone;
- no bags or containers are allowed in the dosing area;
- the patient's hands and mouth must be visible to the pharmacist at all times;
- doses must be consumed in direct view of the pharmacist without turning of the head (excluding takeaway doses);
- dose must be consumed directly from the cup or spoon and placed under the tongue in the case of buprenorphine;
- for buprenorphine sublingual tablets, the patient must remain in full view of the pharmacist until the crushed tablets are dissolved under tongue;
- for buprenorphine sublingual film, the patient must remain in full view of the pharmacist until the film has dissolved under tongue (approximately 30 seconds: <16mg & 1 minute >16mg);

- the empty cup or spoon must be shown to the pharmacist before discarding it;
- the patient must speak to the pharmacist, open their mouth, and have a drink of water after dosing if asked to do so; and
- the patient must leave the pharmacy area and clinic vicinity as soon as they have dosed.

If the pharmacist is not satisfied that the dosing procedure has been met by the patient, they should discuss their concerns with the prescriber.

More detailed guidelines for pharmacists dispensing within the program are available in Section 16.

7.8 Moving to maintenance

If the patient is successfully inducted into the opioid pharmacotherapy program, they can begin the maintenance phase, which is outlined in detail in the following section.



SECTION: 8

Maintenance treatment

In this section you will...

- Gain an understanding of the maintenance phase of treatment;
- Develop an understanding of the therapeutic dosing levels suitable for patients in the maintenance phase; and
- Be provided with the Tasmanian policy on takeaway and missed doses.

8	Maintenance treatment	89
8.1	Methadone	89
8.1.1	Therapeutic dosing levels	89
8.1.2	Dose increases during maintenance	90
8.2	Buprenorphine	90
8.2.1	Therapeutic dosing levels	90
8.2.2	Dose increases during maintenance	90
8.3	Adjustments to prescriptions	90
8.4	Ongoing review	91
8.5	Urine drug screening during maintenance	91
8.6	Takeaway doses: general considerations	92
8.6.1	Safe storage of doses	93
8.6.2	Use of benzodiazepines and takeaway doses	93
8.6.3	Assessing eligibility for takeaway doses	94
8.7	Methadone takeaway doses	95
8.7.1	Weekends and public holidays	96
8.7.2	Exceptional circumstances	96
8.7.3	Methadone split dosing	96
8.8	Buprenorphine dosing schedules and takeaway doses	97
8.8.1	Double dosing	97
8.8.2	Triple dosing	98
8.8.3	Buprenorphine takeaway doses	98
8.8.4	Weekends and public holidays	99
8.8.5	Takeaway dose agreement	99
8.8.6	Interstate transfers	99
8.8.7	Suspension and temporary removal of takeaway doses	99

8.9	Missed doses	101
8.9.1	Effects on opioid tolerance	101
8.9.2	Missed doses in pregnancy	102
8.9.3	Following a missed dose; roles and responsibilities of patients, pharmacists and prescribers	102
8.9.4	Missed doses of methadone	104
8.9.5	Missed doses of buprenorphine	105
8.10	Lost or stolen doses	106
8.11	Vomited doses	107
8.11.1	Buprenorphine	107
8.11.2	Methadone	107
8.12	Continued use of other drugs	107
8.13	Transferring between treatment agents	108
8.13.1	Buprenorphine to methadone	108
8.13.2	From methadone ($\leq 40\text{mg}$) to buprenorphine	109

Section: 8

8 Maintenance treatment

Once the patient has been successfully inducted into the program, maintenance treatment can begin. The following section outlines therapeutic dosing levels suitable for patients in the maintenance phase, as well as the Tasmanian policy on takeaway and missed doses.

In general, most clients will remain on the same dose for lengthy periods, or even indefinitely once stabilised. However, it is not uncommon for clients who have been well stabilised on their dose for some time, to present describing withdrawal symptoms and requesting an increase in their methadone or buprenorphine

When a client presents requesting a dose increase, it is important for the clinician to undertake a comprehensive review. This should include a thorough medical examination and assessment of client's presentation; intoxication and/or withdrawal state; recent drug use, and psychosocial circumstances. There may be other reasons for the client's discomfort including liver disease; drug interactions; alcohol and drug use/cessation, missed doses, injection or diversion of takeaway doses, difficulties with emotional

regulation, anxiety, or a number of social stressors.

In managing this situation the prescriber should try to explore a range of other solutions and options including increased support, regular review and referral. Methadone and buprenorphine doses should not be increased without clinical evidence of opioid withdrawal. Prescribers are encouraged to seek specialist advice and review in these circumstances.

8.1 Methadone

8.1.1 Therapeutic dosing levels

While some patients can be successfully maintained on 30-50mg of methadone, the therapeutic dose for most patients is 50-100mg. There is little evidence to indicate that doses above 100mg are therapeutic for most patients, nevertheless, some patients may require more than 100mg to reach a therapeutic dose. Table 8.1 provides guidelines for authorisation requirements for prescribing various methadone maintenance doses in Tasmania.

Table 8.1: Guidelines for methadone dosing and authorisation at various doses

Methadone Maintenance Dose	Expected Therapeutic Outcomes	Authorisation Requirements
30-50mg	Therapeutic range for some patients	Authorisation not required
50-100mg	Therapeutic range for most patients	Authorisation not required
100mg	Recommended maximum therapeutic dose for maintenance	Authorisation not required
>100mg <120mg	High dose for most patients, therapeutic for some	Second opinion from an ADS Addiction Medicine Specialist recommended
120mg	Maximum allowable dose, therapeutic for some	Second opinion from an ADS Addiction Medicine Specialist recommended
>120mg	High risk dose, patient may be seeking outcome that methadone cannot provide	Authorisation from ADS Clinical Director required

8.1.2 Dose increases during maintenance

Throughout the course of treatment, there are times when a patient may require a dose increase to maintain the therapeutic effects of methadone. The guidelines for dose increases during maintenance are the same as for dose increases during week two of induction, as the same risks and mechanisms for reaching a steady state apply. That is, the maximum total dose increase of methadone in any seven day period is 10mg.

The maximum total dose increase of methadone in any 7 day period is 10mg.

- All dose adjustments, or adjustments to dosing arrangements, must be discussed with the patient and recorded in the patient file.
- The rationale for the changes (including identified risks and changes in clinical stability) and the actual change made to the prescription must be clearly noted in the clinical record.
- The pharmacist must be informed immediately with a fax of the prescription, and the hard copy prescription posted to the pharmacist within 24 hours.

8.2 Buprenorphine

8.2.1 Therapeutic dosing levels

As outlined in Section 7, since buprenorphine doses can be increased more rapidly than methadone, most patients will reach their therapeutic dose more quickly during induction. This is because most patients are stabilised on 24mg of buprenorphine or less. The registration of buprenorphine in Australia specifies that a maximum dose of 32mg of buprenorphine can be prescribed (either per day or in a double or triple dosing regimen). Prescribers should be aware of the implications for prescribing outside of recommended clinical guidelines.

The registration of buprenorphine in Australia specifies that a maximum dose of 32mg can be prescribed per day; this restriction applies whether it is a daily, double, or triple dose.

Patients requiring more than 24mg per day may be seeking outcomes that the drug cannot provide. It is recommended that GP prescribers seek advice from an ADS Addiction Medicine Specialist if the patient is requiring more than 24mg of buprenorphine per day.

The Tasmanian Opioid Pharmacotherapy Program, Policy and Clinical Practice Standards recommends GP prescribers seek advice from an Alcohol and Drug Services Addiction Medicine Specialist if the patient is requiring more than 24mg of buprenorphine per day.

8.2.2 Dose increases during maintenance

Patients are their therapeutic dosing level at the completion of induction into buprenorphine treatment. However, if required the dose may be increased by 2-4mg with a review in approximately 4 days.

8.3 Adjustments to prescriptions

All dose adjustments, or adjustments to dosing arrangements, must be discussed with the patient and recorded in the patient file. The rationale for the changes (including identified risks and changes in clinical stability) and the actual change made to the prescription must be clearly noted in the clinical record. The pharmacist must be informed immediately with a fax of the prescription, and the hard copy prescription posted to the pharmacist within 24 hours.

The rationale for changes (including identified risks and changes in clinical stability) and the actual change made to the prescription must be clearly noted in the clinical record.

8.4 Ongoing review

Assessment is a dynamic and ongoing process that allows the clinician to gather information about the patient's current status. Patient circumstances are fluid and consequently risks status can change. Ongoing review during the maintenance phase allows the clinician to monitor these changes, evaluate the effectiveness of the treatment plan, and modify the plan accordingly.

Once stabilisation is complete and maintenance has commenced, medical reviews can be tapered to fortnightly for a further six to eight weeks. After this period, a medical review that includes a comprehensive assessment including a physical examination (as outlined in Section 5) is required at minimum 3 monthly intervals. When there are significant changes to clinical risk indicators, a thorough review should be conducted. Any changes in medical management must be authorised by the prescribing doctor.

Within the ADS pharmacotherapy program, case management reviews should be conducted at least 6-8 weekly. A comprehensive case management reviews (using the Pharmacotherapy Case Management Review template) is required at minimum 3 monthly intervals. Regular contact with the case manager can assist in identification and coordination of the patient's health needs, as well as monitoring ongoing risk status and treatment effectiveness. This may include the provision of brief interventions and other case management functions (refer to Section 10 for more information).

8.5 Urine drug screening during maintenance

Urine drug screening (UDS) is an important tool to assist in the assessment and review of patients during the maintenance phase. In addition to the assessment and physical examination, a UDS can increase the efficacy and safety of treatment (see Section 5.13). While a UDS can be an important clinical tool, it does not in itself lead to a reduction in drug use.

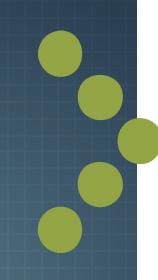
Some of the limitations of a UDS are that:

- it generally detects drugs used recently, and may not indicate a pattern of use;
- it may not be a reliable indication of drug use if not supervised;
- false positive and false negative results do occur; and
- there are significant financial and resource costs associated with urine drug testing.

Medicare Australia limits the frequency of urine drug testing to 21 urine drug tests in the first year of treatment, and 15 tests in following years. Where additional testing is required, costs are not rebated by Medicare and an agreement must be reached about payment of testing.

The benefits of supervised and randomised urine drug screening include:

- useful for identifying polysubstance use that may pose additional risks for patients on the program;
- provision of objective evidence of progress towards treatment goals;
- monitoring of extraneous drug use or diversion;
- an objective form of monitoring when self-report may not be reliable;
- provision of supportive evidence of stability in treatment;
- useful for program evaluation; and
- can be useful for medico-legal purposes.



While urine drug screens are effective at detecting methadone, the detection of buprenorphine requires chromatography procedures. This procedure does not provide information about whether the patient is consuming buprenorphine as prescribed. Enzyme-linked immunosorbent assay (ELISA) or Gas Chromatography and Mass Spectrometry (GCMS) are techniques that accurately detect the presence of buprenorphine, but these are expensive and less readily accessible. Consequently, buprenorphine testing should only be requested when there is a clinical indication. During the maintenance phase, refusal to provide a supervised UDS must be regarded as a positive test result. In these cases, the patient should be requested to attend for a thorough physical examination, which may result in changes to the treatment plan.

8.6 Takeaway doses: general considerations

The main focus and drivers for the Tasmanian Opioid Pharmacotherapy Program, Policy and Clinical Practice Standards (TOPP) are safety, meaningful clinical outcomes, and the need to address impairment or loss of control over drug use which is a feature of drug addiction.

To improve patient safety and ensure the appropriate prescription and use of opioids, the TOPP is necessarily conservative and maintains that many of the patients on the program will not be suitable for takeaway doses.

Tasmanian Opioid Pharmacotherapy Program, Policy and Clinical Practice Standards maintains that many of the patients on the program will not be suitable for takeaway doses.

The program acknowledges that, while some patients are suitable for and may benefit from takeaway doses, they can be unsafe for a large proportion of patients. Takeaway doses are highly desirable and lucrative on the illicit market and hence, the risk of diversion is high.

Expert opinion has suggested that approximately 10-20% of those patients currently on

buprenorphine will be suitable to receive unsupervised dosing (The Royal Australasian College of Physicians, Chapter of Addiction Medicine, 2006). Accordingly, the ADS estimates that only 5-10% of opioid pharmacotherapy patients will be suitable for a limited number of takeaway doses after a period of stabilisation. The Tasmanian Opioid Pharmacotherapy Program is primarily a supervised dosing program. However, it is our therapeutic goal to improve on this situation so that more patients attain clinical stability and are able to appropriately access take home dose privileges within the framework of a supervised dosing treatment program.

The Tasmanian Opioid Pharmacotherapy Program is primarily a supervised dosing program.

There are some clients who once stabilised, work hard to make changes in their life that will result in demonstrated clinical stability and decreased clinical risk. For these clients limits on the provision of takeaways may be seen as restrictive or an impediment to their capacity to fully participate in the community.

It is important that the client's treatment plan supports recovery, and is responsive to the needs of successful clients. Clients who have responded well to opioid pharmacotherapy over a lengthy period of time (2-3 years based upon the research of Simpson and Sells (1986)) and have no clinical risks should review their current treatment plan with a view to reducing off the program, or exploring options of double or triple dosing. If the client is receiving methadone they may elect to discuss with their treatment provider the option of transferring to buprenorphine to access double or triple dosing that allows greater flexibility.

It is important that takeaway doses are not provided during the commencement and induction phase of treatment, particularly methadone treatment, as this is a period of high risk for polysubstance use, drug overdose and death. Therefore, patients are required to attend the pharmacy daily during the first two weeks of methadone induction and the first week of buprenorphine induction. One exception is when the treatment agent

is buprenorphine, as the client may be double dosed, see Section 8.8.1.

8.6.1 Safe storage of doses

Where takeaway doses are approved according to the criteria below, prescribers must advise patients of their responsibility for safe storage of these medications. Patients must also be informed of the risks associated with the consumption of the takeaway dose by anyone other than the patient, particularly children. The provision of this advice should be documented in the patient file.

Patients should be encouraged to purchase a lockable device that can be placed out of reach of children to store their takeaway doses. In the public system, case managers can assist patients in finding a suitable storage device. Even if clinically stable, takeaway doses should not be provided to patients in unpredictable and insecure living arrangements where the storage of takeaway doses may endanger public safety.

Patients should also be informed that the following are NOT suitable storage locations:

- anywhere within reach of children;
- transient accommodation such as motel rooms, boarding houses, caravans, tents, trucks;
- transport vehicles such as cars and motorcycle panniers; and
- eskies or refrigerators.

8.6.2 Use of benzodiazepines and takeaway doses

As noted throughout this document, the concurrent use of benzodiazepines while receiving opioid pharmacotherapy treatment presents a high risk of respiratory depression and even death for patients. Furthermore, there is little evidence to support the efficacy of long term use of benzodiazepines for the management of chronic sleep disturbances, long term anxiety difficulties, or in the context of chronic non-malignant pain management (Morin & Wooten, 1996; Chen & Lader, 1990; and King & Strain, 1990). A more recent study (Kripke, et al., 2012) found that receiving hypnotic prescriptions (including

benzodiazepines) was associated with greater than threefold increased hazards of death even when prescribed <18 pills/year, with greater mortality associated with greater dosage prescribed.

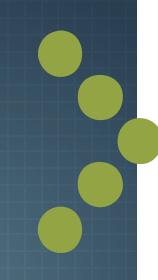
The negative effects of benzodiazepines on memory and learning are well established and are exacerbated when combined with methadone treatment (Rapeli, 2009). The TOPP only supports the short-term use of diazepam in a controlled environment during benzodiazepine withdrawal treatment, until the patient is able to benefit from alternative treatments such as cognitive behaviour therapy (CBT) or anti-depressant medication. Clinicians must consider the extent to which benzodiazepine treatment may actually be hindering effective processing of CBT strategies for managing anxiety.

The Tasmanian Opioid Pharmacotherapy Program, Policy and Clinical Practice Standards advocates a strict policy for the provision of takeaway doses for patients using benzodiazepine medication. Patients treated with medium to high doses of benzodiazepines (i.e. more than 5mg per day of diazepam or equivalent) are ineligible for takeaway doses.

Patients treated with medium to high doses of benzodiazepines (>5mg per day of diazepam or equivalent) are ineligible for takeaway doses.

This will inevitably limit the number of patients eligible to receive takeaway doses. Prescribing doctors and, in public settings, treating teams, should take this opportunity to motivate patients to reduce their benzodiazepine use in order to improve their eligibility for takeaway doses. In relation to benzodiazepine use, the goal of pharmacotherapy treatment is to safely and gradually withdraw patients from benzodiazepines.

Since receiving prescriptions from multiple sources is a common problem with patients reliant on benzodiazepines, the treating doctor is strongly encouraged to register with the Prescription Shopping Information Service



(www.medicareaustralia.gov.au) see Section 6.3.6. Transparency with the patient about the access to this information is imperative for maintaining a strong therapeutic alliance and ensuring the patient's safety. Patients should also be encouraged to access support (e.g. through allied health professionals) for ongoing sleep or anxiety difficulties which may perpetuate the use of benzodiazepines.

For safety reasons and to avoid perpetuating dependence, benzodiazepine treatment should be not initiated during opioid pharmacotherapy. High risk patients presenting with complex issues related to use of high dosages of benzodiazepines should be referred to ADS as per the Tasmanian Shared Care Model (Section 2).

Benzodiazepine treatment should not be initiated during opioid pharmacotherapy.

8.6.3 Assessing eligibility for takeaway doses

When assessing for eligibility for takeaway doses, the prescribing doctor is specifically assessing whether the patient meets criteria for clinical stability, ongoing safety, and whether providing takeaway doses will promote meaningful clinical outcomes. The Royal Australasian College of Physicians, Australasian Chapter of Addiction Medicine Clinical Guidelines: Assessing suitability for unsupervised medication doses in the treatment of opioid dependency (2006) provide a detailed discussion of this issue including a checklist to assist in determining suitability.

Additional criteria regarding the level of clinical stability required prior to provision of takeaway doses for the specific treatment agents are described below.

Clinical stability is indicated once the patient has achieved all of the following clinical outcomes:

- no signs of injecting drug use, including no fresh or recent needle marks;

- no presentations of intoxication with alcohol or any other drugs to the clinic or pharmacy;
- few (1-2 per month), if any, unexplained missed doses;
- few (1-2 per month), if any, unexplained missed appointments;
- adhere to their treatment agreement;
- no traces of polysubstance use or unsanctioned opioid use in random supervised urine samples; and,
- compliance with supervised dosing requirements.

While the patient may have met the criteria for clinical stability, the doctor must also be satisfied that **ongoing safety** is likely to be maintained, which means that:

- the patient is not using more than 5mg of diazepam or equivalent per day (as per policy above);
- the patient does not present with a risk of overdose, injecting drug use, or drug diversion; and
- the patient is able to safely store the takeaway dose. This also means that patients should be in stable living or housing arrangements.

Clinical outcomes:

- providing the takeaway dose will enhance the patient's clinical outcomes and wellbeing;
- the patient can maintain clinical stability with reduced supervision; and
- the patient will be responsible to take the dose on the day and time agreed.

In the ADS pharmacotherapy clinics, endorsement for the provision of takeaway doses is provided by the doctor in conjunction with the treating team. In the private system, the treating doctor is solely responsible for approving takeaway doses, although ADS should be consulted for complex clinical presentations. The Takeaway Dose Risk Assessment Plan (Appendix 8) is a check list to assist clinicians to consider the risk and protective factors associated with the provision of takeaway doses.

It is also important to notify the pharmacist of any changes to prescribing including the provision, suspension and cancellation of doses. As previously discussed (see section 3.11.4) it is important to ensure that all members of the treating team are aware of any changes in the client's care.

Once the patient has met the criteria for eligibility for takeaway doses, all members of the treating team are responsible for ensuring that indicators of stability continue to be assessed. If the prescribing doctor is unsure that the patient is clinically stable, takeaway doses can be ceased until stability and safety is re-established. It is important to communicate this to patients prior to commencing takeaway dosing.

Takeaway doses should not be given without a thorough risk assessment. Patients will only be given takeaway doses when there is clear evidence of clinical stability.

8.7 Methadone takeaway doses

As discussed in Section 7, patients will not be permitted to access methadone takeaway doses during the induction phase, and are therefore required to attend a pharmacy daily for the first two weeks of induction.

One methadone takeaway dose

Patients are eligible for one takeaway dose per week once they have been clinically stable for a continuous period of 3 months.

Once 3 months of clinical stability has been achieved, the patient may have a good case to request one takeaway dose per week from their prescribing doctor. In the public system, the case manager should support the patient through this process, and encourage them to be an active agent in their treatment planning. This includes supporting the patient through a medical review to assess whether providing the takeaway dose will promote positive clinical outcomes and whether the patient is likely to maintain ongoing safety.

Patients are eligible for one (1) takeaway dose per week once they are clinically stable for a continuous period of three months.

If the patient does not have access to a seven-day dosing pharmacy, a takeaway dose for Sundays may be given prior to 3 months. However, the induction phase of treatment must be complete and the patient must meet the above criteria for clinical stability and ongoing safety.

As per the Gateway model outlined in Section 3, buprenorphine remains the induction agent of choice because double dosing allows prescribers to reduce many of the problems and risks associated with methadone takeaway doses. However, if patients on an interstate transfer are well established and stabilised on methadone, a switch to buprenorphine is not required.

Two non-consecutive methadone takeaway doses

After a patient has demonstrated a further 3 months of continuous clinical stability (as defined above) on one methadone takeaway dose, they may be eligible to apply for two takeaway doses per week (non-consecutive). Hence, most patients will have demonstrated six months of continuous clinical stability before being eligible for two non-consecutive takeaway doses.

Most patients will demonstrate six months of continuous clinical stability before being eligible for two (2) non-consecutive takeaway doses per week.

As per the procedure for approving one takeaway dose, the prescribing doctor must first conduct a medical review (including risk assessment), with the additional criterion that the patient must return a clean urine sample in the 7 days prior to commencing on two takeaway doses. Two methadone takeaway doses per week is the maximum number approved by the Tasmanian Opioid Pharmacotherapy Program, Policy and Clinical Practice Standards.

Two (2) methadone takeaway doses per week is the maximum number approved by the Tasmanian Opioid Pharmacotherapy Program, Policy and Clinical Practice Standards.

Table 8.2: Guidelines for the provision of methadone takeaway doses

Time in treatment	Eligibility criteria	Number of takeaway doses permitted per week
Induction Phase	Not Applicable	No takeaway doses permitted
2 week – 3 months	Not Applicable	No takeaway doses permitted
3-6 months of continuous clinical stability	Demonstrated clinical stability Takeaway dose will facilitate meaningful clinical outcomes Ongoing safety likely to be maintained	One takeaway dose permitted
6-9 months of continuous clinical stability	Demonstrated clinical stability on one takeaway dose Takeaway doses will facilitate meaningful clinical outcomes Ongoing safety likely to be maintained Clean urine sample in last 7 days	Two non-consecutive takeaway doses permitted

8.7.1 Weekends and public holidays

Whenever possible, the prescribing doctor should try to maintain current takeaway dose arrangements and avoid additional or consecutive takeaway doses during public holidays. This may require, for example, a temporary change of days. Prescribers can contact the ADS for advice or support around managing takeaway doses during holiday periods.

8.7.2 Exceptional circumstances

In exceptional circumstances (e.g. bereavement, family medical emergency, other significant unexpected life events), patients may be provided with additional or consecutive takeaway doses following consultation with an ADS Addiction Medicine Specialist. In this circumstance, the rationale for these additional takeaway doses, as well as the management plan, should be clearly documented in the patient file. The ADS Addiction Medicine Specialist must provide written confirmation to prescribers regarding exceptional takeaway dose arrangements agreed upon during consultation.

8.7.3 Methadone split dosing

It is possible that high methadone doses or split doses may benefit some patients with rapid opioid metabolism. However, the relationship between plasma methadone levels and treatment outcomes for patients on methadone programs remains contentious.

According to Eap and colleagues (2002), while there is evidence that increasing the dose can assist some patients cease using unsanctioned opioids if the trough (R)-methadone blood levels are below 250ng/mL. However, blood levels are not necessarily a reliable measure of clinical stability and of the appropriate dose. Many patients that are clinically stable and not using illicit opioids, have plasma levels that are below this threshold level. For this reason, regardless of the blood levels, the clinician should focus on titrating the dose against the clinical indicators (evidence of withdrawal or intoxication) and risk and harm.

Eap and colleagues (2002) also point out that beside pharmacokinetic factors,

pharmacodynamic parameters, such as variability in receptors and psychological or social factors, are very important for the success of methadone maintenance treatment. On the other hand, if patients are not responding to treatment and have low trough levels, these authors see no reason not to increase or split the dose.

Unfortunately, the structural and other practical barriers to observed split dosing are substantial. For some patients, there is an added concern about the veracity of the drug use history and clinical safety with split dosing arrangements. This may present a significant risk of diversion and overdose to the patient.

Regardless of these clinical effectiveness doubts, Tasmania does not have the clinical or pharmacy dispensing capacity to manage split dosing among patients registered on the opioid pharmacotherapy program. Given the high levels of problems associated with takeaway doses, including their diversion and unsanctioned use, split dosing is considered unsafe clinical practice in Tasmania.

The Tasmanian Opioid Pharmacotherapy Program cannot support methadone split dosing.

8.8 Buprenorphine dosing schedules and takeaway doses

As outlined in the Gateway model outlined in Section 4, Suboxone® (buprenorphine-naloxone) is the preferred induction and treatment agent for the Tasmanian Opioid Pharmacotherapy Program. As well as being clinically safer than methadone, the ability to double or triple dose most patients means that buprenorphine is more convenient for many patients, requiring fewer visits to the pharmacy. It also means fewer patients will require takeaway doses. Amass et al., 1998 reported that 96% of their subjects chose alternate day dosing over daily dosing.

8.8.1 Double dosing

Once inducted into buprenorphine pharmacotherapy, patients may be trialled on double dosing. This means that the patient can be provided with twice their daily dose in one visit to the pharmacy. Patients are then maintained on this dose for two days, thus not needing to attend the pharmacy the following day. The patient only needs to attend the pharmacy four times per week, making it much more convenient than daily dosing. Double dosing works best for patients on a daily dose of eight to 16mg of buprenorphine.

Double dosing works best for patients on a daily dose of 8-16mg of buprenorphine.

Double dosing for patients on less than 8mg buprenorphine per day is often insufficient to manage withdrawal symptoms. Such patients are likely to require daily dosing. However, a trial of double dosing may be considered appropriate.

Patients on more than 16mg of buprenorphine per day cannot be double dosed since the maximum dose of buprenorphine that can be provided on any one day is 32mg (section 8.2). Some patients on 20mg of buprenorphine per day have reported being successfully managed on a 32mg double dose. A trial of double dosing with 32mg double doses for such patients is appropriate.

If the patient is on a dose between 8-16mg buprenorphine per day, a double dosing trial with close observation by the treating team (including the pharmacist) of the patient's progress is appropriate.

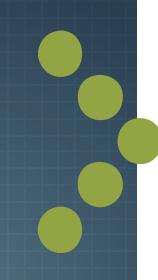
An example of a weekly double dosing schedule for a patient on 12mg of buprenorphine is:

Monday – 24mg double dose

Wednesday – 24mg double dose

Friday – 12mg single dose

Saturday – 24mg double dose



Patients living in rural and remote areas with no access to a 7 day dosing pharmacy can double dose on a Saturday during the induction phase. If a patient with limited pharmacy access is on 20mg of buprenorphine by the end of week 2 of induction, trialling a double dose of 32mg on the second Saturday is appropriate. However, the patient cannot access buprenorphine takeaway doses during the induction phase.

8.8.2 Triple dosing

Patients who have successfully been double dosed for a period of time can be trialled on triple dosing, which requires them to attend the pharmacy only 3 times per week. Triple dosing works best for patients on a daily dose of 8-10mg of buprenorphine.

Triple dosing works best for patients on a daily dose of 8-10mg of buprenorphine.

An example of a weekly triple dosing schedule for a patient on 8mg of buprenorphine is:
Monday – 8mg single dose
Tuesday – 24mg triple dose
Friday – 24mg triple dose.

8.8.3 Buprenorphine takeaway doses

Daily dosing regimens

The TOPP recommends patients on buprenorphine only be maintained on daily dosing schedules if alternative double dosing schedules within the guidelines have been trialled and were not successful.

Only patients on a daily dosing regimen are eligible to receive takeaway doses. The Tasmanian Opioid Pharmacotherapy Program, Policy and Clinical Practice Standards allows for a maximum of two buprenorphine takeaway doses per week, however, takeaway doses can only be provided if the patient is unable to double dose. Double dosing is not suitable when the dose is too high for double dosing, the dose is too low to hold the patient for the full duration, or in the case of pregnant women when single day dosing may be preferable for clinical safety.

Only patients on daily dosing schedules can access buprenorphine takeaway doses.

Requirements for accessing takeaway doses are the same as for methadone: that is, clinical stability is indicated, ongoing safety is likely to be maintained, and provision of takeaway doses will promote meaningful clinical outcomes.

Two (2) buprenorphine takeaway doses per week is the maximum number approved by the Tasmanian Opioid Pharmacotherapy Program, Policy and Clinical Practice Standards.

Buprenorphine takeaway doses can only be provided if the patient is unable to double dose.

Patients will not require access to takeaway doses in the first week of buprenorphine induction as the Tasmanian Opioid Pharmacotherapy Program, Policy and Clinical Practice Standards specify the maximum dose at the end of week one is 16mg daily. Hence, patients can be double dosed on the first Saturday.

Double or triple dosing regimens

Unlike methadone, with the availability of double and triple dosing buprenorphine regimens, the need for takeaway doses due to inconvenience for the patient is reduced and safety on the program enhanced. The Tasmanian Opioid Pharmacotherapy Program, Policy and Clinical Practice Standards does not support patients on double or triple dosing regimens receiving takeaway doses, as their dosing schedule requires them to attend a pharmacy a maximum of 4 times per week, and can be designed to fit within their weekly schedules. Only patients on daily dosing schedules can access buprenorphine takeaway doses.

Patients on low daily doses may display visible signs of opioid withdrawal on the second day, this may indicate the need to increase this double dose. For patients on 16-20mg buprenorphine daily, this will include trialling on a double dose of 32mg.

Table 8.3: Guidelines for buprenorphine takeaway doses for patients on daily dosing schedules

Time in treatment	Eligibility criteria	Number of takeaway doses permitted per week
Induction Phase (0-2 weeks)	Not applicable	No takeaway doses permitted Double dose on first Saturday permitted
2 weeks – 3 months	Not applicable	No takeaway doses permitted
3-6 months of continuous clinical stability	Demonstrated clinical stability Ongoing safety likely to be maintained Takeaway dose will facilitate meaningful outcomes	One takeaway dose permitted
6-9 months of continuous clinical stability	Demonstrated clinical stability on one takeaway dose Ongoing safety likely to be maintained Takeaway doses will facilitate meaningful clinical outcomes Clean urine sample in last 7 days	Two non-consecutive takeaway doses permitted

8.8.4 Weekends and public holidays

Whenever possible, try to maintain current takeaway dose arrangements and avoid additional or consecutive takeaway doses during public holidays. This may require, for example, temporary change of days or double dosing around public holidays. Prescribers can contact the ADS for advice or support around managing takeaway doses during holiday periods.

8.8.5 Takeaway dose agreement

ADS patients, including patients transferred from interstate are required to sign a Takeaway Medication Agreement (Appendix 9) prior to accessing takeaway doses. This agreement includes information about limitations and eligibility for takeaway doses.

8.8.6 Interstate transfers

Patients being transferred from interstate will need to meet the same criteria prior to accessing takeaway doses and double or triple dosing arrangements as locally established patients. That is, they will need to demonstrate the same length of continuous clinical stability in Tasmania before being eligible for takeaway doses. This is regardless of their previous takeaway dose arrangements interstate.

8.8.7 Suspension and temporary removal of takeaway doses

If the prescriber or treating team identifies changes in clinical risk factors for the patient and that takeaway doses are no longer suitable, then the provision of takeaway doses should be suspended. The removal of takeaways doses can be challenging for both the clinician and the patient. Patients may perceive the removal of takeaway doses as a form of punishment and this may lead to overt expressions of



frustration and anger. It is also important to remember that many patients experience feelings of powerlessness and low self-worth and in this context they may interpret the removal of takeaways as confirmation of failure or inadequacies.

For this reason it is very important to talk to patients at the commencement of treatment about the reasons for the restrictions relating to access to takeaway doses and the circumstances that may lead to the removal of takeaway doses. When takeaway doses are to be suspended, it is important to discuss this with the patient and outline the rationale for the suspension. Clear advice should be provided about the conditions under which takeaway doses will be reinstated (e.g. the number of clean urines and the period of time over which these conditions apply).

In some instances, the patient may attend the pharmacy for dosing before they have been informed of changes to their treatment plan, and is denied their takeaway dose by the pharmacist. This scenario can place the pharmacist at increased risk of verbal abuse (or worse).

Procedure for removing or temporarily suspending takeaway doses

When a clinical decision is made to remove or suspend takeaway doses:

- communicate this change to patient immediately or as soon as possible;
- carefully explain of the reason for the removal of takeaway doses and how long this change in their treatment will be in-place (it can be very helpful to provide the patient with this information in writing);
- emphasise that the patient's clinical safety is always a priority and if necessary review the patient's pharmacotherapy treatment agreement;
- ensure that the patient understands what changes need to occur to increase their clinical safety or program compliance (i.e. clean urine drug screens; regular attendance at appointments) and offer strategies and assistance to the patient to support them with these changes;

- always try to explain any changes to the patients treatment with them in-person at the time of their assessment (or review) or when the need for a change to their treatment has been identified;
- if a decision is made to remove takeaway doses in the absence of the patient, every attempt should be made to contact the patient in person and inform them of this change to their treatment;
- if the patient is unable to be contacted then a message should be left for them to contact the prescriber prior to dosing at pharmacy;
- if the prescriber or treating team are unable to contact the patient directly about suspension of takeaway doses, this information should be provided to the patient in writing and a copy sent to the pharmacist;
- if the patient has no fixed abode, then two copies should be sent to the pharmacist. The pharmacist can then provide this letter to the patient and request that they contact their prescriber or treating team regarding their treatment plan;
- the pharmacist/dosing site should also be informed immediately in writing of any changes to dosing arrangements and of any identified clinical or safety risks (or behavioural/treatment contracts and requirements); and
- document in the clinical notes the rationale for the removal of takeaway doses and the ongoing management plan.

It is important NOT to place the pharmacist/dosing site in the position of having to inform a patient that their takeaway doses have been removed. This is the responsibility of the prescriber or treating service.

It is the responsibility of the prescriber to inform patients as soon as possible of any changes to their takeaway dose arrangements.

8.9 Missed doses

The key to effective outcomes for patients receiving opioid pharmacotherapy is supervised dosing. This supports the patient to manage one of the key features of opioid dependence – impairment or loss of control over drug use.

Therefore, patients are required to consume the prescribed dose at the time (hours) and location specified in the treatment plan.

Patients are required to consume their prescribed dose at the time and location specified in their treatment plan.

While patients may miss doses due to personal circumstance, regular unexplained missed doses (i.e. three or more times a month) are often an indication of either clinical instability or unsuitability of the treatment plan and dosing arrangements. Frequently missed doses can have a significant impact on the effectiveness of the treatment, for a more detailed discussion of this issue see Section 12.

The final clinical decision to dose a patient will always rest with the pharmacist and will be based on their assessment of the patient's suitability to dose.

When a patient presents for dosing, it remains the responsibility of the pharmacist to assess and determine if the patient is suitable to dose.

8.9.1 Effects on opioid tolerance

Missed doses can have a significant effect on the patient's opioid tolerance. This places the patient at an increased risk of overdose, particularly if they continue unsanctioned opioid use. These risks are significantly higher for patients receiving methadone than those receiving buprenorphine.

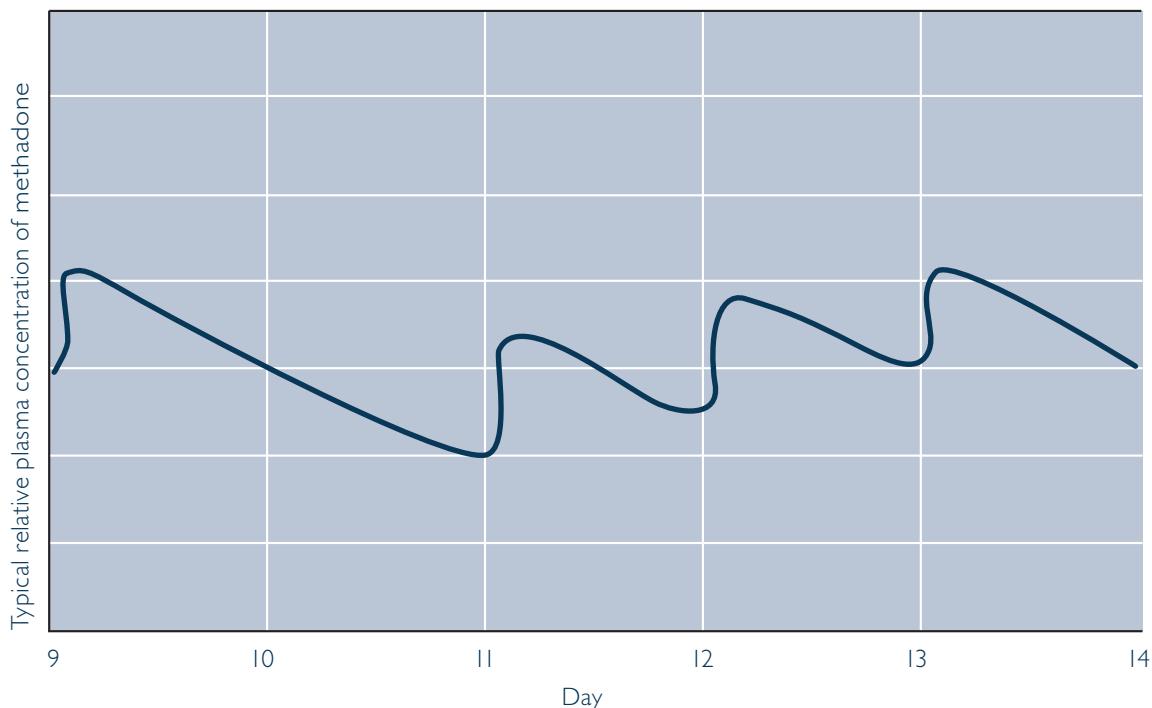


Figure 8.1: Three day recovery to steady state from missed dose at day 10

Note: Reproduced from *The Methadone Briefing. An easy to use reference guide to methadone and methadone prescribing: for health and other professionals*, by Preston (1996) p. 55. Andrew Preston: London.



For example, a patient's methadone blood levels can drop by 25% in one day after missing just one dose. Re-establishing a steady state of methadone levels can take between 3-10 days (see Section 4.2.2), during which time the patient is more likely to relapse into unsanctioned opioid use and be at risk of multiple drug toxicity. Figure 8.1 below demonstrates the effects of missing one dose upon methadone blood levels and is discussed in greater detail in Section 4.

Missing one day of buprenorphine is unlikely to affect the patient as much as missing one day of methadone. However, the time it takes to re-establish a steady state will depend on the treatment agent, dose, and patient.

After 3-4 missed days of either treatment agent, the patient will have a significantly reduced tolerance to opioids. Patients who have missed 3-4 days of treatment require titration back up to their previously therapeutic dose.

Missing 5 days or more will require the patient to be inducted back onto the program.

Intermittent consumption of opioid pharmacotherapy and its associated risks of reduced tolerance and overdose is potentially more hazardous than no treatment at all.

8.9.2 Missed doses in pregnancy

As with all opioid pharmacotherapy the key to effective outcomes for patients is regular/ daily dosing. Missed doses may result in sub optimal dosing and opioid withdrawal. For pregnant women missed doses are critical as they may be at risk of miscarriage. Pregnant women receiving opioid pharmacotherapy should be made aware of this risk and actively encouraged to maintain regular dosing regimens, see Section 11.5.2 missed doses of methadone.

8.9.3 Following a missed dose; roles and responsibilities of patients, pharmacists and prescribers

Ensuring the safety of the patient while in opioid pharmacotherapy treatment is the responsibility of all parties involved: this includes the treating team and pharmacist, as well as the patient themselves. The treating team should

communicate to the patient the consequences of a missed dose, including the increased risks to safety. The following subsection outlines the responsibilities that the patient, the prescriber, and the pharmacist have following a missed dose.

The patient

Patients must share the responsibility for the choices and decisions they make relating to their treatment in the program. Hence, the patient is an 'active partner' in his or her treatment.

Patients are asked to:

- let the prescriber and pharmacist know ahead of time if they cannot attend for dosing due to a predictable life circumstances. The patient may arrange either a temporary transfer or request an exemption to miss the dose for that day;
- contact the prescriber (or ADS case manager) and reaffirm their safety if they miss 1 day of treatment;
- contact the prescriber (or ADS case manager) and negotiate a review if they have missed 2 days of treatment; or
- attend a review with their prescriber and/ or case manager at a mutually suitable time if they have missed 3 or more days of treatment.

The pharmacist

The following information is a guide for dispensing pharmacists.

One missed dose:

When a patient has missed a single dose, it is the responsibility of the pharmacy to assess and determine if the patient is suitable to dose.

When the patient is suitable to dose:

- the pharmacist may dose the patient if the patient is not intoxicated and no other risks or concerns are identified; and
- as soon as possible, the pharmacy notifies the prescriber (or ADS case manager) that the patient has missed a dose.

When the patient is assessed by the pharmacist as not suitable to dose:

- if the patient is not safe to dose it is strongly advised that:

- the pharmacist respond accordingly and not dose the patient; and
- the pharmacist inform the patient that he or she needs to contact the prescriber (or ADS case manager); and
- the pharmacist not dose the patient until they are reviewed by the prescriber (or ADS case manager).

Two consecutive missed doses:

- it is strongly advised that:
 - the patient is **not dosed**; and
 - the pharmacist inform the patient that they cannot be dosed without further approval from their prescriber; and
 - the pharmacist advise the patient to contact their treating prescriber or service and request a review from the prescriber (or ADS case manager); and
 - the pharmacist notify the prescriber (or ADS case manager) of the consecutive missed doses.

Three or more consecutive missed doses:

- it is strongly advised that:
 - the patient is **not dosed**; and
 - that the pharmacist inform the patient that they cannot be dosed without further approval from their prescriber; and
 - the pharmacist advise the patient to contact their treating prescriber or service and request a review from the prescriber (or ADS case manager); and
 - if the patient is pregnant, the pharmacist refer them to the hospital as they are at risk of miscarriage; and
 - the pharmacist notify the prescriber (or ADS case manager) of the consecutive missed doses.

If in doubt, the safest approach is to decline dosing the patient and contact the prescriber.

The prescriber

The prescriber (including input from the treating team in ADS) should ensure that the patient is safe to continue receiving treatment after missed doses. This requires consideration of circumstances surrounding both a missed

dosing period and ongoing patterns of missed doses, as well as evidence of clinical stability (or instability). The prescriber (and treating team) should carefully consider the circumstances of the missed dose(s) and determine the cause. Potential causes regularly observed by ADS clinicians include:

- predictable life circumstance, which will have ideally been communicated by the patient prior to the missed dose;
- unpredictable life circumstances, which may require verification from a family member, significant other, or other treatment agency;
- a planned attempt to engage in unsanctioned drug use;
- unplanned or spontaneous engagement in unsafe practices, such as using alcohol and other drugs;
- unsuitability of the patient's treatment plan and dose scheduling; and
- unsuitability of the opioid pharmacotherapy program for the patient.

Once the most probable cause has been determined and the history of the patient's attendance to the program is considered, the prescriber can decide to either:

- approve continuation of the patient's treatment plan, with appropriate adjustments to dosing in writing (described below) until tolerance is re-established;
- re-negotiate the patient's treatment plan and dosing arrangements, including the cessation of takeaway doses if the criteria for clinical stability are no longer being met; or
- withdraw the patient from treatment (see Section 9 for guidelines on withdrawing from treatment).

Communication between the treating team is important where the changes to the clients' care occur. Prescribers should inform pharmacists in writing of these changes e.g. to confirm recommenced dosing. The following is a guide for prescribers (and ADS case managers) for commencement doses and requirements for reviews after a missed dose.

8.9.4 Missed doses of methadone

One missed dose:

When a patient has missed a single dose, it is the responsibility of the pharmacy to assess and determine if the patient is suitable to dose.

*When the patient is **suitable to dose**:*

- The pharmacist may dose the patient if the patient is not intoxicated and no other risks or concerns are identified;
- as soon as possible, the pharmacy notifies the prescriber (or ADS case manager) that the patient has missed a dose; and the prescriber and/or ADS case manager will record the missed dose in the patient file.

*When the patient is assessed by the pharmacist as **not suitable to dose**:*

- if the patient is not safe to dose it is strongly advised that the pharmacist respond accordingly and inform the patient that they cannot be dosed without further approval from their prescriber;
- it is not advisable to dose the patient until they are reviewed by the prescriber (or ADS case manager);
- following a review, the prescriber (or ADS case manager) will confirm with the pharmacy in writing that in their clinical opinion that dosing may continue (in accordance with the existing prescription and its instructions) or whether an adjustment to the treatment plan is required. In this situation, the prescriber will issue a new prescription which details the dose adjustment. (When the patient represents for dosing, as always it remains the responsibility of the pharmacy to assess and determine if the patient is suitable to dose); and
- the prescriber and/or ADS case manager will record the missed dose and reason in the patient file.

Two consecutive missed doses:

- it is strongly advised that:
 - the patient is **not dosed**; and
 - the pharmacist inform the patient that they cannot be dosed without further approval from their prescriber;

- that the pharmacist advise the patient to contact their treating prescriber or service and request a review from the prescriber (or ADS case manager);
- that the pharmacist notify the prescriber (or ADS case manager) of the consecutive missed doses;
- the prescriber (or ADS case manager) will confirm with the pharmacy in writing that in their clinical opinion the dosing may continue (in accordance with the existing prescription and its instructions) or whether other adjustments to the treatment plan are required and issue a new prescription (when the patient represents for dosing, as always it remains the responsibility of the pharmacy to assess and determine if the patient is suitable to dose); and
- the prescriber (or ADS case manager) will record the missed dose and reason in the patient file.

Three consecutive missed doses:

- it is clinically unsafe to dose in the absence of a medical review and therefore it is strongly advised that:
 - the pharmacy **not dose**; and
 - the pharmacist inform the patient that they cannot be dosed without further approval from their prescriber;
 - the pharmacist advise the patient to contact their treating prescriber or service and request a review from the prescriber (or ADS case manager);
- the prescriber will review the patient; and
- if there is no evidence of intoxication or other risk factors, the patient may be rescripted and recommenced on half the previous dose and re-titrated back up to therapeutic dose according to their overall clinical status (including withdrawal signs and symptoms or on the other hand, signs of emerging opioid toxicity) displayed over subsequent days (or weeks). This will require further reviews of the patient by the prescriber;
- the prescriber will confirm the new arrangements in writing with the pharmacy by issuing a new prescription;
- the prescriber and/or the ADS case manager

- will document the new arrangement in the patient file, including reasons for missed doses; and
- if the patient is pregnant, the patient should be referred to the Emergency Department at the nearest hospital as a matter of urgency as they are at risk of miscarriage; and
- it is important for the prescriber to communicate with the hospital medical staff and collaborate in the management of these complex clinical presentations.

Four consecutive missed doses:

- it is clinically unsafe to dose in the absence of a medical review and therefore it is strongly advised that:
 - the pharmacist **not dose**; and
 - the pharmacist inform the patient that they cannot be dosed without further approval from their prescriber; and
 - the pharmacist advise the patient to contact their treating prescriber or service and request a review from the prescriber (or ADS case manager);
- the prescriber will review the patient; and
- if no evidence of intoxication or other risk factors, the patient may recommence 40mg OR half of usual dose (whichever is lower), and be re-titrated back up to therapeutic dose according to their overall clinical status including withdrawal signs and symptoms displayed over subsequent days (or weeks); this will require further reviews of the patient by the prescriber;
- the prescriber will confirm new dosing arrangements with the pharmacy in writing by issuing a new prescription; and
- the prescriber will document the new arrangement in the patient file, including reasons for missed doses.

Five or more consecutive missed doses:

- it is clinically unsafe to dose in the absence of a medical review and therefore it is strongly advised that:
 - the pharmacy **not dose**; and
 - will inform the patient that he or she needs to contact the prescriber or ADS case manager;

- the prescriber will review patient and manage as a new induction.

If the patient is pregnant:

If the patient is pregnant, refer them to the Emergency Department at the nearest hospital as they are at risk of miscarriage. The prescriber should be contacted and advised to contact the Emergency Department and provide advice on the patient's management. If this is not possible the ADS On Call doctor should be contacted to provide advice and support to the Emergency Department (See Section 11.5.2 Missed Doses During Pregnancy).

If the patient is pregnant and has missed three or more doses, they are at risk of miscarriage and should be referred to the nearest Department of Emergency Medicine.

8.9.5 Missed doses of buprenorphine

Daily dosing

One or two consecutive missed doses:

- follow the same procedures as for methadone.

Three or four consecutive missed doses:

- it is clinically unsafe to dose in the absence of a medical review and therefore it is strongly advised that the pharmacy **not dose**; and
- inform the patient that he or she needs to contact the prescriber or ADS case manager;
- the prescriber will review the patient; and
- if no evidence of intoxication or other risk factors and there are clear signs of withdrawal the prescriber can recommence half to two thirds of the usual daily dose up to a maximum of 16mg. Re-titrate back up to therapeutic dose according to the patients overall clinical stability (including withdrawal signs and symptoms or on the other hand, signs of emerging opioid toxicity) displayed over subsequent days. This will require further reviews of the patient;

- the prescriber will confirm the new arrangements with the pharmacy in writing (with a new prescription);
- the prescriber will document the new arrangement in the patient file, including reasons for missed doses;
- if the patient is pregnant, refer them to the Emergency Department at the nearest hospital as they are at risk of miscarriage. The prescriber should be contacted and advised to contact the Emergency Department and provide advice on the patient's management. If this is not possible the ADS On Call doctor should be contacted to provide advice and support to the Emergency Department (See Section 11.5.2 Opioid treatment during pregnancy).
- it is important for the prescriber to communicate with the hospital medical staff and collaborate in the management of these complex clinical presentations.

If the patient is pregnant, they are at risk of miscarriage and should be referred to the nearest Department of Emergency

Five or more consecutive missed doses:

- it is clinically unsafe to dose in the absence of a medical review and therefore it is strongly advised that the pharmacy **not dose**; and
- inform the patient that he or she needs to contact the prescriber or ADS case manager;
- the prescriber will review patient and manage as a new induction.

Double or triple dosing

Whether the patient is on daily or triple dosing will need to be taken into account when determining recommencement dose.

It should be noted that 'dose' refers to a single day of treatment, so missing a double dose means missing two days treatment.

Determine where in their schedule they are in relation to dose, and then follow the same regulation as daily dosing. Some examples are presented below:

Example 1: If a patient on a double dose attends the day after their scheduled dosing day, this means they have missed one dose and they can receive their daily dose.

Example 2: If a patient on a double dose does not attend on the scheduled dosing day, and attends 2 days later on their next regular scheduled day, this means they have missed two doses and will need to contact their prescriber (or ADS case manager) before they can receive their double dose.

Example 3: If a patient on a triple dose attends the day after their scheduled dosing day, this means they have missed one dose and they can receive a double dose.

Example 4: If a patient on a triple dose attends two days after their scheduled dosing day, this means they have missed two doses and will need to contact their prescriber (or ADS case manager) before they can receive a daily dose.

If in doubt, the safest approach is to decline dosing the patient and contact the prescriber.

8.10 Lost or stolen doses

Lost doses or stolen doses pose a significant risk to the community (see Section 12). There is a very high risk of overdose and death should another individual (other than that for whom the medication is prescribed) consume the methadone or buprenorphine dose. Patients who report lost or stolen doses should be asked to make a formal report to the police. When the patient does not comply with this request or the notification to police does not occur in a timely manner, the matter should be reviewed by the clinical team and a notification made to Tasmania Police.

Patients who report lost or stolen doses should be asked to make a formal report to the police.

Prescribers and case managers should discuss with the patient the circumstances of any lost doses. As the secure storage of medication is a requirement for access to takeaway doses, the patient's suitability for unsupervised dosing should be reviewed. A return to daily supervised dosing is recommended until the patient is able to demonstrate improved stability following a trial period.

8.11 Vomited doses

In general vomited doses are not replaced. However, if this occurs it is important to consider the time that has elapsed and the possibility that some or all of the dose has been absorbed. The treatment agent of choice (i.e. methadone or buprenorphine) will have a direct impact on how vomited doses are managed.

8.11.1 Buprenorphine

Replacement after a vomited dose of buprenorphine is not required because buprenorphine is rapidly absorbed sublingually.

Replacement after a vomited buprenorphine dose is not required because buprenorphine is rapidly absorbed sublingually.

8.11.2 Methadone

After oral consumption, methadone takes approximately 20 minutes to be absorbed. Therefore, if a patient vomits more than 20 minutes after the dose is administered, the patient can be reassured that the dose has been absorbed. The following guidelines apply to partial replacement doses in certain circumstances.

During the induction phase (two weeks):

- if a patient reports vomiting within 20 minutes, the prescriber (or ADS case manager) should consider reviewing the patient 4-6 hours after the initial dose. If withdrawal symptoms are present then a supplement dose of a maximum of half their original dose may be administered.

During the maintenance phase:

- the pharmacist must contact the prescriber for approval before the dose is administered.

- if the patient is observed vomiting by the pharmacist within 20 minutes of the dose, the pharmacists may administer a half dose;
- after administration, the patient must wait in the pharmacy for at least 20 minutes, to monitor for risk of overdose; and

Pregnant patients

- if a patient reports vomiting, the prescriber (or ADS case manager) should review the patient within 4-6 hours. If there are signs of withdrawal, consider a small supplementary dose of no more than half their usual dose up to a maximum of 40mg.

8.12 Continued use of other drugs

Use of other drugs, both prescription and illicit, is common amongst opioid pharmacotherapy patients. Polysubstance use is also common, particularly in the early phase of treatment.

In many cases, it is safer to continue with opioid pharmacotherapy than to withdraw the patient from treatment. However, consideration needs to be given to patient safety while on the program. Information about the patient's concurrent drug use while on the program can be obtained from several sources, including:

- Patient self report:* Developing a good therapeutic rapport that promotes information sharing and emphasises the patient as an active agent in their treatment planning is essential. Encouraging patients to disclose their drug use and responding to it in a non-punitive manner is also essential.
- Random supervised urine drug screens:* This can be a useful tool in detecting unsanctioned opioid and other drug use. Although screening will not provide information about patterns of drug use, they can provide an objective report about the patient's recent drug use.
- Changes in clinical condition or behaviour:* This can be a good indication of unsanctioned drug use, for example, presenting while intoxicated, overdoses, chaotic behaviour, deteriorating medical or mental state.

- Ongoing communication between members of the treating team (for example, between the pharmacist and the prescriber) is also required.
- Regular review: As stated in Section 8.4, a medical review is required at a minimum of 3 monthly intervals. While private prescribers may have limited capacity to communicate with service providers external to the treating team and family and friends, case managers in ADS have the capacity to link in and communicate with alternative service providers, particularly where there are concerns about patient and community safety.

Strategies for addressing the risks associated with concurrent drug use include:

- Regularly providing information about the risks of other substance use in combination with prescription opioids, including written information;
- Using motivational interviewing to discuss what the patient experiences as the positive and not-so-positive aspects of combining other drug use with opioid pharmacotherapy and how this may be impacting on their treatment goals;
- Regularly discussing and encouraging harm minimisation strategies;
- Supporting access to psychosocial interventions and supports;
- Developing strategies for coping with withdrawal from other drugs;
- Discussing strategies for relapse prevention;
- Encouraging the use of non-drug strategies, such as sleep hygiene and relaxation training, to help manage psychological stressors;
- Consider changes in opioid pharmacotherapy treatment, for example, alterations to the dose or the dosing schedule (e.g. going from double day to daily supervised dosing for buprenorphine, removing or suspending takeaway doses);
- Consider change in treatment agent, for example, a switch from methadone to buprenorphine, which is the generally safer medication;

- Consider changes in dosing location; and
- If the risks of other drug use outweigh the benefits of remaining on the program, consider withdrawal from treatment.

Continued high risk drug use is challenging to manage and can seriously compromise the safety and efficacy of opioid pharmacotherapy. Section 12 discusses this in detail and presents strategies for managing this complex issue.

8.13 Transferring between treatment agents

Transferring between pharmacotherapy agents is a complex process in that there are increased risks of opioid toxicity and precipitated withdrawal as would occur during induction. For this reason when transferring a patient between pharmacotherapy agents, private prescribers should seek specialist advice from ADS.

When transferring between pharmacotherapy agents, private prescribers should seek specialist advice from the Alcohol and Drug Service.

8.13.1 Buprenorphine to methadone

As per the Gateway model outlined in Section 4, buprenorphine is the induction agent of choice for a number of reasons (see Section 4.7), one of which is that it is safer and easier to switch from buprenorphine to methadone than the reverse. Nevertheless, a switch from buprenorphine to methadone should only occur if remaining on buprenorphine is contraindicated: that is, the side effects are intolerable (as reported by the patient and observed by the treating team) or the response to treatment is inadequate after a trial period of several weeks.

When switching, the first methadone dose can commence 24 hours after the last dose of buprenorphine, with a maximum initial dose of 25mg. If the patient is on a low dose of buprenorphine (e.g. 4mg or less) then a lower dose of methadone should be given (e.g. 20mg or less).

8.13.2 From methadone ($\leq 40\text{mg}$) to buprenorphine

Transferring from methadone to buprenorphine is more complicated than the reverse, as buprenorphine can displace the methadone from the opioid receptors, leading to precipitated withdrawal. Therefore, there is an increased risk of destabilisation during transfer.

To minimise the likelihood of precipitated withdrawal, patients on methadone are advised to reduce their dose to 40mg or less (preferably 30mg) if possible, and be stable on this lowered dose for one to two weeks before transferring to buprenorphine. The larger the methadone dose, the longer the wait to initiate the first dose of Buprenorphine.

Patients are reviewed more frequently during this period to monitor risk and plan for the reduction and cessation of methadone. One week before switching, a urine drug screen should be conducted. Since commencing buprenorphine during pregnancy is contraindicated (see Section 11), female patients must also complete a pregnancy test.

Patients must present in some degree of mild methadone withdrawal on the day they start buprenorphine, and therefore must cease methadone at least 24 hours before the buprenorphine is initiated. Patients must also be reminded not to take any opioids during this period, including those that contain codeine phosphate (e.g. Panadeine and Panadeine Forte). Patients are also advised not to use other drugs and medications, including alcohol and benzodiazepines. Some patients may have to wait up to 48 hours to be in withdrawal.

If the last dose of methadone was between 10-40mg:

- initial buprenorphine dose may be up to 4mg;
- review 2-4 hours after the first dose or early the next day; and
- an increment of 0.8-4mg may be given if some withdrawal is present but they feel better.

If the last dose of methadone was between 1-10mg:

- initial buprenorphine dose may be up to 2mg;
- review 2-4 hours after first dose or early the next day; and
- the dose may be increased by up to 4mg on day two.

Following the switch, review the patient daily for 2-6 days. The following dose increases may be given:

- if buprenorphine dose is less than 16mg, dose may be increased by 2-4mg per day; or
- if buprenorphine dose is greater than 16mg, dose may be increased by 4-8mg per day.

From methadone ($>40\text{mg}$) to buprenorphine

The preference is to reduce methadone to 40mg or less prior to switching to buprenorphine; however, some patients may suffer consider withdrawal discomfort when attempting to reduce their methadone. This type of switch is more safely conducted in an inpatient setting.

The general principle is to cease methadone dosing (or other prescribed opioids) and delay the initiation of buprenorphine treatment until the patient experiences significant, observable features of opioid withdrawal. This generally means that buprenorphine is not commenced until 48-96 hours after the last dose of methadone, and 16-32 hours after the last dose of other opioids (e.g. MS Contin, OxyContin, Kapanol or MS Mono).

The first dose of buprenorphine is generally 4mg, but in the absence of substantial opioid withdrawal signs, it may be appropriate to give 2mg as the first dose. The patient should be reviewed later the same day, approximately 3-4 hours after the first dose. If the patient is experiencing no increase in withdrawal severity, either subjectively or objectively, another 2 or 4mg of buprenorphine is administered.

If the patient is experiencing a worsening of withdrawal, no further dose is administered that day. Medication such as clonidine (100mcg every three hours) may be required for the rest of the



day for to manage withdrawal symptoms. Peak withdrawal discomfort is experienced during the first day of buprenorphine treatment.

The patient is reviewed daily and the dose titrated until stable. Patients may continue to describe mild withdrawal features for one to two weeks after transfer. It is important to inform the patient that withdrawal symptoms are a normal part of this process and to provide support and strategies to assist them through this transition.



SECTION: 9

Completing treatment

In this section you will...

- Learn how to complete treatment and exit patients from the opioid pharmacotherapy program.

9	Completing treatment	112
9.1	Planned and voluntary withdrawal from opioid pharmacotherapy	112
9.2	Withdrawal from treatment plan	112
9.2.1	Managing withdrawal symptoms	113
9.2.2	Review and monitoring	113
9.2.3	Planned methadone dose reductions	114
9.2.4	Planned buprenorphine dose reductions	114
9.2.5	Switching from methadone to buprenorphine	115
9.2.6	Involuntary discharge from the Opioid Pharmacotherapy Program	115
9.2.7	Pharmacological guidelines for immediate cessation of treatment	115
9.3	Rapid withdrawal from opioid pharmacotherapy	116
9.4	Avoiding secondary problems with alcohol, sedative or hypnotic drugs	117
9.5	Exiting patients	117
9.5.1	Notifying the dosing site/pharmacy	118

Section: 9

9 Completing treatment

9.1 Planned and voluntary withdrawal from opioid pharmacotherapy

Evidence indicates that patients are more likely to have positive long-term outcomes if their opioid treatment episode lasts at least 12 months, and additional benefits if patients remain in treatment for 2-3 years (Simpson & Sells, 1986). Therefore, patients should be encouraged to remain in the program for a minimum of 12 months (Ward, Mattick & Hall, 1998).

The decision to withdraw from the program should involve the patient, prescriber, and case manager (if relevant). The dispensing pharmacist can also be an important source of information about the patient's stability on the program.

However, patients have the right to withdraw from treatment at any time, even if they have been in treatment for less than the desired minimum of 12 months, are clinically unstable, or have psychosocial stressors. It is also important to offer early return to opioid pharmacotherapy (within the constraints of available resources) in the advent of relapse, or if the patient changes their mind about engagement in treatment. In these circumstances, it is important to discuss the risks associated with early treatment termination and to develop a mutually agreeable approach to dose reduction.

Factors that indicate that the patient may be ready to successfully cease treatment include:

- a significant period of clinical stability on the program;
- cessation of other drug or harmful drug use for at least 12 months;
- confidence in ability to abstain from unsanctioned drug use in the absence of opioid pharmacotherapy treatment;

- absence of pressure from others to cease the program; and
- stable psychosocial supports conducive to maintaining abstinence from harmful drug use.

If in reviewing these factors the clinician identifies that a successful outcome is unlikely, then they should openly discuss this with the patient, with a view to encouraging them to remain in treatment until they have addressed the identified risk factors.

9.2 Withdrawal from treatment plan

When the patient enters treatment it is essential to develop, in conjunction with the patient, a treatment plan based on the entry assessment. Similarly, prescribers and case managers should discuss in detail with patients their treatment exit plan. This plan should consider the patient's strengths and skills that they may have developed during treatment, as well as a stepped plan for dose reductions.

Established dosing arrangements should be continued if they are suitable. This means that patients may continue to have access to takeaway doses and alternate day dosing schedules, as part of the withdrawal plan. It may be necessary to return to daily dosing once dose reductions reach lower levels in order to reduce any discomfort and the likelihood of relapse to unsanctioned opioids.

When planning an exit from treatment, it is important to consider and discuss the following points with the patient.

Dose reductions:

- a flexible approach is recommended with an individualised reduction regime tailored to the patient and their circumstances;
- a slow reduction rate is preferable; and

- if relapse is likely or the patient cannot tolerate the dose reductions, dose reduction can be delayed or the dose may be temporarily increased by 2.5 – 5mg for methadone and 2-4mg for buprenorphine.

Increased support as dose decreases:

- increased frequency of review, either from prescriber or ADS case manager, is recommended to monitor progress during dose reduction;
- increased access to counselling, with a focus on skills training and relapse prevention, and other psychosocial supports is recommended;
- increased access to support during the final stages of exiting from opioid pharmacotherapy treatment, during which the patient is likely to experience opioid withdrawal symptoms, is recommended;
- psychoeducation and strategies such as cognitive restructuring can assist patients to develop realistic expectations about the withdrawal process and to develop adaptive coping skills to alleviate the discomfort associated with withdrawal;
- patients should be advised about the likely signs and symptoms of opioid withdrawal, with a plan for managing these symptoms. This might include, for example, information about sleep hygiene as sleep disturbance is a common symptom of withdrawal and should be managed without medications; and
- enlist the support of significant others.

Aftercare:

- ensure the patient has access to a GP;
- encourage ongoing access to counselling and support services, either by referral or as direct support from the treating team; and
- where possible, a structured aftercare program should be offered, either by the treating team or by referral, for at least 3-6 months after treatment completion. This might include planned follow up by the ADS case manager with a focus on relapse prevention, problem solving skills or vocational skills training.

Readmission:

- patients can also re-access treatment if they relapse and they are clinically suitable for opioid treatment; and
- rapid readmission should be available for at least one month after leaving the program.

9.2.1 Managing withdrawal symptoms

Medications (such as benzodiazepines) to manage withdrawal symptoms is not recommended. When a patient presents with evidence of significant withdrawal symptoms, this may be an indication that the rate of dose reduction has been too rapid. In this situation a careful assessment should be conducted and one or more of the following instituted:

- temporarily cease the reduction regimen; and
- temporarily increase the dose to reduce the level of discomfort.

The use of medications to manage withdrawal symptoms is not recommended during planned and voluntary withdrawal from the Opioid Pharmacotherapy Program.

9.2.2 Review and monitoring

In general, patients should be reviewed at 10-14 days post dose reduction, by which time any withdrawal symptoms from previous dose reductions should be evident. This will enable the clinician to assess whether to continue with a reduction regime, to cease dose reduction temporarily, or to increase the patient's dose.

Patients should be reviewed at 10-14 days post dose reduction.

9.2.3 Planned methadone dose reductions

Slow dose reductions are more likely to promote positive outcomes than rapid dose reductions. Patients usually tolerate dose reductions down to approximately 40mg, after which symptoms of methadone withdrawal increase.

Withdrawal symptoms peak approximately two to three days or longer after the final methadone dose, with some patients experiencing withdrawal symptoms for up to 20 days after cessation, depending on the methadone taper.

Table 9.1 provides a guide to methadone dose reductions that are generally well tolerated by patients.

Table 9.1: Recommended methadone dose reductions

Dose of methadone	Recommended reduction rate
Above 80mg per day	10mg per fortnight
40-80mg per day	5mg per fortnight
Below 40mg per day	2.5mg per fortnight

Note: Adapted from Department of Health, Western Australia Government and the Drug and Alcohol Office, (2006). *Clinical policies and procedures for the use of methadone and Buprenorphine in the treatment of opioid dependence*, (p.86).

9.2.4 Planned buprenorphine dose reductions

Slow dose reductions of buprenorphine are more effective than rapid dose reductions. Table 9.2 provides a guide to buprenorphine dose reductions for patients receiving daily or less-than-daily dosing that are generally well tolerated by patients.

Table 9.2: Recommended buprenorphine dose reductions

Dose of buprenorphine	Recommended reduction rate
Above 16mg per day	4mg per week or fortnight
8-16mg per day	2-4mg per week or fortnight
Below 8mg per day	2mg per week or fortnight

Note: Reproduced from Department of Health, Western Australia Government and the Drug and Alcohol Office, (2006). *Clinical policies and procedures for the use of methadone and Buprenorphine in the treatment of opioid dependence*, (p.86).

Most patients are uncomfortable on less-than-daily doses below 8mg. Once patients on less-than-daily dosing reduce to a dose of 8mg, it is preferable to transfer them onto a daily dosing equivalent and continue with a daily dosing reduction regimen. This also permits closer monitoring during withdrawal, with enhanced support from the case manager. Some patients may wish to remain on alternate day dosing whilst reducing, however this is not recommended as the double dose is unlikely to prevent withdrawal symptoms until the next dose is due. The offer of a transfer to daily dosing if symptoms of withdrawal become distressing should remain open at any time during the reduction program.

There is no evidence to support dose reductions in decrements less than 2mg using 0.4mg tablets, since at lower doses the duration of action of buprenorphine diminishes. However, some patients may benefit psychologically from these lower dose decrements. Only patients prescribed Subutex® will be able to access these lower dose decrements. Suboxone® patients requiring access to these lower dose decrements may be switched to Subutex®. Since the withdrawal is likely to be protracted and there is little further reduction in symptom severity, very low dose tapers should not be routinely adopted.

All patients should be asked to attend for daily reviews for five days after their last dose of buprenorphine. This allows for monitoring and appropriate treatment of delayed withdrawal, often seen after finishing a course of buprenorphine.

9.2.5 Switching from methadone to buprenorphine

Some patients report that it is easier to withdraw from buprenorphine than methadone. Patients who are experiencing difficulty in withdrawing from methadone may find it easier to reduce their methadone dose to 30mg, transfer to buprenorphine after a period of stabilisation (as per procedure in Section 8.13.2), and then withdraw from buprenorphine treatment.

There has been some discussion in the literature about the use of naltrexone to assist in relapse prevention and withdrawal from opioids. However, the research and efficacy of its use for opioid withdrawal is limited, with buprenorphine found to be superior (O'Connor et al., 1997). At the time of writing, naltrexone is only approved under the PBS as a relapse prevention pharmacotherapy for the treatment of alcohol dependence. Naltrexone is not registered with The Australian Register of Therapeutic Goods for use in accelerated opioid withdrawal (rapid opioid detoxification) or maintenance substitution therapy. For further information on naltrexone, see Appendix 10.

9.2.6 Involuntary discharge from the Opioid Pharmacotherapy Program

At the beginning of opioid maintenance treatment, patients are informed in writing of their responsibilities and enter into a treatment agreement (Section 6). It is sometimes necessary to discharge a patient from treatment for the safety or wellbeing of the patient, other patients or staff. In some instances rather than discharging the client from the program, it may be appropriate to arrange a transfer to another prescriber or program. When this cannot be achieved, clients should be offered other treatment options.

Involuntary rapid reduction is rarely undertaken, and only done so in extreme instances (see

Section 12.10). Such action must be considered on a case by case basis. Situations that may warrant this action include:

- violence or threatening behaviour against staff or other patients;
- property theft, damage, illegal activity or unacceptable disruption at the service or dosing location;
- diversion, trading and selling of takeaway doses or other substances on or near the treatment program premises or dosing location;
- repeated diversion of methadone or buprenorphine (see also Section 12);
- prescription theft or forgery;
- poor treatment compliance;
- continued intoxication arising from unsanctioned drug use that may significantly compromise the safety and efficacy of opioid pharmacotherapy (there is an overall increased risk from treatment rather than a reduction in risk); and
- continued high risk polysubstance use.

Involuntary rapid reduction is rarely undertaken, and only done so in extreme instances – such action must be considered on a case by case basis.

9.2.7 Pharmacological guidelines for immediate cessation of treatment

In some cases, it may be possible to transfer the patient to another program, service provider, or prescriber, instead of withdrawing them entirely from opioid treatment. If no options remain, methadone or buprenorphine treatment may be withdrawn without the patient's agreement. This is consistent with the 2007 National Opioid Pharmacotherapy Guidelines. Private prescribers are advised to contact an ADS Addiction Medicine Specialist prior to ceasing treatment to discuss possible treatment options or management strategies. If possible, involuntary withdrawal should take no more than 21-28 days for methadone and 14 days for buprenorphine.

Private prescribers are advised to contact an ADS Addiction Medicine Specialist prior to ceasing treatment to discuss possible treatment options or management strategies.

When a patient is being discharged involuntarily, the treating team or prescriber should:

- advise the patient that they are being discharged;
- provide, in writing, reasons for the discharge;
- remind the patient of their reduced tolerance to opioids and increased risk of overdose or death if they resume unsanctioned opioid or other drug use;
- provide relapse prevention strategies;
- inform them of alternative treatment options; and
- if appropriate, provide referrals to alternative treatment options.

If the patient's removal from treatment due to serious violence or threat of violence, immediate discharge from the program may be required to protect the safety of others. Within the ADS, clinicians must ensure that the Clinical Director is informed of such incidences and is actively involved in the decision making process relating to ongoing treatment.

In such cases, clinicians are required to execute their duty of care and notify parties involved in the patient's care (e.g. dosing site and other relevant health professionals). Potential risks about the patient's behaviour should be promptly communicated.

If the patient is being removed due to serious violence or the threat of violence, immediate discharge from the program may be required to protect the safety of others.

Readmission

A management plan regarding subsequent readmission for each patient involuntarily withdrawn from the program should be developed and documented in the patient's file. In cases of serious assault or threat against clinicians or other patients, it may be necessary to decline further treatment. Advice should

always be sought from an Addiction Medicine Specialist of the Alcohol and Drug Service in such cases, and the details of the clinical discussion documented in the patient's file.

9.3 Rapid withdrawal from opioid pharmacotherapy

Although gradual dose reduction is more effective than rapid dose reduction, the latter may be considered under certain circumstances. These circumstances include:

- when the patient wishes to withdraw from the program after only a short period of treatment;
- if the patient is going to prison where there is no access to opioid pharmacotherapy; or
- when the patient is being withdrawn on an involuntary basis due to lack of adherence to their treatment agreement.

Rapid dose reduction is preferably conducted either in an inpatient setting, or an outpatient setting in which there is significant support and opportunity for review. It is recommended that the advice of an Addiction Medicine Specialist is sought before commencing any rapid withdrawal from opioid pharmacotherapy.

The advice of an Addiction Medicine Specialist should be sought before commencing rapid withdrawal from opioid pharmacotherapy.

Tables 9.3 and 9.4 present the suggested dosing regimens for rapid withdrawal from methadone and Buprenorphine.

Table 9.3: Suggested dosing regimen for rapid withdrawal from methadone

Dose of methadone	Recommended reduction rate
Above 80mg per day	10mg per day until the dose reaches 80mg per day
80mg or less per day	5mg per day until withdrawal is completed
Withdrawal should be completed within 21-28 days.	

Table 9.4: Suggested dosing regimen for rapid withdrawal from buprenorphine

Dose of buprenorphine	Recommended reduction rate
Above 16mg per day	4mg per day
16mg or less per day	2mg per day until withdrawal completed
Withdrawal should be completed within 14 days.	

Patients undertaking a rapid withdrawal should be returned to daily supervised dosing. Takeaway doses should not be provided. Alternate dosing schedules (i.e. double and triple dosing) are also NOT appropriate when undertaking a rapid buprenorphine reduction.

Patients undertaking a rapid withdrawal should be returned to daily supervised dosing. Takeaway doses should not be provided. Buprenorphine alternate dosing schedules (i.e. double and triple dosing) are also not appropriate.

9.4 Avoiding secondary problems with alcohol, sedative or hypnotic drugs

During and after withdrawal from opioids, excessive use of alcohol and the inappropriate prescribing of sedative or hypnotic medication are common. This can often result in a long-term shift to alcohol and other drug dependence. The clinician should remain vigilant to the possibility that alcohol consumption or other drug use may increase to hazardous or harmful levels or may lead to a switching in the drug(s) of dependence and provide appropriate interventions.

The prescribing and use of psychotropic medication (in particular, sedative medications of all descriptions) is not recommended for people with a history of alcohol and drug dependence and who have recently withdrawn from opioid pharmacotherapy).

The prescribing and use of psychotropic medication is not recommended for people with a history of alcohol and drug dependence and who have recently withdrawn from opioid pharmacotherapy.

If a patient has a history of recent withdrawal or substance abuse or dependence, the advice of an Addiction Medicine Specialist should be sought prior to prescribing sedative or hypnotic medication. When seeking this advice, prescribers should outline:

- the rationale for the medication;
- identified risks associated with the medication;
- monitoring and review of clinical benefit, risk and harm of the treatment plan;
- the planned duration of treatment/s;
- arrangements for supervision; and
- any dispensing restrictions.

9.5 Exiting patients

When a patient exits an opioid treatment program, or transfers between prescribers, a Notification of Termination of Methadone/Buprenorphine form (available from the Pharmaceutical Services Branch (PSB)) must be completed. This form must be immediately forwarded to the PSB.

Patients must be exited from treatment with one prescriber before commencing treatment with another. This prevents patients being registered simultaneously on two programs and also prevents double dosing.

Patients must be exited from treatment with one prescriber before commencing treatment with another.

A notification of termination of methadone/buprenorphine form must be completed by the current prescriber.



9.5.1 Notifying the dosing site/pharmacy

The prescriber or treating service is responsible for exiting a patient from opioid pharmacotherapy. When preparing to exit a patient from the program, the pharmacy should be notified by the prescriber or case manager. If the patient has outstanding debts with the pharmacy (for dosing), the pharmacy is responsible for managing this issue and putting in place any necessary strategies to ensure payment.

The prescriber or case manager should, however, make the patient aware that failure to pay any outstanding debts with the dosing pharmacy may compromise their potential to re-enter the program in the future. Securing a position with a dosing pharmacy can be difficult if a patient has a history of outstanding debts for dosing.

The patient should be made aware that failure to pay outstanding debts with the dosing pharmacy may compromise their potential to re-enter the program in the future.

It is acknowledged that the cost of pharmacotherapy is a barrier for many patients wanting to access treatment. Public policy discussions are occurring in an effort to address this challenge.



SECTION: 10

Psychosocial interventions in opioid pharmacotherapy

In this section you will...

- Discover the range and types of psychosocial interventions to use whilst providing opioid pharmacotherapy treatment.

10	Psychosocial interventions in opioid pharmacotherapy	120
10.1	Psychosocial and social issues in substance use	120
10.1.1	Psychosocial factors influencing opioid use	120
10.2	Benefits of including psychosocial interventions	121
10.3	Types of psychosocial interventions in opioid pharmacotherapy	121
10.3.1	Behavioural therapy	122
10.3.2	Contingency management	122
10.3.3	Stages of change	123
10.3.4	Motivational interviewing	123
10.3.5	Cognitive behaviour therapy	123
10.3.6	Relapse prevention	124
10.4	Case management	124
10.5	Other psychosocial interventions	126
10.6	Applying psychosocial interventions across the pharmacotherapy treatment spectrum	126
10.6.1	Assessment	127
10.6.2	Stabilisation	127
10.6.3	Maintenance	127
10.6.4	Transition	127
10.7	Providing psychosocial interventions	128

Section: 10

10 Psychosocial interventions in opioid pharmacotherapy

10.1 Psychosocial and social issues in substance use

Providing pharmacotherapy alone does not address the holistic needs of the client. The biopsychosocial model (see Section 3.2) emphasises the biological, psychological and social factors that contribute to the development, maintenance and recovery from, alcohol and other drug issues. A range of factors impact upon a client's engagement and compliance with the pharmacotherapy program, and the success of treatment.

In early 2009, the World Health Organisation (WHO) recognised the need to address psychosocial factors when providing opioid pharmacotherapy treatment in Guidelines for the Psychosocially Assisted Pharmacological Treatment of Opioid Dependence (2009) www.who.int/hiv/pub/idiu/opioid/en/index.html. Similarly, the American Psychiatric Association's Practice Guidelines for the Treatment of Psychiatric Disorders: Compendium (2006) and the National Pharmacotherapy Policy for People Dependent on Opioids (2007) support the inclusion of psychosocial interventions as a key component of opioid pharmacotherapy treatment programs. Accordingly the Tasmanian ADS will ensure that pharmacotherapy and psychosocial intervention programs are well integrated, and that private practitioners are aware of agencies or health professionals that are able to provide psychosocial interventions.

The Tasmanian Alcohol and Drug Service will ensure that pharmacotherapy and psychosocial intervention programs are well integrated into service delivery.

The Tasmanian Alcohol and Drug Service will ensure that private prescribers are aware of agencies and health professionals able to provide psychosocial interventions.

10.1.1 Psychosocial factors influencing opioid use

A range of psychosocial factors can influence the development, maintenance and recovery from alcohol and other drug dependence. Understanding these factors can help identify which psychosocial interventions will be suitable for clients receiving opioid pharmacotherapy.

Psychological considerations

Depression, anxiety, post-traumatic stress disorder (PTSD) and personality disorders are prevalent comorbidities amongst individuals with opioid dependence (WHO, 2009; Teesson & Proudfoot, 2003). A recent Australian study by Ross and colleagues (2005) found a high prevalence of depression, anxiety, PTSD, and personality disorder amongst this treatment cohort. If untreated, the impact of these disorders can negatively influence treatment engagement and treatment outcomes (McLellan et al., 1989).

Many clients accessing the program use opioids and other substances to cope with stress, anxiety, depression, trauma, or other psychological issues. Assisting clients in addressing these issues is likely to improve their coping abilities and positively influence treatment outcomes.

Finally, a majority of people currently registered on the pharmacotherapy program (both publicly and privately) in Tasmania have developed opioid dependence as a consequence of having

access to prescribed or illicit opioids. Individuals with this type of dependence often do not usually identify their use of medications as harmful and can be resistant to registration and treatment on the pharmacotherapy program. Psychological interventions can benefit such clients by addressing in detail the individual's understanding of their current situation, developing insight into the nature of their addiction, and working with resistance to change.

Social considerations

Tasmania is faced with a range of social issues, including comparatively lower socioeconomic indicators, lower levels of employment and education, and poorer health outcomes in comparison to other Australian states and territories (with the exception of the Northern Territory). These factors impact on the individual's ability to access resources required for achieving lifestyle change. Since lifestyle change is central to recovery from addiction, pharmacotherapy treatment programs should include interventions that improve client skills in order to support lifestyle change.

Combined psychosocial considerations

Often the psychological and social factors influencing drug use and dependence are co-occurring and perpetuate one another. For example, social disadvantage and disrupted early family relationships can create poor adjustment and negatively influence psychological development. This can affect a person's ability to maintain stable and positive relationships in the future, which can in turn place them at risk of substance use. Therefore, providing access to a range of psychosocial interventions is important for improving outcomes in opioid pharmacotherapy treatment.

10.2 Benefits of including psychosocial interventions

Key research findings in the alcohol and other drugs literature indicate that:

- psychosocial interventions such as cognitive behavioural approaches can contribute to the effectiveness of opioid agonist treatment

(WHO, 2009; Drummond & Perryman, 2007);

- inclusion of cognitive behavioural therapy and contingency management enhances the effectiveness of opioid pharmacotherapy (Drummond & Perryman, 2007);
- pharmacotherapy is more effective when used in conjunction with counselling (Marsh & Dale, 2006 & McLellan, 1993);
- counselling combined with pharmacotherapy reduces the rates of relapse (Marsh & Dale, 2006);
- relapse prevention interventions can lead to long lasting reductions in injecting-related risk-taking behaviours (O'Neill et al., 1996);
- provision of psychosocial interventions in opioid treatment settings recognises the complex nature of opioid dependence (WHO, 2009);
- treatment programs that do not address underlying psychosocial issues and facilitate lifestyle change have poorer client outcomes and decreased client satisfaction with treatment (Marsh & Dale, 2006); and
- psychosocial interventions are an effective component of treatment plans for individuals receiving opioid pharmacotherapy treatment (National Quality Measures Clearing House, 2009).

10.3 Types of psychosocial interventions in opioid pharmacotherapy

Many of the psychosocial interventions discussed in this section apply to a broad range of substance abuse and misuse problems. For example, psychoeducation, motivational interviewing, cognitive behavioural therapy, drug refusal strategies, and relapse prevention are all appropriate for clients with alcohol abuse problems as well as opioid pharmacotherapy clients. Therefore, flexibility in approaches and the provision of interventions suitable to the client's needs (and within the scope of the clinician's skills) are essential.

However, in any intervention, developing a good rapport and therapeutic alliance is highly



important in influencing positive treatment outcomes. As discussed in Section 6, establishing this rapport should commence from the beginning of the client's engagement into treatment, and be monitored throughout.

In general, psychosocial approaches in pharmacotherapy treatment aim to address factors that maintain addictive behaviour, enhance engagement (compliance) with pharmacotherapy, or treat comorbid mental health issues that contribute to addiction or relapse. The key aspects of most interventions include:

- increasing motivation to change and to abstain or reduce substance use;
- teaching coping skills and enhancing interpersonal functioning;
- developing skills in the area of affect regulation and tolerance;
- identifying and modifying reinforcers of drug use and other maladaptive behaviours; and
- developing social supports and relationships.

(American Psychiatric Association, 2006).

Psychosocial interventions aim to address factors that maintain patients' addictive behaviour, enhance their engagement with pharmacotherapy, and treat comorbid mental health issues that contribute to addiction or relapse.

10.3.1 Behavioural therapy

The aim of behavioural approaches is to modify behaviours developed as a result of conditioned learning (ie. classical and operant conditioning). This approach includes interventions that aim to replace or extinguish conditioned patterns of behaviours (Drummond & Perryman, 2007).

There is a range of behavioural interventions for alcohol and drug dependence which includes education, counselling, relapse prevention, stress management and cognitive behavioural therapy (Ritter, 2007). These interventions are focused on assisting clients to change addictive behaviour

patterns and maintain these patterns over time. Such changes may allow clients to deal differently with emotional issues, adopt new social and coping skills, or deal assertively with conflict. Fundamental to these changes is the ability to avoid relapse and manage cravings in order to decrease their harmful level of drug use. Of all the behavioural approaches, contingency management is known to enhance the effectiveness of opioid pharmacotherapy treatment (Drumond & Perryman, 2007).

10.3.2 Contingency management

Contingency management (CM) is based on the assumption that behaviour is a function of its consequences. This means that how people behave is shaped by the consequences of their behaviour (Higgins & Petry 1990).

Contingency management adopts a structured approach aimed at increasing desired behaviours. The emphasis is on positive behaviours, as punishment is not considered ethically appropriate (WHO, 2009).

Contingency management requires:

- clear definitions of the required behaviour;
 - regular monitoring;
 - identified rewards for behaviour; and
 - positive personal feedback.
- (WHO, 2009).

Contingency management is effective in opioid pharmacotherapy because it reinforces active engagement and participation in treatment. For example, regular attendance at appointments and clean urine drug screens may be reinforced by the provision of takeaway doses (Chutuape et al., 1999; Iguchi et al., 1996; Schmitz et al., 1998; Stitzer et al., 1992).

Contingency management can be applied without comprehensive and formal training (WHO, 2009). This approach is infrequently used despite literature that demonstrates its effectiveness in the treatment of opioid dependent clients (Mills et al., 2010).

10.3.3 Stages of change

The transtheoretical model of behaviour change (Prochaska & DiClemente, 1986) more commonly referred to as the stages of change model is well established in the literature as a motivational and behavioural change theory. This model assumes that clients do not always access treatment already committed to change, and vary in their readiness to control or cease their substance abuse (Prochaska and DiClemente 1986). The stages changes outlined in the Prochaska and DiClemente (1986) model are:

1. precontemplation – the client is not concerned about their substance abuse and/or may not want treatment;
2. contemplation – the client has some concerns and is considering the need for change;
3. preparation – the client has decided to take some action and is moving toward change;
4. action – the client is in the process of changing their usage patterns;
5. maintenance – the client is working toward maintaining previous changes; and
6. relapse – the person has used again and/or discontinued treatment.

A more recent iteration of this model is the 'spiral of change'. This model better demonstrates the effect of learning over time from previous change attempts and includes a final stage of termination (Prochaska, et.al., 1992). This model suggests a spiralling recovering from addiction (rather than it being a linear process) and eventually Exit/Termination from the spiral (Prochaska, et. al. 1992).

Stages of change is a way to understand an individual's motivation to change, and can help conceptualise behavioural change associated with substance use. This model can assist clinicians in selecting treatment interventions and understanding the client's readiness and capacity for behaviour change. The evidence base for this model for treatment matching is yet to be established (Whitelaw et. al. 2000).

In applying this model, clients accessing opioid pharmacotherapy would ideally be

in 'preparation' or 'action' phases. However, regardless of stage of change advice and encouragement should be provided to all clients regardless of their stage of readiness. Providing pharmacotherapy for a client who is identified as contemplative or precontemplative may have implications for the effectiveness of the treatment, due to their ambivalence about engaging in treatment and/or changing their drug use behaviour.

10.3.4 Motivational interviewing

This therapeutic approach is designed to assist clients to improve their motivation and reach a decision to change (Miller, 1983). It draws upon the principles and practices of directive client-centred counselling, cognitive therapy, systems theory and social psychology. Motivational interviewing relies on the use of core communication skills and though client-centred, requires the clinician to maintain a strong focus on purpose and direction (Addy & Ritter, 2000). This approach aims to elicit the client's personal motivation and determination as a basis and strategy for change (Hamilton, King and Ritter 2007). A more comprehensive discussion of motivational interviewing and its application can be found in Miller & Rollnick (2002).

10.3.5 Cognitive behaviour therapy

The most commonly applied psychological intervention is cognitive behaviour therapy, which is delivered in various forms (Drummond & Perryman, 2007). It is based on the principle that addiction is a learned behaviour, and consequently, can be altered. Modification occurs by applying a combination of cognitive approaches to address faulty cognitions, promote positive thinking, and enhance motivation to modify behaviour (Beck at al., 1993).

CBT is known to be one of the most efficacious and evidence based approaches for the treatment of alcohol and other drug use issues. A more detailed discussion of this intervention is beyond the scope of this document and more comprehensive discussion can be found in Beck (1995) and Beck and colleagues (1993).

10.3.6 Relapse prevention

Relapse prevention is a key component of any drug and alcohol intervention, including opioid pharmacotherapy. It is suggested in the literature that 60% – 90% of clients will experience either a lapse to unsanctioned opioid use, or relapse to previous levels of harmful drug use within the first twelve months after treatment (Allsop 1997).

It is important to recognise the distinctions between a lapse and relapse:

- A lapse is often referred to as a 'slip' whereby a person uses drugs and/or alcohol on a number of occasions. At this point the decision between continuing to use substances or learning from the lapse and make a decision to abstain from further use need to be made (Addy and Ritter 2000).
- Relapse occurs when a person resumes using drugs and/or alcohol and they no longer make any attempt to abstain (Addy and Ritter 2000).

There are a number of factors associated with increased likelihood of relapse:

- clients' support systems are not conducive to abstinence;
- clients do not have the belief that they can achieve their goals;
- lack of attention to underlying psychological issues associated with complex social and psychological difficulties;
- clients with cognitive impairment;
- the quality of the client's post-change lifestyle; and
- younger persons; particularly those with poor psychological and social supports. (Marsh & Dale 2006).

Relapse prevention encourages clients to identify triggers to their drug use and reduces the risk of relapse by increasing their capacity to manage their responses to these triggers. Stress, extreme negative or positive emotions, conflict, social and environmental cues and pressures, and the use of other substances are common triggers for relapse into unsanctioned opioid use.

Relapse prevention can be improved by assisting clients to:

- identify relapse warning signs;
- maintain healthy lifestyle changes that decrease their need to use substances;
- develop coping strategies for managing urges and cravings;
- challenge unhelpful thinking styles that perpetuate desire to use drugs;
- utilise positive social and emotional supports;
- adopt strategies for managing lapses; and
- minimise adverse consequences of relapse if it does occur.

Relapse prevention can be delivered at any stage of treatment (Addy and Ritter 2000).

In opioid pharmacotherapy, relapse prevention is particularly important during induction and stabilisation to prevent a return to unsanctioned drug use. A comprehensive review of relapse prevention can be found in Marlatt & Donovan (2005).

Relapse prevention is a key component of any drug and alcohol intervention, including opioid pharmacotherapy.

Relapse prevention encourages clients to identify triggers to their drug use and reduces the risk of relapse by increasing their capacity.

10.4 Case management

There are many case management models including brokerage/generalist, strengths based, assertive community treatment, intensive case management, and clinical case management (Jenner, Devaney and Lee, 2009). A comprehensive discussion of these models is beyond the scope of this document, however a more detailed discussion can be found in Case Management in Alcohol and Other Drug Treatment Settings (Jenner, Devaney and Lee, 2009). Reference can also be made to the Case Management Society of Australia (www.cmsa.org.au).

The case management framework adopted by ADS is based upon the clinical case management model which combines brokerage and treatment (Jenner et. al. 2009). Clinical case management extends the brokerage model (often described as care coordination) to include the provision of services. This recognises that clinical case managers provide specialist interventions and facilitate access to resources.

Case management is a collaborative process between the case manager and the client. It is a direct client service (Case Management Society of Australia 2009). The effectiveness of case management is determined by the nature of the relationship between the client and the case manager. A supportive and respectful relationship promotes the client's feelings of competence and optimism about their capacity for change (Case Management Society of Australia 2009).

The focus of case management is to help clients to identify goals, actively participate in their treatment, and overcome gaps and obstacles within the service system (Addy et., al., 2000). Through this process, the client is supported and empowered to make changes and achieve their goals. The aims of case management are to:

- identify the client's needs and goals;
- facilitate the client's access to services;
- provide clinical interventions for clients;
- empower and advocate on behalf of clients;
- develop client's abilities to negotiate services relevant to their needs; and
- monitor activities and outcomes.

(Addy et al., 2000).

The responsibility of the case manager is to develop a negotiated goal plan, deliver services in accordance with the client's goals, facilitate access to services, and monitor case management activities and progression towards goals. Case management is different from a counselling relationship in that the case manager does not provide intensive, long term psychotherapeutic interventions. Rather, the case manager provides brief interventions and links the client into appropriate counselling

and treatment as required (Addy et., al., 2000). Case managers are well placed to assist clients to access a broad range of psychosocial services.

In the ADS Pharmacotherapy Services Delivery Model, case management occurs in the latter two phases; the maintenance and transition phases (Figure 10.1). Allocation of a case manager occurs once a client is stabilised, and in the maintenance phase. The core responsibilities for the delivery of case management in ADS opioid pharmacotherapy include:

- ensuring that regulatory requirements are met;
- monitoring and managing clinical risk and community safety;
- providing brief and opportunistic interventions (e.g. relapse prevention, motivational interviewing);
- care coordination involving the facilitation of referrals and active support of access to other services; and
- consumer advocacy.

The intensity of case management will change over time depending upon the client's needs and risk status. More intensive case management would usually be provided during the induction and stabilisation phase, and the early stages of maintenance in opioid pharmacotherapy. As the client progresses and clinical risks resolve, the key functions of case management may focus more on monitoring and care coordination, rather than direct clinical interventions. For example, clients with high risk complex needs will require more intensive case management and monitoring than those that are lower risk.

It is anticipated that the increased level of care provided through case management will not only assist in assertively managing risk, but also enhance recovery, rehabilitation, and overall positive outcomes.

10.5 Other psychosocial interventions

Psychosocial interventions can include assistance with accommodation, food, social networks, employment and community connectedness (WHO, 2009). Other more specific interventions include:

- relationship therapy;
- family systems therapy;
- problem solving;
- social skills training;
- insight oriented psychotherapy;
- twelve step programs; and
- social behavioural network therapy.

Research evidence also supports the use of some family therapies as specific interventions for people who are opioid dependent (National Quality Measures Clearinghouse, 2009).

There is a broad range of approaches classified as counselling, psychotherapy and case management. However, these require more definitive evaluation to determine their effectiveness for opioid pharmacotherapy clients

(Drummond & Perryman, 2007). In the context of this document, psychotherapy includes a range of psychological therapies but does not include psychodynamic therapy, which has limited support within opioid pharmacotherapy treatment.

10.6 Applying psychosocial interventions across the pharmacotherapy treatment spectrum

There are four identifiable phases in the delivery of opioid pharmacotherapy: assessment, stabilisation, maintenance and transition. These phases are presented in Figure 10.1.

Ideally clients progress through these phases in sequential order. However as a result of lapses or relapses, patients may return to the stabilisation or assessment phases prior to achieving maintenance. For example, a client may reach maintenance, then relapse, and require re-stabilisation.

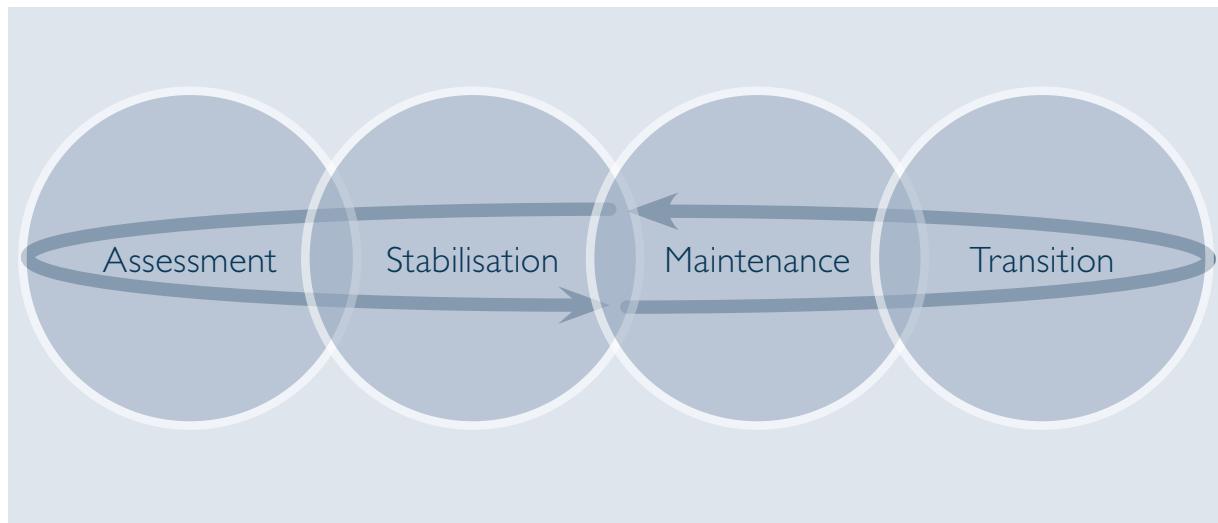


Figure 10.1: Tasmanian alcohol & drug service pharmacotherapy services delivery model: phases of opioid pharmacotherapy

Ideally clients progress through these phases in sequential order. However as a result of lapses or relapses, patients may return to the stabilisation or assessment phases prior to achieving maintenance.

The following section summarises each phase and suggests the types of psychosocial interventions that may be suitable.

10.6.1 Assessment

In this phase, mental health stability, comorbidities and other social issues are crucial to the identification of risk and protective factors. Referrals to other specialist and social services may be necessary to enhance social and psychological stability prior to initiation onto the pharmacotherapy program.

A thorough assessment allows the clinician to identify appropriate psychosocial interventions that may positively support pharmacotherapy treatment outcomes throughout treatment. Section 5 contains more information on assessment of risk and protective factors, which include psychosocial factors.

10.6.2 Stabilisation

During this phase, encouraging the client to make connections between their psychosocial health status and drug use is important. Brief and opportunistic strategies can include:

- psycho-education;
- crisis management;
- implementing safety and harm minimisation strategies;
- motivation enhancement (motivational interviewing);
- relapse prevention;
- strategies to reduce illicit substance use; and
- strategies for improving sleep and sleep hygiene.

10.6.3 Maintenance

Once maintenance is established, the patient is encouraged to engage in in-depth discussions with their case manager about how psychosocial factors are affecting their drug use patterns. At this time it is useful to review the treatment plan and assist the client to identify strategies that may help them to achieve their treatment goals. In reviewing and up-dating the treatment plan consideration should be given to the client's risk and protective factors. These factors may have an impact on the client's capacity

to maintain changes, engage in treatment, reduce or abstain from drug use and ensure program compliance.

Some psychosocial intervention strategies appropriate in this phase include:

- psychotherapy;
- in depth relapse prevention;
- problem solving;
- goal setting;
- communication skills;
- stress management;
- anger management;
- assertiveness training;
- strategies for improving sleep;
- pain management;
- maintaining motivation for change;
- cognitive restructuring of unhelpful thinking styles;
- craving management;
- emotional regulation;
- creating appropriate emotional and behavioural boundaries;
- managing antecedents or triggers of drug use;
- encouraging positive replacement behaviours;
- assisting the client develop interests and hobbies;
- addressing gaps in vocational functioning;
- re-establishing supportive relations;
- parenting interventions;
- crisis management plans;
- addressing issues of grief, loss, and adjustment; and
- addressing housing, accommodation, and legal issues.

10.6.4 Transition

The transition phase refers to a period in time where the client's circumstances are changing. This period may require more intensive psychosocial intervention to reduce the risk of relapse once pharmacotherapy treatment is completed, or while being transferred to another provider. The focus of interventions



at this time should be on sustaining lifestyle changes, maintaining motivation, and relapse prevention. Assertive follow-up is also essential during any transition to ensure easy access to treatment services, and to assist in separation after lengthy periods of engagement.

10.7 Providing psychosocial interventions

Clinicians can deliver many of the psychosocial interventions described in this section as part of case management. When the interventions required are more intensive and need to be provided for a longer period a referral should be made to a psychosocial program.

In Tasmania, the alcohol and drug sector is comprised of both public and community sector organisations. A range of programs and services are offered by the community sector, with the majority of these organisations providing specialist psychosocial interventions. Within the Alcohol and Drug Services, the Psychosocial Program is responsible for the delivery of these interventions.

It is recognised that private practitioners may be limited in their capacity to deliver psychosocial interventions. In this instance the TOPP recommends that the prescriber regularly reviews and monitors the client's circumstances and facilitates access to these interventions/services as required.

More complex issues may require specialist interventions beyond the scope of the alcohol and drug sector (e.g. acute mental health conditions, sexual abuse, insight oriented psychotherapy). In such circumstances appropriate referrals should be made to specialist services such as mental health, private psychologists and psychiatrists, and other highly specialised community sector organisations (such as Tasmanian Sexual Assault Services). Sections 11 and 12 contain more specific information about interventions and management strategies for specific population groups and clients with complex presentations.



SECTION: II

Specific population groups

In this section you will...

- Gain an understanding of how to deal with and manage clients from specific population groups.

II	Specific populations receiving opioid pharmacotherapy	130
II.1	Comorbid mental health disorders	130
II.1.1	Depression	130
II.1.2	Anxiety	130
II.1.3	Psychotic disorders	131
II.1.4	Mental health inpatient admission	132
II.1.5	Self-harm	132
II.1.6	Trauma	132
II.2	Cognitive impairment	133
II.3	Working with families and significant others	133
II.4	Female clients	134
II.5	Pregnancy	134
II.5.1	Opioid withdrawal in pregnancy	135
II.5.2	Opioid treatment during pregnancy	135
II.5.3	Methadone treatment during pregnancy	136
II.5.4	Management of methadone dose after birth of the baby	137
II.5.5	Use of buprenorphine in pregnancy	137
II.5.6	Use of other substances during pregnancy	139
II.6	Management of neonatal care	139
II.6.1	Neonatal abstinence syndrome and its management	139
II.6.2	Breastfeeding while on methadone	140
II.6.3	Breastfeeding while on buprenorphine	140
II.7	Blood-borne viruses	141
II.7.1	HIV/AIDS	141
II.7.2	Hepatitis B	141
II.7.3	Hepatitis C	141
II.7.4	General advice	142
II.8	Culturally sensitive practice	142
II.8.1	Supporting Aboriginal communities	142
II.8.2	Culturally and linguistically diverse groups	143
II.9	Young people	144
II.9.1	Young people and opioid pharmacotherapy	144
II.10	Recently released prisoners	145
II.11	Older persons	146

Section: II

II Specific populations receiving opioid pharmacotherapy

As stated throughout this document, a significant proportion of clients who present for opioid pharmacotherapy treatment will often have multiple and complex presentations. Sections 4 and 5 discuss many of these complexities in the context of treatment contraindications and precautions, and assessing for risk and protective factors. However, the following section (and Section 12) provides more detailed recommendations regarding specific population groups and strategies to manage concurrent and complex clinical and social issues. It is important for prescribers and case managers involved in the delivery of opioid pharmacotherapy to be aware of other services that may be involved in their client's care and to ensure services are delivered in a collaborative manner (see Section 3.12).

II.1 Comorbid mental health disorders

Opioid dependent clients often present with comorbid mental health disorders, including mood disorders (e.g. depression or bipolar disorder), anxiety disorders (e.g. generalised anxiety disorder or post traumatic stress disorder) and other serious mental illnesses (e.g. psychotic disorders). It is often difficult to distinguish whether the comorbid mental health concerns commenced prior to, or as a result of, harmful drug use. Regardless of the direction of the causal link, clinicians should:

- aim to gain insight into and assess the client's presenting psychological issues;
- liaise with and seek advice from appropriately trained clinicians who have experience in working in mental health; and
- liaise with or refer to Mental Health Services when working with clients with chronic and enduring or severe psychiatric comorbidities.

It may be difficult to determine a client's mental state when they first enter the opioid pharmacotherapy program. After several weeks on the program it may be easier to determine their mental state and assess for the presence of thought disorder and perceptual or mood disturbances in the absence of chaotic drug use. Therefore, it is important to monitor the client's mental state, especially during the early phases of treatment and induction.

II.1.1 Depression

Recommendations for the treatment of moderate to severe depression usually include cognitive behavioural therapy in combination with antidepressant medication. Indeed, depression has been linked to poor psychosocial outcomes and increased rates of relapse to unsanctioned opioid use in opioid dependent clients (Havard, 2006). However, combining antidepressants with opioid pharmacotherapy can pose risks to safety and the effectiveness of treatment, as drugs such as fluvoxamine and tricyclic antidepressants can interact with opioids (see appendices for drug interactions). This needs to be taken into consideration when developing a treatment plan for such clients.

Some antidepressant medications can influence the safety and effectiveness of opioid pharmacotherapy.

II.1.2 Anxiety

While some clients report only experiencing anxiety symptoms soon after using substances, there is evidence that substance use can also result in the development of longer term anxiety symptoms. Among opioid pharmacotherapy clients, it is common for clients with anxiety issues to have an anxiety disorder such as Post Traumatic Stress Disorder (PTSD), Panic Disorder and Generalised Anxiety Disorder (GAD) (Marsh & Dale, 2006).

The 2007 National Survey of Mental Health and Wellbeing (ABS, 2008) reported markedly higher rates of recent experience of both affective and anxiety disorders amongst people who regularly use drugs, in comparison with the general Australian population. The prevalence of affective disorders in the general population was estimated to be 6%, whereas amongst participants reporting regular drug use, this rate was 31%. Similarly, the estimated rate of anxiety disorders amongst the general population was 14%, and 38% amongst people regularly using drugs (ABS, 2008).

The coexistence of these types of disorders with substance disorders is important to consider as they can maintain and reinforce one another, particularly if left untreated.

Cognitive behavioural strategies such as goal setting and problem solving are recommended in the literature for treatment of anxiety disorders. Clients with anxiety are more likely to be prescribed benzodiazepines for the management of their anxiety symptoms. However, this is not considered appropriate as benzodiazepines have high dependence potential and can result in overdose when combined with other central nervous system depressants (Marsh & Dale, 2006). For these reasons benzodiazepines are not recommended for people who are drug dependent or have a history of dependence.

Treatment with benzodiazepines may place the opioid pharmacotherapy client at greater risk of overdose, falls, accidents and cognitive impairment. Access to an allied health professional who is able to provide psychological intervention and can assist the client to develop anxiety management skills and promote resilience is recommended.

Treatment of anxiety disorders with benzodiazepines for people who are drug dependent or have a history of dependence is not recommended by the Tasmanian Opioid Pharmacotherapy Program, Policy and Clinical Practice Standards.

II.I.3 Psychotic disorders

For clients with chronic and enduring serious mental illnesses, a shared care arrangement involving mental health services is recommended (see Section 3 for a discussion on shared care). If a client is receiving treatment for a psychotic illness, it is important to be aware of treatment compliance or non-attendance with their mental health service provider. If there are concerns about non-compliance, the opioid pharmacotherapy clinician should:

- actively liaise with the client's mental health key worker;
- encourage the client to adhere to their mental health treatment plan;
- increase the frequency of medical and case management reviews; and
- review access to takeaway doses.

If clients are actively psychotic at any phase of the program it will affect their ability to consent to treatment and to adhere to the treatment plan. In such cases, the preference is to manage the psychotic illness first and then reassess for suitability on the opioid pharmacotherapy program once mental state is stable and managed by mental health professionals.

If a client with a well managed psychotic disorder experiences a deterioration of mental state resulting in an acute psychotic episode, the opioid pharmacotherapy clinician should:

- review takeaway dose arrangements;
- switch to daily dosing;
- increase frequency of review;
- case manager and/or prescriber should actively liaise with the treating psychiatrist
- engage in assertive follow up; and
- continue monitoring risks.

Finally, when clients are coming off the opioid pharmacotherapy program, there is an increased risk of exacerbation of positive symptoms as their pharmacotherapy dose decreases. To manage this risk, antipsychotic medication, and frequency of review by their mental health practitioner, may need to be increased. Hence, it is essential to inform the client's mental health practitioner about plans for opioid pharmacotherapy treatment cessation.

11.1.4 Mental health inpatient admission

If a client is admitted to an inpatient psychiatric unit for an acute episode, the opioid pharmacotherapy provider should liaise with the treating doctor to ensure that:

- the client continues to receive their opioid maintenance treatment;
- the treating doctor is aware of the risks and restrictions associated with the prescription of benzodiazepines for clients receiving opioid maintenance therapy;
- there is a reduction regimen in place either prior to or on discharge if a client is receiving short term benzodiazepine treatment; and,
- the opioid pharmacotherapy provider has access to discharge information including current mental health status, risks identified, medications prescribed and mental health follow-up arrangements.

11.1.5 Self-harm

The risk of suicide or accidental death in the AOD population is higher than the general population (Haw & Hawton, 2011). Clients with extreme and rapidly changing mood cycles may be at a higher risk of impulsive self-harm. Therefore, assessing for suicidal thoughts, ideation, and risk of self-harm is a routine part of maintaining client safety on the opioid pharmacotherapy program. During the regular review of a client, if risk indicators are present, a referral should be made to an appropriately qualified mental health clinician for more thorough assessment and ongoing management.

Furthermore, if a client has a history of self-harm, particularly involving overdoses, this must be taken into consideration when assessing suitability for takeaway doses. More frequent reviews are required during a period of increased risk of self-harm.

If risk indicators are present, a referral for a psychiatric assessment should be made to an appropriately qualified mental health clinician.

Clients who are actively suicidal should not be provided with takeaway doses.

11.1.6 Trauma

Many clients receiving opioid pharmacotherapy are likely to have been exposed to trauma, abuse, or even repeated traumas (Enoch, 2011). According to Simpson and Miller (2002), female AOD clients have a higher rate of childhood sexual abuse than male clients (31-74% compared to 16%). However, there is evidence to suggest that feelings of shame are particularly intense for males who have been sexually abused.

While trauma exposure does not always result in clients developing symptoms of PTSD, those who do develop symptoms have a high likelihood of abusing substances. Marsh and colleagues (2007) estimate that 25% of all AOD clients have symptoms of PTSD.

During the assessment interview:

- do not question the client about their experience of trauma unless they voluntarily share this information;
- be mindful of the feelings of shame, guilt, self-blame and powerlessness associated with trauma and abuse;
- be prepared to contain such feelings in a respectful and sensitive manner; and
- avoid asking questions that encourage the client to revisit their traumatic experience.

For some clients, substance use is a way of coping with their traumatic memories and experiences. Following stabilisation, clients may recall past traumatic events and memories more vividly, experience grief and loss in relation to their life trajectory, and develop an increased awareness of how their abuse history has affected their life. This can become overwhelming and exacerbate symptoms of anxiety and PTSD. It may also increase the risk of self-harm, specifically related to the inability to regulate and tolerate extreme or negative emotions.

Pharmacotherapy clinicians are encouraged to monitor the client's experience of trauma and its impact on their mental health and wellbeing. Clinicians are advised not to question or pursue this issue if the client does not wish to discuss it, as this may re-expose the client to the trauma

or result in destabilisation. When a client does disclose a history of trauma, it is important to normalise and validate their experience. Not all clients require trauma counselling; however, referral to specialist trauma counselling service is appropriate if requested by the client.

11.2 Cognitive impairment

Acute and prolonged use of substances, particularly opioids, alcohol, cannabis, benzodiazepines and methamphetamine, can be associated with mild to severe cognitive impairment (Ornstein et al., 2000; Fernandez-Serrano, et al., 2011). Repeated alcohol withdrawal can also increase the risk of brain injury. Open and closed head injuries as a result of motor vehicle accidents, assaults and falls are also more likely amongst individuals with substance use issues (De Boni, et al., 2011; Gjerde, H, 2011; Cash & Philactides, 2006).

Cognitive impairment may be indicated by deficits in memory functioning (e.g. visual and verbal), information processing (e.g. slow to understand and process information) and executive functioning (e.g. problems with decision making or problem solving) (Chrisman & Zimmer, 2005). New learning ability, concentration difficulties and poor organisational and planning skills are also indicative of impairment.

Cognitive impairment is strongly linked to poor treatment retention and outcomes, and increased risk of relapse (Prosser et al., 2006 & Vocci, 2008). For example, clients with cognitive impairment may forget appointments and have difficulty understanding and remembering conversations, directions and instructions. They may also have difficulty learning new skills or making changes to their routine.

When cognitive impairment is suspected, clinicians should consider the following:

- use the Alcohol Related Brain Injury checklist with clients presenting with alcohol related issues;
- refer the client for further assessment by a qualified clinician, such as a psychologist, neuropsychologist or neurologist;

- refer the client for further medical investigations including brain imaging;
- consider the effects of the cognitive impairments on the treatment planning, for example, restricting access to takeaway doses; and
- use simple and straight forward behavioural interventions rather than complex cognitive interventions, such as lists, reminder services and clear and concise written information.

11.3 Working with families and significant others

Treatment outcomes can be improved by working with the client's family (with the client's consent) and significant others. According to the literature, approaches that build on the client's social support system have a much better chance of success (Rowland et al., (2000)). When working with families, the following areas should be considered:

- providing information about the program;
- providing psycho education about substance use;
- providing strategies that family members can use to help the client during stabilisation, e.g. craving management and relapse prevention;
- supporting the client's attendance and treatment compliance ;
- maintaining appropriate boundaries and supports;
- family safety (e.g. security and storage takeaway doses); and
- crisis management (e.g. what to do in the event of an overdose).

If the client has a partner who is also opioid dependent, the recommendation is to have both the client and the partner engaged in treatment. This reduces exposure to ongoing drug use, reduces the risk of relapse, and promotes program compliance and treatment adherence.

11.4 Female clients

Recent research and consultations with clients and practitioners in AOD services has highlighted the need for consideration of female specific issues in mixed gender services (Marsh et al. 2007). Women's experience of substance use is psychologically, socially and physiologically unique compared to men (Bernard 1981; Cowen et al., 2003; Hser et al., 2005; Thomas 1997). The following are some of the critical issues to consider when engaging female clients (not limited to opioid treatment):

- Women tend to suffer from the physical effects of drug use sooner than men (e.g. liver cirrhosis, reproductive and sexual dysfunctions), despite evidence that men tend to use substances at more harmful levels (Thomas 1997);
- Women tend to suffer greater levels of shame and stigmatisation compared to men, partly due to societal norms in which women are not expected to have issues with drugs (Copeland et al., 1993; Cowen et al., 2003; Jarvis et al., 1998; Swift & Copeland 1998);
- The experience of shame and powerlessness is often amplified for women who display PTSD symptoms. This is a special consideration for women given the higher rates of experience of childhood sexual abuse and assault compared to men (Grupp 2006; Jarvis et al., 1998; Neale 2004);
- Early victimisation is associated with a greater risk of adult substance dependence among females than among males (Warren et al., 2002);
- Women are more likely to benefit from self-help groups and to benefit from additional support services in the community than men (Grella et al., 2006);
- Female clients are more likely to have children in their care than male clients; and
- In comparison to the general population, women presenting to AOD services survive significantly higher levels of violence at home (Miller et al., 1989).

The implications of these factors for opioid pharmacotherapy include that:

- women should be offered the option of a female worker (Grupp 2006);
- if possible, female clients with a known history of sexual assault and abuse should be offered a female clinician or support person where this option is not available. The client's preferences should be noted in the clinical record;
- the dose titration for female clients needs to be closely monitored during the induction phase to ensure that the dose is not increased too rapidly and that the client is not over sedated; and
- female clients may require referral to health and community support services, particularly when they have children in their care.

11.5 Pregnancy

There is an increased risk of the occurrence of complications during pregnancy among women who use opioids. Some of the primary risks include, but are not confined to the following:

- miscarriage;
- pre-eclampsia;
- intrauterine hypoxia or anoxia;
- intrauterine infection;
- intrauterine growth retardation;
- premature labour; and
- antepartum and postpartum haemorrhage.

A number of factors are associated with these complications, including poor antenatal care, tobacco use and inadequate maternal nutrition. Babies born to opioid dependent mothers are at risk of developing neonatal abstinence syndrome (NAS) (Ebner et al., 2007).

The National Clinical Guidelines for the Management of Drug Use During Pregnancy, Birth and Early Development Years of the Newborn (NSW Health, 2006) should be consulted for more detailed information beyond the scope of this document.

11.5.1 Opioid withdrawal in pregnancy

Complications can result in:

- miscarriage during the first trimester;
- premature labour during the third trimester;
- foetal hypoxia and distress; and
- high risk of return to dependent illicit opioid use and/or other substance use, and associated harms.

As a consequence, the provision of specialist care by an obstetrics team in combination with drug and alcohol specialists is required to manage opioid withdrawal in pregnancy. In these circumstances it may be necessary for the ADS to assume the ongoing care of these clients in order to address their complex needs.

Acute opioid withdrawal during pregnancy is associated with significant risk to mother and child; in these situations an ADS Addiction Medicine Specialist should be contacted to provide specialist advice to the obstetric team.

Babies of opioid dependent mothers are at risk of neonatal abstinence syndrome and sudden infant death syndrome (SIDS). Section 11.6 outlines care for the neonate of an opioid dependent mother.

11.5.2 Opioid treatment during pregnancy

The provision of opioid pharmacotherapy treatment during pregnancy has a number of benefits which include:

- assists in the stabilisation of drug use and lifestyle;
- reduces or eliminates illicit opioid use, which may help to stabilise the in utero environment; and
- improve access to comprehensive antenatal and postnatal care.

Opioid treatment does not increase the risk of congenital abnormalities in the foetus.

There have been insufficient controlled studies involving adequate follow up periods to demonstrate the safety of buprenorphine during pregnancy and breastfeeding. Therefore, methadone remains the only registered treatment for pregnant and breastfeeding women.

Methadone remains the only registered treatment for pregnant and breastfeeding women.

Whilst it is the preferred option for a woman continuing with her pregnancy to transfer to methadone maintenance treatment, there may be situations in which a women may opt to remain on buprenorphine. This is discussed in Section 11.5.3.

The Australian Drug Evaluation Committee (ADEC) has classified opioid analgesics (i.e. Buprenorphine and methadone) as Category C: "have caused, or may be suspected of causing, harmful effects on the human foetus or neonate without causing malformations. These effects may be reversible" (Department of Health and Ageing, 2011).

In addition the ADEC note that opioid analgesics may cause respiratory depression in the neonate, and withdrawal symptoms have been identified in cases of prolonged use by the mother (Department of Health and Ageing, Therapeutic Goods Association, 2011).

The aims of treatment for pregnant women are consistent with those for the treatment aims of all pregnant women:

- minimise the likelihood of complications; and
- provide comprehensive antenatal and postnatal care.



Whenever possible, antenatal care should be managed collaboratively with obstetric services that have the resources to provide specialist care in the management of drug dependence during pregnancy. Some pregnant women may be reluctant to advise health providers and practitioners that they are clients of the opioid pharmacotherapy program. Clients should be counselled and advised of the importance of a holistic, collaborative approach between alcohol and drug services and other relevant services throughout their pregnancy.

Antenatal care should be managed collaboratively with obstetric services.

Missed doses

As with all opioid pharmacotherapy the key to effective outcomes for patients is regular daily dosing. Missed doses may result in sub-optimal dosing and opioid withdrawal. For pregnant women missed doses are critical as they may be at risk of miscarriage. Pregnant women receiving opioid pharmacotherapy should be made aware of this risk and actively encouraged to maintain regular dosing regimens (see Sections 8.9.2).

Pregnant women receiving opioid pharmacotherapy should be made aware of the risks associated with missed doses and actively encouraged to maintain regular dosing regimens.

If a pregnant patient reports vomiting, the prescriber (or ADS case manager) should review the patient within 4-6 hours. If there are signs of withdrawal, consider a small supplementary dose of no more than half their usual dose up to a maximum of 40mg or 8mg of buprenorphine.

11.5.3 Methadone treatment during pregnancy

Adherence to the following principles is important in the treatment of opioid dependence in pregnancy:

- Pregnant women should be maintained on an adequate dose of methadone to achieve stability and prevent relapse or continued illicit opioid drug use. Women already in methadone treatment who become pregnant can continue in treatment;
- Antenatal and postnatal care should be managed in collaboration with a specialist obstetric service which is experienced in the management of drug dependency during pregnancy;
- The second trimester of pregnancy is the most suitable period to conduct dose reductions if required; and
- The bioavailability of methadone is decreased in the later stages of pregnancy. It may be necessary to increase the dose in the third trimester of pregnancy to avoid withdrawal symptoms and minimise additional drug use;
- Breastfeeding can be promoted.

Although there are other treatment options available for opioid dependant pregnant women, methadone is the preferred treatment option for the client. Methadone generally provides safer and more stable conditions throughout the pregnancy. Alternative treatment options should be considered in cases when a pregnant opioid dependent woman uses opioids less than three times per week, has been using opioids for less than three months or has been using very small quantities of opioids.

The decision to start methadone treatment for a pregnant woman must include a thorough assessment of the risks associated with continuing drug use and, when some uncertainty about the level of opioid dependence exists, the risks associated with treating her with a dependence forming opioid pharmacotherapy.

In the case that a pregnant woman is assessed as suitable for methadone treatment, early stabilisation on a methadone program is critical.

As pregnancy progresses, there is a progressive lowering of maternal serum methadone levels associated with a constant methadone dose.

This is the result of:

- an increase in the total body fluid space;
- an increase in tissue reservoirs binding methadone;
- enhanced hepatic drug metabolism in late pregnancy; and
- metabolism of methadone by the foetus and placenta.

These physiological changes and the advancing stages of pregnancy reduce the bioavailability of methadone. This results in treatment at a previously stable dose becoming potentially less effective in maintaining the client in a comfortable state. This can cause problems for the client later in pregnancy such as relapse to other drug use and premature labour. Consideration of increasing the methadone dose during the later stages of pregnancy must balance the benefits and risks. An increase in the client's methadone dose may be provided to avoid withdrawal symptoms and prevent concurrent drug use.

The aim is to achieve stability with the lowest dose possible and also importantly, a dose that is not associated with sedation. Nevertheless, if a woman requires a high dose to cease unsanctioned opioid use, then a high dose should be prescribed. If the mother is experiencing symptoms of opioid withdrawal, it is reasonable to assume that the foetus is also feeling the negative effects of these symptoms. If the dose is increased during the pregnancy the patient should be made aware that dose reductions will commence after the delivery of the baby.

National Pharmacotherapy Policy for people dependent on opioids (Department of Health and Ageing, 2007) advises that it is preferable for a woman to be maintained on methadone pharmacotherapy to the point of delivery. Intermittent opioid and other drug use is not recommended as it can be harmful to the foetus. For this reason, in the situation where a pregnant woman on methadone pharmacotherapy seeks to reduce or cease

treatment, the advice and a review by an Addiction Medicine Specialist is recommended.

It is preferable for a woman to be maintained on methadone pharmacotherapy to the point of delivery.

11.5.4 Management of methadone dose after birth of the baby

When the daily methadone dose is increased substantially during the pregnancy, serious consideration should be given to reducing the dose to avoid sudden onset of sedative effects of methadone, which will in turn be associated with an increased risk of overdose and accidents, including a risk of dropping the new born baby. Any such dose reduction should occur immediately (first dose after parturition). While there is no evidence base to guide decision-making on such dose reductions, the clinician may consider an immediate reduction to the pre-pregnancy dose and with careful monitoring (several times a day), re-traiting the dose as clinically indicated. During the hospital admission the patient will need to be seen and assessed every day during the reduction period.

11.5.5 Use of buprenorphine in pregnancy

Whilst it is the preferred option for a woman continuing with her pregnancy to transfer to methadone maintenance treatment, there may be situations in which a women may choose to remain on buprenorphine. In such situations, it is essential that the client is clearly informed of the benefits and risks associated with buprenorphine maintenance, both to themselves and their babies.

It is preferable for Subutex® to be used rather than the cessation of all opioid treatment during pregnancy. Discontinuation of buprenorphine treatment results in increased risk to mother and baby.



Women who become pregnant while on the combination product (Suboxone®) should be switched to either methadone or to Subutex®. In the case that a stable client receiving Suboxone® becomes pregnant, her continuation on Subutex® may be suitable. However, this should be done with an increased frequency of clinical reviews to monitor the changing nature in her health status throughout the pregnancy. Counselling regarding treatment options should be provided, and support offered when a choice of action is made. Should the client wish to continue with buprenorphine, it is preferable that the client sign a consent form (For a copy of this form, contact the Alcohol and Drug Service).

The management of women with Suboxone® in pregnancy and breast feeding is absolutely contraindicated.

Education about the uncertainty of the potential risks as well as the benefits of buprenorphine treatment during pregnancy and breastfeeding should be provided by the clinician. This should involve a discussion of the available evidence relating to the woman and baby both in utero and postnatal. It has been suggested that the safety profile and milder withdrawal associated with the sudden cessation of Buprenorphine maintenance may be safer for the neonate (Dunlop et al., 2009). Furthermore, it is hypothesised that buprenorphine maintenance treatment during pregnancy may produce less severe neonatal abstinence syndrome (Jasinski, Pevnick & Griffith, 1978; Schottenfeld, 1995) and a reduced risk of respiratory depression (Walsh & Elssenberg, 2003; Davids & Gaspar, 2004). The client should be made aware that however, conclusive evidence about the assessment of buprenorphine safety in pregnancy will be unavailable for some years.

Should a practitioner suspect that a woman is not capable, or has impaired capacity, to provide informed consent for such decisions, the standard procedure for obtaining informed consent should be followed.

Because significant gaps in knowledge remain about the use of buprenorphine as a maintenance treatment during pregnancy, frequent and regular clinical reviews should be conducted by the treating doctor and the multi-disciplinary team. It is recommended that pregnant women should be reviewed on a weekly to fortnightly basis to 30 weeks gestation and weekly thereafter until delivery.

The Clinical Guidelines for the Use of Buprenorphine in Pregnancy (2003) suggest that the usual maintenance doses of buprenorphine associated with a significant reduction in heroin use are between 12 and 24mg per day. It is important that pregnant clients are encouraged to be stabilised on adequate doses of Subutex®. The available data for buprenorphine dose and incidence of NAS suggest no significant correlation. Therefore, low doses of Subutex® should not be encouraged as an end in itself. The maximum recommended dose for pregnant women should be no more than 32mg daily.

In adhering to the general principles of opioid maintenance during pregnancy, dose increments may be required throughout the pregnancy, especially during the third trimester. It is important that withdrawal symptoms are avoided as much as possible as they may cause considerable distress to the foetus and lead to preterm labour and foetal loss.

As there is inadequate data available regarding pregnancy and use of Subutex®, dosing on a frequency less than daily (e.g. alternate day dosing) is not recommended. A proportion of clients on buprenorphine will experience opioid withdrawal when dosing with buprenorphine occurs less frequently than daily. It is recommended that all pregnant women on buprenorphine be placed on a daily dosing schedule during pregnancy.

11.5.6 Use of other substances during pregnancy

There is a range of other substances, including nicotine, cannabis, benzodiazepines, alcohol, amphetamines and cocaine, which present potential risks to pregnant women and their babies. Pregnant women should be discouraged from using these substances; in particular the use of multiple sedative drugs increases the risk of fatal and non-fatal overdose.

Safety of use of sedatives whilst on buprenorphine treatment is unknown. Overdoses on combinations of buprenorphine and benzodiazepines have been reported and, as such, the use of benzodiazepines by pregnant women cannot be recommended.

A meta-analysis of studies reporting adverse outcomes of psychotropic medications used in pregnancy reported a 2-3 fold increase in cleft lip and palate with first trimester exposure to diazepam and a 7-fold increase with alprazolam, although these results have not been consistently replicated in other studies (Austin & Mitchell, 1998). No long term neurodevelopmental sequelae were reported.

In addition, a benzodiazepine abstinence syndrome may occur, which may include tremors, hypertonicity, irritability, excessive sucking, vomiting and diarrhoea. The onset of these withdrawal signs may be delayed and the syndrome may persist for up to 5 weeks. A combination of opioid plus benzodiazepine dependence may be associated with a particularly severe and drawn out abstinence syndrome in the neonate.

Contrary to self-reporting, controlled studies of plasma, urine or hair markers of smoking demonstrate that most pregnant smokers do not quit. In Tasmania in 2009, 23.9% of pregnant women attending public sector ante-natal clinics smoked during their pregnancy (Department of Health and Human Services, 2011). In addition, amongst people who regularly inject drugs (PWID), the rate of tobacco use is dramatically higher than in the general population (93% v. 22%) (Stafford & Burns, 2011; ABS, 2010).

Cigarette smoking is associated with increased peri-natal morbidity and mortality, growth retardation & behavioural abnormalities.

There is evidence of increased risk of in utero foetal demise associated with smoking, with highest risk amongst women over 40. There is an increased risk of infant mortality associated with smoking, with highest risk amongst women 20 – 29 years of age. There is a 3-fold increase in risk of Sudden Infant Death Syndrome (SIDS) associated with maternal smoking in pregnancy.

Both pre- and postnatal exposure to tobacco smoke has been identified as a major risk factor for SIDS (Fleming & Lair, 2007). It is important that all pregnant clients and parents of infants are informed of the risks associated with tobacco use, and provided with appropriate pharmacological and/or counselling support if requested. It is important to note that reducing tobacco use does not reduce exposure to nicotine and is not a helpful strategy.

11.6 Management of neonatal care

Neonates born to mothers on opioid pharmacotherapy programs, or women who have been regularly using other opioids (e.g. heroin, morphine) during their pregnancies, are at risk of developing a NAS from opioids.

11.6.1 Neonatal abstinence syndrome and its management

To date there is insufficient data to determine whether the NAS is more or less likely with buprenorphine compared to methadone. Early data suggests the incidence of NAS is similar to that seen with methadone. In accordance with current management strategies for neonates experiencing withdrawal, ideally the infant remains with the mother where possible.



Opioid dependent women are not recommended for out-of-hospital delivery as there is a need for prolonged monitoring of the neonate in the first five days after delivery. All babies born to opioid dependent mothers should be observed by experienced staff for withdrawal symptoms. A validated scale should be used to assess the presence and severity of NAS (see Appendix II).

It is usual for withdrawal symptoms to commence within the first 12-48 hours after delivery; however they may not become apparent for up to one week. Withdrawal from additional substances (e.g. benzodiazepines) which are concurrently used with methadone or buprenorphine may delay the onset of symptoms. Experienced staff should regularly observe babies born to opioid dependent mothers to assess for any withdrawal signs in the baby.

The supportive treatment of neonatal withdrawal involves minimising environmental stimuli and enhancing the baby's comfort. Treatment with morphine should be considered for infants who exhibit severe signs of withdrawal (NSW Health, 2006), but morphine may depress respiration and should be used with extreme caution. There is evidence to suggest that the addition of phenobarbitone to morphine can assist in managing NAS (Coyle, Fergusson, Lagasse et al., 2002). It is recommended that neonatal care be managed in collaboration with a specialist obstetric or paediatric service experienced in the management of babies born to drug dependent mothers.

In addition, the use of opioid antagonist medication, such as naloxone, is strictly contraindicated for neonates born to opioid dependent mothers as it may precipitate withdrawal. If required, mechanical ventilation should be provided.

Due to risk of precipitated withdrawal, the use of opioid antagonists (e.g. naloxone) is strictly contraindicated for neonates born to opioid dependent mothers.

For more detailed information on the management of NAS refer to the National Clinical Guidelines for the Management of Drug Use During Pregnancy, Birth and the Early Development Years of the Newborn (NSW Health, 2006).

11.6.2 Breastfeeding while on methadone

It is understood that only small amounts of methadone are present in breast milk. Women not using any other drugs should be encouraged to breastfeed regardless of their methadone dose. Two notable exceptions to this are when the woman is HIV positive, or when a woman who is Hepatitis C positive has cracked or bleeding nipples.

Breastfeeding may reduce the severity of the NAS. Women receiving high doses of methadone should be advised to wean their babies slowly to avoid withdrawal in the infant.

11.6.3 Breastfeeding while on buprenorphine

There is insufficient clinical data available on the safety of breastfeeding for women on buprenorphine, however, the amount of buprenorphine in breast milk is small and considered to be clinically insignificant.

Women who choose to breastfeed while taking Subutex® should be informed of the risks (i.e. the presence of reduced amounts of buprenorphine in the breast milk; reduced breast milk production) to enable them to make an informed decision. These women should be supported in their decision.

When a woman weans her baby from breast milk, she should be informed to do this slowly in order to avoid the infant experiencing withdrawal.

In cases where a decision is made to continue breastfeeding while the mother is on buprenorphine, neonates and infants should be regularly reviewed to monitor their development by Child Health, and/or a Paediatrician.

11.7 Blood-borne viruses

All clients accessing the Tasmanian Opioid Pharmacotherapy Program (OPP) should have their blood borne virus (BBV) status reviewed and monitored throughout treatment. Prior to BBV testing it is important to ensure that pre and post discussion is provided by appropriately trained clinicians. Hepatitis A & B Vaccinations should also be offered to all clients. When there are significant and complex issues related to the management of a BBV and opioid dependence (e.g. pain), it is recommended that regular and timely consultations occur between the specialists involved in the clients care.

Clients accessing the Opioid Pharmacotherapy Program should have their blood borne virus status reviewed and monitored throughout treatment.

Hepatitis A and B vaccinations should also be offered.

11.7.1 HIV/AIDS

As previously stated, clients with HIV or AIDS have priority access to the Tasmanian OPP. Clients who are HIV-positive will require additional services and should be managed in collaboration with these. In the early stages of HIV infection, clients are usually able to cope with the routine and conditions of opioid treatment. However, the medical, psychological and social implications of HIV or AIDS may require some flexibility in the arrangements for ongoing treatment, especially when the HIV infection is advanced.

Client dosing must be monitored closely due to the interactions between medications for the treatment of HIV or AIDS and opioid pharmacotherapy treatment agents. Clients may require higher doses of methadone or buprenorphine if tolerance to opioids has developed as a result of other pain relief medications.

11.7.2 Hepatitis B

Both new and current OPP clients should be encouraged to undertake investigations to determine their Hepatitis B status. However, pre immunisation serology is not routinely recommended by the NHMRC for clients identified as being at high risk for blood borne viruses. Therefore clients may be vaccinated without pre immunisation serology as this vaccination given to individuals who have immunity is not contraindicated.

Hepatitis B vaccinations should be available and provided to all clients on the OPP. It is strongly recommended that vaccinations should be provided to the sero-negative partners and close family contacts of clients who are Hepatitis B sero-positive and potentially infectious.

Refer clients who are chronic carriers of Hepatitis B to a gastroenterologist for specialist assessment and follow-up.

11.7.3 Hepatitis C

Hepatitis C is a major public health concern, and a significant source of spread is through injecting drug use. As with Hepatitis B, both new and current OPP clients should be encouraged to undertake investigations to determine their Hepatitis C status.

A high percentage of individuals entering opioid pharmacotherapy will be Hepatitis C positive. If an individual has been infected with Hepatitis C, it is important to ascertain their Hepatitis B status, as co-infection with Hepatitis B may increase the aggressiveness of the illness.

Offer education and counselling to clients about Hepatitis C infection; and encourage the client to reduce high-risk behaviours, with an aim to minimise the spread of the virus. Information should include advice on reducing hazardous use of all drugs (including alcohol) and managing ill health due to Hepatitis C.

Organise specialist assessment and follow-up according to National Health and Medical Research Council guidelines for clients infected with Hepatitis C. Clinicians may also like to view the National Hepatitis C Resource Manual (Online version of National Hepatitis C



Resource Manual 2nd Edition & PDF printable version of National Hepatitis C Resource Manual 2nd Edition (PDF 1374 KB).

11.7.4 General advice

Clients should be provided with education regarding harm minimisation strategies for reducing the risks of infection with blood borne viruses. Examples of these strategies include:

- not sharing injecting equipment (also including tourniquets, spoons, and water);
- not sharing objects that may be vehicles for exchanging blood (including razors, toothbrushes, and combs);
- safe injecting practices;
- using other modes of administration, e.g. oral, nasal; information regarding prevention and treatment of sexually transmitted diseases;
- information regarding safe sex practices;
- regular access to GP and other support services; and
- assertiveness and negotiation skills.

11.8 Culturally sensitive practice

It is important for health services to ensure culturally responsive strategies that take into account the practices and beliefs of a particular population group, so that the relevant initiatives are acceptable, accessible, persuasive and meaningful (Ministerial Council on Drug Strategy, 2004). People who access alcohol and drug services and opioid pharmacotherapy treatment programs are not a homogenous group. There are numerous social and cultural groups within the Australian population, many of which have distinguishing features and different needs. These include culturally and linguistically diverse (CALD) people and Aboriginal people.

Culturally sensitive practice recognises these differences between cultures and groups. It takes account of differences in the way that groups communicate, relate to one another and how this translates into interactions with health care providers (Chrisman & Zimmer, 2000). Cultural sensitivity does not mean, however, that a person need only be aware of

the differences. A culturally competent clinician views all clients as unique individuals and understands that their life experiences, beliefs, values, and language affect their impressions and expectations of clinical service delivery, including their acceptance of a diagnosis, treatment and their compliance (Chrisman & Zimmer, 2000).

11.8.1 Supporting Aboriginal communities

The need for action to support the Aboriginal communities is entrenched in the National Drug Strategy and the Tasmanian Drug Strategy. It is also an identified priority action under the Alcohol, Tobacco and other Drug Services' Future Service Directions – A Five Year Plan 2008/09 – 2012/13. A key focus of this is to work closely with the Aboriginal communities to establish appropriate services and strategies that are designed to improve outcomes for clients.

The Alcohol and Drug Service recommends working collaboratively with the statewide Aboriginal Health Service and other Aboriginal organisations.

When working with Aboriginal clients, it is important to be mindful that the Aboriginal 'community' is heterogeneous. Mills and colleagues (2010) list the following as important considerations for clinicians engaging with clients from Aboriginal communities:

- The concepts of family (which include immediate and extended family) and community and their importance in the Indigenous culture;
- A holistic concept of health that requires consideration and treatment that includes physical, psychological, social, cultural and spiritual health;
- Indigenous people are faced with death and serious illness within their extended family more often and at a younger age than non-Indigenous people. This can be associated with high rates of trauma, grief and loss in Indigenous communities;

- There are also issues of grief, loss and trauma regarding the European invasion and Indigenous treatment since then (e.g. stolen generations);
- Current issues of stigma and victimisation exist today which are likely to impact on mental health and AOD use. Issues of domestic violence, poverty and family AOD use are also likely to play a key role;
- Counsellors should be aware of the impact of intensely distressing levels of shame that many Indigenous clients experience. This shame can be exacerbated when dealing with a non-Aboriginal counsellor/worker;
- Consider that you may be viewed as a member of a culture that has caused damage to Indigenous culture;
- Direct questioning can be perceived as being threatening and intrusive and therefore should be kept to a minimum. A method of three-way talking may often be helpful, in which a client uses a third person (such as a family member) as a mediator to exchange information with the service provider;
- Be respectful of cultural prohibitions such as:
 - referring to a dead person by name;
 - referring to certain close relatives by name (for example, a Torres Strait Islander male may not refer to his brother-in-law by name);
 - do not appear to criticise elders or family members;
 - confiding personal information to a member of the opposite sex – men's and women's business are usually kept separate (this may require a same sex AOD worker);
 - clinicians should also use the words 'unsupervised dosing' rather than 'takeaways', because the latter term can be misconstrued and lessens the significance of opioid pharmacotherapy medications.
- Be aware of various levels of literacy.

To ensure that Aboriginal clients receive culturally safe and holistic service, the Alcohol and Drug Services shall work collaboratively with the statewide Aboriginal Health Service and other Aboriginal organisations as appropriate, where possible and with consent from the client.

11.8.2 Culturally and linguistically diverse groups

In general, ethnic groups are underrepresented in Alcohol and other Drug Services (Alcohol & Other Drugs Unit of the Commonwealth Department of Health and Ageing, 2008). This is likely to reflect some of the difficulties associated with accessing treatment, rather than a lower prevalence of alcohol and other drug (AOD) use issues (Reid, Crofts & Beyer, 2001). Barriers to accessing treatment include:

- language difficulties;
 - feelings of shame and guilt;
 - lack of familiarity with services;
 - stigma;
 - fears associated with AOD treatment; and
 - different expectations of treatment and difficulty clarifying cultural difference between the client and the clinician.
- (Reid, Crofts & Beyer, 2001)

In working with people of culturally and linguistically diverse backgrounds it is important to consider:

- their particular experiences and circumstances in the context of their migration;
 - any group or subgroup membership (e.g. religious affiliation; refugee); and
 - the influence of their culture or country of origin on their values and beliefs.
- (Marsh, Dale & Willis, 2007)

It is also important not to make assumptions about an individual's culture as this may vary significantly from person to person. However, the clinician should enquire about expectations of family; understanding of healing; perceptions related to substance use and any interpersonal communication conventions (Mills et al., 2010). When there is a language barrier, an accredited



interpreter should be used. Clinicians should avoid using family members and friends as interpreters (except in emergency situations), as this can compromise the clinical interaction by restricting client disclosure and confidentiality.

Whenever possible the client should be referred to a clinician of the same culture. However, when this is not possible, efforts should be made to ensure that the client and the clinician are linked to a 'cultural consultant' (e.g. key worker at the Migrant Resource Centre). This consultant can assist both the client and clinician to identify any cultural issues that may need to be considered during treatment (Marsh & Dale, 2006).

It is important to note that the Tasmanian Opioid Pharmacotherapy Policy and Standards for Clinical Practice do not change as a result of an individual's cultural background. This program is bound by specific regulatory requirements. Culturally sensitive practice requires the clinician to consider their own cultural beliefs and values, and to adjust the way in which they communicate and relate to clients of different cultures. This is the key to culturally sensitive practice and to ensuring respectful and effective interactions and treatment.

11.9 Young people

'Young people' or 'youth' are terms used to describe persons aged between 15 and 24 years (United Nations Division for Social Policy and Development, 2003). This term is generally used to reflect the developmental phase of the lifespan and the inherent challenges this brings in the transition to adulthood. In general, of those using substances, young people tend to use alcohol and cannabis, and are often polysubstance users. The proportion of young people using heroin and opioids is quite low (Petroulias, et al., 2006). The rate of young people with clinically significant alcohol and other drug use issues is generally low; nonetheless, they do present to alcohol and drug services with significant drug use problems and serious social and psychological difficulties. There are high rates of lifetime and current mental health disorders amongst young people

accessing AOD services (Grella et al., 2001).

Traditional adult style approaches to service provision are not appropriate or effective when working with young people because of the impact of the developmental processes, physical differences, and differences in belief and value systems (Winters, 1999). The young person's stage of cognitive and psychological development will influence their ability to engage and the types of treatment interventions offered. While cognitive behavioural strategies are considered first choice interventions for adults, behavioural strategies are often more suitable when working with young people.

The following are key strategies and considerations for assessing and engaging with young people who are affected by AOD issues:

- include the family;
- be flexible in your approach;
- provide practical and concrete strategies (e.g. harm reduction strategies);
- explore and be aware of the influence (good and bad) of their peers;
- work closely with other agencies already involved with the young person; and
- monitor mental and physical health issues and link clients to specialist youth services when required (Marsh et al. 1997).

11.9.1 Young people and opioid pharmacotherapy

Even if a young person has a serious opioid use problem, they may not be neuroadapted to opioids (a requirement of treatment entry). Therefore, opioid pharmacotherapy is not the treatment of choice for young people, especially for adolescents aged 12-17 years. If a young person does meet the criteria for treatment with opioid pharmacotherapy, buprenorphine is the preferred treatment option, unless the young person is pregnant or there are significant safety issues such as risk-taking. The clinician should also broaden their approach to include the role of significant others such as family.

If a young person is assessed as being suitable for opioid pharmacotherapy, buprenorphine is the preferred treatment option.

If possible, consent should be obtained from the young person to involve a family member in the treatment process. The success of opioid pharmacotherapy can be enhanced by inclusion of a family member who is able to provide support, assist with transport to appointments, monitor other drug use, and ensure regular daily dosing. The nature of family relationships should be assessed and taken into consideration when developing the treatment plan.

Family members and significant others should be provided with detailed information about the program and its requirements so that they can support and facilitate treatment compliance. Treatment planning might also include linking the family member or significant other into additional support services that can provide AOD psychoeducation and skills in relationship building and boundary setting.

Issues such as intergenerational drug use in the family of origin and the nature of peer networks should also be considered. Peers and families can either mitigate or magnify the risks for young people so it is important to assess and monitor these relationships. Research indicates that, regardless of the family's relationship to the young person's problem, they almost always need to be involved in the solution, as treatment that does not include the family is less likely to be successful.

11.10 Recently released prisoners

Clients usually have to demonstrate neuroadaptation to be eligible for the Tasmanian opioid pharmacotherapy program. However, recently released prisoners with a history of opioid dependence or a history of pharmacotherapy treatment are at an increased risk of overdose or death if they return to high levels of opioid use after their release (Kinner, 2006). For these clients, the risk of overdose or death if not on the program may outweigh the risk of placing a non-neuroadapted client on the program. Consequently, such clients are able to access the program even if they do not display neuroadaptation. They should be commenced on a lower dose, titrated slowly, and reviewed more frequently than other clients during the early phases of treatment.

For recently released prisoners with a history of opioid dependence, or who have received opioid treatment in prison, the following strategies are recommended:

- a well developed release plan that specifies readily accessible dosing arrangements once released;
- an initial appointment with a case manager or prescribing doctor within 1-2 days of release from prison;
- an assertive follow up model of service delivery; and
- supported access to multiple services such as housing, employment, and family support services.

Given the high risk of overdose and death for recently released prisoners who are opioid dependent it is important that the care provided is assertive and well coordinated. There is also a requirement for planned, timely and effective communication between Correctional Health and ADS to ensure a seamless clinical handover and manage this priority group safely and within each service's resources.

11.11 Older persons

Individuals aged over 60 constitute only a small proportion of clients who present to AOD services nationwide. However, as our population ages there will need to be greater consideration of how this will impact on the delivery of services, including opioid pharmacotherapy.

While advancing age does not indicate diminished competence (Sprehe 2003) older persons often present with complex health and mental health issues.

Older age is significantly associated with high rates of physical and intellectual impairment (Jette, 1996). There is an increased prevalence of mental health issues and complex risk factors (including physical vulnerabilities) for this cohort which needs to be considered as part of the treatment plan (Butler, Lewis and Sunderland, 1998). Delirium (associated with adverse medication reactions), depression (particularly among the medically ill) and anxiety disorders are not uncommon. Substance misuse will often involve prescribed medications and has been identified as a risk factor for suicide.

Like other clients, engaging older peoples in treatment requires good rapport and a holistic treatment plan (Zarit & Zarit, 1998). This may include the involvement of family members, carers and regular input from general practitioners, other medical specialists and services.

Opioid pharmacotherapy prescribers should be aware of and monitor:

- co-existing medical and mental health issues;
- medications prescribed for the treatment of these conditions (e.g. drug interaction effects; potential for over-sedation and falls);
- potential need for dose adjustments and/or change of treatment agent; and
- mobility and functional capacity that may impact on access to dosing.

Integrated and collaborative practice is an important aspect of service delivery for this client group. This may mean that the way that opioid pharmacotherapy is delivered in the future will need to be adapted to reflect these changing needs.



SECTION: 12

Managing complex presentations

In this section you will...

- Be provided with specific recommendations on the management of clients who with complex presentations.

12	Managing complex presentations	149
12.1	Consultation and liaison services	149
12.2	Managing hospitalised clients with opioid dependence	149
12.2.1	Dosing during admission	149
12.2.2	Treating opioid dependent clients not currently registered on the opioid treatment program	150
12.2.3	Anaesthesia	151
12.2.4	Acute pain	151
12.3	Persistent pain	152
12.3.1	Managing pain in primary care	153
12.4	Therapeutic dependence	153
12.5	Section 59E: addiction medicine review	154
12.6	Sudden cessation of opioid pharmacotherapy	156
12.7	Managing aggression and threatening behaviour	156
12.7.1	Defining aggressive behaviour	156
12.7.2	Warning signs of aggression	157
12.7.3	Responding to aggressive behaviour	157
12.8	Continued high risk drug use and polysubstance use	158
12.8.1	Benzodiazepines	159
12.8.2	Benzodiazepine dependence	159
12.8.3	Alprazolam restrictions	160
12.9	Drug dependent behaviours	160
12.9.1	Drug seeking	160
12.9.2	Intoxication	161
12.9.3	Diversion	161
12.9.4	Requests for additional takeaway doses	162
12.9.5	Injecting takeaway doses	163
12.9.6	Frequently missed doses	163
12.9.7	Stabilised clients seeking dose increases	164
12.9.8	Prescription theft and forgery	164
12.10	Involuntary discharge from the opioid pharmacotherapy program	164



12.11	Public safety issues	165
12.11.1	Regular and unexplained lost or stolen dose	165
12.11.2	Consumption of methadone/buprenorphine by a child	165
12.11.3	Consumption of methadone or buprenorphine by a non-opioid dependent adult	166
12.12	Managing overdose	167
12.12.1	Methadone	167
12.12.2	Buprenorphine	167
12.13	Boundary violation and boundary crossing	167
12.14	Professional reporting	168

Section: 12

12 Managing complex presentations

A significant proportion of clients who present for opioid pharmacotherapy treatment will have multiple and complex presentations. Complexities relating to high risk situations, assessing for risk and protective factors, frequently missed doses and managing challenging behavioural presentations are discussed in this section. Collaborative practice underpins the provision of opioid pharmacotherapy (see Section 3.14) and is essential for the delivery of services to clients with multiple and complex needs.

12.1 Consultation and liaison services

ADS South provides access to a Consultation and Liaison Service (CLS) for the Royal Hobart Hospital. Services offered by the CLS include providing support for addressing actual or potential complications that may arise for in patients who are also receiving opioid pharmacotherapy. The service operates between 9am – 4:30 pm and can be accessed by:

- phone (0413 668 043);
- pager (#9436); or
- email (ads-southconsultationservice@dhhs.tas.gov.au).

The Alcohol and Drug Services North and North West do not currently have a dedicated hospital consultation and liaison service. Clinical advice and support is provided to hospitals throughout the region by the local ADS Addiction Medicine Specialist.

For the **North/North East region of Tasmania** (including the central midlands and Flinders Island) the **Alcohol and Drug Services North, Launceston (6336 5577)** should be contacted.

The **Alcohol and Drug Services North West, Ulverstone (6429 8555)** provides services to the **North West coast** from Deloraine to Smithton, Queenstown, and King Island.

12.2 Managing hospitalised clients with opioid dependence

If an opioid pharmacotherapy client requires hospitalisation, he or she is responsible for informing the inpatient facility that they are receiving opioid maintenance therapy and from which service. Once informed, the hospital doctor should:

- Verify the client's identity;
- Contact the prescriber (PSB will be able to provide this information) or case manager to discuss:
 - the pharmacotherapy treatment agent;
 - the client's pharmacotherapy treatment requirements;
 - dosing arrangements, including access to takeaways;
 - date and time of last dose;
 - any issues related to client management on the program; and
 - risks associated with the treatment of the client's medical condition.
- Contact the dosing pharmacy to confirm the date of the last dose and determine if the client has any takeaway doses in their possession.

12.2.1 Dosing during admission

Once admitted, dosing at the client's usual pharmacy should be ceased and the prescription cancelled. Pharmacists should await confirmation from the prescriber before recommencing dosing. The prescriber must be notified of the client's admission to hospital and make the necessary arrangements to cease dosing. This should include confirmation in writing to the pharmacy of the cancellation of the prescription and the cessation of dosing. Dosing should then be conducted by the hospital pharmacy.



The client should be closely monitored for signs of intoxication or withdrawal. The prescriber should be actively involved and informed of any issues relating to the management of the client's opioid pharmacotherapy treatment during admission. A specialist alcohol and drug consultation and review can be obtained via the CLS outlined above if there are any concerns about the client.

During admission, clients are requested to hand their takeaway opioid pharmacotherapy medication to ward staff. Hospital staff should then:

- check that the container has not been tampered with or altered;
- verify the takeaway dose with the patient and the prescriber and/or Alcohol and Drug Services; and
- ensure secure storage of takeaway doses.

Clients admitted to hospital are required to hand takeaway medications in their possession to the ward staff.

If a client refuses to hand over their takeaway doses, they should not be dosed by the hospital pharmacy.

Dosing by the hospital pharmacy can only occur after the client has handed any takeaway medication in their possession to hospital staff. **If the takeaway dose is no longer required it should be returned to the pharmacy or destroyed** in accordance with the guidelines presented in the Poison's Act, 1971.

If methadone or buprenorphine are not available at the hospital pharmacy, the **verified takeaway doses may only be dispensed after consultation with the prescriber and verification from the patient that the dose has not been tampered with and contains a full dose.** If the dosing clinician and or hospital doctor have concerns that the medication may have been tampered with, they should not administer the dose and immediately contact the prescriber for advice on clinical management. The takeaway dose should

be returned to the pharmacy or destroyed in accordance with the guidelines presented in the Poison's Act, 1971.

Prior to discharge, follow up arrangements should be made with the opioid pharmacotherapy prescriber to re-establish pharmacotherapy post-discharge. Takeaway pharmacotherapy doses should not be given back to clients on discharge. The pharmacotherapy prescriber will need the following information:

- confirmation of the discharge date;
- confirmation of the date and time of the last dose;
- information about any takeaway doses that the client may have had in their possession and how these were managed and;
- details of the client's clinical management during the admission including any clinical or behavioural management issues.

Takeaway doses should never be given back to clients on discharge.

Once this information is provided the prescriber can then provide the pharmacy with written confirmation of the recommencement of dosing (including the date of the last hospital dose and the date the first dose is to be provided by the community pharmacy) and a new prescription.

12.2.2 Treating opioid dependent clients not currently registered on the opioid treatment program

If an opioid dependent client who is not receiving opioid pharmacotherapy is admitted to hospital, they may experience opioid withdrawal while they are unable to access opioids. Consequently, clients experiencing withdrawal during an admission may become agitated and aggressive and may discharge themselves against medical advice. Clients may also self-medicate with unsanctioned opioids creating difficulties for their medical management. Therefore, it is important that opioid withdrawal is identified and effectively managed during admission.

Methadone and buprenorphine can be used to manage opioid withdrawal during an admission; however this can only be provided and managed by an ADS Addiction Medicine Specialist. Buprenorphine is the treatment agent of choice: it allows for easier transition to other treatments (i.e. methadone or buprenorphine maintenance treatment) post discharge. If a client demonstrates clear signs of opioid withdrawal, the ADS should be contacted and an Addiction Medicine Specialist consultation review arranged. Medically managing a client's opioid withdrawal during admission may reduce the likelihood of discharge against medical advice.

Prior to the commencement of treatment for opioid withdrawal, the client will require a comprehensive assessment (including the commencement on the Clinical Opiate Withdrawal Scale (COWS) (Appendix 7). Medical withdrawal management is initiated when:

- there is clear evidence of withdrawal symptoms;
- withdrawal symptoms are likely to impact on treatment of the medical condition; and
- there is an increased risk that the client may discharge themselves from hospital prematurely, placing them at risk.

The client's analgesic requirements also need to be considered. As discussed throughout this document, buprenorphine can complicate analgesic use because of its partial agonist properties and high μ -opioid receptor affinity. In this circumstance, it may be more appropriate to use methadone to manage opioid withdrawal, or provide alternative symptomatic relief.

Ideally, methadone and buprenorphine treatment for opioid withdrawal during admission should be ceased prior to discharge. If further treatment is required, discharge planning should include arrangements for the client to be managed post-discharge by an approved prescriber.

The client should also be informed that treatment of withdrawal with methadone or buprenorphine post discharge does not constitute entry to ongoing opioid maintenance

therapy. If maintenance therapy is required, a specialist alcohol and drug consultation can be arranged to help facilitate access to an opioid pharmacotherapy prescriber.

12.2.3 Anaesthesia

Clients being admitted for major surgery are responsible for informing their doctor that they are taking methadone or buprenorphine. Clients may require higher doses of anaesthesia if there is evidence of cross tolerance between methadone and other anaesthetic agents. Sharing this information with the treating doctor allows for the development of an effective treatment plan that informs both the surgical procedure and the management of postoperative pain.

If a client treated with high dose buprenorphine is admitted for surgery, the last dose of buprenorphine can be administered 48 hours before surgery to ensure sufficient μ -opioid receptors are available for a full μ -OR agonist to work on and provide adequate analgesia (e.g. morphine). If the client is prescribed a buprenorphine dose higher than 16mg daily reducing the last dose to 16mg or less will make it more likely that there will be sufficient unoccupied μ -Ors available.

12.2.4 Acute pain

Pain can be defined as an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage (International Association for the Study of Pain (IASP) in National Pain Strategy, 2010, pg.11).

Clients receiving opioid pharmacotherapy who experience acute pain may receive inadequate treatment of their pain. This may be because analgesia is withheld due to fears that it may create problems associated with underlying substance dependence. At other times, the analgesic doses prescribed may not be appropriate to overcome opioid associated factors, such as tolerance. The potential issue of opioid induced hyperalgesia (reduced analgesic efficacy and increased stimuli sensitivity in opioid dependent individuals) (RACP, 2009) may also compromise pain management in this group.



When clinically indicated, opioid pharmacotherapy clients should receive analgesia (including parenteral analgesia if appropriate) for acute pain management.

The provision of analgesia to individuals receiving opioid pharmacotherapy is complex and requires careful assessment and planning. Therefore, it is strongly recommended that an ADS Addiction Medicine Specialist and the Prescriber are actively involved in clinical decision making relating to the provision of analgesia.

It is strongly recommended that an ADS Addiction Medicine Specialist and the Prescriber are actively involved in treatment planning and clinical decision making relating to the provision of analgesia.

Opioids in addition to the patient's current methadone or buprenorphine pharmacotherapy dose - may be indicated to relieve acute pain. This course of action may result in an increased risk of opioid induced ventilatory impairment. Therefore the client's level of consciousness and respiratory function should be closely monitored with appropriate supervision in an appropriate health care setting.

A well developed treatment plan that actively involves a Pain Medicine Specialist, an ADS Addiction Medicine Specialist and the Prescriber and that includes plans for the tapering and ultimate cessation of any additional opioid medication is recommended prior to discharge from any health care facility. In the event that a patient requires additional opioids on discharge from hospital following an acute pain admission, the drug and dosing regime should be discussed with the ADS and approval must also be sought by the treating GP from PSB.

Managing acute pain in clients on buprenorphine

Due to the partial agonist, pharmacokinetic, characteristics of buprenorphine, patients maintained on buprenorphine may have a diminished response to full agonist opioids prescribed for analgesia. Clients on high dose buprenorphine for opioid pharmacotherapy, who suffer severe pain, may require considerably higher doses of full agonist opioid analgesia than individuals not on buprenorphine treatment (Lintzeris et al., 2001).

Managing acute pain in clients on methadone

Opioid tolerance as a consequence of ongoing methadone opioid pharmacotherapy, may also be a significant factor requiring management. A higher dose of opioid medication may also be required when managing acute, moderate to severe pain in this patient group. As indicated above, there is no regulatory impediment to prescribing opioids in acute severe pain. However, attention must be paid to patient safety this includes close monitoring of the patient's level of consciousness and respiratory function.

There are specific strategies that can be employed to assist in acute pain management. These will vary according to the clinical circumstances. The advice is to discuss these circumstances with an ADS Addiction Medicine Specialist or a Pain Specialist.

12.3 Persistent pain

A clinically convenient definition of chronic non-cancer pain, also known as 'persistent non-malignant pain', is pain present for more than 3 months. An earlier definition suggested pain persisting beyond the time of normal healing, but this is debateable e.g. in applying that older definition to persistent pain arising from osteoarthritis.

Patients with persistent pain require a comprehensive biopsychosocial assessment. This will include:

- the diagnosis or exclusion of serious and specific diagnosable and treatable disorders;
- assessment of the type of pain (nociceptive, neuropathic or neuroplastic);

- assessment of acuity;
- assessment of activity;
- assessment of risk for chronicity;
- disability and work loss (mostly associated with psychosocial factors); and
- the risk of aberrant use of opioids (Fishman et al. 2010).

Detailed education, care planning and a range of treatment modalities may be provided by a community clinical team consisting of the general practitioner, physiotherapist and psychologist in conjunction with other members as required, or by a multidisciplinary pain service if clinically indicated.

There is evidence to suggest that continued opioid use reduces analgesic efficacy, may reduce an individual's pain threshold (opioid induced hyperalgesia) and can increase somatic focussing (Ballantyne & Mao, 2003). This would suggest that clients receiving opioid pharmacotherapy might be at increased risk of persistent pain.

12.3.1 Managing pain in primary care

In the primary care setting there are regulatory provisions that mean additional opioids cannot be prescribed to patients registered on opioid pharmacotherapy without an authority, for clinical safety reasons. People who are opioid dependent can be at increased personal risk due to overuse of prescribed medications and in other circumstances, may divert some or even all of this medication for inappropriate non-medical purposes. The significant risk of overdose and death associated with the unsafe use of opioids in combination is an important consideration.

Due to regulatory requirements, other opioids cannot be prescribed to patients registered on opioid pharmacotherapy without an authority.

The management of patients with persistent non-malignant pain arising in association with illicit opioid use or alternatively, in patients who have developed a 'therapeutic opioid dependence', is often complex.

Consideration must be given to the range of psychosocial issues that contribute to the client's circumstances. Regardless of the pathway to persistent pain, treatment is multimodal and pays attention to key psychological and behavioural aspects.

The management of persistent non-malignant pain using a unimodal approach such as the provision of an opioid medication alone is invariably unsuccessful (Fishman et al. 2010).

The aim of interventions in chronic pain management is to relieve pain and improve function (National Pain Summit Initiative, 2010).

The management of persistent non-malignant pain using a unimodal approach such as the provision of an opioid medication is invariably unsuccessful.

The management of pain should be in accordance with the principles outlined in the National Pain Strategy (2010) (www.painsummit.org.au/strategy/Strategy-NPS.pdf/view). This strategy is an integrated approach to improving the management of acute, persistent and cancer-related pain.

12.4 Therapeutic dependence

Therapeutic opioid dependence is defined as dependence that has developed following the use of opioids for the treatment of acute pain associated with a medical condition Queensland Health, Alcohol and Drug Dependence Services (1988), consequently, the dependence is on prescribed opioids. In such cases, dependence on the opioid medication can become a larger problem than the underlying medical condition, which may have diminished in importance or resolved. In Tasmania, many clients access the opioid pharmacotherapy program due



to therapeutic opioid dependence (see also Section 2).

Clients who state that they are in severe pain and request opioid treatment can present a therapeutic dilemma to the clinician.

Determining whether the problem is principally one of (severe) pain or opioid dependence can be difficult. Furthermore, the treatment of therapeutic opioid dependence in association with persistent pain is complex.

Good clinical assessment and management requires attention to a range of psycho-social factors, as well as biological or medical factors. Furthermore, a clinical team may be required to address the complexity of the client's needs. This team may include specific treatment services or specialists such as:

- multidisciplinary pain clinic (Royal Hobart Hospital);
- specialist medical practitioner;
- general practitioner;
- Addiction Medicine Specialist;
- allied health (physiotherapist; occupational therapist; psychologist; social worker); and
- key worker or case manager (either a nurse or allied health professional) who coordinates the key services.

Clients with therapeutic opioid dependence can be referred to ADS for a specialist Addiction Medicine Assessment in accordance with Sect 59E of the *Poisons Act 1971* (see below). The ADS will provide advice in relation to potential substance dependence and offer specialist advice and treatment strategies. The client may then be appropriately managed by their general practitioner and medical specialist if:

- there is no history or evidence of illicit or unsanctioned drug use;
- the client is not associated with drug culture;
- there is a significant medical condition;
- persistent pain is the predominant presenting problem; and
- there is no evidence of seeking over the counter opioids from pharmacies.

Effective treatments for clients with therapeutic opioid dependence require realistic treatment goals and clear boundaries that are negotiated between the client and clinician. These clients are often resistant to treatment and reluctant to engage with AOD services. This is because they do not identify themselves as drug users. Clinicians should be sensitive to the client's perceptions and experience of being referred to an alcohol and drug service.

A nonjudgmental approach, open and honest communication, working with resistance, and using motivational approaches can facilitate the successful engagement of reluctant clients (Marsh and Dale, 2006). Psychoeducation in relation to drug dependence and effective pain management can assist the client's understanding of their situation and help facilitate a shift in their perceptions about treatment.

12.5 Section 59E: addiction medicine review

The PSB monitors and issues authority prescriptions for the supply of Schedule 8 drugs under Section 59E of the *Poisons Act 1971*. As part of this process, the PSB may advise a medical practitioner to seek a specialist alcohol and drug assessment to review whether a client is dependent on opioids (see Figure 12.1).

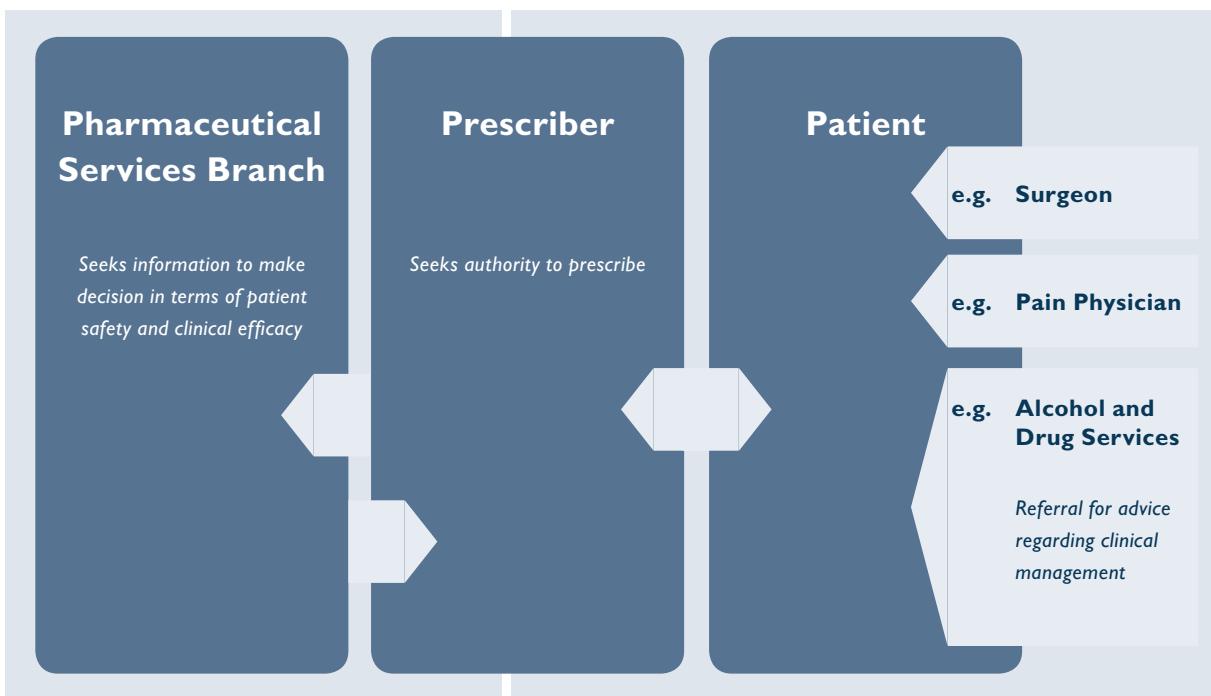


Figure 12.1: Section 59E Model

These recommendations are usually made once a client has come to the attention of the PSB (e.g. as a result of opioid drug seeking behaviour or concerns related to escalating doses), or at the request of the Expert Advisory Panel (EAP). Membership of the EAP includes the two pharmacists from Pharmaceutical Services Branch, DHHS (who have substantial experience in community pharmacy), a general practitioner representative of the RACGP (with experience in managing pain and addiction), a Pain Medicine Specialist and an Addiction Medicine Specialist (as well as other specialists). The EAP is a non-statutory panel that provides specialist advice to the PSB on the management of clients receiving long term Schedule 8 medications.

When receiving these referrals and recommendations, the ADS will:

- request and obtain collateral clinical information including specialist reports and investigations;
- undertake a comprehensive specialist assessment (including a supervised urine drug screen);
- make recommendations about the client's ongoing management (including dosing arrangements, referrals for

specialist interventions, opioid withdrawal management); and

- determine the client's need and suitability for opioid pharmacotherapy, opioid rotation or opioid reduction regimens.

If there is clear evidence of illicit drug use, high risk polysubstance use, drug seeking behaviour (prescription shopping), or other problematic behaviours, the recommendation may be for the client to be managed by the ADS. The ADS can provide access to comprehensive treatment planning and management through a multidisciplinary team.

The client's GP (or doctor who was prescribing the opioids) is responsible for providing information to the client about opioid dependence and ADS processes. This means that the client should be clearly informed of the reason for the referral to the ADS and of the purpose of the Addiction Medicine Specialist assessment and the possible outcomes of this review, including a change in their current treatment or medications (e.g. opioid rotation or cessation of current prescribed medications).

For more information regarding the specialist medical assessment, contact the Alcohol and Drug Service.

The client's GP (or doctor who was prescribing the opioids) is responsible for providing information to the client about opioid dependence and Alcohol and Drug Services processes.

12.6 Sudden cessation of opioid pharmacotherapy

Clients who suddenly cease opioid pharmacotherapy usually experience withdrawal symptoms and are at increased risk of overdose and death if they return to illicit drug or unsanctioned opioid use.

Sudden cessation of opioid pharmacotherapy increases the client's risk of overdose and death.

While there are many factors that influence treatment retention, the client should also be informed of the potential risks associated with the sudden cessation of treatment.

Dropping off the program

Sometimes clients unexpectedly exit treatment. This can occur once a client has been stabilised for some time; however, it more frequently occurs during the stabilisation phase. Unexpected drop-out often indicates a return to other drug or illicit opioid use. However, for longer term and stabilised clients, it can also indicate sudden relocation or, in some instances, incarceration.

If a client unexpectedly drops out of the program:

- attempt to follow-up with the client to ensure their safety; and
- reinstitute treatment if safe to do so.

If a client intentionally disengages from treatment:

- provide harm reduction advice;
- provide advice about withdrawal management and risk of overdose; and
- inform the client that they can return to treatment in the future.

In Tasmania, the opioid pharmacotherapy program is a maintenance program and not an access program (i.e. sporadic access to treatment rather than regular, daily access); therefore, retention in treatment is preferred. Some clients may make several attempts to commence treatment before they are able to sustain and commit to treatment and associated lifestyle change; this is normal in the process of behaviour change. Potentially each time the client makes contact or engages in treatment, their trust and confidence increases and maintenance treatment is often achieved.

12.7 Managing aggression and threatening behaviour

Prior to commencement of treatment with the ADS, a treatment agreement is negotiated with the client and they are advised of their rights and responsibilities while in the program (see Section 6 and Appendix 5). This process helps establish that physical and verbal aggression towards staff and other clients is not tolerated. Staff are also obliged to adhere to the agency's Code of Conduct and not engage in aggressive behaviours.

Challenging behaviour, including aggression, can be the result of poor communication and interpersonal skills, or poor emotional regulation. Furthermore, some individuals may display this type of behaviour due to a trauma history. Identifying and managing challenging behaviours such as intimidation, aggression, and verbal abuse, is an important skill for clinicians delivering pharmacotherapy. The ADS provides regular training for staff and has policies and procedures to support and guide clinicians in managing aggressive and threatening behaviour.

12.7.1 Defining aggressive behaviour

Aggressive behaviour is any behaviour that creates intimidation and fear or causes offense to others. Aggressive behaviours can be directed towards an individual, a group of individuals, or property; can occur in any location (on or off site), and at any time (during or out of work hours) (Lee et al., 2003). It may be face to face, over the telephone, or by written correspondence.

Aggressive behaviour is more than being upset. Aggressive behaviour can manifest in a number of ways, including:

- threats to harm others or self;
- physical or verbal harassment or bullying;
- physical violence (e.g. hitting, kicking, grabbing, holding, spitting, punching, use of weapon) towards people or objects (including departmental property);
- raised or shouting voice and use of obscenities;
- use of innuendoes, racist, or sexist comments;
- vulgar noises, expressions or gestures;
- stalking and exhibition of offensive material;
- blocking entry or exits and refusal to move when requested;
- unlawfully detaining staff, other clients and general public; and
- other violent conduct contradicting accepted community norms.

12.7.2 Warning signs of aggression

Not all people display the same warning signs: some may become restless and agitated whereas other can become quiet and withdrawn prior to an aggressive episode.

The following is a list of common physical cues or warning signs preceding aggression:

- flushed face and neck;
- protrusion of blood vessels in the neck, forehead and temples;
- rising volume and pitch of voice;
- grimacing or frowning;
- clenched jaw muscles;
- teeth grinding;
- flared nostrils;
- rapid, shallow breathing;
- increased gesticulation and increased excitability;
- sweating and beading along the forehead, hairline or upper lip;
- trembling limbs;
- clenching fists;
- fidgeting hands;

- increased coarseness of language;
- standing up during a seated interview;
- agitated pacing;
- fixed and prolonged gaze; and
- entering personal space.

In addition to physical cues, there are three main verbal cues:

- verbal threats, which should always be taken seriously;
- ritualistic repetition of the same thing over and over; and
- depersonalising language, including foul or demeaning language, which may signal the impending onset of an attack (e.g. scum, dog).

12.7.3 Responding to aggressive behaviour

All clinicians have a professional responsibility to try to reduce the risk of aggression. This can be achieved by having an understanding how aggression manifests itself and an awareness of events and behaviours that may increase the likelihood of aggression (e.g. waiting for lengthy periods in the waiting room). In managing aggression it is also important to provide opportunities for the client to choose alternative options. This includes making a change from aggression, by taking responsibility for managing their emotional responses and behaviour.

Clinical responses to aggression include diffusion, control of aggression, and termination of contact.

Step 1: Informal warning: Diffusion of aggression

Attempt to defuse the situation by using personal communication skills to refocus the client on the matter being discussed, and issue an initial warning. It is important to give this warning as soon as a client becomes threatening or aggressive. Furthermore:

- use concise and calm communication including active listening techniques;
- speak clearly and slightly slower than normal;
- adopt a balanced neutral posture;

- use simple words and short sentences to avoid confusion;
- allow the client time to process what has been said;
- remain focused on the issue and avoid negative statements;
- use non-verbal listening skills to indicate interest;
- allow the client to tell their story;
- acknowledge the client's story using both verbal and non-verbal communication skills;
- reflect the content of the client's story by paraphrasing and summarising key points without being obtrusive or unnecessarily interrupting; and
- use open questioning to clarify and/or direct the conversation where possible.

If an extremely aggressive person is encountered, it may be more appropriate to attempt to take control of the situation by use of assertion and direction, rather than initial warning and attempting to refocus. This will be determined by several situational variables including the circumstances, location, the client, and personal skills of the staff involved.

If a physical assault occurs, police intervention should be sought immediately.

Step 2: Formal warning: Controlling aggression

If step 1 does not result in diffusion of anger, assume control of the situation by use of a consequence warning that is outcome focussed and uses assertive negotiation skills. (e.g. "I will have to terminate this visit if we can't keep to the issue and I don't want to have to do that." Or "If you continue to swear at me, I will end this interview"). Furthermore:

- maintain the use of balanced neutral posture to reinforce the verbal request;
- use non-threatening gestures to emphasise the verbal message, if appropriate;
- continue to use concise and calm communication including active listening techniques; and
- use assertive repetition to take control and direct the conversation by using the same simple message.

Step 3: Termination of the contact

If the situation escalates, ask the person to leave, remove yourself from the situation, or terminate the telephone call. If a co-worker has requested a client to leave the premises, try not to inflame the situation, avoid threatening language and maintain personal safety. If a person refuses to leave when requested, the most senior person on location not involved in the incident should call the police to remove the aggressive person from the premises. Inform the person that the police have been called.

If a staff member cannot withdraw to safety or the situation has escalated to a physical or potentially physical encounter, the worker should raise attention and seek immediate help. Some workplaces (e.g. ADS) have duress alarms in interview rooms.

Step 4: Reasonable force

If a worker cannot retreat in response to a physical threat, he or she is entitled by law to use such reasonable force to defend themselves, enabling them to escape to safety until further assistance arrives. Reasonable force is an amount of force sufficient to stop an attack or to prevent injury and should not be greater than required. Legal expectation is for retreat from a situation of violence whenever possible. Occasionally a situation may occur wherein the only protection is by occurrence of actual harm to the offender. If this is absolutely necessary, then it is acceptable in law.

In extreme situations when there are concerns about ongoing risk to staff and others, legal advice may be sought in relation to the use of legal orders and other strategies to ensure safety and manage risk.

12.8 Continued high risk drug use and polysubstance use

Unsanctioned substance use during the early stages of opioid pharmacotherapy is common. In addition to the strategies highlighted in Section 8, clients with problematic polysubstance use may require assistance to reduce or cease other drug use. It is important to collaborate with the client to achieve the identified treatment goals.

Strategies for achieving these goals may include:

- selective detoxification;
- planned reduction regimens;
- relapse prevention;
- skills to cope with withdrawal symptoms; and
- contingency management techniques that reinforce behaviour change.

Establishing a therapeutic alliance with the client is important for maintaining engagement in treatment. This also requires ongoing review and assessment of the risks and benefits of treatment for the client, including the risks associated with withdrawal from treatment. Given the intensity of treatment required for clients with continued high risk polysubstance use, a multidisciplinary treatment team approach through the ADS is recommended (see also Section 3).

12.8.1 Benzodiazepines

The use of benzodiazepines amongst clients receiving opioid pharmacotherapy is not uncommon. Generally, these clients can be classified into three groups: those who occasionally use benzodiazepines when opioids are unavailable; those who are benzodiazepine dependant, and those who are seeking intoxication (on any drug) (Queensland Health, 2008).

Clients who use occasionally have usually had experience in using benzodiazepines to relieve uncomfortable withdrawal symptoms when they have been unable to obtain opioids. These clients are more likely to use benzodiazepines during the stabilisation phase of opioid pharmacotherapy treatment (to manage discomfort), when methadone and buprenorphine doses are still relatively low.

Clinicians should be aware of any such history and should actively encourage clients to use strategies such as rest, hot baths, positive self talk, self soothing, and relaxation strategies to relieve discomfort during stabilisation. Clients should also be informed about the risks of concurrent benzodiazepine use and opioid pharmacotherapy.

Those clients seeking intoxication states are often the most challenging to manage as a result of their potential to use any substance to achieve intoxication. This can create challenges in terms of clinical safety. In these circumstances a careful and thorough assessment is required to determine the client's suitability for opioid pharmacotherapy.

12.8.2 Benzodiazepine dependence

Some clients may have comorbid benzodiazepine dependence. Opioid pharmacotherapy is not a treatment for benzodiazepine dependence. Consequently, benzodiazepine use does not automatically cease following stabilisation on opioid pharmacotherapy. These clients will require more assertive management and monitoring.

A benzodiazepine reduction regimen must be implemented prior to or at the commencement of maintenance opioid pharmacotherapy treatment.

If the client is dependent on benzodiazepines, a benzodiazepine reduction regimen must be implemented prior to, or at the commencement of, maintenance opioid pharmacotherapy. It is important not to abruptly cease benzodiazepine medication, as this may increase medical risks associated with benzodiazepine withdrawal (such as seizures and delirium). The doctor should transfer the client to a long acting benzodiazepine (such as diazepam) and commence a reduction regimen. In these situations it is important to complete a Benzodiazepine Reduction Agreement (Appendix I2) with the client. This will assist the client to understand what to expect and the restrictions associated with the reduction regimen.

Benzodiazepine cessation can be very challenging and as such the client should be offered a range of strategies to assist them. A carefully developed treatment plan should include:

- detailed reduction regimen;

- regular assertive follow-up;
- daily supervised dosing or restricted quantity/pick up;
- referral for specialist AOD psychosocial interventions;
- registration and monitoring with the Medicare Prescription Shopping Information Service; and
- Selective detoxification if required.

In addition, benzodiazepines should not be commenced for clients receiving maintenance opioid pharmacotherapy.

Benzodiazepines should not be commenced for clients receiving maintenance opioid pharmacotherapy.

In the event that a client may relapse to benzodiazepine use, it is important that the clinician assesses the clinical risks, and if necessary reinstates safety measures such as a return to daily dosing and increased monitoring. The treatment plan should also be reviewed in collaboration with the client, and the goals of treatment re-set for another attempt at a benzodiazepine reduction.

Given the substantial risks associated with concurrent use of benzodiazepines and opioids, the advice of an Addiction Medicine Specialist should be obtained in relation to assessment, and the development of an appropriate reduction regimen to achieve cessation of benzodiazepines.

12.8.3 Alprazolam restrictions

It is important to be aware that alprazolam cannot be prescribed for clients receiving opioid pharmacotherapy without the written approval of the Clinical Director of the Alcohol and Drug Service (Section 59C, *Poisons Act, 1971*). Alprazolam is listed as a declared restricted substance (Declared Restricted Substance Order, 1990) under the *Poisons Act 1971*.

Alprazolam cannot be prescribed for clients receiving opioid pharmacotherapy in Tasmania without the written approval of the Clinical Director of the Alcohol and Drug Service.

12.9 Drug dependent behaviours

People with significant alcohol and other drug use issues, particularly those who are drug dependent, often develop maladaptive patterns of behaviour that support or enable their drug dependence. These behaviours are referred to as drug dependent or drug related behaviours.

In general, these behaviours, as discussed below, were not usually part of the individual's patterns of behaviour prior to the development of their substance dependence. During the early stages of treatment, it is common for these drug dependent behaviours to occur. However, after time spent in therapeutic treatment, these behaviours become less necessary, and tend to decrease. For some clients these behaviours and associated activities are more entrenched. Therefore, close monitoring and support are required to ensure that treatment is not compromised by the behaviours. It is also necessary to regularly review the treatment plan with the client and to include strategies that may assist in reducing other drug use.

12.9.1 Drug seeking

Entrenched patterns of drug use and strong urges and cravings to use can result in clients engaging in drug seeking behaviours. This may include presenting to hospitals or a doctor's surgery (afterhours) seeking medications.

Clients receiving opioid pharmacotherapy may present complaining that they are experiencing significant withdrawal as a result of a missed, lost, vomited, or stolen dose. These clients may be seeking additional methadone or buprenorphine for a range of reasons.

In these situations, the prescriber must be contacted as soon as possible and the dose should never be replaced. The client must be referred back to their prescriber for assessment and support. It is important to remember that

both methadone and buprenorphine have a long half-life, and as a result, it is unlikely that a client will experience significant withdrawal after missing one day's dose: this is particularly the case for stabilised clients,

12.9.2 Intoxication

It is not uncommon for some clients to seek intoxication states. In general these clients tend to seek opioids and/or benzodiazepines. This client group can be difficult to manage in private practice, as their behaviour can, at times, be chaotic, and the combination of drugs used, unpredictable. These clients are at high risk of falls, accidents, overdose and death, particularly during opioid stabilisation.

It is advisable for these clients to be referred to the Alcohol and Drug Service. It can be difficult to assess clients who are seeking intoxication, and to determine if opioid pharmacotherapy is a safe and suitable treatment option for them. The complexity of their drug use behaviours and psychosocial circumstances are best addressed by a multidisciplinary team. In some instances, these clients may also require an inpatient admission for a selective detoxification followed by an opioid rotation or induction. In these circumstances the inpatient admission can significantly reduce the risks during stabilisation.

12.9.3 Diversion

Diversion occurs when methadone and buprenorphine doses are not used as intended. For the purposes of this document, diversion includes:

- selling, trading or giving opioid medication to others;
- removal of doses from the dosing point; and
- secretion of doses for selling and injecting.

Possession, use, administration, sale and supply of a controlled drug are criminal offences under Part 3 of the Misuse of Drugs Act 2001. Diversion should be reported to the Tasmania Police if there is clear evidence of real and imminent risk to the individual or to the community.

Unfortunately, the potential for diversion remains an issue for opioid pharmacotherapy

programs. A number of risks such as overdose and death are associated with the use of diverted medications. Diversion has implications for client and public safety as well as the reputation of the program. These activities may sometimes discourage pharmacists from becoming or remaining involved in the program. Diversion to illicit use not only has significant risks (such as opioid overdose; bacterial infection and transmission of blood borne viruses from unhygienic injection practices) it also undermines the therapeutic rationale and effectiveness of opioid pharmacotherapy.

When diversion is suspected or attempted, the pharmacist should discuss their concerns with the client and clarify the requirements for dosing. The pharmacist should also immediately notify the prescriber or case manager. The client's management and continued participation on the program should be reviewed by the prescriber or the clinical team. The following actions are recommended:

- If there is evidence **of diversion of takeaway doses**, takeaway doses should be ceased immediately and daily supervised dosing instituted for a period of 6 months;
- If **diversion of a supervised buprenorphine dose** occurs, takeaway doses should be ceased immediately for 6 months and a review of dosing arrangements undertaken to determine suitability for dosing;
- If **diversion of a supervised methadone dose** occurs, doses should be made up to 200ml with water or cordial and administered in 50ml aliquots, and takeaway doses removed for 6 months;
- When there is **continued diversion of buprenorphine**, a transfer to methadone may be considered if a comprehensive clinical assessment indicates that this is safe and appropriate treatment;
- In circumstances of high risk polysubstance use, a decision might be reached that continuing treatment with buprenorphine is, on balance, still the safer option but conditional upon the removal of takeaway dose privileges, and increased clinical monitoring and supervision; and

- If there is a **subsequent or repeated diversion**, the client will be removed from the program, undergo involuntary detoxification (with appropriate follow-up support and patient education about the risk of overdose), and may not be considered for re-entry to the program for 3 months.

Diversion is a very serious concern: it requires considerable planning, confidence and intent by the client. It is very rarely a spontaneous event. Engaging in diversion also raises issues about the client's engagement in treatment, compliance and stability. For this reason a six month period of supervised dosing and increased medical and case management reviews and monitoring is recommended.

Diversion is often related to a client being 'stood over' by another person. Hence, it is important that any factors contributing to diversion are considered and that the client is offered strategies to deal with intimidation. If a client discloses that they are being intimidated or harassed for takeaway doses, it may be necessary to transfer them to another pharmacy. A return to daily dosing can also assist in these situations as the client will no longer be targeted for their takeaway doses. Dosing pharmacies (pharmacists) should also be made aware of any issues associated with intimidation of clients for takeaway doses. This will allow them to monitor events at the dosing site, notify prescribers of possible diversion, and, if necessary communicate their concerns to police.

When diversion occurs the clinician should discuss this event with the client. The client should be made aware of the breach of the treatment agreement, and a warning letter provided detailing the reasons for the clinical concern and consequences of any further breaches. The treatment plan must be reviewed and should include increased monitoring and review, and any other changes to the client's management (such as cessation of takeaway doses).

In reviewing the client's management and continued participation on the program, the prescriber and clinical team should consider

the therapeutic benefits of the program for the client, the risk to clinical and public safety, damage to the reputation of the program, and the management options in the event that diversion re-occurs.

The risk of diversion can be reduced by:

- the careful assessment of a client's suitability for takeaway doses;
- the provision of clear information to clients about the risks and consequences of diversion;
- the provision of clear guidelines and policies about the process for the management of diversion for dosing sites and pharmacies; and
- regular communication and support (liaison visits) to dosing sites/pharmacists.

12.9.4 Requests for additional takeaway doses

It is not uncommon for clients to feel restricted by the requirements for supervised dosing. This may result in clients attempting to secure additional takeaway doses from their prescriber or dosing pharmacist. It is important for all those involved in the delivery of the Tasmanian OPP to be aware of the regulatory requirements outlined in this document (see Section 8) in relation to the provision of takeaway doses. It is acknowledged that there are situations in which some clients do attempt to procure takeaway doses for the purposes of diversion. This policy and the restrictions associated with the provision of takeaway doses have been developed in the interest of client and public safety.

Prescribers and pharmacist should not feel compelled or allow themselves to be coerced into providing takeaway doses. The clinician should clearly explain the opioid pharmacotherapy guidelines and clinical practice standards, and the restrictions that this places on their practice. When a client continues to pursue this issue they should be told that nothing more can be done without further advice. The prescriber should advise the client that they will seek clarification from the Alcohol and Drug Service; and the pharmacist should

inform the client that they will contact the prescriber.

12.9.5 Injecting takeaway doses

As outlined in Section 4, the injection of methadone and buprenorphine poses significant risks to the individual, including venous damage, emboli and tissue necrosis, and the transmission of infectious diseases such as HIV and hepatitis (if injecting equipment is shared). There is also a very significant risk of overdose associated with the injection of takeaway doses. Injecting buprenorphine or combined buprenorphine-naloxone can also result in precipitated withdrawal in opioid dependent clients.

As methadone and buprenorphine are designed for oral administration, injection of these drugs changes the rate of metabolism, and as a result, clients may report that their dose is not adequate. Prescribers should always check for evidence of injection as part of a regular review. When there is evidence of the injection of takeaway doses, all takeaway doses should be ceased and daily supervised dosing initiated.

12.9.6 Frequently missed doses

As discussed earlier in Section 8, opioid maintenance therapy requires the client to be to be dosed daily (with the exception of twice or third daily buprenorphine dosing regimens). Missed dosing may result in suboptimal dosing and the client may experience opioid withdrawal. Clients who miss three or more consecutive doses of methadone may be at increased risk of overdose; possibly related to loss of tolerance (reversal of neuroadaptation), or the use of other depressant drugs. Missed doses may be more common amongst clients receiving buprenorphine as they are less likely to experience uncomfortable withdrawal symptoms (Queensland Health, 2008).

Pharmacists are required to notify the prescriber of any missed doses. It is important to monitor the frequency and regularity of missed doses as this may be a sign of instability. Missed doses do not always mean that a client is using other substances. However, where there is a recent history of intoxication or polysubstance use, it is important to closely monitor and

review the client to ensure they are not at risk of overdose.

Careful attention should be paid to any regularity or patterns associated with missed doses, such as missed doses following takeaway doses, or where there may be some indication of planned drug use concurrent with takeaway doses. Missed doses may also reflect changes in psychosocial factors and may signal social or psychological distress or other increased stressors.

It is important to always explore with the client the circumstances associated with any missed doses. For example, the client may be experiencing difficulties with transport, dosing around work hours, or may be feeling uncomfortable with pharmacy staff, or feel pressured by other clients accessing the same pharmacy. The clinician should also explain to the client the impact that missed doses may have on the effectiveness of their treatment. Frequently missed doses have an impact on stabilisation and can result in a 'steady state' never being attained or maintained (see Section 7 Safe Treatment Induction), particularly during induction. In these situations, re-stabilisation should be considered in order to achieve steady state.

Where regular unexplained missed doses continue (i.e. three or more times a month) and every attempt has been made to ensure the suitability of the treatment plan and dosing arrangements, the prescriber should review the client's suitability for treatment. This should include a consideration of the risks associated with missed dosing and any other identified risks that contribute to the client missing doses. Motivational interviewing should be used to encourage the client to consider the harms and risks associated with their current circumstances, versus the advantages and disadvantages of continuing or discontinuing opioid maintenance therapy.

Within the public programs, the prescriber and case manager are required to review any clients who are facing difficulties with program compliance as a result of regular and unexplained missed doses with the multidisciplinary team.



Where the clinical team identify serious concerns related to the client's continuation on opioid pharmacotherapy, they should also seek the guidance of the Clinical Director, ADS. Private prescribers are encouraged to seek the advice and support of the ADS in similar circumstances. This may involve a review of the client by an Addiction Medicine Specialist, or the temporary transfer of the client to the public program where more assertive follow-up and case management may assist with stabilisation and enhanced program compliance.

12.9.7 Stabilised clients seeking dose increases

It is not uncommon for clients who have been well stabilised on their dose for some time to present describing withdrawal symptoms and requesting an increase in their methadone or buprenorphine. In general, most clients will remain on the same dose for lengthy periods, or even indefinitely once stabilised.

When a client presents requesting a dose increase, it is important for the clinician to undertake a comprehensive review. This should include a thorough medical examination and assessment of client's presentation; intoxication and/or withdrawal state; recent drug use, and psychosocial circumstances. There may be other reasons for the client's discomfort including liver disease, drug interactions, alcohol and drug use/cessation, missed doses, injection or diversion of takeaway doses, difficulties with emotional regulation, anxiety, or a number of social stressors.

In managing this situation the prescriber should try to explore a range of other solutions and options including increased support, regular review and referral. Methadone and buprenorphine doses should not be increased without clinical evidence of opioid withdrawal. Prescribers are encouraged to seek specialist advice and review in these circumstances.

12.9.8 Prescription theft and forgery

Prescription theft and forgery is a criminal offence under Part 3 of the Misuse of Drugs Act 2001. Changing or tampering with prescriptions and prescription theft should be reported to

the Tasmania Police if there is clear evidence of real and imminent risk to the individual or to the community.

Clinicians are strongly encouraged to seek advice and guidance in relation to these serious clinical matters. Within the ADS these complex clinical issues should be reviewed by the multidisciplinary team with the involvement of senior managers and, where appropriate, the Clinical Director, ADS. Private practitioners involved in the delivery of the Tasmanian OPP are also encouraged to contact an Addiction Medicine Specialist within the ADS for support and advice.

If there is clear evidence of prescription theft by a client, their continued participation on the program should be reviewed. Prescription theft may warrant involuntary removal from the program. However, careful consideration should be given to the therapeutic benefit to the individual and risk to the community.

12.10 Involuntary discharge from the opioid pharmacotherapy program

At the commencement of treatment, the client is required to sign a treatment agreement which outlines activities or circumstances that may lead to involuntary removal from the program. These include:

- violence or threatening behaviour towards the treating team or other clients;
- theft or other illegal behaviour at the treatment centre or at the dosing site;
- diversion, trading and selling of takeaway doses;
- prescription theft or forgery;
- continued high risk polysubstance use; and
- poor treatment compliance.

In some instances rather than discharging the client from the program, it may be appropriate to arrange a transfer to another prescriber or program. When this cannot be achieved, clients should be offered other treatment options.

When reviewing a client's suitability for continued treatment on opioid pharmacotherapy, consideration should be given to:

- the safety of those involved in the delivery of treatment;
- the safety of other clients;
- the safety of the client receiving treatment; and
- the safety of the community.

Clients should be made aware of any breaches of the treatment agreement by the provision of a formal warning letter, including the consequences associated with any further breaches.

There are circumstances where rapid or abrupt cessation of opioid treatment is warranted, such as violence, assault or threatened assault to members of the treating team or other clients (see Section 9, Completing Treatment).

ADS clinicians are required to seek the advice of the Clinical Director in relation to these complex clinical matters and subsequent clinical decision making.

12.11 Public safety issues

12.11.1 Regular and unexplained lost or stolen dose

As outlined in Section 8, lost doses pose a significant risk to the community. There is a very high risk of overdose and death should another individual (other than that for whom the medication is prescribed) consume the methadone or buprenorphine dose. Clients who report lost or stolen doses should be asked to make a formal report to the police. When the client does not comply with this request, or the notification to police does not occur in a timely manner, the matter should be reviewed by the clinical team and a notification made to Tasmania Police.

Clients who report lost or stolen doses should be asked to make a formal report to the police.

Both methadone and buprenorphine are schedule 8 medications and are therefore subject to the *Poisons Act 1971* and its accompanying regulations. Prescribers and case managers have a responsibility to ensure public safety and should routinely review how clients store and manage their takeaway doses.

Regular and unexplained lost or stolen doses are a significant cause for concern. It may signal:

- a return to unsanctioned drug use;
- a change in the individual's psychosocial circumstances;
- diversion of takeaway doses; or
- intimidation by others seeking illicit methadone or buprenorphine.

Prescribers and case managers should discuss with the client the circumstances of any lost doses. As the secure storage of medication is a requirement for access to takeaway doses, the client's suitability for unsupervised dosing should be reviewed. A return to daily supervised dosing is recommended until the client is able to demonstrate improved stability following a trial period.

As outlined in the section 12.9.6 (Frequently missed doses), regular and unexplained missed doses may sometimes indicate that opioid pharmacotherapy is an unsuitable treatment option. Prescribers are advised to review the client's suitability for the program and to explore the risks and benefits of continuing or discontinuing treatment with them. Decisions about treatment cessation should be made with the input and advice of the multidisciplinary team and the ADS Clinical Director. Private prescribers should also seek the advice and guidance of the ADS in these situations.

12.11.2 Consumption of methadone/buprenorphine by a child

Ingestion of methadone or buprenorphine is extremely dangerous for a child. These drugs are potentially fatal when consumed, even in small quantities. Such a situation is a medical emergency, and is best managed by emergency services.

The ingestion of methadone or buprenorphine by a child is a medical emergency and must be managed by emergency services on 000.

The circumstances in which ingestion by a child may occur include:

- failure of clients to secure takeaway doses adequately; and
- deliberate administration of the substance to a child by a client or other child.

Recommended Procedure in case of Actual or Suspected Ingestion by a Child:

- assess the level of consciousness and monitor this continuously until the child is in the care of ambulance or other qualified staff;
- refer the child to a hospital emergency department without delay, providing as much information as possible regarding the amount and time of ingestion;
- administer oxygen if available;
- give consideration to the administration of naloxone in circumstances where the child is displaying signs of respiratory depression. Any treatment given should be documented;
- notify the prescriber, the PSB and the Alcohol and Drug Service of the incident.

In the event of depression of respiratory or cardiac function:

- establish a clear airway;
- begin assisted or controlled ventilation with oxygen;
- intravenous fluids and other supportive measures should be employed as indicated; and
- the long duration of action of buprenorphine should be taken into consideration when determining the length of treatment needed to reverse the effects of an overdose.

As a result of the prolonged half-life of methadone and buprenorphine there may be a delay in the onset of symptoms of overdose. For this reason prolonged observation (a minimum of 24 hours) is required for a child suspected of overdose.

As a result of the prolonged half-life of methadone and buprenorphine longer observation (a minimum of 24 hours) is required for a child suspected of overdose.

If a child has ingested methadone or buprenorphine, the child has been placed at risk of harm and the appropriate authorities must be notified. Child Protection Services should be notified as a matter of priority by phoning 1300 737 639 (24 hours). Tasmania Police may become involved at the request of Child Protection or if urgent action or assistance is sought by the notifier.

In the case that a child has ingested methadone or buprenorphine by any means, the child has been placed at significant risk of harm and the appropriate authorities must be notified.

12.11.3 Consumption of methadone or buprenorphine by a non-opioid dependent adult

As with children, the consumption of methadone or buprenorphine (outside of a clinical setting or without clinical advice and direction) by a non-opioid dependent individual is dangerous and can result in overdose and death. The same medical emergency procedures should be followed as outlined for children. However, consideration should also be given to the possible recent use of other substances, in particular other opioids, alcohol or benzodiazepines.

The ingestion of methadone or buprenorphine by a non-opioid dependent adult is a medical emergency and must be managed by emergency services on 000.

12.12 Managing overdose

An overdose is a medical emergency and must be managed by emergency services on 000

Symptoms of opioid overdose may last for 24 hours or more, depending on the opioid used. Death generally occurs from respiratory depression. Signs and symptoms of opioid overdose include:

- pinpoint pupils;
- nausea;
- dizziness;
- feeling intoxicated;
- sedation/loss of consciousness (nodding off);
- unsteady gait, slurred speech;
- snoring;
- hypotension;
- slow pulse (bradycardia);
- shallow breathing (hypoventilation);
- frothing at the mouth (pulmonary oedema); and
- coma.

Symptoms of opioid overdose may last for 24 hours or more. Death generally occurs from respiratory depression.

12.12.1 Methadone

In Australia, the delivery of opioid pharmacotherapy is very safe. However deaths can occur during stabilisation on methadone. These are usually associated with the concurrent use of other drugs, particularly alcohol, benzodiazepines, and antidepressants (Henry-Edwards et al., 1993). Naloxone promptly reverses opioid induced coma and should be administered as a prolonged infusion when treating methadone overdose. It is insufficient to administer a single dose as it will wear off within one hour, leaving clients at risk of relapse into coma as a result of the long lasting effects of methadone. Prolonged observation is required for those clients suspected of overdose (at a minimum 12 hours).

As a result of the prolonged half-life of methadone and buprenorphine longer observation (a minimum of 12 hours) is required for an adult suspected of overdose.

12.12.2 Buprenorphine

For opioid tolerant individuals, the risk of lethal overdose on buprenorphine is lower than for other opioids such as methadone. Buprenorphine has a high affinity for μ (mu) opioid receptors, and is not easily displaced by the antagonist, naloxone. Doses of 10 – 30 times the normal naloxone dose used to reverse heroin overdose (up to 10 – 35mg/70kg) may be required to partially reverse the effects of buprenorphine toxicity. Conversely, cases have also been reported where much smaller doses (2-4mg) of naloxone have been effective in reversing the effects of buprenorphine.

In the event of depression of respiratory or cardiac function:

- establish a clear airway;
- begin assisted or controlled ventilation with oxygen;
- intravenous fluids and other supportive measures should be employed if available and appropriate as indicated; and
- the long duration of action of buprenorphine should be taken into consideration when determining the length of treatment needed to reverse the effects of an overdose.

12.13 Boundary violation and boundary crossing

The term 'boundary' is defined as the edge of appropriate professional behaviour (Gutheil & Gabbard, 1998). Boundaries help to create an environment of safety and predictability within which the therapeutic relationship can develop. An understanding of professional boundaries and ethical practice is essential for working with clients in the opioid pharmacotherapy program. Professionals must be aware of departures from good practice and how such departures can be prevented or addressed.



Serious boundary violations often begin with less serious departures from accepted practice. Gutheil and Gabbard (1998) discuss a number of examples of boundary crossings or violations, including:

- giving or accepting gifts to or from a client;
- self disclosure of the clinician during treatment;
- the use of threats by the clinician;
- inappropriate physical contact with the client;
- meeting with the client outside of the treatment setting; and
- providing the client with access to personal mobile or home phone numbers.

Following correct or agreed procedure is an essential part of professional integrity, objectivity, and ethical practice. Abiding by correct procedure is one way in which a practitioner expresses respect for clients and fellow colleagues. Bypassing procedure and disregarding professional boundaries can introduce inequality and exploitation of clients.

Boundary violations and unprofessional behaviour by clinicians can result in significant harm to clients, including psychological, physical and sexual harms. Care must be taken that the client does not develop a relationship with their case manager based upon over attachment and/or idealisation. Clinical interventions must be provided within the scope of clinical practice and the resources available. Exploitation of clients can also reinforce long held feelings of worthlessness and abandonment and can increase their risk of engaging in high risk behaviours including self-harm.

Clients should receive respectful and professional treatment from professionals within the program, which literally means equal attention to all clients and in accord with professional standards of practice.

12.14 Professional reporting

If the client is a registered health care professional, there are mandatory reporting requirements as part of The Health Practitioners Regulation National Law (see Section 14 Legislative Requirements).

When there is evidence that a health practitioner may be practising in a manner that may put clients at risk of harm, including practising under the influence of drugs and/or alcohol, there is a requirement to notify the Australian Health Practitioner Regulation Agency (AHPRA).

Health professionals are strongly encouraged to contact the Australian Health Practitioner Regulation Agency (1300 419 495) to seek advice and guidance in relation to these issues. Within the ADS, these complex clinical issues should be reviewed by the multidisciplinary team with the involvement of senior managers and where appropriate the Clinical Director, ADS. Private practitioners involved in the delivery of the Tasmanian OPP are also encouraged to contact an Addiction Medicine Specialist within the ADS for support and advice.



SECTION: I3

Transfers

In this section you will...

- Be provided with the requirements for the management and coordination of transfers for the Tasmanian Opioid Pharmacotherapy Program.

I3	Transfers	170
I3.1	Prescribing across Australian jurisdictions	170
I3.2	Unsanctioned transfers	170
I3.3	Clients travelling to Tasmania	171
I3.3.1	Transfers of clients into the Tasmanian OPP	171
I3.4	Intrastate transfers of Tasmanian opioid pharmacotherapy clients	174
I3.4.1	Temporary transfer within Tasmania	175
I3.4.2	Permanent transfer of clients within Tasmania	176
I3.5	Interstate transfers of Tasmanian opioid pharmacotherapy clients	176
I3.5.1	Temporary interstate transfer	178
I3.5.2	Permanent interstate transfer	179
I3.6	Overseas travel	179
I3.7	Transfer of dosing location	180
I3.7.1	Sharing of Information	181

Section: 13

13 Transfers

13.1 Prescribing across Australian jurisdictions

Recent health reforms at a national level have led to a proposed agreement that allows prescriptions written by nationally registered medical practitioners to be recognised in other states. Tasmania has chosen not to support this agreement and therefore the legislation and regulations of the Tasmanian jurisdiction should be observed. Consequently, in Tasmania, prescriptions for opioid pharmacotherapy from other jurisdictions (states and territories) will not be recognised (refer Section 15.2.1 Authority to Treat a Patient).

While it is accepted that prescriptions written by nationally registered medical practitioners are recognised in some states, the TOPP does not recommend continued prescribing by Tasmanian prescribers for either temporary or permanent interstate transfers.

Prescriptions for opioid pharmacotherapy from other jurisdictions (states and territories) are not recognised in Tasmania.

Misuse of prescription opioids occurs in Tasmania, as it does in other Australian jurisdictions. In addition, prescription fraud and 'doctor' or prescription shopping have also been reported. The prescription of opioids and other drugs of dependence in Tasmania is subject to regulatory requirements under the Poisons Act 1971. Dispensing pharmacists are also required to comply with Tasmanian regulations in relation to opioids.

In addition, there are restrictions in relation to the dispensing and supply of certain scheduled substances that have been prescribed by a medical practitioner in other Australian jurisdictions. These restrictions apply to Schedule 8 (narcotic) substances and Declared Restricted Substances (S4D's).

All opioid pharmacotherapy medications are Schedule 8; therefore, these restrictions apply to all prescriptions for buprenorphine and methadone.

13.2 Unsanctioned transfers

An unsanctioned transfer occurs when a client already registered on the opioid pharmacotherapy program presents to another prescriber (usually in a different state or town) requesting treatment, and no arrangements have been made to facilitate a transfer. It is not uncommon for this to occur without the prescriber's knowledge, particularly if a client has poor planning and organisational skills or when their social circumstances have become chaotic.

The National Pharmacotherapy Policy for People Dependent on Opioids (2007) specifies that transfers should be arranged in accordance with the relevant state policy and procedures and should not occur until arrangements between the prescribers have been finalised. Unsanctioned transfers of clients already registered for pharmacotherapy services in other states or towns will not be accepted by the Tasmanian opioid pharmacotherapy program. Clients will be advised to return to their opioid treatment provider and to make the necessary arrangements for a transfer.

Unsanctioned transfers will not be accepted and clients will be advised to return to their opioid treatment provider.

If a client chooses not to return to their treatment provider and to cease opioid maintenance treatment, withdrawal medications for symptomatic relief should not be provided. Opioid maintenance treatment is the most effective treatment for clients who are opioid dependent and for this reason clients should be encouraged to continue on the opioid pharmacotherapy program. This approach has been adopted because withdrawal management is not evidence-based or considered an

effective treatment for people who are opioid dependent. This is because many opioid dependent people who attempt to withdraw rapidly often relapse to opioid use or dependence. In addition they are at a high risk of potential overdose as a result of changes in tolerance levels (Kenny et al., 2009).

The only situation where an unsanctioned transfer may be accepted for management would be on compassionate grounds. These circumstances would need to be substantiated by a relevant authority or health practitioner. If the unsanctioned transfer is accepted, a process will immediately be initiated with the prescriber to ensure that detailed clinical information is urgently provided to support a safe transfer of care. This must occur before any treatment is commenced.

13.3 Clients travelling to Tasmania

From 1 July 2010, a client's pharmacotherapy prescriber must be practising (i.e. consulting the client) within Tasmania. Consistent with this, opioid pharmacotherapy prescriptions will not be recognised from any other jurisdiction. Only methadone and buprenorphine prescriptions that are issued in the state of Tasmania are considered valid in Tasmania. All clients from interstate wishing to travel to Tasmania will be required to secure a Tasmanian prescriber through an interstate transfer prior to their arrival.

Only methadone and buprenorphine prescriptions issued in the state of Tasmania are considered valid in Tasmania.

13.3.1 Transfers of clients into the Tasmanian OPP

Requests for temporary or permanent transfer of interstate clients to the Tasmanian Opioid Pharmacotherapy Program (OPP) are accommodated as efficiently as possible within time and resource constraints.

Transfers to the Tasmanian OPP are managed by the ADS opioid pharmacotherapy program. This includes transfers to Tasmania from other states or countries. The public program has the capacity to manage the administrative tasks associated with a transfer through their case management systems. They can also provide information to interstate prescribers and clients about the Tasmanian program requirements, and assess, review and monitor new clients during the vulnerable transition period following transfer.

All interstate transfers to Tasmania are managed by the Tasmanian Alcohol and Drug Service opioid pharmacotherapy program.

All transfers to the Tasmanian OPP are treated in the same way as a new referral. This means that clients requesting admission may not get immediate access to the program and cannot be guaranteed a position. Access to the program is prioritised (as detailed in Section 2), and during times of increased demand there may be a waiting period as a result of the small number of prescribers and dosing pharmacies in Tasmania. Unsanctioned transfers of clients already registered for pharmacotherapy services in other states or towns will not be accepted by the Tasmanian opioid pharmacotherapy program; see Section 13.7

Transfers to the Tasmanian public opioid pharmacotherapy program cannot be guaranteed.

Treatment is provided according to the assessment of medical urgency, potential to benefit, and on the basis of the principle of fairness. This ensures those who present first get treated first and prevents people jumping the queue (except when this is warranted for clinical or public health reasons or on compelling compassionate grounds. Examples include pregnant women, persons recently released from prison, clients with HIV, and in cases where substantiated family bereavement has taken place).

Clients already receiving opioid pharmacotherapy treatment in their home state are advised to remain with their present prescriber until all the necessary transfer arrangements have been made. This may prevent the client being disappointed when advised that they must return home immediately to continue treatment.

A temporary transfer to or from the Tasmanian OPP is generally for a period of no more than 4 weeks, with any extension being at the discretion of the prescribing doctor.

A temporary transfer to or from the Tasmanian opioid pharmacotherapy program is generally for a period of no more than 4 weeks.

The following steps should be followed to process a transfer to the program.

Step 1 – Formal referral: Request for referral to the Tasmanian OPP

A formal referral from a clinician is required prior to the acceptance of a temporary or permanent transfer to Tasmania. Clients who contact the Tasmanian OPP to request a transfer should be advised to discuss the request with their treating doctor or case manager.

A temporary or permanent transfer request must be received four weeks prior to the requested transfer appointment date. Clinicians wanting to make a referral can access the Request for Transfer to the Tasmanian Opioid Pharmacotherapy Program form or contact the

Alcohol and Drug Services to request a form to be faxed or emailed directly to them.

A temporary or permanent transfer request must be received 4 weeks prior to the transfer date.

Requirements for entry into the program should be discussed with the referrer. Access to these guidelines may be of assistance in outlining the program requirements to the referrer.

The transferring clinician will also need to ensure that the client has read and signed the Tasmanian OPP Treatment Agreement (Appendix 5). Clients should be made aware that a temporary transfer is limited to four weeks and does not constitute a permanent transfer. This is important, as the request for transfer cannot be considered without this signed documentation.

The Tasmanian OPP Treatment Agreement details the Tasmanian guidelines for the delivery of opioid pharmacotherapy. Clients must be made aware of the program guidelines including:

- limitations on takeaway doses;
- restrictions relating to the prescribing of benzodiazepines and the potential requirement for participation in a reduction regimen;
- frequency of medical and case management reviews; and
- urine drug screening requirements.

The transferring clinician should ensure that the client has read and signed the Tasmanian opioid pharmacotherapy program treatment agreement.

The completed forms should then be faxed or emailed back to the clinic to which the transfer is being requested. The client cannot be considered for transfer to Tasmania unless both forms are completed.

Step 2 – Review of request for transfer to Tasmanian OPP

The referral is then reviewed by a Tasmanian OPP case manager; usually the same staff member who has dealt with the initial request. The case manager reviews the completed Request for Transfer form to assess whether the client meets the Tasmanian OPP admission criteria. The potential Tasmanian prescriber or case manager should also examine any existing client files or contact data (if available) and phone the Pharmaceutical Services Branch (PSB) to check whether the client has previously been registered on the Tasmanian OPP.

If the client has previously been registered on the program in Tasmania, the client's clinical file is retrieved and reviewed, paying particular attention to:

- clinical safety, including polysubstance and injecting drug use;
- treatment efficacy;
- outstanding pharmacy debt;
- poor treatment compliance, including repeated missed doses;
- code of conduct violations;
- comorbid diagnoses, including mental illness and pain presentations; and
- matters relating to child protection or care of children.

As stated in previous sections, clients accessing opioid pharmacotherapy will often have complex presentations. However, caution is required when accepting transfers to the Tasmanian OPP, particularly if the client has not been adequately assessed or has been managed in a program with different safety standards.

Step 3 – Clinical team review of request for transfer

The case is referred to the clinical team (which includes at least one ADS Addiction Medicine Specialist) for a discussion. Consideration should be given to particular issues or concerns about:

- clinical safety, including poly-substance and injecting drug use;
- treatment efficacy;

- client behaviour, including aggression or clinical misconduct;
- the client's current dose exceeding the upper limits of doses approved in Tasmania (See Section 8);
- split dosing, which is not approved in Tasmania; and
- clients using benzodiazepines with doses exceeding the upper limits of that approved by the Tasmanian OPP.

Step 4 – Communicating with the referrer

Regardless of the outcome of the Request for Transfer, it is essential to ensure that timely and clear information is provided to the referrer. If a client is to be accepted into the program, this should be communicated as soon as possible to the referring Clinician. Requirements for entry into the program should again be discussed with the referrer.

If a client is accepted, a formal transfer letter should be requested from the referrer.

This letter should detail:

- current and previous drug use;
- duration and treatment compliance;
- current treatment/management plan;
- clinical and/or behavioural safety issues;
- medical history including current medications;
- mental health history;
- personal and family history;
- social circumstances; and
- legal issues.

A comprehensive transfer from the referrer must be provided for the client to be accepted for transfer.

Step 5 – Stabilisation of client

Prior to accepting a transfer, staff from the Tasmanian OPP must ensure that the client is clinically stable. If the clinical team have identified issues in relation to client stability or current treatment practices that are not consistent with the guidelines of the Tasmanian OPP, these issues and any proposed necessary changes in treatment should be discussed with the prescriber. Every effort should be made to ensure the stability of the client and to prepare them for any changes in their usual treatment regimen that may be required as a result of their transfer to the Tasmanian OPP.

Clients with hazardous polysubstance use may also require stabilisation and documented clinical and laboratory evidence of this stability (e.g. results of clinical examination or urine drug screen). This allows the Tasmanian OPP treating team to plan appropriate treatment options prior to the client's presentation.

Step 6 – Arranging an appointment

If the client is accepted for transfer into the program, the case manager or prescriber books the client an appointment for registration on the Tasmanian OPP. Prior to transfer, the following documents are to be provided to the client (via their referrer):

- Information for Clients Transferring to the Tasmanian OPP – which contains information about the client's initial appointment time and how to access the clinic;
- Tasmanian OPP Information for Clients; and

For copies of these documents contact the Alcohol and Drug Service.

Step 7 – At the appointment

At the initial transfer appointment, the client will need to:

- complete a Consent to Treatment form (for a copy of this form, contact the Alcohol and Drug Service);
- have a full assessment undertaken including a urine drug screen; and
- have a photograph taken and introductory information for the dosing pharmacy prepared.

A change of prescriber can sometimes be a stressful life event. For this reason it is important to ensure that newly transferred clients are closely monitored and reviewed regularly by the prescriber and case manager.

13.4 Intrastate transfers of Tasmanian opioid pharmacotherapy clients

Clients seeking a temporary or permanent transfer of treatment or dosing arrangements should give their case managers or prescribers as much notice as possible of their request. To allow for sufficient time to complete administrative tasks associated with transfers, notice of 1 week is required.

Transfers requests outside these timeframes cannot be guaranteed. If there is clear evidence of an emergency or urgent circumstance requiring unscheduled travel, prescribers and case managers will endeavour to complete transfers promptly.

Requests for transfer to another service should preferably be made in writing and addressed to the case manager or prescriber. A request should clearly outline the following information:

- destination(s);
- dates of travel;
- departure and arrival times;
- planned stopovers;
- mode of transport;
- addresses for accommodation; and
- any other relevant supporting documentation.

The client's prescriber must be notified of any proposed transfer as legal responsibility rests with them. If a client wishes to change their arrangements before departure, they must give their case manager at least 48 hours (two working days) notice.

Ideally, the case manager who organises a temporary transfer should contact the clinic or prescriber and dispensing pharmacist at the end of the transfer period to check that the transfer arrangements were successful.

If any breach (e.g. dose diversion) is reported,

this should be clearly recorded in the client's file and acted upon as if it had occurred within the local Tasmanian OPP program. In such a case, any future request for a temporary transfer must first be carefully reviewed and endorsed by the team or prescriber before being granted.

13.4.1 Temporary transfer within Tasmania

The procedure for a temporary intrastate transfer of a client is as follows:

- Discuss the client's travel plans with the client and photocopy any relevant documentation such as bus tickets;
- Contact the opioid treatment clinic or private prescriber nearest the address at which the client will be staying. Request that the client be accepted as a temporary transfer and secure an appointment date and time. Ascertain whether there are any special conditions or other information that the client needs to be aware of;
- Fax or email a transfer letter to the new clinic or prescriber and send the original by post. This letter should include the client's methadone or buprenorphine dose, length of time on the opioid treatment program, takeaway doses permitted, date and time of appointment with new clinic or prescriber and personal identifying details. It may also include any information that the clinic has requested, e.g. Medicare card, Health Care card, driver's licence;
- A referral letter, preferably written by the current prescribing doctor, should be sent to the new clinic or prescriber outlining the client's drug use history, medical history, opioid treatment program compliance, general conduct and treatment progress. This should be mailed to the new clinic or prescriber. This letter may also be faxed or emailed if the new clinic or prescriber requests;
- If required by the temporary clinic or prescriber, contact the nearest dosing pharmacy and request dosing of the client (this is occasionally requested by private prescribers);
- The client will need to collect a copy of the transfer letter to present to the temporary clinic or prescriber. Inform the client that unless this letter is collected prior to departure and they have photo identification such as drivers licence, 18+ card or passport, the transfer will not proceed;
- The prescriber must complete a *Notification of termination of Methadone/ Buprenorphine treatment* form and forward it to PSB. Failure to forward this termination form precludes the patient from pharmacotherapy or other drugs of dependence treatment by another practitioner;
- The new prescriber must make a new application for authority, and this will only be approved once the previous authority is terminated. These procedures ensure that a patient does not receive pharmacotherapy from two prescribers concurrently;
- Cancel the prescription and dispensing from the client's usual pharmacy from the appropriate date, and advise the pharmacist not to dose the client until requested by the usual prescriber to recommence dosing. These arrangements should be confirmed with the pharmacist in writing. Include the pharmacist's name when writing notes;
- Advise the client to contact the usual prescriber or case manager upon returning and before recommencing dosing at their usual pharmacy;
- Prior to the client recommencing dosing at their usual pharmacy, contact the temporary clinic/prescriber to request information about the transfer and any concerns that there may have been regarding the client. Confirm the date of the client's last dose;
- Forward a written request to the usual pharmacy to recommence dosing the client; and
- Documentation of the procedure for intrastate transfer is to be completed in the progress notes.

13.4.2 Permanent transfer of clients within Tasmania

The procedure for permanent intrastate transfer of a client is as follows:

- Discuss the client's travel plans with the client and photocopy any relevant documentation such as bus tickets;
- Contact the clinic or private prescriber nearest the address at which the client will be staying. Request that the client be accepted as a permanent transfer and secure an appointment date and time. Ascertain whether there are any special conditions or other information that the client needs to be aware of;
- Request clear written instruction from the receiving clinic to ensure these requirements can be met and communicate this clearly to the client;
- Fax a transfer letter to the new clinic or prescriber and send the original by post. This letter will include the client's methadone or buprenorphine dose, length of time on the opioid treatment program, takeaway doses permitted, date and time of appointment with new clinic or prescriber and personal identifying details. It may also include any information that the clinic has requested, e.g. Medicare card, Health Care card, driver's licence, etc;
- A referral letter, preferably written by the current prescribing doctor, should be sent to the new clinic or prescriber outlining the client's drug use history, medical history, opioid treatment program compliance, general conduct and treatment progress. This should be mailed to the new clinic or prescriber. This letter may also be faxed or emailed if the new clinic or prescriber requests;
- The client will need to collect a copy of the transfer letter to present to the new clinic/prescriber. Inform the client that unless this letter is collected prior to departure and they have photo identification such as a drivers licence, 18+ card or passport, the transfer will not proceed;
- Cancel the prescription and dispensing from the client's usual pharmacy from the appropriate date and advise the pharmacist in writing not to dose the client again. Include the pharmacist's name and the date of the client's last pick-up dose in the notes;
- Contact the new clinic/prescriber following the allocated appointment time to ensure that the client presented and was seen; and

The prescriber must complete a *Notification of termination of Methadone/Buprenorphine treatment* form and forward it to PSB. Failure to forward this termination form precludes the patient from pharmacotherapy or other drugs of dependence treatment by another practitioner.

The new prescriber must make a new application for authority, and this will only be approved once the previous authority is terminated. These procedures ensure that a patient does not receive pharmacotherapy from two prescribers concurrently.

13.5 Interstate transfers of Tasmanian opioid pharmacotherapy clients

Clients seeking a temporary or permanent transfer of treatment arrangements should give their case managers or prescribers as much notice as possible of their request. To allow for sufficient time to complete administrative tasks associated with transfers, notice of 4 weeks is required.

Interstate transfers of Tasmanian opioid pharmacotherapy clients to other states are the responsibility of the prescriber. However, the ADS opioid pharmacotherapy program is able to assist private prescribers with more complex transfers involving international travel.

While it is accepted that prescriptions written by nationally registered medical practitioners are recognised in some states, the TOPP does not recommend continued prescribing by Tasmanian prescribers for interstate transfers.

For both temporary and permanent interstate transfers, it is recommended that the client should be transferred to a prescriber in that jurisdiction. This policy places an emphasis on

risk management and clinically safe delivery of opioid pharmacotherapy.

The Tasmanian Opioid Pharmacotherapy Program, Policy and Clinical Practice Standards does not recommend continued prescribing by Tasmanian prescribers for temporary or permanent interstate transfers.

The Tasmanian Opioid Pharmacotherapy Program, Policy and Clinical Practice Standards recommends transfer to another prescriber in that jurisdiction.

The provision of opioid prescriptions for clients travelling interstate (even for short periods of time) reduces the capacity of the Tasmanian prescriber to safely deliver opioid pharmacotherapy. The geographical separation of client and prescriber means that the prescriber is unable to:

- urgently review and examine the client;
- assess the client for concurrent opioid or other polysubstance use; and
- closely monitor treatment compliance.

The provision of opioid pharmacotherapy outside the client's state of origin exposes the client to significant risk, as the usual regulatory constraints that restrict or prohibit access to prescriptions for other opioids and benzodiazepines in the state of origin are no longer in place. This means that clients registered on opioid pharmacotherapy in Tasmania can obtain these same medications in another jurisdiction, therefore placing them at risk of a serious adverse event including overdose and death.

The provision of opioid prescriptions for clients travelling interstate reduces the capacity of the prescriber to safely delivery opioid pharmacotherapy.

When the policy of another jurisdiction prohibits an interstate transfer (e.g. some jurisdictions no longer accept temporary transfers) an interstate prescription should ONLY be provided for a limited period of time (no more than 2 weeks).

The TOPP recommends that a decision to provide an interstate prescription for opioid pharmacotherapy should be made in consultation with the Tasmanian Alcohol and Drug Service. A rationale for the decision and a detailed management plan should be developed and documented in the clinical record.

The decision to provide an interstate prescription for opioid pharmacotherapy should be made in consultation with the Tasmanian Alcohol and Drug Service.

Safe storage of takeaway doses cannot be assured while travelling. As a result of the increased risks associated with transfers, daily supervised dosing is recommended where no interstate prescriber can be sourced. Takeaway doses should only be provided in exceptional circumstances, when there is restricted access to daily dosing, and should be determined in consultation with the Alcohol and Drug Service.

As a result of the increased risks associated with transfers, daily supervised dosing is recommended where no interstate prescriber can be sourced.

Even where a prescriber can be sourced for temporary transfers, the provision of takeaways is not recommended. This is because of difficulties securing takeaway doses while travelling and the increased risk that is associated with change and transitions in care. This policy is consistent with the TOPP guidelines that restrict the provision of takeaway doses for all clients transferring into the Tasmania Opioid Pharmacotherapy Program.

Even where a prescriber can be sourced for temporary transfers, the provision of takeaways is not recommended.

13.5.1 Temporary interstate transfer

A temporary transfer from the Tasmanian OPP is generally for a period of no more than 4 weeks, with any extension being at the discretion of the prescribing doctor.

The procedure for a temporary transfer of a client to another state is as follows:

- Discuss the client's travel plans with the client and photocopy any relevant documentation such as plane, bus or rail tickets;
- Contact the opioid treatment clinic or private prescriber nearest the address at which the client will be staying. Request in writing that the client be accepted as a temporary transfer and secure an appointment date and time. Ascertain whether there are any special conditions or other information that the client needs to be aware of;
- Fax or email a transfer letter to the new clinic or prescriber and send the original by post. This letter will include the client's methadone or buprenorphine dose, length of time on the opioid treatment program, takeaway doses permitted, date and time of appointment with new clinic or prescriber and personal identifying details. It may also include any information that the clinic has requested, e.g. Medicare card, Health Care card, driver's licence;
- A referral letter, preferably written by the current prescribing doctor, should be sent to the new clinic or prescriber outlining the client's drug use history, medical history, opioid treatment program compliance, general conduct and treatment progress. This should be mailed to the new clinic or prescriber. This letter may also be faxed or emailed if the new clinic or prescriber requests;
- If required by the temporary clinic or prescriber, contact the nearest dosing pharmacy and request dosing of the client (this is occasionally requested by private prescribers);
- The client will need to collect a copy of the transfer letter to present to the temporary clinic or prescriber. Inform the client that unless this letter is collected prior to departure and they have photo identification such as drivers licence, 18+ card or passport, the transfer will not proceed;
- Cancel the prescription and dispensing from the client's usual pharmacy from the appropriate date and advise the pharmacist not to dose the client until requested by the Tasmanian prescriber or case manager. These arrangements should be confirmed with the pharmacist in writing. Include the pharmacist's name when writing notes;
- Advise the client to contact their Tasmanian prescriber or case manager upon returning and before recommencing dosing at their usual pharmacy;
- Prior to the client recommencing dosing at their usual pharmacy, contact the temporary clinic or prescriber to request information about the transfer and any concerns that there may have been regarding the client. Confirm the date of the client's last dose;
- Forward a written request to ask the usual pharmacy to recommence dosing the client; and
- Documentation of the procedure for interstate transfer is to be completed in the progress notes.

13.5.2 Permanent interstate transfer

The procedure for permanent interstate transfer of a client is as follows:

- Discuss the client's travel plans with the client and photocopy any relevant documentation such as plane, bus or rail tickets;
- Contact the clinic or private prescriber nearest the address at which the client will be staying. Request that the client be accepted as a permanent transfer and secure an appointment date and time. Ascertain whether there are any special conditions or other information that the client needs to be aware of;
- Request clear written instructions from the receiving clinic to ensure these requirements can be met and communicate this clearly to the client;
- Fax a transfer letter to the new clinic or prescriber and send the original by post. This letter will include the client's methadone or buprenorphine dose, length of time on the opioid treatment program, takeaway doses permitted, date and time of appointment with new clinic or prescriber and personal identifying details. It may also include any information that the clinic has requested, e.g. Medicare card, Health Care card, driver's licence, etc;
- A referral letter, preferably written by the current prescribing doctor, should be sent to the new clinic or prescriber outlining the client's drug use history, medical history, opioid treatment program compliance, general conduct and treatment progress. This should be mailed to the new clinic or prescriber. This letter may also be faxed or emailed if the new clinic or prescriber requests;
- The client will need to come in and pick up a copy of the transfer letter to present to the new clinic/prescriber. Inform the client that unless this letter is collected prior to departure and they have photo identification such as drivers licence, 18+ card or passport, the transfer will not proceed;
- Cancel the prescription and dispensing from the client's usual pharmacy from the appropriate date and advise the pharmacist not to dose the client again. These arrangements should be confirmed in writing to the pharmacist. Include the pharmacist's name and the date of the client's last pick-up dose in the notes;
- Contact the new clinic/prescriber following the allocated appointment time to ensure that the client presented and was seen; and
- De-register the client from the Tasmanian OPP. This should be completed within 5 days; and
- The prescriber must complete a *Notification of termination of Methadone /Buprenorphine treatment* form and forward it to PSB. Failure to forward this termination form precludes the patient from pharmacotherapy or other drugs of dependence treatment by another practitioner.

13.6 Overseas travel

Transfers for Tasmanian opioid pharmacotherapy clients to other countries are the responsibility of the prescriber. However, the ADS opioid pharmacotherapy programs are able to assist private prescribers with more complex transfers involving international travel.

A client seeking an overseas transfer must first contact the relevant embassy or consulate to check on policies and requirements regarding the possession and use of methadone or buprenorphine in the countries they are travelling through or to. This information should then be given to the case manager organising the transfer. The client's prescriber must be notified of any proposed transfer as legal responsibility rests with them.

Clients planning overseas travel should give their case managers or prescribers as much notice as possible of their request. To allow for sufficient time to complete administrative tasks associated with transfers, notice of 4 weeks is required.

The procedure for permanent or temporary overseas transfer of a client is as follows:

- Discuss the client's travel plans with the client and photocopy any relevant documentation such as plane tickets (the client should clearly outline the destination(s), dates of travel, departure and arrival times, planned stopovers along the way, the mode of transport, addresses for accommodation) and any other relevant supporting documentation;
- The client must contact the relevant embassy or consulate to check on policies and requirements regarding the possession and use of methadone or buprenorphine (takeaway doses) in the countries they are transiting through and travelling to, then provide this information to the case manager organising the transfer;
- Based on this information regarding possession and use of methadone or buprenorphine in the country the client will be transiting and travelling to, attempt to organise an agency that will accept the client during their transfer. Ask the client if they have any contacts in the country of destination that might be able to identify the nearest ATODS or private prescriber in that location and provide contact details. Also advise the client to inquire through the relevant embassy or consulate about the nearest ATODS or private prescriber. If the client and Tasmanian OPP staff are unable to identify an accepting transferring agency, the client will have to reconsider their options (i.e. change of destination of travel, reduction in dose prior to travel or deregistration);
- A referral letter, preferably written by the current prescribing doctor, should be prepared detailing current management and outlining the client's drug use history, medical history, opioid treatment program compliance, general conduct and treatment progress. This should be faxed/mailed/ emailed to the international prescriber. A copy of this letter should also be provided to the client;
- It is unacceptable to provide takeaway doses or support a client wishing to travel while clinically unstable; relevant laws related to the possession of takeaway doses must be considered, as must access to continuing treatment and most importantly, local regulatory and clinical requirements. Authorisation may be sought from the Clinical Director, Alcohol and Drug Service for increased numbers of takeaway doses in a very stable client where all relevant requirements of the receiving country have been attended to, including the provision of a letter from the prescriber; and
- There are web sites such as <http://www.indro-online.de/nia.htm> which is the Coordinating and Information Resource Centre for International Travel by Clients Receiving Methadone and other Substitution Treatments for Opiate Addiction ("The Travel Resource Centre"). This site provides information on countries that provide opioid substitution treatment. This provider is contactable by email on: INDROeV@t-online.de.

13.7 Transfer of dosing location

If a client has not changed prescriber but is to transfer between dosing sites within Tasmania, the PSB is to be notified by phone immediately of the change. To avoid the potential for double dosing, the prescriber should notify the previous dosing site and have them cancel all prescriptions.

The procedure for temporary and permanent transfer of a dosing site within Tasmania is as follows:

- Discuss the client's travel plans with the client and photocopy any relevant documentation such as bus tickets. This should be copied and placed in the client record;

- Contact the dosing pharmacy nearest to the planned destination and forward a written request that the client be accepted for dosing. If necessary, contact the nearest opioid treatment clinic and obtain information about the nearest dosing pharmacy;
- Fax prescription(s) and a letter of introduction to the temporary pharmacy. This letter will contain a photograph of the client, the client's methadone or buprenorphine dose, date(s) of dose(s) required, and takeaway doses permitted. Send the originals by post within 24 hours;
- The client will need to collect a copy of the letter of introduction to present to the temporary pharmacy. Inform the client that unless this letter is collected prior to departure and they have photo identification such as drivers licence, 18+ card or passport, the transfer will not proceed;
- Cancel the prescription and dispensing from the client's usual pharmacy and advise the pharmacist not to dose the client until requested to recommence by the prescriber or case manager. These arrangements should be confirmed in writing to the pharmacist. Include the pharmacist's name when writing notes;
- Advise the client to contact their prescriber or case manager upon returning and before recommencing dosing at their usual pharmacy. This will allow the prescriber time to issue a new prescription;
- Prior to the client recommencing dosing at their usual pharmacy, contact the temporary pharmacy to request information about the dosing and any concerns that there may have been regarding the client. Confirm the date of the client's last dose and any takeaway doses that may have been dispensed;
- Forward a written request asking that the usual pharmacy recommence dosing the client; and
- Documentation of the procedure for pharmacy transfer is to be completed in the progress notes.

13.7.1 Sharing of Information

If possible, and with the client's consent, all relevant information about the client's clinical presentation and care should be made available to the receiving clinical service. This includes any significant or potential risks to the client, treatment providers and the community. A transfer cannot be accepted without the client's consent to release information, and the provision of such relevant clinical information.

A transfer cannot be accepted without the provision of relevant information and the client's consent to release information.

If client consent is not given, disclosing information to another person or organisation involved in the ongoing care of the client is possible, provided appropriate attention to confidentiality of this information is maintained. The giving and receiving of this clinical information is critical to the continuation of good clinical care and can be readily defended on the basis of each doctor's duty of care to the client and public safety. It is also essential to inform the clinical team's decision making processes and capacity to provide the level of care required by the client.

If a service provider lacks information about the previous treatment of a new client and initial assessment raises concerns about potential violence, he or she should contact the previous prescriber to determine the potential risk. In Tasmania PSB (phone (03) 6233 3293) can be contacted to find the name of the previous prescriber.

It is appropriate to delay the start of treatment until all the necessary information is available to make an informed decision about suitability for treatment.



SECTION: 14

Legislative requirements

In this section you will...

- Gain an overview of the different legislation that has a direct impact on the implementation and delivery of the Tasmanian Opioid Pharmacotherapy Program, Policy and Clinical Practice Standards; and
- Be provided with a brief summary of the key pieces of legislation, their implications for clinical service delivery and links to further information.

14	Legislative requirements	184
14.1	<i>Poisons Act 1971</i>	184
14.2	<i>Alcohol and Drug Dependence Act 1968</i>	185
14.3	<i>Mental Health Act 1996</i>	185
14.4	<i>Misuse of Drugs Act 2001</i>	186
14.5	<i>Guardianship Administration Act 1995</i>	186
14.6	<i>Children, Young Persons and Their Families Act 1997</i>	187
14.7	<i>Family Violence Act 2004</i>	188
14.8	<i>Personal Information Protection Act 2004</i>	188
14.9	<i>Right to Information Act 2010</i>	189
14.10	<i>Firearms Act 1996</i>	190
14.11	<i>Vehicle and Traffic Act 1999</i>	191
14.12	<i>Health Practitioners Regulation National Law (Tasmania) Act 2010</i>	191

Section: 14

14 Legislative requirements

There are a number of important pieces of legislation that have a direct impact on the implementation and delivery of the Tasmanian Opioid Pharmacotherapy Program, Policy and Clinical Practice Standards. In general these relate to: the regulation and prescribing of opioid pharmacotherapy; the provision of involuntary and emergency treatment; managing harm to self and others; public safety; individual capacity; and privacy and confidentiality. The following section provides a brief summary of these key pieces of legislation, their implications for clinical service delivery and links to further information.

14.1 Poisons Act 1971

The prescription and dispensing of opioids in Tasmania is subject to regulatory requirements under the *Poisons Act 1971*, which includes the prescribing of opioid medications and other drugs of dependence. Dispensing pharmacies are also required to comply with Tasmanian regulations in relation to opioids. This Act specifies the administrative guidelines for the prescribing and dispensing of opioid pharmacotherapy.

The prescription and dispensing of opioids and other drugs of dependence in Tasmania is subject to regulatory requirements under the Poisons Act 1971 and associated regulations.

There are restrictions in relation to the dispensing and supply of certain scheduled substances that have been prescribed by a medical practitioner in other jurisdictions (states and territories). These restrictions apply to Schedule 8 (narcotic) substances and Declared Restricted Substances (S4D's). All opioid pharmacotherapy medications fall within Schedule 8; therefore, these restrictions apply to all prescriptions for buprenorphine and methadone.

Prior to commencing treatment, the authorised prescriber must obtain authority for each client from the Pharmaceutical Services Branch (PSB) (Section 59E of the *Poisons Act, 1971*). An application, Authority to Administer, Prescribe Opioid Pharmacotherapies form (Appendix 13) must be forwarded to the PSB for approval to prescribe opioid pharmacotherapy. This authority issued to the practitioner is valid only for that client, and cannot be transferred.

Prior to commencing opioid pharmacotherapy treatment, the authorised prescriber must obtain authority from the Pharmaceutical Services Branch.

If the client leaves treatment or the prescriber ceases to treat the client for any reason, the prescriber is required to cancel the authorisation. This is done by sending a Notice of Termination of Methadone/Buprenorphine Treatment form (Appendix 14) to the PSB.

The Act prevents the issuing of an authority for that client from another prescriber until the termination notification is received. These procedures ensure that a client does not receive pharmacotherapy from two prescribers concurrently.

All clinicians involved in the delivery of opioid pharmacotherapy in Tasmania must be familiar with this Act, and in particular, with Sect 59E: Authority for making drugs available to certain clients.

14.2 Alcohol and Drug Dependence Act 1968

The *Alcohol and Drug Dependency Act 1968* (ADDA) makes provision with respect to the treatment and control of persons suffering from alcohol or other drug dependency. However, the ADDA does not expressly confer the power to compulsorily treat an individual.

Under the ADDA, a person may be detained in a treatment centre pursuant to an admission application. The ADDA distinguishes between admission applications initiated by a client (called a 'personal or voluntary application') and applications made by a relative or welfare officer (called an 'involuntary application').

The Alcohol and Drug Dependency Act 1968 does not confer the power to compulsorily treat an individual.

The Act is primarily used to regulate admission and detention of persons suffering alcohol or drug dependency.

An application for discharge can be made to the Alcohol and Drug Dependency Tribunal. The Tribunal has authority to hear and determine applications by clients or a relative of the client. It consists of five members, three of whom are medical practitioners, and two of whom are persons with suitable qualifications or experience.

The ADDA is currently under review because it contradicts contemporary alcohol and other drugs research, literature and practice. Numerous amendments have been made to the ADDA since it was first enacted in 1968 which have rendered it confusing and difficult to apply. The definitions contained within the ADDA are also outdated and therefore it is seldom used.

14.3 Mental Health Act 1996

Clients with an alcohol and drug dependency and a mental illness can be involuntarily detained in an approved hospital pursuant to the *Mental Health Act 1996* (MHA) provided the criteria are met. As the prevalence of individuals with comorbid mental health and substance use issues is relatively high, the nature of risk to self or others often becomes an issue for the alcohol and other drug sector (Mills et al., 2010) see Section 11.1 Comorbid Mental Health Disorders).

However there is a need to demonstrate that the person appears to have a mental illness within the meaning of the Act; namely that:

- there is, in consequence, a significant risk of harm to the person or others;
- the person's detention is necessary to protect the person or others; and
- the approved hospital is properly equipped and staffed for the care and treatment of the person.

The MHA does not provide authority for a person to be detained for treatment of their alcohol or drug dependence.

Under the Mental Health Act 1996, clients with an alcohol and drug dependency and a mental illness can be involuntarily detained for the purposes of treatment.

The Act does not provide authority for a person to be detained for the purpose of treating their alcohol or drug dependency.

A review of the MHA 1996 formally commenced in October 2006, and a new *Mental Health Act* is currently being developed as a result of feedback obtained through the review's consultation phase. The new Act will be based on the current MHA, but will have a focus on treatment as opposed to the current focus on detention.

14.4 Misuse of Drugs Act 2001

The purpose of this Act is to prevent and manage the misuse of drugs. Part 3, Minor Offences, has a number of divisions that have application to the opioid pharmacotherapy program:

Division 3: Possession, use and administration of a controlled drug:

Section 24: It is an offence to possess, use or administer a controlled drug to another person;

Division 4: Sale and supply of a controlled drug:

Section 26: It is an offence to sell or supply a controlled drug to another person;

Division 5: Miscellaneous, Section 28: Unlawful conduct in relation to prescriptions:

Section 28 (2) It is an offence to:

- (a) forge a prescription;
- (b) possess a prescription knowing it to have been forged or unlawfully altered;
- (c) utter a prescription knowing it to have been forged or unlawfully altered;
- (d) unlawfully alter a prescription;
- (e) obtain a prescription by means of conduct that the person knows to be false, misleading or deceptive, or
- (f) possess a blank prescription form without a lawful excuse

This legislation has implications for diversion; trading and selling of takeaway doses and also for the theft, forgery, changing or tampering of prescriptions (see Section 12 Managing Complex Presentations).

While there are no mandatory reporting provisions in this Act, health professionals have a duty of care to consider the potential risks for individuals and the community. If there is clear evidence of real and imminent risk to the individual or to the community as a result of these activities, a report should be made to Tasmania Police.

Clinicians are strongly encouraged to seek advice and guidance in relation to these complex

clinical matters. Within the ADS, these complex clinical issues should be reviewed by the multidisciplinary team with the involvement of senior managers and where appropriate the Clinical Director, ADS. Private practitioners involved in the delivery of the Tasmanian OPP are also encouraged to contact an Addiction Medicine Specialist within the ADS for support and advice.

14.5 Guardianship Administration Act 1995

The *Guardianship Administration Act 1995* (GAA) is a substitute decision-making framework for persons with a disability. The GAA establishes the Guardianship and Administration Board (GAB), and provides it with the authority to deal with financial and lifestyle matters for people with disabilities whose ability to make decisions is affected. The functions of the Board are extensive and include powers in relation to: the appointment of a guardian; the appointment of an administrator; enduring powers of attorney; emergency situations; and consent to medical or dental treatment and statutory wills.

Under the GAA, the GAB can:

- Appoint an administrator to control the financial affairs of a person with a disability for up to 3 years (Part 7 GAA);
- Appoint a guardian to make accommodation or health care decisions on behalf of a person with a disability for up to 3 years (Part 4 GAA);
- Give direct consent to specific medical treatment on behalf of a person with a disability (Part 6 GAA); and
- Appoint an emergency guardian or administrator for up to 28 days in urgent circumstances (Part 8 GAA).

The Guardianship Administration Act 1995 is a substitute decision-making framework for persons with a disability.

The Act is not applicable to a person who lacks capacity to make decisions because of alcohol or drug dependence only.

The provisions contained in Part 7 of the GAA (Administration Orders) are not applicable to a person who lacks the capacity to make decisions for him or herself because of an alcohol or drug dependency, unless there is also evidence of a disability such as acquired brain injury, dementia or depression. However, there are instances where the GAA may be applicable for some individuals with alcohol and other drug use issues related to acute physical and mental health disabilities (i.e., liver disease, diabetes, cardiovascular problems and cognitive impairment).

There are provisions within the GAA for such issues to be addressed via an Emergency Guardianship Application. Under both an emergency application and a full application, the GAB may appoint a guardian who may have the power to make decisions in relation to alcohol and drug treatment (Section 40 & Part 6 of the GAA).

14.6 Children, Young Persons and Their Families Act 1997

All health professionals in Tasmania have mandatory obligations to report concerns about the abuse or neglect of a child or unborn child under Section 14.3 of the *Children, Young Persons and Their Families Act 1997*. All registered health professionals are 'prescribed persons' and therefore should be familiar with this Act and of their mandatory obligation to report information relating to child abuse and neglect.

Section 53A provides certain protections for individuals who report concerns as required by the Act. Specifically, section 53A provides that a person providing information:

- (a) cannot, by virtue of providing the information, be held to have breached any code of professional etiquette or ethics, to have departed from any accepted standards of professional conduct or to have contravened any Act; and
- (b) to the extent that he or she has acted in good faith, incurs no civil or criminal liability in respect of providing the information.

The Act also provides some protection around the identity of a person who has made a report of abuse or neglect under the Act by preventing the person's identity from being disclosed in certain circumstances (section 16).

All health professionals in Tasmania have mandatory reporting obligations regarding concerns of abuse or neglect of children.

In relation to child protection, interventions with AOD clients who are parents involve monitoring the safety and wellbeing of children while delivering interventions to improve parents' lives (Marsh, Dale & Willis, 2007). During the assessment process, clinicians should aim to collect information to:

- Enhance the protection and care for children by accurately assessing and managing the potential risk of harm to a child in their client's care; and
- Improve the quality of life for parents by working in a multi-systemic manner with the parents to address other areas of difficulty that impact on their parenting capacities.

A routine element of clinical assessment should include inquiries regarding the child/ren's welfare and overall family wellbeing. These issues are best raised in the context of a supportive therapeutic relationship. If there are indicators of child protection concerns, the clinician has an obligation to carefully consider these and to consult with Child Protection Services (1300 737 639).

14.7 Family Violence Act 2004

The *Family Violence Act 2004* provides for the safety, psychological wellbeing and interests of people affected by family violence. In this Act 'family violence' includes any of the following types of conduct committed by a person (directly or indirectly,) against that person's spouse or partner:

- i. assault (including sexual assault);
- ii. threats, coercion, intimidation or verbal abuse;
- iii. abduction; and
- iv. stalking.

This includes attempting or threatening to commit such conduct and may also encompass any of the following:

- i. economic abuse;
- ii. emotional abuse or intimidation; and
- iii. contravening an external Family Violence Order, an interim Family Violence Order, a Family Violence Order or a Police Family Violence Order.

The Family Violence Act 2004 provides for the safety, psychological wellbeing and interests of people affected by family violence.

Individuals with substance use issues often have complex social circumstances. Alcohol and other drug use can have a significant impact on interpersonal and family relationships.

Trauma and family of origin abuse and neglect are often present in the lives of individuals with problematic substance use issues. For this reason clinicians involved in the delivery of the Tasmanian OPP should regularly review and assess the social circumstances of clients and give consideration to the safety and wellbeing of both the individual and the family (See Section 5).

All health professionals in Tasmania have a duty or obligation to report incidences of family violence. Tasmanian family violence legislation contains a mandatory reporting provision (Section 38), but the relevant section has not commenced. This means that reporting under

this Act is not mandatory. However, health professionals are encouraged to report these incidences to the Family Violence Referral and Response Line on 131 444.

The Act does provide some protections for those sharing information in relation to family violence and these are contained in Sect 39 (Protection from liability for voluntary or mandatory information).

A person who informs a police officer (through mandatory or voluntary reporting) that he or she believes, reasonably suspects or knows that family violence has occurred or is likely to occur, or who provides any further information to a police officer in respect of such belief, suspicion or knowledge is protected from liability by virtue of Section 39. A person who provides this information:

- (a) cannot, by virtue of doing so, be held to have breached any code of professional etiquette or ethics, or to have departed from any accepted form of professional conduct; and
- (b) insofar as he or she has acted in good faith, incurs no civil or criminal liability in respect of informing a police officer; or the provision of further information.

It is important to note that when children and young people are present in a family where an incident of family violence has been reported, an automatic notification is made under the *Children and Young Persons Act 1997*. Family violence is considered to be a form of child abuse. There is clear evidence that children and young people, who live with and experience family violence, can develop trauma similar to that of children and young people who grow up in a war zone or experiencing a natural disaster (Anthony 1988).

14.8 Personal Information Protection Act 2004

The *Personal Information Protection (PIP) Act 2004* regulates the collection, maintenance, use, correction and disclosure of personal information relating to individuals. Health professionals should always strive to maintain

client confidentiality, however, there are situations when workers will be required or permitted to break a client's confidentiality (i.e. conditions of exception).

The PIP Act 2004 regulates the collection, maintenance, use, correction and disclosure of personal information relating to individuals.

Schedule 1 of the Act (Sections 6, 9, 10, 11, and 16) provides information about the Use and Disclosure of information, including the circumstances under which information may be disclosed without seeking the consent of the individual. There are a number of circumstances in which this may be deemed necessary, however, there are several areas that are of particular interest to clinicians involved in the delivery of the Tasmanian OPP. It is important clinicians are aware that as personal information custodians, they are not to disclose information about an individual for a purpose other than what it was intended, unless:

- (d) the personal information custodian reasonably believes that the use or disclosure is necessary to lessen or prevent:
 - i. a serious threat to an individual's life, health, safety or welfare; or
 - ii. a serious threat to public health or public safety.
- (e) the personal information custodian has reason to suspect that unlawful activity has been, is being, or may be engaged in, and uses or discloses the personal information as a necessary part of its investigation of the matter or in reporting its concerns to relevant persons or authorities; or
- (f) the use or disclosure is required or authorised by or under law. See Schedule 1, 2.1: Use and Disclosure

The PIP Act 2004 guides and supports practitioners in making sound judgments about the timely and appropriate disclosure of information without consent. This Act supports the health practitioner to execute their duty of

care by setting out the provisions under which relevant information can be made available, to ensure the safe and appropriate treatment of the individual and public safety.

14.9 Right to Information Act 2010

The Right to Information Act 2010 (RTI) replaces the Freedom of Information Act 1991. The RTI provides members of the public with the right to obtain information, other than exempt information, contained in the records of the Government, and public authorities.

The Right to Information Act 2010 provides members of the public with the right to obtain information, other than exempt information, contained in the records of the government, and public authorities.

The Act:

- mandates greater proactive release of information by the Government;
- spells out the factors to be considered when applying the overarching public interest test;
- creates clear timelines for processing applications, if the information is not readily available; and
- increases the powers of the Ombudsman for external review and monitoring;

It should be noted that personal information, namely information that would identify a person, is generally categorised as exempt information under the RTI Act. On this basis while an application may be made for access to personal information, the applicant does not have a right to that information. Rather, an assessment would need to be made as to whether the information should be released.

14.10 Firearms Act 1996

The possession of firearms in Tasmania is governed by the *Firearms Act 1996*. This Act details the legal and license requirements associated with the possession, use, safe keeping, and disposal of firearms and the purchase and dealing in firearms. An application must be lodged to obtain a permit to possess a firearm in the state of Tasmania. There are certain restrictions associated with the granting of a license to possess a firearm: these are described in Division 5 (Applications), Sect 29 (General Restrictions on Granting License).

There are three sections of the Act that have application to health practitioners working in the alcohol and other drug sector. These relate to the restrictions associated with:

- the handling of firearms while under the influence of drugs;
- the disclosure of information relating to the safety of an individual to possess or use a firearm; and
- restrictions that may prohibit an individual from possessing or using a firearm.

All health practitioners have a responsibility to ensure the safety of their clients, their families and the community. Health professionals should be aware of their responsibilities relating to the disclosure of information relating to the possession and use of firearms where there is the potential risk for harm to the individual and the community.

Section 120 of the Act makes specific reference to the use of alcohol and other drugs and the restrictions relating to the use and handling of a firearm. It specifies that a person must not handle or use a firearm while the person is under the influence of alcohol or any other drug.

The Firearms Act 1996 specifies that a person must not handle or use a firearm while they are under the influence of alcohol or any other drug.

Section 130 (1) & (2) relates to firearm prohibition orders. Under this section the:

Commissioner may, by order, prohibit the person from possessing or using a firearm if, in the Commissioner's opinion, the person is unfit, in the public interest, to possess or use a firearm. A firearms prohibition order takes effect on the day on which it is served and is in force until it is revoked.

Under the Act a prescribed person must disclose certain information (section 148). In this section, prescribed persons can include a medical practitioner, a registered nurse or a person in the psychology profession.

- (1) A prescribed person is to inform the Commissioner, by notice in writing, if he or she reasonably believes that:
- (a) a client or client is likely to possess or use a firearm; and
 - (b) such possession or use would be unsafe, for the client or client or another person. This may be due to the client's or client's mental or physical condition or because the client or client would be a threat to public safety.

A prescribed person is to inform the Commissioner if a client is likely to possess or use a firearm, and that this would be unsafe for the client or another person.

If a clinician has concerns regarding a client's ability to safely possess and/or use a firearm, a Section 148 Notice is to be completed. This forms requests the clinician to specify the client's name and address and the reason for the opinion held in relation to the client. A failure to act in accordance with the provisions of the *Firearms Act 1996* is punishable by either a monetary penalty or for a term of imprisonment not exceeding 2 years or in some cases both.

14.11 Vehicle and Traffic Act 1999

As discussed in Section 4, the provision of opioid pharmacotherapy has implications for an individual's capacity to drive and operate machinery. This is particularly significant during induction onto opioid pharmacotherapy. In addition, some of the risks associated with substance use and dependence include motor vehicle, domestic, and workplace accidents.

Ability to engage in these activities is unlikely to be affected once the client is stabilised in treatment or stabilised after a dose increase. If a client is unfit to drive due to an impaired mental state or medical condition, he or she has a responsibility to cease driving and notify the licensing authority in Tasmania. However, this often does not occur.

Health professionals involved in the delivery of the Tasmanian OPP have a duty of care to the client and the community relating to fitness to drive. Therefore, if a clinician observes that a client is unfit to drive due to a known impairment and is, subsequently, a risk to road safety, they have a duty to report this to the Registrar of Motor Vehicles. This is consistent with Part 8, Section 63 (Report of unfit driver or defective vehicle) of the *Vehicle and Traffic Act 1999*. Whilst notification under this Act is not mandatory, there is an obligation or duty to report possible risks to road safety that may be a consequence of an unfit driver. The Act has the following provisions in place in relation to the individual who has made the report:

- (1) A person incurs no civil or criminal liability for reporting to the Registrar, in good faith, that another person may be unfit to drive a motor vehicle or that a motor vehicle or a trailer may be defective; and
- (2) A person incurs no civil or criminal liability for reporting to the Registrar, in good faith:
 - (a) the results of a test or examination carried out under this Act; or
 - (b) an opinion formed as a result of conducting such a test or examination.

Tasmanian OPP clinicians have a duty of care to the client and community relating to fitness to drive.

If a clinician observes that a client is unfit to drive, they have a duty to report this to the registrar.

14.12 Health Practitioners Regulation National Law (Tasmania) Act 2010

A process is now underway to achieve a single national regulatory framework for the registration and accreditation of health professionals in Australia. This scheme allows health professionals to practice in all jurisdictions across Australia without the need to meet additional registration and accreditation conditions for each state.

The *Health Practitioners Regulation National Law Act 2010* enables Tasmania to participate in the National Registration and Accreditation Scheme for Health Professionals. This scheme establishes a regulatory framework across all aspects of professional practice including registration, accreditation, complaints and conduct, health and performance, privacy and information sharing.

This legislation aims to ensure public safety through a number of mechanisms including:

- mandatory criminal and identity checks; and
- mandatory reporting by health practitioners and employers of impaired practitioners or practitioners who may have engaged in inappropriate conduct.

Of relevance to those involved in the provision of OPP is the mandatory requirement to report when there is evidence that a health practitioner may be practising in a manner that may put clients at risk of harm, or when they may be practising under the influence of drugs and alcohol.



When a health professional is receiving treatment for an alcohol and other drug use issue (such as opioid dependence) the treating health professional has an obligation to thoroughly assess and monitor the individual. This includes assessing the potential impact of the client's substance use conditional upon their capacity to fulfil their role as a health professional. Where there is evidence of risk to public safety, the health practitioner must report this to the regulatory authority.

Health professionals are strongly encouraged to contact the Australian Health Practitioner Regulation Agency (1300 419 495) to seek advice and guidance in relation to these issues. Within the Alcohol and Drug Service, these complex clinical issues should be reviewed by the multidisciplinary team with the involvement of senior managers and where appropriate the Clinical Director, Alcohol and Drug Service. Private practitioners involved in the delivery of the Tasmanian OPP are also encouraged to contact an Addiction Medicine Specialist within the ADS for support and advice.



SECTION: 15

Prescriber training and authorisation

In this section you will...

- Gain an understanding of the training and authorisation process for medical practitioners who prescribe buprenorphine and methadone for the treatment of opioid dependence.

15	Prescriber training and authorisation	194
15.1	Process of prescriber authorisation	194
15.1.1	Initial application	194
15.1.2	Probationary period	194
15.1.3	Ongoing authorisation	194
15.2	Regulations relating to pharmacotherapy prescribing	195
15.2.1	Authority to treat a patient	195
15.2.2	Maximum caseload	197
15.2.3	Dose limits	197
15.2.4	Patients aged 16 and under	197
15.2.5	Takeaway doses	197
15.2.6	Arrangements to cover absence from practice	197

Section: 15

15 Prescriber training and authorisation

Medical practitioners who prescribe buprenorphine and methadone for the treatment of opioid dependence must be authorised by the Clinical Director, Alcohol and Drug Services, Department of Health and Human Services.

Medical Practitioners who prescribe buprenorphine and methadone for the treatment of opioid dependence must be authorised.

15.1 Process of prescriber authorisation

15.1.1 Initial application

To become an authorised prescriber, a medical practitioner must:

Make an application to the ADS Clinical Director, DHHS:

- Undertake training in opioid dependence and pharmacotherapy with an ADS Addiction Medicine Specialist. Prescribers will also be invited to attend ADS and observe pharmacotherapy practice during a clinic;
- Complete and return a multi question exam (and achieve a passing grade); and
- Agree in writing to prescribe in accordance with the policies and clinical practice standards described in the Tasmanian Opioid Pharmacotherapy Program: Policies and Clinical Practice Standards (TOPP, 2011).

Upon completion of the above requirements, a recommendation will be made by the ADS Addiction Medicine Specialist to the ADS Clinical Director that the practitioner be authorised to prescribe pharmacotherapy in Tasmania for a probationary period.

15.1.2 Probationary period

An initial twelve month period of probationary authorisation will apply. This involves:

- Monthly peer support, review and advice sessions with an ADS Addiction Medicine Specialist for the first 6 months;
- Ongoing peer support, review, and advice sessions negotiated as required for a further six months;
- Full authorisation by the ADS Clinical Director upon completion of the 12 month probationary period; and
- Once authorised, a prescriber may build a caseload gradually according to their capacity.

15.1.3 Ongoing authorisation

Ongoing authorisation requires annual renewal through the completion of a refresher program. This program is a competency based e-learning package accredited by the College of General Practitioners for ongoing professional development. Participation in professional development opportunities (e.g. interactive clinical practice review meetings and Pharmacotherapy Network Meetings facilitated by ADS) is strongly encouraged. No patient will be dosed until PSB has been contacted and an authorisation number has been provided in the TOPP.

Prescribers wishing to cease prescribing opioid pharmacotherapy must notify the ADS Clinical Director well in advance (ideally 8 weeks prior) to ensure that patients can be transferred to other treatment providers without disruption to treatment.

15.2 Regulations relating to pharmacotherapy prescribing

15.2.1 Authority to treat a patient

No patient will be given a prescription or dosed with methadone or buprenorphine until PSB has been contacted and an authorisation number has been provided. Consequently, medical practitioners must apply for an authority to prescribe a narcotic substance under Section 59E of the *Poisons Act 1971* for every patient commencing pharmacotherapy treatment.

A prescription for methadone or buprenorphine cannot be provided until an authority and authority number has been issued by PSB.

The Authority to Prescribe Opioid Pharmacotherapies form must be completed, signed by the medical practitioner, and faxed or posted to Pharmaceutical Services Branch (PSB) DHHS. (Refer to Figure 15.1 S59 Authority Flow Chart, below and Figure 12.1, Section 12). In urgent cases, an authority number can be obtained over the telephone (6233 2064), and the signed application then forwarded by the practitioner.

The authority issued to the practitioner is valid only for that patient, and cannot be transferred. If the patient leaves treatment or the prescriber ceases to treat the patient for any reason, a *Notification of termination of Methadone/Buprenorphine treatment* form must be sent to PSB. Failure to forward this termination form precludes the patient from pharmacotherapy or other drugs of dependence treatment by another practitioner.

Another practitioner planning to prescribe for the same patient must make a new application for authority, which will only be approved once the previous authority is terminated.

A locum may prescribe under the authorised practitioner's authority, but cannot alter any doses or takeaway dose conditions. If a change in treatment is required, the locum can phone an ADS Addiction Medicine Specialist to seek further advice and support. These procedures ensure that a patient does not receive pharmacotherapy from two prescribers concurrently.

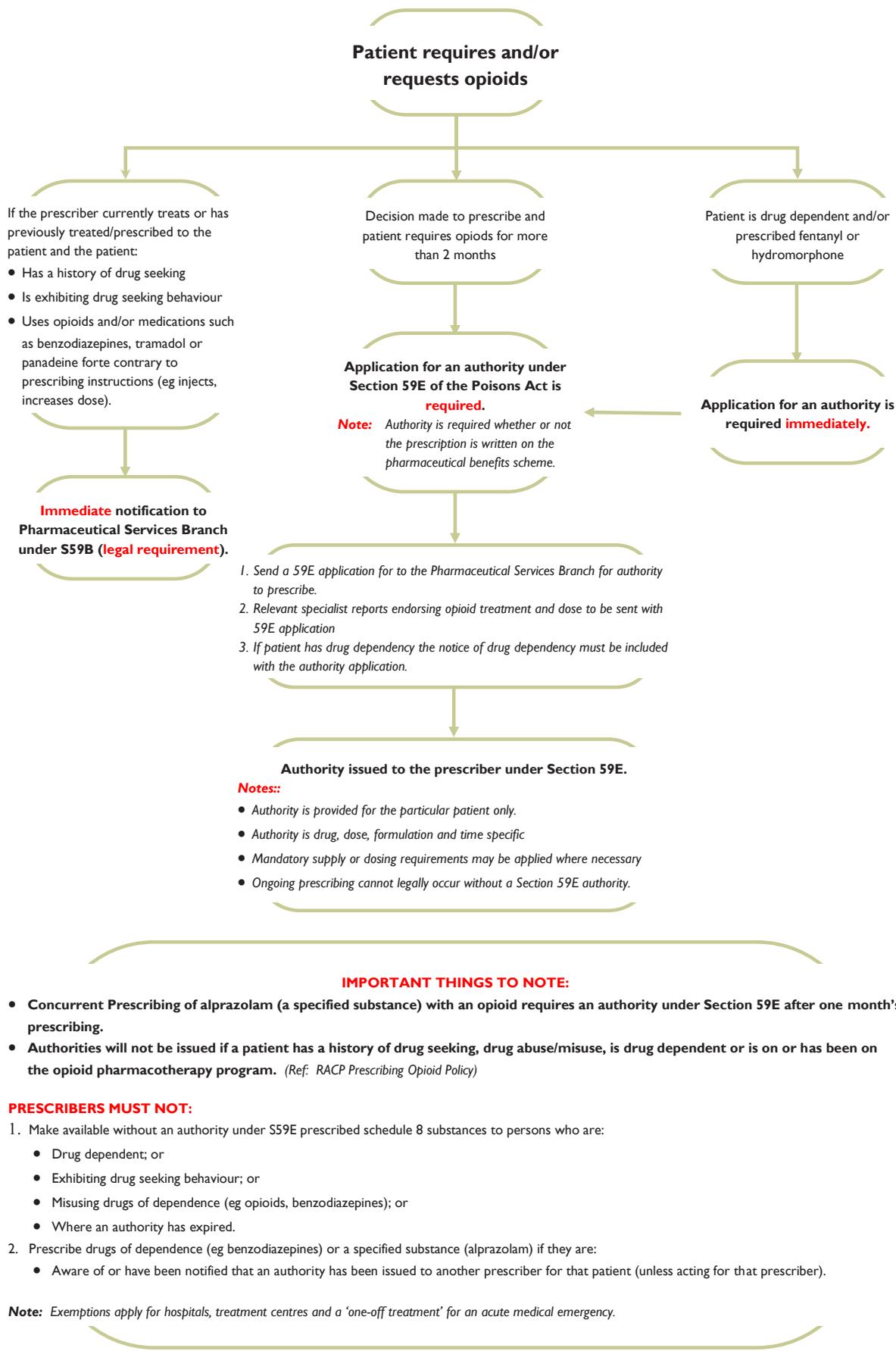


Figure 15.1: Prescribing S8 opioids and drugs of dependence quick reference guide

15.2.2 Maximum caseload

The ideal caseload of opioid pharmacotherapy patients for each prescriber will vary depending on:

- The complexity of the patient presentations;
- The suitability of the practice setting; and
- The capacity of the practice setting to provide high quality and safe opioid pharmacotherapy treatment without compromising the quality of treatment provided to non-opioid pharmacotherapy patients.

A medical practitioner in full time general practice can prescribe methadone or buprenorphine to a maximum of 20 patients. Practitioners with clinical skills and an interest in this area can apply to the Clinical Director ADS to increase this number. It is anticipated that caseloads for beginning prescribers will build over time towards this maximum.

A medical practitioner in full time general practice can prescribe methadone or buprenorphine to a maximum of 20 patients.

15.2.3 Dose limits

The maximum daily dose for methadone is 120mg. To exceed this dose, authorisation from the ADS Clinical Director is required. A thorough explanation of dose limits is provided in Section 8 – Maintenance treatment.

The registration of buprenorphine in Australia specifies that a maximum dose of 32mg of buprenorphine can be prescribed (either per day or in a double or triple dosing regimen).

For patients requiring a daily dose of more than 24mg of buprenorphine, the advice of an ADS Addiction Medicine Specialist is recommended.

Medical practitioners already exceeding these dose limits when this Policy and Clinical Practice standards document is first published are asked to contact an ADS Addiction Medicine Specialist to discuss each patient and review their clinical status and treatment plan.

15.2.4 Patients aged 16 and under

Opioid pharmacotherapy treatment is generally contraindicated for patients aged 16 years and under. Prior to commencing treatment for these patients, the prescriber must request an exemption in writing from the ADS Clinical Director. The request for an exemption should include a second opinion from an Addiction Medicine Specialist.

For further information regarding cautions and contraindications related to age, the concept of informed consent, and working with young people, see Sections 4, 6, & 11 respectively.

15.2.5 Takeaway doses

Takeaway doses may only be prescribed in accordance with the policy and clinical practice standards set out in Section 8 of this document.

15.2.6 Arrangements to cover absence from practice

Prescribers should take measures to ensure that all of their pharmacotherapy patients have sufficient prescription cover during periods of the prescriber's absence, such as annual leave. Ideally, each pharmacotherapy prescriber should have a practice colleague trained in pharmacotherapy who can provide cover; however, it is acknowledged that this is not possible in most current practices.

Prescribers should take measures to ensure that all of their pharmacotherapy patients have sufficient prescription cover during periods of the prescriber's absence.

In emergency situations, ADS will provide backup support for prescribers absent from their practice as needed, provided this may be done safely.



SECTION: 16

Pharmacy instructions

In this section you will...

- Understand the role of pharmacies who participate in the opioid pharmacotherapy program; and
- Gain an overview of the requirements of pharmacies who participate in the opioid pharmacotherapy program.

16	Pharmacy instructions	201
16.1	Approval and accreditation to dose	201
16.1.1	Pharmacy approval	201
16.1.2	Pharmacist accreditation to dose	202
16.1.3	Service delivery changes	202
16.1.4	Ongoing training and support	202
16.2	Patient orientation to a community pharmacy	203
16.3	Dosing procedure	203
16.3.1	Supervised doses	203
16.3.2	Takeaway doses	206
16.4	Regulatory requirements	209
16.4.1	End of month	209
16.4.2	Dispensing of the prescription and completing the PSB narcotic return	209
16.4.3	Drug storage and handling	209
16.4.4	Prescriptions	210
16.5	Dosing errors	211
16.5.1	Methadone	211
16.5.2	Buprenorphine	212
16.6	Dosing challenges	212
16.6.1	Intoxication	213
16.6.2	Behavioural Considerations	214
16.6.3	Identifying diversion of dose	215
16.6.4	Minimising Diversion of Dose	216
16.6.5	Missed doses	217
16.6.6	Vomited doses	218
16.6.7	Drug interactions	218
16.6.8	Side effects and adverse drug reactions	218
16.7	Financial considerations	218
16.7.1	Payment by patients	218

16.8 Documentation	219
16.8.1 Recording doses	219
16.8.2 Maintaining patient records	219
16.8.3 Blind dosing	219
16.8.4 Supplementary doses	219
16.8.5 Communication between pharmacists	219
16.8.6 Computer dosing programs	219
16.8.7 Pharmacy transfers	220

Section: 16

16 Pharmacy instructions

Pharmacists are an essential component of the opioid pharmacotherapy treating team. Patients can receive opioid pharmacotherapy treatment either from the Alcohol and Drug Service (ADS) or private prescribers. Many patients receiving opioid pharmacotherapy treatment from the ADS are dosed at the onsite pharmacy (Alcohol and Drug Service Pharmacy), particularly during stabilisation. However, the majority of opioid pharmacotherapy patients in Tasmania are dosed at community pharmacies. Access to a community pharmacy that dispenses methadone and buprenorphine means that many patients can conveniently dose near their home or work location.

The participation of pharmacists in the program is voluntary. Therefore, the role of the ADS includes supporting community pharmacies to be approved to provide services for opioid pharmacotherapy clients.

Due to the nature of dosing, pharmacists have regular ongoing contact with patients, and are able to provide critical information to the treating team about the progress of the patient on the program. The pharmacist's role includes:

- developing a positive rapport with the opioid pharmacotherapy patients;
- monitoring patients' progress on the program;
- monitoring daily levels of intoxication or withdrawal;
- observing patient behaviour whilst in the pharmacy;
- communicating with patients after dosing to ensure that the dose has been consumed;
- encouraging the patient to take the dose at approximately the same time each day;
- maintaining regular contact with the prescriber and treating team; and
- working as a part of the ADS, prescriber and treating team to ensure the best outcome for the patient.

16.1 Approval and accreditation to dose

To become a dosing site for opioid pharmacotherapy, a pharmacy requires approval from the ADS. In addition, each pharmacist involved in the provision of dosing is required to obtain accreditation. The ADS can assist pharmacists and pharmacies with this process.

16.1.1 Pharmacy approval

Pharmacy approval is coordinated by pharmacists at the ADS, who are contactable on (03) 6230 7983. The key criteria for obtaining pharmacy approval to dose are that:

- all pharmacists involved in dosing are accredited within Tasmania; and
- the pharmacy has a designated area in which dosing can occur.

An ADS pharmacist is available to provide the pharmacy with:

- the paperwork required to commence dosing;
- general support to discuss the practicalities of dosing;
- onsite support on the first day of dosing if required; and
- staff training.

When establishing a dosing service, the provision of a suitable dosing environment to enable private and confidential consultation is essential. The pharmacist in charge of this service at the location needs to ensure the provision of a private, safe and confidential dosing site for patients. Further information can be obtained from the Pharmacy Board of Australia's Codes and Guidelines on at their website: <http://www.pharmacyboard.gov.au/Codes-Guidelines.aspx>

Once approval is obtained, the ADS will inform the pharmacy's nominated wholesaler(s) of the approval as an opiate pharmacotherapy dosing site. Consequently, the dosing medication (methadone liquid/syrup, Subutex® and Suboxone®) and associated dosing cups and takeaway dose bottles are supplied to the pharmacy by the wholesaler.

16.1.2 Pharmacist accreditation to dose

Accreditation to undertake opioid pharmacotherapy dosing requires each pharmacist to undertake a short professional development program and complete a short exam. The ADS recommends that all pharmacists complete their accreditation to dose opioid pharmacotherapy during their intern year. Dosing without accreditation will place the pharmacist working outside accepted standards of practice and this is not recommended.

For pharmacists not already accredited, successful completion of 'open book' exams for both methadone and buprenorphine is required. ADS will supply the exams and corresponding resource material in electronic format. Completed exams can be faxed to (03) 6230 7950 for marking and accreditation by the ADS. For alternative ways to submit exams contact the ADS Pharmacy on (03) 6230 7984 or (03) 6230 7983. Participants will be notified of results. Pharmacists coming from interstate also need to complete the training.

If a pharmacy is undergoing Quality Care Pharmacy Program (QCPP) certification and a pharmacist(s) has misplaced their accreditation letter, ADS will supply written confirmation that the pharmacist is on the accreditation register. ADS can be contacted on (03) 6230 7984 or (03) 6230 7983.

16.1.3 Service delivery changes

ADS should be informed in advance if a dosing pharmacy changes ownership. The preference is always for the pharmacy to continue dosing. If this is not possible, ADS requires four weeks notice to arrange alternative dosing sites for patients and to negotiate an approval process for the change of ownership.

Due to the impact on patients and their dosing schedules, pharmacists should also provide the ADS with adequate notice (4 weeks) if:

- they no longer want to be part of the opioid pharmacotherapy program;
- they change their operating hours, including a change of opening days;
- they no longer want to continue dosing a particular patient; or
- they no longer want to provide a particular opioid replacement pharmacotherapy.

Alcohol and Drug Services should be informed as soon as possible when a pharmacy no longer wants to continue dosing a particular patient, or they no longer want to be part of the opioid pharmacotherapy program.

16.1.4 Ongoing training and support

The ADS has a wide range of resources available to dosing pharmacies, including regular newsletters and information sheets about topical issues.

The ADS pharmacy can also provide the following:

- training for pharmacy staff (either one-on-one, group, written or verbal formats);
- advice & resources for the dosing pharmacy to set up a safe dosing process; and
- supportive learning environment to pharmacists, intern pharmacists, and student pharmacists with onsite visits to the ADS Pharmacy (situated in Southern Tasmania).

The ADS pharmacy is open every day (with reduced hours on weekends & public holidays), and is available to provide advice to dosing pharmacies at any time.

ADS Pharmacy

Location:

Grd Flr Carruthers Building
St Johns Park, New Town TAS 7008

Open 7 days

Contact:

Ph: 1300 139 641 Fax: 03 6230 7992

Contacting prescribers or case managers

As members of the extended treating team, it is important that pharmacists contact ADS or the patient's private prescriber when there is evidence of poor compliance, illicit drug use or drug seeking and other inappropriate or unacceptable behaviours. This includes:

- missed doses;
- suspected or confirmed dose diversion;
- requests for psychoactive over the counter (OTC) medication;
- repeated requests to the pharmacist to provide takeaway doses outside of prescription instructions;
- presenting with prescriptions for psychoactive medications (that are restricted) not prescribed by the patient's pharmacotherapy doctor;
- erratic or aggressive behaviour;
- presenting intoxicated; or
- worrisome physical appearance or psychological health.

16.2 Patient orientation to a community pharmacy

The process for accepting new patients will vary between pharmacies. After discussing a prospective patient with the ADS or a private prescriber, it is recommended that the patient attends the pharmacy for an interview. The following topics should be discussed during the interview:

- supervised dosing procedures;
- maximum number of patients that can be in the pharmacy at the one time;
- opening times and dosing hours;
- code of conduct and acceptable behaviour (see also below);
- consequences of diversion or attempted diversion;
- procedures for takeaway doses (if applicable);
- cost of dosing, including the patient's responsibility to ensure that payments are made in a timely way;

- requirements and cost for ancillary medication dosing; and
- payment procedures, for example options such as weekly or daily payments, making payments in advance, and in some circumstances, the option of automatic Centrelink deductions.

At the time of the interview the patient should sign an agreement with the pharmacist acknowledging their understanding of these requirements, see Appendix 15 for an example.

16.3 Dosing procedure

Dosing procedures will vary between pharmacies. The following procedures are recommended for supervised dosing and takeaway doses.

16.3.1 Supervised doses

All supervision of opioid pharmacotherapy must be provided by the pharmacist, and patients are encouraged to attend the pharmacy at the same scheduled time. Routine attendance not only helps the patient achieve a steady state of medication in their system, it also helps develop a consistent routine for accessing their medication. Patients in the induction phase (the first 1-2 weeks of treatment – see Section Seven), should be dosed at approximately the same time each day, and a divergence of more than 12 hours from this scheduled time should be avoided.

Pharmacists can help patients establish a dosing routine by dosing at approximately the same time each day during the induction phase.

Prior to attending the pharmacy, patients should be informed that:

- only the patient can pick up their dose;
- the patient must enter the pharmacy alone;
- no bags or containers are allowed in the dosing area;
- the patient's hands and mouth must be visible to the pharmacist at all times;

- the dose must be consumed in direct view of the pharmacist without turning of the head;
- the dose must be consumed directly from the cup or spoon;
- for buprenorphine tablets, the dose must be placed under the tongue, and the patient must remain in full view of the pharmacist until the crushed tablets are dissolved;
- for buprenorphine tablets and film, the dose must be placed under the tongue (and on the buccal mucosa when more than two films are required), taking care not to overlap and adequate time allowed for them to dissolve;
- the empty cup or spoon must be shown to the pharmacist before discarding;
- the patient must speak to the pharmacist, open their mouth, and have a drink of water or cordial after dosing if asked to do so; and
- the patient must leave the pharmacy area and clinic vicinity as soon as they have dosed.

For buprenorphine and methadone (including supervised and takeaway doses), the pharmacist should:

- ensure that each patient has an identification sheet containing the patient's name and photograph;
- confirm the patient's identification when they present for dosing, refer to photo ID, confirm date of birth, address and normal dose, and compare the patient's signature with that from the previous day;
- observe the patient for signs of intoxication (Appendix 16 & 17);
- check that the prescription is valid and not expired;
- if using a dosing program, ensure the patient's file is open on the computer and the correct dose is listed;
- check the last recorded dose and any communication notes;

- record the dose on the "Medication Administration Chart" and complete details for that day including dose, quantity/volume, time, and signatures of the dosing pharmacist and patient;
- ensure the patient signs and pays for the dose before they receive it; and
- prepare the dose.

For methadone the pharmacist should:

- give the dose after the patient has eaten, to minimise nausea (recommended);
- check the dose in both mg and mL;
- measure the dose using a disposable syringe or an approved pump;
- double check the dose against the prescription (or photocopy) and then check the amount measured again;
- be sure not to confuse mg & mL – see Section 16.5.1;
- place in a clean disposable cup and dilute (with cordial or water) to a final volume of 100 mL of the liquid (this can either be in one cup all diluted or the one cup part diluted with a second cup of liquid);
- give the preparation to the patient to drink;
- ask the patient to drink again after the dose; and
- ask the patient to show the pharmacist the empty cup and to speak clearly with them (this helps ensure the entire dose has been taken).

For buprenorphine sublingual tablets the pharmacist should:

- give the patient diluted lemon cordial to drink prior to dosing to cause salivation and speed up dose absorption;
- check if the prescription is for Subutex® or Suboxone® – these formulations are not interchangeable;
- check the number of tablets of each strength required;
- count the tablets into a pill crusher (crush different strengths separately) or break into rough pieces;

- crush tablets until they resemble coffee grounds. (Crushing the dose is recommended to discourage the diversion of the dose. Studies indicate that crushing does not cause significant loss of potency (Simojoki et al., 2010))
- **DO NOT** crush tablets into a fine powder;
- use a different tablet crusher for Subutex® and Suboxone®;
- tip the dose into a disposable spoon or cup and give to the patient;
- observe the patient placing the dose under their tongue – this is when diversion is most likely to occur;
- do not allow the patient to swallow the dose or talk while the dose is dissolving;
- maintain pharmacist supervision until the dose is dissolved; and
- check the patient's mouth for any undissolved pieces once the dose is dissolved, and ask the patient to lift their tongue and pull back their cheeks.

For buprenorphine sublingual film the pharmacist should:

- advise the patient not to eat immediately before dosing (as it may interfere with absorption);
- advise the patient not to smoke, drink caffeinated beverages (coke, coffee), clean teeth or use a mouth wash prior to dosing (as these can dry the mouth and effect absorption);
- ensure the patient has clean and completely dry hands;
- give the patient some water to moisten the mouth;
- check the number of each strength of sachet required; half doses cannot be administered as the film should not be cut;
- fold the sachet along the dotted line and tear down at the slit as indicated on the packaging. Do not open the sachets until time of administration;
- hand the film to the patient (either in the original sachet or in a transparent medicine cup);

- ensure that the patient holds the film between two fingers by its outer edges and places it sublingually (under the tongue) one film at a time. If multiple films are needed, the first two (and strongest strengths) are placed under the tongue either side of the frenulum and any remaining are placed in the inside of the cheeks. (Buccal administration is an off-liecence method of use, but the bioavailability of sublingual and buccal administration are similar);
- observe the patient placing the dose under their tongue – this is when diversion is most likely to occur;
- ensure that once the film has been placed in the mouth, the patient does not attempt to move the film, nor chew or swallow the film until fully dissolved (usually 2 to 5 minutes);
- if the film accidentally sticks to another part of the mouth the patient should be reassured that the dose will be absorbed, but they must keep their mouth closed so mucous membranes can be in contact with the dose;
- the film adheres to mucus membranes within seconds and it is difficult to remove 30 to 60 seconds after application. Under normal circumstances, post-dose supervision by the pharmacist need not exceed 1 minute. It is important that the film is not allowed to overlap in the mouth as this will impair mucosa adherence and prolong supervision time; and
- when checking the tongue, if the film is rolled into a lump, the pharmacist should observe the patient until full absorption has occurred.

Note: Adapted from Suboxone Sublingual Film, Product Information, TGA Product and Consumer Medicine, 2011. Retrieved September 22, 2011, from <https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/PICMI?OpenForm&t=&q=buprenorphine&r=/>

Double & triple buprenorphine dosing

Whilst buprenorphine dosing (either as Subutex® tablets, Suboxone® tablets or Suboxone® film) is initially daily, when patients are stabilised they can be dosed every second or third day. The dose is usually doubled to cover a 48 hour period and tripled to cover a 72 hour period (to a maximum of 32mg dosed at any one time). Because of the limitations of the maximum dose, some patients will be unsuitable for this regimen. Of those patients eligible, some will not be comfortable and will need to be changed back to daily dosing. The procedure for dosing is the same as described above. For more details on alternate day dosing schedules see Section 8.8.

Pharmacists are reminded that:

The registration of buprenorphine in Australia specifies that a maximum dose of 32mg can be prescribed per day.

This restriction applied whether it is a daily, double or triple dose.

16.3.2 Takeaway doses

To receive unsupervised (takeaway doses), patients need to be assessed by their prescriber as meeting clinical stability criteria (see Section 8). The prescriber is required to specify authorisation of unsupervised (takeaway) doses on the prescription, and details should be recorded in the patient record. Misuse of takeaway doses poses serious risks to both the patient and the general public; hence patients are only provided with takeaway doses if they demonstrate clinical stability. Only prescribers can authorise takeaway doses (see Section 8). Providing takeaway doses outside of prescriber authorisation is a serious breach of the *Poisons Regulations 2008*.

Most new patients on opioid pharmacotherapy treatment require daily supervised doses for a period of time before becoming eligible for takeaway doses. The pharmacy is pivotal in ensuring the prescriber is kept up to date with how the patient is presenting over time, and contributes to the overall assessment of the patient's stability.

Only prescribers can authorise takeaway doses. Providing takeaway doses outside of prescriber authorisation is a serious breach of the Poisons Regulations 2008.

Changes to takeaway doses

Patients may present to the pharmacy requesting a change to their takeaway dose regimen; and should be advised to contact their prescriber directly to negotiate changes to takeaway doses.

A pharmacist can only nominate the day the takeaway is collected (in consultation with the patient) if the day has not been allocated on the prescription.

The following changes cannot be made by the pharmacist and require written approval by the prescriber:

- changing the day that the takeaway dose can be collected when the prescription specifies the day;
- changing the number of takeaway doses;
- providing an extra takeaway dose;
- providing a takeaway from 'next week's' doses;
- changing the way in which the takeaway dose is supplied, for example, providing two consecutive takeaway doses when two non-consecutive takeaway doses have been prescribed; and
- change the dilution volume of the takeaway dose from a final volume of 100mL.

Child-resistant containers

All takeaway doses must be provided to the patient in child-resistant packaging, as stated in national legislation (Therapeutic Goods Act 1989, Therapeutic Goods Order No. 80). A separate container is required for each day's takeaway dose. The takeaway bottle must be labelled to show which day the dose is to be consumed. The ADS provides 100mL takeaway dose bottles with a child resistant lid free of charge from the pharmacy's designated wholesaler.

All takeaway doses must be provided to the patient in child-resistant packaging, as stated in national legislation (Therapeutic Goods Act 1989, Therapeutic Goods Order No. 80).

Labelling

Takeaway doses must be labelled in accordance with legislation and the instructions specified on the prescription. Appropriate Cautionary and Advisory labels (C&A) should be used. To comply with the legislation, the following information must be included on the container:

- name of drug and concentration;
- day and date it needs to be consumed;
- patient's name;
- prescription number (a requirement of PSB);
- name, address, and telephone number of the pharmacy;
- Cautionary and Advisory (C&A) Label I.

In addition, it is preferred that the following warnings are added to the label:

- do not inject;
- may cause death or serious injury if taken by another person; and
- to be taken by mouth by the person named on the label on the day stated on the label.

These warnings can be prepared in the pharmacy's dispensing program as a separate generic label and also placed on the bottle.

Numbers or letters required on the label must be at least 1.5mm high and in clear and distinct contrast to the background.

Takeaway doses have the same labelling requirements as other S8 medications.

When there is a computer dosing program in use it will generate a takeaway dose label on request. Where the pharmacy uses a manual system for dosing, a label can be prepared using the dispensing program. An example of a takeaway dose label is shown in Figure 16.1.

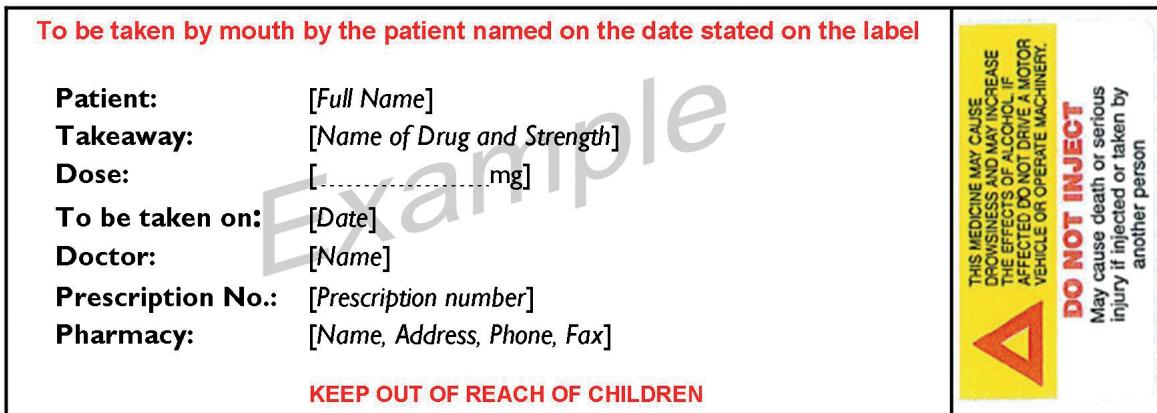


Figure 16.1: Example of takeaway dose label

Methadone takeaway procedure

For methadone takeaway doses:

- complete the appropriate section on the dosing sheet for the day the takeaway dose is to be consumed;
- clearly mark that the dose was supplied as a takeaway dose;
- ask the patient to sign and pay for the dose prior to dispensing;
- measure the dose (as described above) and place in an approved takeaway container;
- dilute the dose with filtered or purified water (not tap water) so that the total volume is 100mL. If the doctor requests a greater dilution and larger bottles are unavailable, divide the dose between bottles and label accordingly. This means the patient will need to consume the contents of several bottles for the one dose;
- the takeaway dose cannot be left undiluted or diluted with an amount less than 100mL (unless the dose is prepared for a hospital, prison, or nursing home setting for dosing by a health professional);
- do not dilute the dose with any other fluid as there is the possibility it may affect the stability of the methadone;
- ensure that the child proof lid is tightly closed to prevent spilling; The lid can also be secured with tape to help prevent spillage and for security reasons;
- inform the patient that spilt doses are not replaced;
- label the takeaway dose with directions and a C&A Label I;
- hand the takeaway dose to the patient (not to a third party); and
- provide the patient with a paper bag if they do not have somewhere to put the takeaway dose. This helps to maintain the patient's confidentiality.

Buprenorphine (Subutex® & Suboxone®) takeaway dose procedure

For buprenorphine tablet takeaway doses:

- complete the appropriate section on the dosing sheet for the day that the takeaway dose is to be consumed;
- clearly mark that the dose was supplied as a takeaway;
- ask the patient to sign and pay for the dose before they receive it;
- check the tablet type and strength and crush the dose (as described above). It is recommended that the dose is crushed to diminish its "street" value. Studies show no appreciable loss of potency with crushing (Simojoki et al., 2010);
- place the crushed doses into an approved takeaway container;
- ensure that the child proof lid is tightly closed to prevent spilling. The lid can also be secured with tape to help prevent spillage and for security reasons;
- inform the patient that spilt doses are not replaced;
- label the takeaway dose with directions and a C&A Label I;
- hand the completed takeaway dose to the patient (not to a third party); and
- provide the patient with a paper bag if they do not have somewhere to put the takeaway dose.

For Suboxone® film takeaway doses:

- complete the appropriate section on the dosing sheet for the day that the takeaway dose is to be consumed;
- clearly mark that the dose was supplied as a takeaway;
- ask the patient to sign and pay for the dose before they receive it;
- check the strength and number of films required;
- place the unopened film packets in a box and seal it;
- label the takeaway dose with directions and a C&A Label I;

- hand the completed takeaway dose to the patient (not to a third party); and
- provide the patient with a paper bag if they do not have somewhere to put the takeaway dose.

For all takeaway doses

Due to the risks to patient and public safety, takeaway doses should never be given to a third party to collect, transport or administer to the patient, such as a family member, employer or partner. The takeaway dose is the sole responsibility of the patient, and therefore needs to be handed directly to them. If there are concerns about requests for takeaway doses to be given to someone other than the patient, the pharmacist can contact the prescriber for advice.

***Give the takeaway dose directly to the patient.
DO NOT give the takeaway dose to a
third party.***

16.4 Regulatory requirements

The prescription of opioids in Tasmania is subject to regulatory requirements under the *Tasmanian Poisons Act 1971*. All opioid pharmacotherapy medications are Schedule 8 (S8) medications and dispensing of pharmacotherapy is also subject to the same legislative requirements. For more information see Section 14: Legislative Requirements.

16.4.1 End of month

At the end of each month, a copy of all dosing sheets need to be sent to the PSB. PSB collates data on dosing on behalf of the ADS.

These sheets can either be sent via facsimile or post, the details are:

Postal address:
Attention: Chief Pharmacist
Pharmaceutical Services Branch
GPO Box 125
Hobart 7001

Facsimile address: 03-6233 3904

16.4.2 Dispensing of the prescription and completing the PSB narcotic return

It is important the prescription for pharmacotherapy doses is dispensed in the pharmacy's dispensing program. The prescription provides the pharmacy with the authorisation to dose the patient. In addition, it is used by PSB to assess that the patient can be dosed (i.e. there are no restrictions or other concurrent prescriptions). When the prescription is dispensed it is important to record all relevant details (i.e. dosage, frequency, takeaway doses and the dates for which the prescription is valid – first to last dose inclusive). It is recommended that the prescription is entered into the pharmacists dispensing program as soon as it is received so this data is electronically transferred to the PSB DORA system.

When recording the prescription electronically it can be useful to create a generic item for each drug formulation and use this to record dispensing in the pharmacy dispensing program. The created "drug" needs to be specified as S8 to enable automatic transmission to PSB. For advice on how to do this, please contact the ADS pharmacy.

16.4.3 Drug storage and handling

Since methadone and buprenorphine are S8 medications, they must be stored in a S8 narcotic approved safe. Within a pharmacy, S8 medications can only be handled under the direct supervision of a pharmacist.

Within a pharmacy, S8 medications can only be handled under the direct supervision of a pharmacist.

16.4.4 Prescriptions

Interstate prescriptions

Tasmanian legislation and regulations do not allow pharmacists to dispense interstate prescriptions for S8 and S4D medications.

Tasmanian pharmacists CANNOT dispense opioid pharmacotherapy for patients with prescriptions from interstate doctors.

Possession of prescriptions

Once a dosing site has been secured, it is the prescriber's responsibility to post (or fax, then immediately post) the prescription to the pharmacy. As per Section 6, patients should never be directly handed a prescription for opioid pharmacotherapy. If a patient presents with a prescription, the pharmacist should not dispense from this prescription and should contact the prescriber as soon as possible.

Similarly, any ancillary medications that require staged supply, should be sent to the pharmacy, as for the S8 prescriptions.

Prescribers are required to send prescriptions for opioid pharmacotherapy patients directly to the pharmacist.

DO NOT dispense a prescription for opioid pharmacotherapy if it is presented by the patient.

Patients on both S8 and S4D medications

A patient on the pharmacotherapy program cannot have S4D medications prescribed by anyone other than the pharmacotherapy prescriber. If a patient presents with a prescription for an S4D medication from another doctor, the pharmacist has a duty of care to contact the opioid pharmacotherapy prescriber and S4D prescribing doctor. Retain the prescription as evidence as it may be required by the prescribing doctor or PSB, and do not dispense the S4D medication.

DO NOT dispense S4D medications prescribed to the patient by a doctor other than the pharmacotherapy prescriber.

Alprazolam

Alprazolam can only be prescribed for an opioid pharmacotherapy patient with the approval of the Alcohol and Drug Services Clinical Director. If a pharmacotherapy patient presents with an alprazolam prescription, confirm the prescription with the prescriber and the ADS Clinical Director before dispensing.

Expired prescriptions

Patients may present for dosing after a prescription has expired for a number of reasons. Prior to prescription expiration, the patient will need to arrange an appointment with their prescriber for a prescription renewal. Pharmacists are encouraged to remind patients in the weeks leading up to their prescription expiration to make an appointment with their prescriber. The pharmacist can contact the prescriber to negotiate an extension of an expired prescription. This will be followed up with a posted (or faxed and then immediately posted) confirmation from the prescriber. Regardless of the reason, the pharmacist should NOT dose the patient without a current prescription.

DO NOT dose the patient if the prescription is expired, regardless of the reason for the expiration.

It is expected that the patient will contact their prescriber or case manager if they are unable to attend the medical or case management review for the purpose of renewing their prescription. This appointment will need to be rescheduled as soon as possible. If the patient does not attend their review appointment the prescriber or case manager may advise them that a new prescription will not be issued until a clinical review is undertaken.

Changes to dosing

To prevent dosing errors or someone other than the prescriber trying to change a patient's dose, verbal communication about a prescription change for both supervised and takeaway doses must be confirmed by a faxed (and posted) prescription. This communication should also confirm the cancellation of the previous (old) prescription.

Confirm all prescription changes with the prescriber prior to dispensing.

Unexpected changes to a new prescription

Sometimes the pharmacist will observe an unexpected change to a new prescription. For example, the dose may have altered or a patient who previously had access to takeaway doses may now not have takeaways documented on the new prescription. The pharmacist can contact the prescriber to check whether the prescriber is no longer approving the provision of takeaway doses. Regardless of the reason for the change, the pharmacist cannot provide takeaway doses until prescribed. Confirmation by post (or fax and immediate post) is required before dispensing, including the cancellation of the previous (old) prescription.

16.5 Dosing errors

All dosing errors should be responded to promptly and referred to the prescribing doctor. The pharmacist should immediately assess the level of risk and respond accordingly. A patient who receives a dose in excess of that usually prescribed, is at risk of overdose and therefore a dosing error may constitute a medical emergency requiring immediate intervention (See Section 12.12: Managing Overdose).

If the pharmacist is unsure of how to respond to dosing errors, they should speak with their supervisor and contact the prescriber or an ADS Addiction Medicine Specialist for advice.

Prescribers must be notified immediately of all dosing errors.

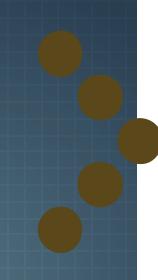
16.5.1 Methadone

In Australia, methadone liquid/syrup is supplied in a concentration of 5mg/mL. The pharmacist should take care when transposing mLs for mgs. For example, if a patient is prescribed 25mg (i.e. 5mL) and the pharmacist gives 25mLs (i.e. 125mg), this equates to a five-fold error. Such errors can be fatal.

Methadone liquid/syrup is supplied in a concentration of 5mg/mL and pharmacists should take care when transposing mLs to mgs.

Methadone dosing errors require an immediate response because it is absorbed rapidly and the peak effect occurs within 2-4 hours of ingestion (see Section 4.1). A patient who receives a methadone dose in excess of that usually prescribed is at risk of overdose and the dispenser should follow the following procedures:

1. Assess the patient's level of consciousness and
2. Call the Ambulance Service and request emergency assistance;
3. Clearly explain to the client that a dosing error has occurred and that they will require an urgent medical review;
4. Monitor the patient continually until they are in the care of the Ambulance Service or other medically qualified staff;
5. In the event of depression of respiratory or cardiac function:
 - establish a clear airway;
 - begin assisted or controlled ventilation with oxygen;
 - intravenous fluids and other supportive measures should be employed if available and appropriate as indicated; and
 - the long duration of action of methadone and buprenorphine should be taken into consideration when determining the length of treatment needed to reverse the effects of an overdose.

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6. If there is a delay in the provision of emergency services, request advice regarding first aid measures required;
 7. Advise the prescriber immediately, (or an ADS Addiction Medicine Specialist if the prescriber cannot be contacted), and make a written record of the event;
 8. The prescriber should contact the Emergency Department to provide advice on the patient's management. If this is not possible the ADS On Call doctor should be contacted to provide advice and support to the Emergency Department; and
 9. If possible, accompany the patient to the Emergency Department and provide a detailed handover to admitting staff.

Caution:

Inducing vomiting may be dangerous and is contraindicated. Medical advice and support should be sought immediately. In circumstances where medical help is not readily available or the patient 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.

While clinical evidence suggests that patients who have been on a dose > 40mg/day consistently for two months or longer will generally tolerate a single double dose without significant symptoms, it is still important to recognise that lower doses may compromise patient safety. This is particularly true in the cohort of patients who regularly use other depressant medications. Observations should occur in a hospital setting where appropriate protocols are established to assess, monitor and manage these risks.

If the patient has left the dosing site and cannot be located, every attempt must be made to contact them by:

- telephoning any other contact numbers that the patient has provided; or
- contacting the prescriber to request next of kin contact numbers; or
- contacting the police to request their assistance to find the patient; or

- requesting that the police organise for an ambulance to be on standby to attend to the patient.

16.5.2 Buprenorphine

Buprenorphine is generally safer in overdose, in view of its partial μ opioid receptor agonist actions. Hence buprenorphine dosing errors are usually less dangerous than methadone (full agonist) dosing errors. Nevertheless, buprenorphine dosing errors can still pose a significant risk, as it is a long acting depressant drug that can be associated with serious toxicity in overdose, particularly in the presence of other depressant drugs.

Therefore the procedure for managing a dosing error are the same as for methadone (see Section 16.5.1).

It is preferable for the pharmacy to have a process for recording dosing errors and the reason for the error. Pharmacists should examine and change their dosing protocols to minimise errors occurring again.

16.6 Dosing challenges

The following section will provide information relating to dosing procedures in certain circumstances. In the situation that a pharmacist is unsure about the safety of providing a dose to a patient, support and advice can be accessed from the patient's prescriber and/or the ADS. The patient should not be dosed until the pharmacist has assessed them as safe to receive this. The risk of overdose or death to a patient who is not safe to be dosed outweighs the discomfort of withdrawal experienced from delaying or missing one dose.

If the private prescriber is unavailable, clinical staff at the ADS are available for advice. Contact details are available on Page 200.

A prescription is an authorisation to supply a medication by the patient's medical prescriber; and is not a mandate to provide drugs. The pharmacist carries his or her duty of care obligations and therefore must make the final decision to dose the patient. Therefore, the pharmacist should dispense opiate medication only if it is safe to dose the patient.

If you are unsure, DO NOT DOSE.

The Alcohol and Drug Service can be contacted for advice at any time.

16.6.1 Intoxication

Patients should always be assessed for signs of intoxication prior to dosing. Intoxication can be the result of:

- excessive use of a drug;
- combination of certain drugs (including alcohol); or
- the patient's dose being too high.

Signs of intoxication will vary depending on the drug. A list of signs and symptoms of opioid intoxication is included in Table 2.1 of Section 2. See also Section 12: Managing Overdose, for further information. A full list of signs of intoxication for alcohol and a range of drugs is included in Appendix 16 & 17.

It is important to remember that dosing an intoxicated patient has the potential to result in severe harm or death.

The ADS specifies that patients cannot be dosed if they have a blood alcohol level (BAL) of greater than 0.00. Intoxication results from excessive use of one drug (including alcohol) or a combination of drugs. Patients should always be assessed by the dosing pharmacist before the administration of a methadone or buprenorphine dose. This assessment should ensure that the patient is not showing evidence of intoxication due to opioids or other drugs, see Section 5: Assessment.

Common signs of intoxication include:

- slurred speech;
- unsteady gait;
- drowsiness/nodding;
- pupil constriction;
- shallow breathing;
- smell of alcohol.

While deaths due to methadone alone are not uncommon; deaths almost always involve other CNS depressant drugs such as the benzodiazepines, alcohol, antidepressants and major tranquillisers. Patients will often argue they are sleepy because they could not sleep the night before or because they are legitimately prescribed other medication which is affecting them. The cause of intoxication is irrelevant. It should be clearly explained to the patient that to dose them in this state would be clinically unsafe and inappropriate and that as a healthcare professional, you will not under any circumstances do anything that could compromise their safety. Other actions may be indicated in addition under such circumstances.

The clinician has a duty of care to do whatever is necessary and reasonable to prevent the patient from driving or engaging in any other risky occupational or recreational activities. Additional actions may be required to ensure the patient is closely monitored and kept safe until the effects of the drugs wear off.

The risk of lethal overdose on buprenorphine in an opioid-tolerant individual is substantially less than that associated with the use all other opioid agonists including methadone. This is due to the ceiling dose response effects of buprenorphine. However, while overdose on buprenorphine is relatively uncommon, there is greater risk in combination with other sedative drugs, such as alcohol, benzodiazepines, antidepressants, and major tranquillisers. Several such deaths have been reported.

Patients who appear to be intoxicated with alcohol or CNS depressant drugs (including benzodiazepine, major tranquilliser and anti-depressant medications) should not be given their dose, nor given a takeaway dose at that time. If you suspect a patient may be intoxicated contact the prescriber for instructions. If you are unable to contact the prescriber the patient should be referred to the nearest hospital emergency department.

Pharmacists have a duty of care in such circumstances to inform medical staff at the local hospital emergency department of the patient's clinical status and to advise that they have

withheld the usual daily opioid pharmacotherapy dose because of concern about a drug affected presentation at their pharmacy.

Ideally, pharmacists should have access to a Breathalyser to test patients if they suspect alcohol intoxication; however, this is not possible in most pharmacies. Therefore, pharmacists are encouraged to be alert for other signs of alcohol intoxication, such as the smell of alcohol on the patient's breath or slurred speech.

The ADS specifies that patients cannot be dosed if they have a blood alcohol level (BAL) of greater than 0.00.

This policy is designed to illustrate to opioid pharmacotherapy patients that it is unsafe to use alcohol, and to encourage them to modify their consumption of alcohol, see Section 4: Pharmacology.

If a pharmacist believes that a patient is alcohol affected the following steps are recommended:

- ask the patient about their presentation in a non-judgemental manner, being mindful that patients may be uncomfortable disclosing substance use or fearful of potential consequences;
- explain their concerns about dosing; if there are obvious objective signs of intoxication, or if the patient discloses unsanctioned or risky substance use;
- do not dose or give the patient their takeaway doses if they are intoxicated with alcohol or other CNS depressant drugs (e.g. benzodiazepines or opioids; dosing intoxicated patients has the potential to cause adverse outcomes such as overdose and even death);
- inform the prescriber or ADS that the patient is intoxicated and dosing was refused. It may be possible to dose the patient in a few hours when they are no longer intoxicated. Before initiating a later dose, the pharmacist should discuss this with the prescriber;

- contact their prescriber or ADS (available 24 hours) for further advice or if you are unsure of what action to take;
- direct the patient to their prescriber if they have further questions; and
- **Telephone 000 or Mobile 112** if the patient is severely intoxicated, to request ambulance transport of the patient to the Emergency Department.

DO NOT dose or provide takeaway doses to intoxicated patients.

Ancillary medications when intoxicated

Many patients on opioid pharmacotherapy will also be on daily collection of ancillary medications. If it is inappropriate to dose the pharmacotherapy medication due to intoxication, then it is also unwise to be dosing or supplying CNS depressant medications.

The pharmacist may ask the patient to return later that or the following day when they are no longer alcohol affected.

Observation of patients

It is important for all pharmacy staff to observe patients as they enter the pharmacy for dosing. It is possible, for example, for an intoxicated patient to appear fine to dose while standing at the counter but may have an unsteady gait while walking to the counter. If a pharmacy staff member observes behaviour that indicates that the patient is unsafe to dose (e.g. unsteady gait, disorientation, or 'nodding' when not aware they are being observed), the staff member should raise their concern with the pharmacist.

16.6.2 Behavioural Considerations

All patients are expected to follow a code of conduct whilst attending a pharmacy for dosing. Prior to entering the ADS pharmacotherapy program, patients must review and sign a code of conduct, see Section 6.2.1. This code stipulates that the following behaviours may result in withdrawal from the program

- 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, especially where there is an ongoing pattern of diversion; and
- Dealing of substances in and around the service or dosing facility.

It is also important for the pharmacist to set limits and make clear that certain behaviours are not acceptable to pharmacy staff. Therefore, it is important for the pharmacist and patient to have a similar contract that outlines the pharmacy's code of conduct, acceptable behaviours, and patient rights and responsibilities. A sample contract is provided in Appendix 15.

Pharmacists are encouraged to have a contract with patients that outline the pharmacy's code of conduct and patient rights and responsibilities.

Inappropriate and unacceptable behaviour includes displays of aggression, offensive language, disruptive behaviour or intimidation, and coercion suggesting that pharmacy staff do not act in a clinically safe or professionally appropriate manner. Section 12 provides some guidance on de-escalating these types of behaviours. Pharmacists should communicate with the prescriber and/or contact ADS for advice if the patient's behaviour is concerning pharmacy staff. When patient behaviours are extreme or if there is suspicion of drug diversion, dealing, or other criminal activity, it is appropriate to inform the police. Allowing such behaviours to go unaddressed can put other members of the community at risk and bring the opioid pharmacotherapy program into disrepute.

Contact police if there is any evidence of drug diversion, dealing, or other criminal activity in or around the pharmacy.

Patients are also expected to adhere to requests made by the pharmacist regarding dosing procedures see Section 6.1.6: Rights and Responsibilities. These procedures ensure that doses are delivered safely and consumed by the patient. If the patient's behaviour contravenes the code of conduct, the pharmacist has the right to refuse dosing either temporarily or permanently.

The pharmacist has the right to refuse dosing either temporarily or permanently if the patient's behaviour contravenes the code of conduct.

It is important for the pharmacist to inform the prescriber if the patient's behaviour is inappropriate. This will assist the prescriber in determining the patient's safety and stability on the program.

Maintaining professional boundaries

It is important for the pharmacist and pharmacy staff to be professional and maintain clear boundaries with patients. This includes:

- not accepting gifts or favours;
- not socialising with the patient;
- not loaning the patient money or personal items; and
- not inviting the patient to the pharmacist's home.

16.6.3 Identifying diversion of dose

Diversion of doses poses significant risks to the safety of both the patient and the general public. Diversion can also be an indicator of clinical instability, thus affecting the patient's suitability on the program. A more detailed discussion of the risks associated with diversion can be located in Section 12.

Diverted doses can be injected by the patient to increase the effects of the drug or sold to another member of the public.

The diversion itself may not be directly observed by the pharmacist or pharmacy staff. However, certain patient behaviours and body language may indicate diversion

or attempted diversion of supervised doses. These can include:

- not wanting to stay for the supervision period;
- causing distractions;
- reading books or magazines close to the face and mouth;
- touching their mouth with their hand or sleeve;
- browsing the shop;
- spitting, coughing, sneezing;
- general out of character or inconsistent behaviour;
- nervousness;
- closely watching the pharmacist; and
- suspicious interaction with other patients or acquaintances after dosing.

Note: Adapted from Department of Health, Western Australia Government, 2006.

If the pharmacist has reason to believe that a patient is diverting a dose, it is appropriate for the pharmacist to ask the patient about this behaviour and to inform the patient of their concerns. It is also appropriate for the pharmacist to request to see the patient's hands. The patient should also be informed that the prescriber will be informed of these concerns. Diversion of takeaway doses may be more difficult for pharmacists to identify, but pharmacists sometimes report observing patients appearing to exchange money for takeaway doses outside the pharmacy.

16.6.4 Minimising Diversion of Dose

To minimise risk and avoid unnecessary suspicion of diversion, patients should be provided with clear guidance about how their medication will be given, the risks associated with misuse of doses, and how they should present at the pharmacy each day. The pharmacist may also communicate to patients what behaviours could be considered as signs of diversion.

Diversion of supervised doses can be reduced by the following procedures:

For both methadone and buprenorphine:

- dose one patient at a time;
- do not allow other people (including children where possible) in the dosing area while a patient is being dosed;
- do not allow bags, drinks, or other containers in the dosing area;
- ensure the patient throws away (into a designated bin) or hands back any items used during dosing;
- observe the patient throughout the dosing process, especially when the dose is placed in the mouth and immediately afterwards;
- once the dose is placed in the mouth, ensure that the patient keeps their hands away from their mouth; and
- CCTV monitoring is useful as it can record any inappropriate behaviour; it is important to tell patients about monitoring as they tend to modify their behaviour accordingly.

For buprenorphine:

- ask patients to remove chewing gum from their mouth prior to dosing;
- ask the patient where possible to remove dentures while still maintaining the dignity of the patient;
- for buprenorphine tablets, roughly crumble the dose to large granule size and place under the tongue; the patient must remain in full view of the pharmacist until the crushed tablets are dissolved;
- for buprenorphine film, the dose must be placed under the tongue, taking care not to overlap multiple films, and ensuring adequate time for them to dissolve;
- dispense the dose in a clear plastic cup or disposable spoon;
- avoid powdering the dose; and
- view and inspect the mouth cavity after the patient reports the dose has been absorbed.

For methadone:

- use an individual disposable cup for each patient;
- do not pour methadone into another drink container; and
- always dilute the dose to approximately 100mL with water or cordial.

16.6.5 Missed doses

Missed doses can be a sign of clinical instability and can impact on the effectiveness of opioid pharmacotherapy (see Section 8: Missed Doses and Section 12.9.6: Frequently Missed Doses).

Missing one or more doses affects steady state of drug blood levels. At commencement of treatment prescribers should clearly explain to patients the importance of not missing doses. They should also explain the process to be followed in the event doses are missed. When this does occur, the prescriber or ADS case manager should discuss the reasons again with a view to enhancing the patients treatment engagement and adherence. It may be clinically unsafe to dose and it is strongly advised that the pharmacist resumes dosing on the instruction of the prescriber (or ADS case manager).

It is important to note that the final clinical decision to dose a patient will always rest with the pharmacist and will be based on their assessment of the patient's suitability to dose.

When a patient presents for dosing, it remains the responsibility of the pharmacist to assess and determine if the patient is suitable to dose.

The following procedures should be followed when a dose is missed.

One missed dose:

*When the patient is **suitable to dose**:*

- the pharmacist may dose the patient if the patient is not intoxicated and no other risks or concerns are identified; and
- as soon as possible, the pharmacy notifies the prescriber (or ADS case manager) that the patient has missed a dose.

*When the patient is assessed by the pharmacist as **not suitable to dose**:*

- if the patient is not safe to dose it is strongly advised that the pharmacist respond accordingly and inform the patient that they cannot be dosed without further approval from their prescriber; and
- inform the patient that he or she needs to contact the prescriber (or ADS case manager); and
- the patient should not be dosed until they are reviewed by the prescriber (or ADS case manager).

Two consecutive missed doses:

- it is strongly advised that:
 - the patient is **not dosed**;
 - the patient is informed that they cannot be dosed without further approval from their prescriber;
 - the patient is advised to contact their treating prescriber or service and request a review from the prescriber (or ADS case manager); and
 - the prescriber (or ADS case manager) is notified of the consecutive missed doses.

Three or more consecutive missed doses:

- it is strongly advised that:
 - the patient is **not dosed**;
 - the patient is informed that they cannot be dosed without further approval from their prescriber;
 - the patient is advised to contact their treating prescriber or service and request a review from the prescriber;
 - if the patient is pregnant, refer them to the hospital as they are at risk of miscarriage; and
 - the prescriber (or ADS case manager) is notified of the consecutive missed doses.

If the patient misses three (3) or more consecutive doses, the pharmacist should only resume dosing on the instruction of the prescriber.

The prescriber will determine the appropriate recommencement dose for the patient after three or more missed doses.

If in doubt, the safest approach is to decline dosing and contact the prescriber for advice. On the basis of the number and pattern of missed doses and other clinical assessment, the prescriber can determine whether the patient's immediate and ongoing treatment plan needs to be adjusted.

16.6.6 Vomited doses

Sometimes patients will report having vomited a dose and consequently request a replacement dose. The pharmacist cannot authorise a replacement dose. Replacement doses can only be provided following the instruction and provision of a prescription from the prescriber. If the pharmacist witnesses the patient vomiting, the pharmacist should contact the prescriber concerned (Section 8.8: Missed Doses contains guidelines for replacing doses and what to do if the pharmacist has not witnessed this event).

There are special considerations for a patient who is pregnant or reports to be pregnant (see Sections 8 and 11 for guidelines). For patients who experience genuine problems with nausea or vomiting related to dosing, it is important to discuss with the prescriber the use of an antiemetic prior to the dose, and in the case of methadone, sitting quietly for 20 minutes.

As buprenorphine is absorbed sublingually, vomiting after the dose has been absorbed will have no effect on the blood levels of the drug. If a patient vomits whilst the dose is being absorbed (i.e. they still have pieces of the dose in their mouth) the blood levels may be affected, but unfortunately it would be extremely difficult to determine how much of the dose has been absorbed. In such cases the dose would usually not be replaced.

The pharmacist cannot authorise a replacement dose. Replacement doses can only be provided after authorisation from the prescriber.

16.6.7 Drug interactions

Pharmacists should be aware of medications that may interact with the patient's pharmacotherapy treatment. A list of drug interactions is listed in Appendix 1 & 3.

Some over the counter (OTC) medications can also interfere with the patient's pharmacotherapy. Furthermore, they may impact on the results of patient's urine sample results. Patients should be informed of the potential impact of OTC medications on their pharmacotherapy treatment and urine testing, see Section 9.1: Planned and Voluntary Withdrawal from Opioid Pharmacotherapy.

16.6.8 Side effects and adverse drug reactions

The pharmacist should contact the prescribing service if they believe the patient is experiencing an adverse reaction to pharmacotherapy. Of particular concern is the development of serotonin syndrome in patients on opioid medication and an SSRI SNRI. If the patient is significantly unwell, or the reaction occurs outside business hours, the pharmacist should seek urgent medical advice.

16.7 Financial considerations

Pharmacists are reimbursed for their participation in the opioid pharmacotherapy program by charging the patient a daily dosing fee.

16.7.1 Payment by patients

Patients are required to pay a fee for the administration of their dose. This fee is set by each pharmacy and is part of the contract between the pharmacy and the patient. The Tasmanian Opioid Pharmacotherapy Program, Policy and Clinical Practice Standards recommend that pharmacies do not allow patients to accumulate debts for dosing. Patients should be advised that they are required to make payment prior to dosing.

The fee is part of the patient's responsibilities and the pharmacy has the right to refuse dosing if the patient does not pay the fee and accumulates a debt.

To minimise restricted access to dosing due to the accumulation of debt, pharmacists are advised to request payment for dosing before the dose is dispensed. Pharmacists can also arrange for patients to pay for their weeks dosing ahead of time (e.g. on pay day) or direct debited from the patient's pay (e.g. via Centrepay).

In cases where patients are experiencing difficulty meeting these costs, pharmacists are encouraged to work with them to establish a payment plan and/ or encourage the patient to discuss other options with their case manager.

A policy of NO PAYMENT, NO DOSE is recommended.

16.8 Documentation

16.8.1 Recording doses

All the doses dispensed for a drug on a particular day can be recorded on a summary sheet (either by hand or electronically). This can ease the process of writing up the narcotic registers at the end of day. If a summary sheet is used, it must be signed by the pharmacist, stored in a designated folder, and kept for two years – the same length of time as the narcotic register. The ADS/PSB approved summary sheets can be obtained by contacting the Alcohol and Drug Service.

16.8.2 Maintaining patient records

It is recommended that each opioid pharmacotherapy patient dosing at the pharmacy has a separate folder that is kept in a secure place and accessible only by the pharmacist. The folder should contain:

- an identification sheet;
- a notes sheet;
- copy of prescription(s); and
- dosing administration charts for both pharmacotherapy and ancillary medications.

Colour coding the folders with a different colour for each of the three pharmacotherapy

preparations can help prevent dosing errors and improve dosing efficiency.

16.8.3 Blind dosing

Some prescribers may request a patient to be dosed without the patient being aware of the amount that they are receiving. This dosing technique requires the patient's consent. A blind dosing sheet for each of the pharmacotherapy drugs includes a section for the patient's witnessed consent, for copies of these forms, contact the Alcohol and Drug Service.

16.8.4 Supplementary doses

During the induction phase, patients may receive supplementary doses, as directed by the prescriber. To assist in dosing in this circumstance, an induction dosing sheet for each of the pharmacotherapy drugs, with ability to record several doses for copies of these forms, contact the Alcohol and Drug Service.

While supplementary doses can be prescribed, the TOPP does not support split dosing regimens (See Section 8).

16.8.5 Communication between pharmacists

Good internal communication systems are essential for reducing dosing errors and improving dosing efficiency. One strategy is having a diary or book in which information that pharmacists need to know about a patient can be recorded. Notes can then be attached to the dosing sheet so that they are seen and read by the pharmacist before the patient is dosed; (e.g. circumstances or agreements that have been put in place to assist dosing stability for patients.)

16.8.6 Computer dosing programs

Computer dosing programs are available to assist with the dosing process for methadone, Subutex® and Suboxone®. Such programs can be attached to an approved automated pump for methadone. These programs have many advantages over a paper system, including:

- they are an additional checking process for the pharmacist;
- they provide photo identification;

- they alert the pharmacist when the prescription is due to expire;
- they prevent the dose being marked as dispensed once the prescription is expired;
- they provide an electronic narcotic register; and
- a summary of the daily dosing for each drug can be printed at the end of day.

For further information regarding dosing programs, please contact an ADS pharmacist on (03) 6230 7984 or (03) 6230 7983.

16.8.7 Pharmacy transfers

Pharmacists are required to follow procedure when transferring patients. To ensure a smooth transfer occurs, the pharmacy from which the patient is transferring should communicate with the new pharmacy and confirm when the final dose was given. This helps prevent double dosing the patient and the occurrence of potentially dangerous dosing errors. The original pharmacy must complete a confirmation of last dose sheet and fax or post this and a confirmation of the patient's dosing schedule to the receiving pharmacy. The receiving pharmacy will require a new prescription from the prescriber: it is not appropriate to continue using the old prescription. The new pharmacy will need to confirm the dosing schedule with the prescriber. For more information see Section 14 Transfers.



ACRONYMS

ACTH	Adreno-Cortico-Trophic Hormone	DSM-IV-TR	Diagnostic and Statistical Manual, 4th revision, text revision
ADDA	Alcohol and Drug Dependence Act (1968)	EAP	Expert Advisory Panel
ADEC	Australian Drug Evaluation Committee	EBP	Evidence Based Practice
ADH	Anti Diuretic Hormone	ELISA	Enzyme-linked immunosorbent assay
ADS	Alcohol and Drug Services	ESR	Erythrocyte Sedimentation Rate
AHPRA	Australian Health Practitioner Regulation Agency	FOI	Freedom of Information
AIWB	Australian Institute of Health and Welfare	GAA	Guardianship Act (1995)
ANCD	Australian National Council on Drugs	GAB	Guardianship and Administration Board
AOD	Alcohol and Other Drug	GAD	Generalised anxiety disorder
ATI	Advocacy Tasmania Incorporated	GCMS	Gas Chromatography and Mass Spectrometry
ATOD	Alcohol, Tobacco and Other Drugs	GP	General Practitioner
BAL	Blood Alcohol Level	HAART	Highly active antiretroviral therapy
BBV	Blood Borne Virus	HBV	Hepatitis B Virus
BD	Bis Die (Latin) a medication need to be taken twice a day	HIV	Human immunodeficiency virus
C&A	Cautionary and Advisory	ICD 10	International Classification of Diseases
CALD	Culturally and Linguistically Diverse	ID	Identification
CAT	Clinical Assessment Tool	IDRS	Illicit Drug Reporting System
CBT	Cognitive Behaviour Therapy	Kg	Kilogram
CCTV	Close Circuit Television	mcg	Micrograms
CLS	Consult Liaison Service	mg	Milligrams
CNS	Central Nervous System	MHA	Mental Health Act (1996)
COWS	Clinical Opioid Withdrawal Scale	mL	Millilitres
DHHS	Department of Health and Human Services, Tasmania	NAS	Neonatal Abstinence Syndrome
		NCADA	National Campaign Against Drug Abuse
		NDSHS	National Drug Strategy Household Survey

NEPOD	National Evaluation of Pharmacotherapies for Opioid Dependence	SIDS	Sudden Infant Death Syndrome
NSAIDS	Nonsteroidal anti-inflammatory drugs	SNRI	Serotonin Noradrenaline Reuptake Inhibitor
NSMHWB	National Survey of Mental Health and Wellbeing	SOWS	Subjective Opiate Withdrawal Scale
NSP	Needle Syringe Program	SSRI	Selective Serotonin Reuptake Inhibitor
OPP	Opioid pharmacotherapy programs	TAD	Takeaway Dose
OR	Opioid Receptors	TGA	Therapeutic Goods Administration
OTC	Over the Counter Medications	TOPP	Tasmanian Opioid Pharmacotherapy Program Policy and Clinical Practice Standards
PBS	Pharmaceutical Benefits Scheme	UDS	Urine drug screen
PCA	Patient Controlled Analgesia	WHO	World Health Organisation
PCA	Patient Controlled Analgesia		
PIP	Personal Information Protection Act (2004)		
PRIM	Protective and Risk Indicator Model		
PSB	Pharmaceutical Services Branch (Tasmanian Department of Health and Human Services)		
PSB OCHO	Pharmaceutical Services Branch (Office of the Chief Health Officer)		
PTSD	Post traumatic stress disorder		
PWID	People who inject drugs		
QCPP	Quality Care Pharmacy Program		
RACP	Royal Australian College of Physicians		
RBT	Random breath testing		
RCT	Randomised controlled trial		
RTI	Right to Information(2010)		
S4D	Schedule 4 Drugs – Declared Restricted Substances		
S8	Schedule 8 (Drug)		



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Recommended Reading

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APPENDICES

Appendix I

Possible Drug Interactions with Methadone

Drug	Status of Interaction	Effect	Mechanism
Alcohol	Clinically important	Increased sedation, increased respiratory depression. Combination may also have increased hepatotoxic potential.	Addictive central nervous system depression.
Barbiturates	Clinically important	Reduced Methadone levels. Increased sedation. Addictive CNS depression.	Barbiturates stimulate hepatic enzymes involved in methadone maintenance.
Benzodiazepines	Clinically important	Enhanced sedative effect.	Addictive CNS depression.
Buprenorphine	Clinically important	Antagonist effect or enhanced sedative and respiratory depression.	Buprenorphine is a partial agonist of opiate receptors.
Carbamazepine	Clinically important	Reduced methadone levels.	Carbamazepine stimulates hepatic enzymes involved in methadone metabolism.
Chloral Hydrate	Clinically important	Enhanced sedative effect.	Additive CNS depression.
Chlormethiazole	Clinically important	Enhanced sedative effect.	Additive CNS depression.
Cimetidine	Two cases have been reported in patients taking methadone as analgesia.	Possible increase in methadone plasma levels.	Probably by inhibiting hepatic enzymes involved in methadone metabolism.
Ciprofloxacin	Case in a patient taking methadone.	Enhance sedative effect and respiratory depression requiring naloxone.	Probably by inhibiting hepatic enzymes involved in methadone metabolism.
Cisapride Domperidone Metoclopramide	Theoretical	Theoretically might increase the speed of onset of methadone absorption but not the extent.	Possibly by reversing the delayed gastric emptying associated with opioids.

Drug	Status of Interaction	Effect	Mechanism
Cyclazine and other sedating anti-histamines. (cyclazine is not available in Australia)	Clinically important	Anecdotal reports of injection of cyclazine with opioids causing hallucinations. Reports of injections of high doses of dephénydramine to achieve 'buzz'.	Addictive psychoactive effects. Anti muscarinic effects at high doses.
Desipramine	Clinically important	Raised desipramine levels by up to a factor or two.	Unknown mechanism not seen with other tricyclic antidepressants.
Other tricyclic antidepressants	Theoretical	Enhanced sedative effect which is dose dependent.	Addictive CNS depression.
Disulfiram	Avoid in combination with methadone formulations containing alcohol (check with manufacturer).	Very unpleasant reaction to alcohol which can be dangerous.	Disulfiram inhibits metabolism of alcohol allowing metabolites to build up.
Erythromycin	In theory should interact but combination has not been studied.	Increase in methadone levels.	Decreased methadone metabolism.
Fluconazole	In theory the same as ketoconazole.		
Fluoxetine Sertraline	Clinically important	Raised methadone levels but not as significant as for fluvoxamine.	Decreased methadone metabolism.
Fluvoxamine	Clinically important	Raised plasma methadone levels.	Decreased methadone metabolism.
Other SSRIs	Theoretical		
Grapefruit juice	Should interact in theory and there have been several anecdotal reports.	Raised methadone levels.	Decreased methadone metabolism.
Indinavir	Clinically important	Raised methadone levels.	Decreased methadone metabolism.
Ketoconazole	Clinically important	Raised methadone levels.	Decreased methadone metabolism.
MAOI (including selegiline and moclobemide)	Severe with pethidine through unlikely with methadone and has never been described.	CNS excitation, delirium, hyperpyrexia, convulsions, hypotension or respiratory depression.	Unclear, avoid the combination if possible.

Drug	Status of Interaction	Effect	Mechanism
Meprobamate	Clinically important	Enhanced sedative and respiratory depressant effect.	Addictive CNS depression
Naltrexone	Clinically important	Blocks effect of methadone (long acting).	Opioid antagonist – competes for opiate receptors.
Naloxone	Clinically important	Blocks effect of methadone (short acting) but may be needed if overdose suspected.	Opioid antagonist – competes for opiate receptors.
Nevirapine	Clinically important	Decreased methadone levels.	Increased methadone metabolism.
Nifedipine	Has been demonstrated in vitro only.	Increased nifedipine levels. No effect on methadone levels.	Methadone increased metabolism o nifedipine.
Omeprazole	To date demonstrated only in animals.	Increased methadone levels.	Possibly an effect on methadone absorption for the gut.
Pentazocine		Antagonist effect or enhanced sedative and respiratory depression.	Pentazocine is a partial antagonist of opiate receptors with weak antagonist effect.
Phenobaritone	See barbiturates above		
Phenytoin	Clinically important	Reduced methadone levels.	Phenytoin stimulates hepatic enzymes involved in methadone metabolism.
Propanolol	To date demonstrated only in animals. Significance in humans is not known. Exercise caution when co-administering.	Enhanced lethality of toxic doses of opioids.	
Rifampicin	Very important. Most patients are likely to be affected.	Reduced methadone levels.	Rifampicin stimulates hepatic enzymes involved in methadone metabolism.
Rifabutin	Occasionally clinically important.	Decreased methadone levels.	Increased methadone metabolism.
Ritonavir	Clinically important.	Ritonavir may decrease plasma methadone levels.	Increased methadone metabolism.
Thioridazine	Clinically important.	Enhanced sedative effect which is dose dependent.	Enhanced CNS depression.

Drug	Status of Interaction	Effect	Mechanism
Other protease inhibitors	Theoretical	May raise or lower methadone plasma levels.	Inhibits methadone metabolism.
Urine acidifiers e.g. ascorbic acid – vitamin C	Clinically important	Reduced plasma methadone levels.	Increased urinary excretion of methadone.
Urine alkalisers e.g. sodium bicarbonate	Clinically important	Increased plasma methadone levels.	Reduced urinary excretion of methadone.
Zidovudine	Clinically important	Raised plasma levels of zidovudine. No effects on methadone levels.	Unknown
Zopiclone	Clinically important	Enhanced sedative and respiratory depressant effect.	Addictive CNS depression.
Other opioid agonists	Clinically important	Enhanced sedative effect. Enhanced respiratory depression.	Addictive CNS depression.
Other CNS depressant drugs (e.g. neuroleptics, hyoscine)	Clinically important		Addictive CNS depression.

Note: Reproduced from the Western Australian *Clinical policies and procedures for the use of methadone and buprenorphine in the treatment of opioid dependence*, 2006.

Appendix 2

Medications Metabolised by Cytochrome

This information is based on the listing at <http://medicine.iupui.edu/flockhart/table.htm>

Inhibitors (potentially increasing blood levels of buprenorphine)	Substances	Inducers (potentially decreasing blood levels of buprenorphine)
HIV Antivirals: Delviridine Indinavir Nelfinavir Ritonavir Other: Amiodarone Cimetidine Clarithromycin Erythromycin Fluconazole Fluvoxamine Grapefruit juice Itraconazole Ketoconazole Nefazodone Norfloxacin Verapamil	Macrolide antibiotics: Clarithromycin Erythromycin Anti-arrhythmics: Quinidine Benzodiazepines: Alprazolam Diazepam Midazolam Immune modulators: Cyclosporine Tacrolimus HIV Antivirals: Indinavir Nelfinavir Ritonavir Saquinavir Prokinetic Cisapride Antihistamines: Astemizole Calcium Channel Blockers: Amlodipine Diltiazem Felodipine Nifedipine Verapamil	HMG CoA Reductase Inhibitors: Atrovastatin Cerivastatin Lovastatin NOT pravastatin Simvastatin Steroids: Estradiol Hydrocortisone Progesterone Testosterone Miscellaneous: Buspirone Dapsone Fentanyl LAAM Methadone Ondansetron Propranolol Quinine Tamoxifen Trazodone Zolpidem

Note: Reproduced from the Western Australian *Clinical policies and procedures for the use of methadone and buprenorphine in the treatment of opioid dependence, 2006*.

Appendix 3

Possible Drug Interactions with Buprenorphine or Buprenorphine-Naloxone

Drug	Status of Interaction	Effect	Mechanism
Alcohol	Clinically important	Increased sedation, increased respiratory depression. Combination may also have increased hepatotoxic potential.	Addictive central nervous system depression.
Benzodiazepines	Clinically important	Enhanced sedative effect.	Addictive CNS depression
Methadone and other opioids	Clinically important	Buprenorphine's antagonist effect may precipitate withdrawal in patients taking other opioids, or enhanced sedative and respiratory depression.	Buprenorphine is a partial agonist of opiate receptors.
Naltrexone and naloxone	Clinically important	Greatly reduced antagonist effect of naltrexone and naloxone.	Buprenorphine has higher affinity for opioid receptors than naltrexone and naloxone.

Drugs that inhibit CYP 3A4

Erythromycin and other macrolide antibiotics	Clinically important	Raised buprenorphine levels	Decreased buprenorphine metabolism
HIV protease inhibitors such as indinavir, ritonavir, saquinavir	Clinically important	Raised buprenorphine levels	Decreased buprenorphine metabolism
Ketoconazole and other azole antifungal agents	Clinically important	Raised buprenorphine levels	Decreased buprenorphine metabolism

Drugs that induce CYP 3A4

Carbamazepine	Theoretical	Reduced buprenorphine levels	Increased buprenorphine metabolism
Barbiturates, e.g. phenobarbitone	Clinically important	Reduced buprenorphine levels. Increased sedation Addictive CNS depression.	Increased buprenorphine metabolism
Phenytoin	Theoretical	Reduced buprenorphine levels	Increased buprenorphine metabolism
Rifampicin	Theoretical	Reduced buprenorphine levels	Increased buprenorphine metabolism

Note: Reproduced from the New South Wales *Clinical guidelines for methadone and buprenorphine treatment of opioid dependence.*, 2006.

Appendix 4

ADS Clients Rights and Responsibilities Brochure

Alcohol and Drug Services

Client Rights and Responsibilities



SAMPLE ONLY

If you have a comment or complaint about our service we suggest that you:

1. Complete a Client/Carer Feedback form (available online or at our Alcohol and Drug Service offices) and/or; Discuss the matter with your Key Worker/Case Manager
2. Ask to speak with the Unit Manager or Service Manager:
Phone: 1300 139 641
Mail: GPO Box 125,
HOBART TAS 7001
Web: www.dhhs.tas.gov.au

Useful contacts

Advocacy Tasmania	1800 005 131
Alcohol and Drug Information Service (24 hour)	1800 198 024
Health Complaints Commission	1800 001 170
Ombudsman Tasmania	1800 001 170

Useful information

Tasmanian Charter of Health Rights and Responsibilities	Found at: www.healthcomplaints.tas.gov.au
Australian Charter of Health Care Rights	Personal Information Protection Act 2004
	Right to Information Act (RTI) 2009
	Found at: www.ombudsman.tas.gov.au

For further information

Alcohol and Drug Service
Department of Health and Human Services
GPO Box 125
Hobart TAS 7001
Phone: 1300 139 641
www.dhhs.tas.gov.au

Tasmania
Explore the Possibilities

Published March 2012
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The Alcohol and Drug Service

The Alcohol and Drug Service works closely with you to reduce the harms caused by alcohol, tobacco and other drugs.



As a client of the Alcohol and Drug Service you are an important partner in planning your care and managing your life. When you are well informed, participate in treatment decisions and communicate openly with your doctor and other health professionals, you help make your treatment as effective as possible.

Your rights

As a person who is receiving alcohol and drug services, you have the right to:

- be treated with respect and dignity;
- receive the best care that we can provide;
- discuss options for care in terms and language that you can understand;
- have your personal health information protected and treated appropriately;
- express concerns to your health care provider without fear of affecting your care; and
- involve others in your care e.g. family members, carers and/or guardians.

Your information is kept confidential

With your consent we will collect personal information from you to help us provide you with the most appropriate and effective treatment. This information is stored securely and is restricted to health professionals who have a duty of care towards you and/or those who are involved in your treatment.

In exceptional circumstances, it is possible that certain information may have to be released. If you wish to access your personal records, please discuss this with your Key Worker/Case Manager. They will provide you with information regarding the process for accessing your records based on the information you are seeking.



What is expected of you

In providing you with the best possible treatment, the Alcohol and Drug Service expects you to:

- respect the rights, safety and privacy of others;
- treat others with respect, dignity and courtesy;
- provide accurate information;
- identify your needs and bring concerns to staff;
- ask questions if the information given is unclear;
- actively participate in your care and discharge planning;
- keep appointments, or notify in advance if unable to do so; and
- be aware that Alcohol and Drug Services is a smoke free environment.

Appendix 5

ADS Pharmacotherapy Treatment Agreement

Department of Health and Human Services

ALCOHOL AND DRUG SERVICES

Alcohol and Drug Services  PHARMACOTHERAPY TREATMENT AGREEMENT	*Affix patient identification label here
	Client ID/ URN:
	Family Name:
	Given Name(s):
	DOB:/...../..... Sex: F <input type="checkbox"/> M <input type="checkbox"/>

This is an agreement between Alcohol and Drug Services and the Client for Opioid Pharmacotherapy Treatment

I agree to the following conditions, which apply to all clients entering treatment onto the Tasmanian Opioid Pharmacotherapy Program:

I AGREE:

1. To travel to the designated Alcohol and Drug Service and attend all scheduled appointments with my case manager and prescribing doctor.
2. That if I miss 2 or more doses, I will be required to attend the designated Alcohol and Drug Service for a case management and/or medical review.
3. To arrange my own transport to and from the Pharmacy/dosing site.
4. That when attending for dosing, only my children and/or partner may accompany me onto the Pharmacy/dosing site. If I am attending for dosing at St John's Park, my children will not be permitted to accompany me into the dosing room.
5. To attend for dosing at the scheduled time where a specific time is allocated (as instructed by the Pharmacy/dosing site or Alcohol and Drug Services), and accept that I will not be dosed outside of these set dosing times.
6. To attend for dosing in person and accept that my dose will not be given to anyone on my behalf.
7. To provide urine and/or blood for random drug screening or to be breathalysed as requested.
8. The payment for each dose is required before receiving medication. Payment is my responsibility and is a private agreement with the Pharmacy/dosing site. The amount to be paid for dosing is determined by the Pharmacy/dosing site and is not the responsibility of the Alcohol and Drug Service.
9. To consume my medication under supervision. I understand that if I attempt to divert my medication I may be removed from the program.
10. To leave the Pharmacy/dosing site immediately after completion of my dosing.
11. To behave in an acceptable manner towards staff at all times and I will not harass staff at the Pharmacy/ site regarding doses, takeaways or other issues. Behaviours that are not acceptable include swearing, hostile or aggressive actions, intimidation, damage to property and threatening behaviour towards staff or other clients. Any issues regarding dosing will be discussed with my case manager or prescribing doctor.
12. Not to bring any weapons or drugs (legal or illegal) to either the Alcohol and Drug Service or the Pharmacy/dosing site.
13. To accept responsibility for my behaviour at my nominated Pharmacy/dosing site. I accept that my dose may be declined if the pharmacist believes I am intoxicated. I accept that in such circumstances I will need to attend the Alcohol and Drug Service for review with my case manager and/or doctor.
14. If my nominated Pharmacy/dosing site chooses not to continue to dose me for any reason, it will be my responsibility to locate another Pharmacy/dosing site. If I am unable to locate another Pharmacy/dosing site, I understand I may not be able to continue on the pharmacotherapy program.

Continued next page...

 <p>Alcohol and Drug Services PHARMACOTHERAPY TREATMENT AGREEMENT</p>	*Affix patient identification label here Client ID/ URN: Family Name: Given Name(s): DOB: / / Sex: F <input type="checkbox"/> M <input type="checkbox"/>
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15. To accept the conditions concerning access to takeaway medication within the Tasmanian Pharmacotherapy Program. I understand takeaway access is governed by safety and stability concerns. I accept that takeaway medication will only be provided while the treatment team feel it is safe to do so.
16. If the treatment team believe takeaway medication is no longer safe for me or the community, they may suspend my access to takeaways.
17. To provide 5 working days notice to my case manager when requesting alternative dosing arrangements within Tasmania. I agree to provide 4 weeks notice when requesting an interstate transfer and 6 weeks notice when requesting an international transfer. In the event of an emergency transfer request, I agree to provide documentation to substantiate any request.
18. That my continuation on the program will depend on whether Alcohol and Drug Service staff believe treatment is safe and in my best interest. I understand that continued use of opioids, amphetamines, benzodiazepines, alcohol or other drugs of concern may result in a greater risk to my health whilst I am on the pharmacotherapy program. I accept that if I continue to use such substances then the Alcohol and Drug Service staff may need to withdraw me from the pharmacotherapy program as part of their duty of care to me and the wider community.
19. That any suspicion of drug dealing or any other illegal activities or unacceptable behaviour within the vicinity of the service or nominated Pharmacy/dosing site may result in the police being called and commencement of processes that may lead to removal from the program.

Additional conditions relating to your treatment with ADS include:

.....
.....
.....
.....
.....
.....

I have read and understood the above treatment contract. I understand that my continuation within the pharmacotherapy program will be reviewed if I do not adhere to the above conditions. I accept that if I breach the above conditions then I may be withdrawn from the program.

Client Name (clear print):

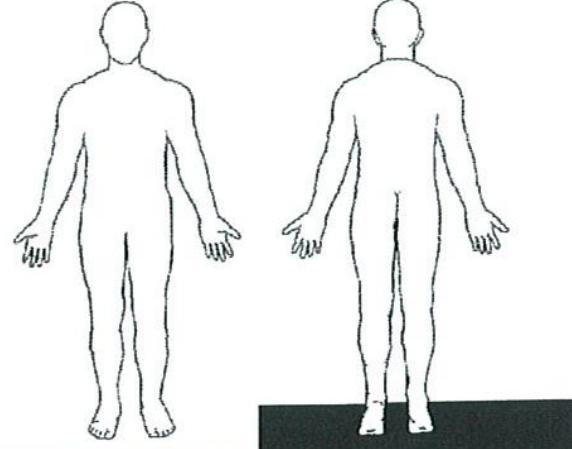
Client Signature: Date: / / 20

Clinician's name (clear print):	Designation:
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Clinician's signature:	Date: / / 20	Time:
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Appendix 6

ADS Opioid Pharmacotherapy Program Confidential Client Identification Form

Department of Health and Human Services		ALCOHOL AND DRUG SERVICES
<p>Alcohol and Drug Services Opioid Pharmacotherapy Program CONFIDENTIAL CLIENT IDENTIFICATION</p> <p></p>		
<p>*Affix patient identification label here</p> <p>Client ID/ URN: Family Name: Given Name(s): DOB: / / Sex: F <input type="checkbox"/> M <input type="checkbox"/></p>		
<p><input type="checkbox"/> Alcohol and Drug Services – NORTH 13 Mulgrave Street, LAUNCESTON TAS 7250 Ph: 6336 5577 Fax: 6336 5567</p> <p><input type="checkbox"/> Alcohol and Drug Services – NORTH WEST 11 Grove Street, ULVERSTONE TAS 7315 Ph: 6429 8555 Fax: 6429 8599</p> <p><input type="checkbox"/> Alcohol and Drug Services – SOUTH GPO Box 125, HOBART TAS 7000 Ph: 6230 7901 Fax: 6230 7922</p>		
<p>Client Details</p> <p>Address:</p> <p>Suburb: State: Postcode:</p>		
<p>Patient (PSB) No: Marital Status:</p> <p>Mother's Maiden Name:</p> <p>Height: Weight:</p> <p>Eye Colour: Hair Colour:</p> <p>Personal Identification Provided:</p>		
<p>Distinguishing Features</p> <p>Please mark any tattoos or distinguishing features on the diagram below:</p> <p> Front Back</p> <p>Insert photo here</p> <p>Date of Photo: / / 20.....</p>		
<p>Clinician's name (clear print): Designation:</p> <p>Clinician's signature: Date: / / Time: Page I</p>		

 <p>Alcohol and Drug Services Opioid Pharmacotherapy Program PROOF OF IDENTITY</p>	*Affix patient identification label here Client ID/ URN: Family Name: Given Name(s): DOB: / / Sex: F <input type="checkbox"/> M <input checked="" type="checkbox"/>
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Patient Identification (this page is for completion by Alcohol and Drug Services ONLY)

Instruction: Clients are required to provide 100 points of identification. A copy (scanned or photocopied) MUST be obtained of all documents provided as proof of identity. These should also be marked on the checklist (below) as being sighted.

It is important to check that the photograph is embedded into the identification and the signature on any document produced as proof of identity matches the signature on the consent section of the application for treatment.

A copy of the first page (ONLY) of this identification form should be provided to pharmacists in addition to a letter of introduction at the commencement of the dosing arrangements. This document should also accompany any and inter/interstate transfer documentation.

Check <i>(for completion by Alcohol and Drug Services ONLY)</i>	Points with Photo	Points without Photo	ID Sighted <input checked="" type="checkbox"/>
- Photo Identity Card	100		<input type="checkbox"/>
- Current Australian passport	100		<input type="checkbox"/>
- Minor (18 years or less) with a parent or guardian	100		<input type="checkbox"/>
- Current International passport	100		<input type="checkbox"/>
- Patient known to the Medical practice for more than 5 years	75		<input type="checkbox"/>
- Current Tasmanian motor driver's licence or firearm licence	100	25	<input type="checkbox"/>
- Acknowledgement of current name/date of birth/address from records held by a Government Authority	40	25	<input type="checkbox"/>
- Licence or permit issued under Australian law	40	25	<input type="checkbox"/>
- Identity card or licence issued by a Government Authority outside of Australia	40	25	<input type="checkbox"/>
- Current identification card with name/date of birth/address issued by a Government Authority	40	25	<input type="checkbox"/>
- Current identification card with name/date of birth/ address issued by a tertiary institution	40	25	<input type="checkbox"/>
- Acknowledgement of current name/date of birth/address from a recognised professional body or trade association	40	25	<input type="checkbox"/>
- Medicare card	40	25	<input type="checkbox"/>
- Healthcare card	40	25	<input type="checkbox"/>
- Under 18 card	40	25	<input type="checkbox"/>
- Credit card	40	25	<input type="checkbox"/>
- Name and address on the Australian electoral roll		25	<input type="checkbox"/>
- Acknowledgement of current name/date of birth/ address from records held by a financial body		25	<input type="checkbox"/>
- Acknowledgement of current name/date of birth/address from owner or managing agent of rented domestic/business premises		25	<input type="checkbox"/>
- Acknowledgment of current name/date of birth/address from an insurance company		25	<input type="checkbox"/>
- Certified copy or extract of a birth certificate; a citizenship certificate or a marriage certificate		25	<input type="checkbox"/>
- Authorised Identification Form ie tattoos, scars, height, and hair colour		25	<input type="checkbox"/>
TOTAL			

Clinician's name (clear print): Designation:

Clinician's signature: Date: / / Time: Page 2

Appendix 7

ADS Clinical Opiate Withdrawal Scale (COWS)

<p>Department of Health and Human Services</p>  <p>Clinical Opiate Withdrawal Scale (COWS) Single Use</p>	<p>ALCOHOL AND DRUG SERVICES</p> <p>*Affix patient identification label here*</p>																																																																	
<p>For each item, circle 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 increased pulse rate would not add to the score.</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td colspan="2">Resting Pulse Rate: Beats/minute Measured after patient is sitting or lying for one minute</td> <td rowspan="11" style="vertical-align: middle; text-align: center; font-size: 2em; opacity: 0.5;">SAMPLE ONLY</td> </tr> <tr> <td>0</td> <td>pulse rate 80 or below</td> </tr> <tr> <td>1</td> <td>pulse rate 81 – 100</td> </tr> <tr> <td>2</td> <td>pulse rate 101 – 120</td> </tr> <tr> <td>4</td> <td>pulse rate greater than 120</td> </tr> <tr> <td colspan="2">Sweating: over past ½ hour not accounted for by room temperature or patient activity</td> </tr> <tr> <td>0</td> <td>no report or chills or flushing</td> </tr> <tr> <td>1</td> <td>subjective report of chills or flushing</td> </tr> <tr> <td>2</td> <td>flushed or observable moistness on face</td> </tr> <tr> <td>3</td> <td>beads of sweat on brow or face</td> </tr> <tr> <td>4</td> <td>sweat streaming off face</td> </tr> <tr> <td colspan="2">Restlessness: observation during assessment</td> </tr> <tr> <td>0</td> <td>able to sit still</td> </tr> <tr> <td>1</td> <td>reports difficulty sitting still, but is able to do so</td> </tr> <tr> <td>2</td> <td>frequent shifting or extraneous movements or legs/arms</td> </tr> <tr> <td>3</td> <td>unable to sit still for more than a few seconds</td> </tr> <tr> <td colspan="2">Pupil Size:</td> </tr> <tr> <td>0</td> <td>pupils pinned or normal size for room light</td> </tr> <tr> <td>1</td> <td>pupils possibly larger than normal for room light</td> </tr> <tr> <td>2</td> <td>pupils moderately dilated</td> </tr> <tr> <td>5</td> <td>pupils so dilated that only the rim of the iris is visible</td> </tr> <tr> <td colspan="2">Bone or joint aches: If patient was having pain previously, only the additional component attributed to opiates withdrawal is scored.</td> </tr> <tr> <td>0</td> <td>not present</td> </tr> <tr> <td>1</td> <td>mild diffuse discomfort</td> </tr> <tr> <td>2</td> <td>patient reports severe diffuse aching or joints/muscles</td> </tr> <tr> <td>4</td> <td>patient is rubbing joints or muscles and is unable to sit still because of discomfort</td> </tr> <tr> <td colspan="2">Runny nose or tearing: not accounted for by cold symptoms or allergies</td> </tr> <tr> <td>0</td> <td>not present</td> </tr> <tr> <td>1</td> <td>nasal stuffiness or unusually moist eyes</td> </tr> <tr> <td>2</td> <td>nose running or tearing</td> </tr> <tr> <td>4</td> <td>nose constantly running or tears streaming down cheeks</td> </tr> <tr> <td colspan="2" style="background-color: red; color: white; text-align: right;">TOTAL COWS SCORE:</td> </tr> </table>		Resting Pulse Rate: Beats/minute Measured after patient is sitting or lying for one minute		SAMPLE ONLY	0	pulse rate 80 or below	1	pulse rate 81 – 100	2	pulse rate 101 – 120	4	pulse rate greater than 120	Sweating: over past ½ hour not accounted for by room temperature or patient activity		0	no report or chills or flushing	1	subjective report of chills or flushing	2	flushed or observable moistness on face	3	beads of sweat on brow or face	4	sweat streaming off face	Restlessness: observation during assessment		0	able to sit still	1	reports difficulty sitting still, but is able to do so	2	frequent shifting or extraneous movements or legs/arms	3	unable to sit still for more than a few seconds	Pupil Size:		0	pupils pinned or normal size for room light	1	pupils possibly larger than normal for room light	2	pupils moderately dilated	5	pupils so dilated that only the rim of the iris is visible	Bone or joint aches: If patient was having pain previously, only the additional component attributed to opiates withdrawal is scored.		0	not present	1	mild diffuse discomfort	2	patient reports severe diffuse aching or joints/muscles	4	patient is rubbing joints or muscles and is unable to sit still because of discomfort	Runny nose or tearing: not accounted for by cold symptoms or allergies		0	not present	1	nasal stuffiness or unusually moist eyes	2	nose running or tearing	4	nose constantly running or tears streaming down cheeks	TOTAL COWS SCORE:	
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<p>Source: Wesson Dr, Ling W. The clinical opiate withdrawal scale (COWS). J Psychoactive Drugs 2002; 35: 253-259.</p> <p>Clinician's name (clear print): Designation:</p> <p>Clinician's signature:..... Date:/...../20..... Time 24 hour clock, midnight = 00:00</p>																																																																		

Appendix 8

ADS Pharmacotherapy Takeaway Dose Risk Assessment Plan

Department of Health and Human Services		ALCOHOL AND DRUG SERVICES																																																																																																																																																																																																																																																																																																																						
 <p>Pharmacotherapy</p> <p>TAKE-AWAY DOSE</p> <p>Risk Assessment Plan</p>		*Affix patient identification label here Client ID/ URN: Family Name: Given Name(s): DOB: / / Sex: F <input type="checkbox"/> M <input checked="" type="checkbox"/>																																																																																																																																																																																																																																																																																																																						
Date of Registration: / / 20 Last Medical Officer Review: / / 20 Last Case Manager Review: / / 20 Current Takeaways or Dosing Regime: Methadone <input type="checkbox"/> Biodone® <input type="checkbox"/> Subutex® <input type="checkbox"/> Suboxone® <input type="checkbox"/> Dose: mgs Current takeaway dose arrangements : None <input type="checkbox"/> One <input type="checkbox"/> Two <input type="checkbox"/> Three <input type="checkbox"/> Specify any restrictions or double/triple dosing arrangements Takeaway Request and Reason: Illness <input type="checkbox"/> Work <input type="checkbox"/> Travel/Holidays <input type="checkbox"/> Pharmacy Closure <input type="checkbox"/> Compassionate Grounds <input type="checkbox"/> Other <input type="checkbox"/> (specify): Verification (has this been provided; travel documents/rosters): Yes <input type="checkbox"/> No <input type="checkbox"/> (specify)..... Urine Drug Screens: Last Urine Drug Screen: / / 20 Clean <input type="checkbox"/> Dirty <input type="checkbox"/> Comments: Previous Drug Screen/s: / / 20 Clean <input type="checkbox"/> Dirty <input type="checkbox"/> Comments: / / 20 Clean <input type="checkbox"/> Dirty <input type="checkbox"/> Comments: Risk Assessment (consider both protective and risk factors for the client):																																																																																																																																																																																																																																																																																																																								
<table border="1"> <thead> <tr> <th colspan="2">Issues</th> <th colspan="3">Risk Rating</th> <th colspan="2">Issues</th> <th colspan="3">Risk Rating</th> </tr> <tr> <th>Indication of Recent Use</th> <th>Yes</th> <th>No</th> <th>Low</th> <th>Med</th> <th>High</th> <th>Mental Health</th> <th>Yes</th> <th>No</th> <th>Low</th> <th>Med</th> <th>High</th> </tr> </thead> <tbody> <tr> <td>Reported Substance Use:</td> <td></td> <td></td> <td></td> <td></td> <td></td> <td>Reported Mental Health Issues:</td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>• Opioids</td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td></td> <td></td> <td></td> <td>• Stressors</td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td></td> <td></td> <td></td> </tr> <tr> <td>• Benzodiazepines</td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td></td> <td></td> <td></td> <td>Depression</td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td></td> <td></td> <td></td> </tr> <tr> <td>• Amphetamines</td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td></td> <td></td> <td></td> <td>• Anxiety</td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td></td> <td></td> <td></td> </tr> <tr> <td>• Alcohol</td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td></td> <td></td> <td></td> <td>• Psychosis</td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td></td> <td></td> <td></td> </tr> <tr> <td>• THC</td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td></td> <td></td> <td></td> <td>• Suicidality/harm to others</td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td></td> <td></td> <td></td> </tr> <tr> <td>• Polydrug use</td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td></td> <td></td> <td></td> <td>• Cognitive/behavioural issues</td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td></td> <td></td> <td></td> </tr> <tr> <td>• Doctor shopping</td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td></td> <td></td> <td></td> <td>Mental Health comments:</td> <td colspan="3"></td> <td colspan="3"></td> </tr> <tr> <td>• Presenting intoxicated</td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td></td> <td></td> <td></td> <td>.....</td> <td colspan="3"></td> <td colspan="3"></td> </tr> <tr> <td>• Injects dose</td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td></td> <td></td> <td></td> <td>.....</td> <td colspan="3"></td> <td colspan="3"></td> </tr> <tr> <td>• Diversion</td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td></td> <td></td> <td></td> <td>.....</td> <td colspan="3"></td> <td colspan="3"></td> </tr> <tr> <td>• UDS (clean/dirty)</td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td></td> <td></td> <td></td> <td>Physical Health</td> <td colspan="3"></td> <td colspan="3"></td> </tr> <tr> <td>Environment</td> <td>Yes</td> <td>No</td> <td>Low</td> <td>Med</td> <td>High</td> <td>Reported health conditions (please specify):</td> <td colspan="3"></td> <td colspan="3"></td> </tr> <tr> <td>• Safe storage</td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td></td> <td></td> <td></td> <td>.....</td> <td colspan="3"></td> <td colspan="3"></td> </tr> <tr> <td>• Children in the home</td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td></td> <td></td> <td></td> <td>.....</td> <td colspan="3"></td> <td colspan="3"></td> </tr> <tr> <td>• Stable relationship</td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td></td> <td></td> <td></td> <td>.....</td> <td colspan="3"></td> <td colspan="3"></td> </tr> <tr> <td>• Family/Social support</td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td></td> <td></td> <td></td> <td>Program compliance</td> <td>Yes</td> <td>No</td> <td>Low</td> <td>Med</td> <td>High</td> </tr> <tr> <td>• Employment</td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td></td> <td></td> <td></td> <td>• Missed appointments</td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td></td> <td></td> <td></td> </tr> <tr> <td>• Domestic violence</td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td></td> <td></td> <td></td> <td>• Missed doses</td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td></td> <td></td> <td></td> </tr> <tr> <td>• Recent release from prison</td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td></td> <td></td> <td></td> <td>• Behavioural Inconsistencies/Incongruence</td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td></td> <td></td> <td></td> </tr> <tr> <td>• Unstable living conditions</td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>• Homelessness</td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>• Vulnerability</td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> </tbody> </table>			Issues		Risk Rating			Issues		Risk Rating			Indication of Recent Use	Yes	No	Low	Med	High	Mental Health	Yes	No	Low	Med	High	Reported Substance Use:						Reported Mental Health Issues:						• Opioids	<input type="checkbox"/>	<input type="checkbox"/>				• Stressors	<input type="checkbox"/>	<input type="checkbox"/>				• Benzodiazepines	<input type="checkbox"/>	<input type="checkbox"/>				Depression	<input type="checkbox"/>	<input type="checkbox"/>				• Amphetamines	<input type="checkbox"/>	<input type="checkbox"/>				• Anxiety	<input type="checkbox"/>	<input type="checkbox"/>				• Alcohol	<input type="checkbox"/>	<input type="checkbox"/>				• Psychosis	<input type="checkbox"/>	<input type="checkbox"/>				• THC	<input type="checkbox"/>	<input type="checkbox"/>				• Suicidality/harm to others	<input type="checkbox"/>	<input type="checkbox"/>				• Polydrug use	<input type="checkbox"/>	<input type="checkbox"/>				• Cognitive/behavioural issues	<input type="checkbox"/>	<input type="checkbox"/>				• Doctor shopping	<input type="checkbox"/>	<input type="checkbox"/>				Mental Health comments:							• Presenting intoxicated	<input type="checkbox"/>	<input type="checkbox"/>										• Injects dose	<input type="checkbox"/>	<input type="checkbox"/>										• Diversion	<input type="checkbox"/>	<input type="checkbox"/>										• UDS (clean/dirty)	<input type="checkbox"/>	<input type="checkbox"/>				Physical Health							Environment	Yes	No	Low	Med	High	Reported health conditions (please specify):							• Safe storage	<input type="checkbox"/>	<input type="checkbox"/>										• Children in the home	<input type="checkbox"/>	<input type="checkbox"/>										• Stable relationship	<input type="checkbox"/>	<input type="checkbox"/>										• Family/Social support	<input type="checkbox"/>	<input type="checkbox"/>				Program compliance	Yes	No	Low	Med	High	• Employment	<input type="checkbox"/>	<input type="checkbox"/>				• Missed appointments	<input type="checkbox"/>	<input type="checkbox"/>				• Domestic violence	<input type="checkbox"/>	<input type="checkbox"/>				• Missed doses	<input type="checkbox"/>	<input type="checkbox"/>				• Recent release from prison	<input type="checkbox"/>	<input type="checkbox"/>				• Behavioural Inconsistencies/Incongruence	<input type="checkbox"/>	<input type="checkbox"/>				• Unstable living conditions	<input type="checkbox"/>	<input type="checkbox"/>										• Homelessness	<input type="checkbox"/>	<input type="checkbox"/>										• Vulnerability	<input type="checkbox"/>	<input type="checkbox"/>												
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• Benzodiazepines	<input type="checkbox"/>	<input type="checkbox"/>				Depression	<input type="checkbox"/>	<input type="checkbox"/>																																																																																																																																																																																																																																																																																																																
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• THC	<input type="checkbox"/>	<input type="checkbox"/>				• Suicidality/harm to others	<input type="checkbox"/>	<input type="checkbox"/>																																																																																																																																																																																																																																																																																																																
• Polydrug use	<input type="checkbox"/>	<input type="checkbox"/>				• Cognitive/behavioural issues	<input type="checkbox"/>	<input type="checkbox"/>																																																																																																																																																																																																																																																																																																																
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• Injects dose	<input type="checkbox"/>	<input type="checkbox"/>																																																																																																																																																																																																																																																																																																																					
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• UDS (clean/dirty)	<input type="checkbox"/>	<input type="checkbox"/>				Physical Health																																																																																																																																																																																																																																																																																																																		
Environment	Yes	No	Low	Med	High	Reported health conditions (please specify):																																																																																																																																																																																																																																																																																																																		
• Safe storage	<input type="checkbox"/>	<input type="checkbox"/>																																																																																																																																																																																																																																																																																																																					
• Children in the home	<input type="checkbox"/>	<input type="checkbox"/>																																																																																																																																																																																																																																																																																																																					
• Stable relationship	<input type="checkbox"/>	<input type="checkbox"/>																																																																																																																																																																																																																																																																																																																					
• Family/Social support	<input type="checkbox"/>	<input type="checkbox"/>				Program compliance	Yes	No	Low	Med	High																																																																																																																																																																																																																																																																																																													
• Employment	<input type="checkbox"/>	<input type="checkbox"/>				• Missed appointments	<input type="checkbox"/>	<input type="checkbox"/>																																																																																																																																																																																																																																																																																																																
• Domestic violence	<input type="checkbox"/>	<input type="checkbox"/>				• Missed doses	<input type="checkbox"/>	<input type="checkbox"/>																																																																																																																																																																																																																																																																																																																
• Recent release from prison	<input type="checkbox"/>	<input type="checkbox"/>				• Behavioural Inconsistencies/Incongruence	<input type="checkbox"/>	<input type="checkbox"/>																																																																																																																																																																																																																																																																																																																
• Unstable living conditions	<input type="checkbox"/>	<input type="checkbox"/>																																																																																																																																																																																																																																																																																																																						
• Homelessness	<input type="checkbox"/>	<input type="checkbox"/>																																																																																																																																																																																																																																																																																																																						
• Vulnerability	<input type="checkbox"/>	<input type="checkbox"/>																																																																																																																																																																																																																																																																																																																						

 <p>Pharmacotherapy</p> <p>TAKE-AWAY DOSE</p> <p>Risk Assessment Plan</p>	<p>*Affix patient identification label here</p> <p>Client ID/ URN:</p> <p>Family Name:</p> <p>Given Name(s):</p> <p>DOB: / / Sex: F <input type="checkbox"/> M <input type="checkbox"/></p>
---	---

Recommendations: Medical Officer: Yes No Case Manager: Yes No

.....
.....

Current Risk Status (TAG/PRIM): Low Medium High

Pharmacotherapy Clinical Meeting:	Date: / / 20.....
<input type="checkbox"/> Request Approved	<input type="checkbox"/> Verification Required?
<input type="checkbox"/> Request Denied	<input type="checkbox"/> Specify verification required:

Identified Issues/Risk:

.....
.....

Reason (detail rationale or any issue or concerns):

.....
.....
.....
.....

Plan:

.....
.....
.....
.....
.....
.....
.....
.....

Clinician's name (clear print): Designation:

Clinician's signature: Date: / / 20..... Time: am/pm

Appendix 9

ADS Takeaway Medication Agreement

Department of Health and Human Services		ALCOHOL AND DRUG SERVICES
Alcohol and Drug Services  TAKEAWAY MEDICATION AGREEMENT		*Affix patient identification label here
		Client ID/ URN: Family Name: Given Name(s): DOB: / / Sex: F <input type="checkbox"/> M <input type="checkbox"/>
<p><input type="checkbox"/> 13 Mulgrave Street, LAUNCESTON 7250 <input type="checkbox"/> 11 Grove Street, ULVERSTONE 7315 <input type="checkbox"/> ADS Pharmacotherapy Program, GPO Box 125, HOBART 7001</p> <p style="text-align: center;">Please Read Carefully</p> <p>I have discussed takeaway medication with my case manager and/or doctor. I am aware of and understand the following issues relating to takeaway medication:</p> <ul style="list-style-type: none">• Methadone and buprenorphine are dangerous medications that can cause death when taken by individuals other than the person for whom they have been prescribed.• When methadone or buprenorphine are mixed with other depressant drugs such as benzodiazepines, alcohol or other opioids the effects are unpredictable and may lead to drug overdose or death.• I accept responsibility for the safe storage and use of all takeaway doses I receive. I will store all doses out of reach of children and am aware a locked cabinet is recommended for the storage of takeaway medication. In order to reduce the risk of theft, the whereabouts of the dose will not be made known to other persons.• The dose must be consumed according to the directions given by the prescriber. When more than one takeaway dose is provided, each dose must be taken on the day for which it is prescribed. Doses should not be stored up, and no more than the daily prescribed dose should be taken.• All doses are to be swallowed (for methadone) or dissolved under the tongue (for buprenorphine).• Takeaway medication is not to be sold, swapped or otherwise given away.• There will be no replacement of doses that are spilled, vomited, lost or stolen. If any of these occur, my prescriber must be notified as soon as possible.• Takeaway medication will be provided while the treatment team feel it is safe to do so. If the treatment team believe takeaway medication is no longer safe for me or the community, they may suspend my access to takeaways.• My access to takeaway medications will be suspended if my urine test detects opioids, benzodiazepines or amphetamines. Refusal or inability to provide a urine sample on request will be deemed to be a positive urine test.• My access to takeaway medication will also be suspended if staff assess me as being under the influence of any substances; if I have diverted (or attempt to divert) my supervised pharmacy dose; if my social circumstances change (and are deemed to be unsuitable for takeaway medication); or if other circumstances arise and my treatment team believe takeaway medication is a risk to myself or the community.• Any deviation from this agreement will result in a review of my access to takeaway medication, and may lead to a suspension of takeaways. <p>I _____ have today discussed with _____, (Name of client) _____ (Name of staff member) the rules and risks associated with takeaway medication and agree to the terms listed above.</p> <p>Signature of Client: _____ Date: ____ / ____ / 20 ____</p> <p>Witness Name: _____ Signature: _____</p> <p>Designation: _____ Date: ____ / ____ / 20 ____</p>		

Appendix 10

Fact Sheet: Naltrexone

Naltrexone is a highly specific opioid antagonist with a high affinity for opiate receptor sites. It competitively inhibits opioid antagonist, such as methadone, heroin and slow-release morphine if they are present.

Naltrexone is indicated for relapse prevention in patients already detoxified from opioids and seeking assistance to remain abstinent.

Naltrexone (REVIA®) is available as 50mg tablets on the PBS for relapse prevention in the management of alcohol dependence but **not** for opioid dependence, however it is available on private prescription. Naltrexone implants are not licenced with the TGA and there is insufficient evidence from randomised trials to evaluate the effectiveness of sustained-release naltrexone (1)

Naltrexone is not registered in Australia for the use of opioid withdrawal and naltrexone treatment is only appropriate for opioid users who are committed to long-term abstinence with social supports and preferably engaged in counselling.

Contraindications to use of naltrexone are:-

1. Physiological dependence on opioids. Patients currently dependent should be referred to special services.
2. Acute opioid withdrawal.
3. Opioids for chronic pain states.
4. Acute hepatitis or liver failure as naltrexone can be hepatotoxic in high doses.
5. Known adverse reactions or sensitivity to naltrexone.

Precautions:

1. Women who are pregnant or breastfeeding as naltrexone is categorised as a B3 risk in pregnancy
2. Patients concurrently dependent on multiple drugs
3. Patients with impaired renal function
4. Patients with a major psychiatric illness including depression
5. Children and adolescents aged less than 18 as the effects of naltrexone in these populations are unknown.

The greatest problem associated with naltrexone treatment is the increased risk of death from an opiate overdose due to loss of tolerance in patients returning to opioid use after being treated with naltrexone.

Effectiveness of naltrexone treatment for relapse prevention is limited because only a minority of opioid dependent people seek naltrexone treatment and among those entering treatment there is a higher rate of dropping out of treatment.

Before considering the use of naltrexone it is recommended that you contact and discuss the situation with a specialist at the Alcohol and Drug Services.

Note: Reproduced from I. Lobmaier P, Kornor H, Kunoe N, BjØrndal A. Cochrane: Sustained-Release Naltrexone for Opioid Dependence, 2008.

Appendix II

Neonatal Withdrawal Scoring Instrument (Finnegan Scale)

NEONATAL WITHDRAWAL SCORING INSTRUMENT	*Affix patient identification label here Client ID/ URN: _____ Family Name: _____ Given Name(s): _____ DOB: / / Sex: F <input type="checkbox"/> M <input type="checkbox"/>
---	--

NEONATAL WITHDRAWAL SCORING CHART (TERM INFANTS) MR 520

DATE AND TIME IN HOURS

Note: Reproduced from the Western Australian Clinical policies and procedures for the use of methadone and buprenorphine in the treatment of opioid dependence, 2006.

Appendix 12

ADS Benzodiazepine Reduction Agreement

Department of Health and Human Services		ALCOHOL AND DRUG SERVICES					
 <p>Alcohol and Drug Services BENZODIAZEPINE REDUCTION AGREEMENT</p>	*Affix patient identification label here						
		Client ID/ URN:					
		Family Name:					
		Given Name(s):					
		DOB: / / Sex: F <input type="checkbox"/> M <input type="checkbox"/>					
Agreement to Terms:							
<p>1. I, request and consent to a benzodiazepine reduction program with the assistance of Dr</p> <p>2. I understand that benzodiazepine medication is addictive and can cause me to become drowsy and feel sedated. This can affect my capacity to drive through reducing my attention and concentration. I also understand this medication may also impair my memory and reaction time.</p> <p>3. I understand I should not use other drugs while taking benzodiazepines, especially other sedatives such as alcohol, and cannabis. I understand I should not use other medications including over the counter medications without first checking with Dr or the Pharmacotherapy Unit.</p> <p>4. I understand that a benzodiazepine reduction plan will be developed and given to me and I agree to follow this plan.</p> <p>5. I understand that this is a reduction program and that the aim is to have me benzodiazepine free by the end of the program. I am aware that I will be given an appropriate dose of diazepam and that my dose will be reduced by two to five mg per fortnight.</p> <p>6. I understand that I am required to attend a single nominated pharmacy on a daily basis to collect my medication.</p> <p>7. I understand that there may be some withdrawal symptoms during my treatment and I will seek counselling support to assist me to manage these feelings and experiences.</p> <p>8. I understand not to request extra benzodiazepines through general practitioners or through other sources and to be open and honest with my doctor and case manager.</p> <p>9. I agree to attend the clinic for all scheduled review appointments. I am aware that scripts will not be given to me if I do not attend for my medical and counselling appointments.</p> <p>10. I agree to give permission for information to be shared between my doctor and Medicare for the purposes of monitoring my progress.</p> <p>11. I understand that if I fail to adhere to this agreement my benzodiazepine prescription may be stopped and I will not receive further benzodiazepines from the clinic.</p>							
Authorisation of Agreement:							
Patient Name: (clear print)							
Patient signature:..... (signature)		Date: / / 20.....					
<table border="1"><tr><td>Clinician's name (clear print):</td><td>Designation:</td></tr><tr><td>Clinician's signature:</td><td>Date: / / 20..... Time:</td></tr></table>				Clinician's name (clear print):	Designation:	Clinician's signature:	Date: / / 20..... Time:
Clinician's name (clear print):	Designation:						
Clinician's signature:	Date: / / 20..... Time:						

Appendix 13

Notice of Drug Dependency and Application for an Authority to Administer, Prescribe or Supply Buprenorphine/Methadone for Opioid Pharmacotherapy – Under Section 59E Poisons Act 1971

CONFIDENTIAL	
 <p>Tasmania DEPARTMENT of HEALTH and HUMAN SERVICES</p> <div style="border: 1px solid black; padding: 5px; text-align: center;"> NOTICE OF DRUG DEPENDENCY AND APPLICATION FOR AN AUTHORITY TO ADMINISTER, PRESCRIBE OR SUPPLY BUPRENORPHINE/ METHADONE FOR OPIOID PHARMACOTHERAPY Under Section 59E Poisons Act 1971 </div>	
TICK DATA AS APPROPRIATE PLEASE USE BLOCK LETTERS ATTACH CERTIFIED PHOTO TO APPLICATION	
REG NO: _____	
I, Dr _____	State Reg. No (Office Use)
Postcode: _____	
Telephone number: _____	Fax number: _____
certify that this patient is suffering from drug dependency and, in my opinion, buprenorphine/methadone is required in support of treatment and buprenorphine/methadone will be administered in accordance with the relevant clinical guidelines.	
Please indicate whether treatment is for Maintenance: methadone <input type="checkbox"/> Maintenance: buprenorphine <input type="checkbox"/> Withdrawal: (buprenorphine only) <input type="checkbox"/> Maintenance: buprenorphine/naloxone <input type="checkbox"/>	
PATIENT'S NAME <small>(FAMILY NAME)</small> _____ <small>(GIVEN)</small> _____ <small>(ALIAS)</small> _____	
Patient's Address: <small>(Full Residential Address)</small> _____ Postcode: _____	
Mother's Maiden Name: _____	
Date of Birth:	Gender: Male / Female <small>(circle appropriate one)</small> _____ Height: cm
Usual Occupation: _____ Working: <input type="checkbox"/> Yes <input type="checkbox"/> No	
Anticipated Date of First Dose: _____ Anticipated Date of Last Dose: _____	
Name of Pharmacy Administering buprenorphine/methadone Under Supervision: _____	
Name of Treatment Facility for Buprenorphine Withdrawal <input type="checkbox"/> In Patient <input type="checkbox"/> Out patient	
Name of former prescriber: <small>(leave blank if there is no former prescriber)</small>	
If prior Buprenorphine/Methadone Maintenance: <small>(leave blank if there is no prior Buprenorphine/Methadone maintenance)</small>	Age when first registered: years, and Date of last dose of Buprenorphine/Methadone :
Grounds for drug dependency: Iatrogenic <input type="checkbox"/> Illicit <input type="checkbox"/> IVDU <input type="checkbox"/> Y / N (circle)	
Drug(s) involved: (please circle) Other specify _____	
Anamorph Dilaudid tablets/injections Durogesic Endone Heroin Kapanol methadone syrup Morphine injections MS Contin MS Mono Norspan Ordine Oxycontin Oxynorm liquid/capsules Physeptone pethidine Sevredol Subutex Temgesic	
Signature of medical practitioner: _____ Date: _____	
All correspondence marked "Confidential" To: Secretary, Attention Pharmaceutical Services, DHHS, GPO Box 125 HOBART TAS 7001 For further information contact: Pharmaceutical Services Branch Tel. (03) 6233 2064 Fax. (03) 6233 3904	

Appendix 14

Notice of Termination of Methadone/Buprenorphine/Suboxone/Subutex Prescribing



CONFIDENTIAL REG NO:

NOTICE OF TERMINATION OF METHADONE/BUPRENORPHINE/SUBOXONE/SUBUTEX PRESCRIBING

DETAILS MUST BE COMPLETED **LEGIBLY** TO PREVENT DELAY

TICK DATA AS APPROPRIATE: (PLEASE USE BLOCK LETTERS)

I, DR	OF:	POSTCODE
TELEPHONE NUMBER: (03)		FAX NUMBER: (03)
NOTIFY THAT THIS PATIENT IS NO LONGER ATTENDING FOR TREATMENT WITH METHADONE./BUPRENORPHINE/SUBOXONE		
PATIENT'S NAME: (FAMILY NAME) (GIVEN NAME(S))		
PATIENT'S ADDRESS: (FULL <u>RESIDENTIAL</u> ADDRESS) POSTCODE		
NUMBER OF WEEKS ON PROGRAM:		
DATE OF LAST DOSE DISPENSED: / /		
NAME OF PHARMACY WHERE PATIENT HAS BEEN ADMINISTERED METHADONE/BUPRENORPHINE/SUBOXONE DOSES:		
PATIENT:- <input type="checkbox"/> LEFT BY MUTUAL AGREEMENT <input type="checkbox"/> DECEASED <input type="checkbox"/> LEFT AGAINST ADVICE OF TREATMENT TEAM <input type="checkbox"/> TRANSFER — INTERSTATE <input type="checkbox"/> REQUESTED TO LEAVE <input type="checkbox"/> — INTRASTATE TO DR..... <input type="checkbox"/> CEASED TO PICK UP METHADONE <input type="checkbox"/> COMPLETED PROGRAM <input type="checkbox"/> IMPRISONMENT <input type="checkbox"/> HOSPITALISED <input type="checkbox"/> OTHER, SPECIFY:		
SIGNATURE OF MEDICAL PRACTITIONER:		DATE:
ALL CORRESPONDENCE TO MARKED "CONFIDENTIAL" PHARMACEUTICAL SERVICES DEPARTMENT OF HEALTH AND HUMAN SERVICES GPO Box 125 HOBART TAS 7001		FOR FURTHER INFORMATION: PHARMACEUTICAL SERVICES TEL: (03) 6233 2064 FAX: (03) 6233 3904

Appendix 15

Pharmacy – Client Contract

The following contract is to be signed by clients participating in the Community Program for Opioid Pharmacotherapy Program to ensure doses are dispensed as discreetly as possible and without disrupting the normal daily operations of the pharmacy.

It is important to understand these guidelines fully before enrolling with this dispensing site.

METHADONE – I must drink my methadone as per prescription **instructions** and program guidelines. It is my responsibility to satisfy the duty pharmacist that I have swallowed my dose by:

drinking my dose in front of the duty pharmacist (unless otherwise authorised by my **methadone** prescriber);

speaking to the duty pharmacist immediately after swallowing my dose.

BUPRENORPHINE – I must take my medication as per prescription **instructions** and program guidelines. It is my responsibility to satisfy the duty pharmacist that my dose has dissolved by:

placing my dose under my tongue and waiting until the pharmacist says I may leave the pharmacy (unless otherwise authorised by my **buprenorphine** prescriber). This may take up to eight minutes.

My medication will not be dispensed to me if, in the opinion of the duty pharmacist, I present as **apparently intoxicated** or behaving as if under the influence of alcohol and/or drugs.

I understand that if I am troubled by nausea and **vomiting**, no dose of **methadone** will be replaced unless the duty pharmacist has seen me vomit and my prescriber has authorised a replacement dose.

I understand that no dose of **buprenorphine** will be replaced if the dose is accidentally handled by me, dropped, chewed or swallowed, unless specifically authorised by my prescriber.

Rudeness, verbal abuse, disruptive or threatening **behaviour** and acts of violence are unacceptable and will result in restriction or cancellation of community dispensing and possible termination of my treatment and/or police being called.

Any suspicion of drug dealing or other **criminal activity** on or within the vicinity of these premises will result in the police being called.

I must attend for my dose at the **times nominated** by this dispensing site. If for any reason I am unable to attend during these times I understand I will have to miss that day's dose.

I must dose at this site on the **days/dates** arranged by my prescriber. Exceptions to this are only given in cases of medical emergency and must be authorised by my prescriber.

Missing two or more consecutive scheduled doses means I cannot be dosed by this pharmacy until I have been reviewed by my prescriber. A pattern of missed consecutive scheduled doses may result in the cessation of my treatment.

I will keep **appointments** as scheduled by my prescriber. Failure to do so may result in my dispensing site being instructed to cease dosing me.

Overdue payments will lead to termination of my community dispensing arrangements.

If difficulties or **problems** arise in any area, I agree to discuss these with my prescriber.

If for any reason the community pharmacy **refuses to continue** my daily dosing, it is my responsibility to discuss this with my prescriber.

If I am unable to find another community dispensing site willing to dispense to me, I understand I may be required to commence a **detoxification** (reduction) regimen.

I also give permission for my prescriptions to be **faxed** to my dispensing outlet and for the duty pharmacist and my prescriber to exchange information concerning my medical history, social well-being and/or any other relevant information related to my participation in this treatment program.

I understand community pharmacists have an obligation to **report breaches** of this contract to my prescriber.

SPECIAL TIMES/CONDITIONS AND/OR CHARGES RELATING TO THIS PHARMACY/ DISPENSING SITE:

I have read, understood and accept the conditions printed above.

CLIENT NAME: _____

SIGNATURE: _____ DATE: _____

DUTY PHARMACIST

NAME: _____

SIGNATURE: _____ DATE: _____

Pharmacy Stamp or Name

*A copy should be retained by both the pharmacy and the client.

Note: Reproduced from the Western Australian *Clinical policies and procedures for the use of methadone and buprenorphine in the treatment of opioid dependence*, 2006.

Appendix 16

Assessment of Acute Intoxication

Class of Drug	Intoxication	Overdose
Opioids (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
Alcohol	Relaxation Disinhibition Impaired coordination Impaired judgement Decreased concentration Slurred speech Ataxia Vomiting	Disorientation/confusion Respiratory depression Loss of consciousness Loss of bladder control
Benzodiazepines (e.g. diazepam, oxazepam, flunitrazepam)	Disinhibition Sedation Drooling Incoordination Slurred speech Lowered blood pressure Dizziness	Stupor/coma Ataxia Confusion Respiratory depression
Stimulants (e.g. amphetamines, cocaine)	Hyperactivity Restlessness Agitation Anxiety/nervousness Great dilation of pupils Elevated blood pressure Increased pulse Raised temperature Sweating Tremor	Panic attacks Acute paranoid psychosis Seizures Cardiac arrhythmias Myocardial ischaemia Hypertensive crisis Cerebrovascular accidents Hyperpyrexia Dehydration
Cannabis	Relaxation Decreased concentration Decreased psychomotor performance Impaired balance Conjunctival infection	Paranoid psychosis Confusion Agitation Anxiety/panic Hallucinations

Signs and symptoms to look for/enquire about.

Intoxication		Toxicity	
Slurred speech	Alcohol foetor	Drowsiness	Nausea and vomiting
Unsteady gait	Disinhibition	Shallow breathing	Confusion
Drowsiness	Drooling	Poor circulation	
Pupil constriction	Dizziness	Lowered temperature	
Conjunctival infection	Itching/scratching	Slow pulse	
		Headache	

Note: Reproduced from the New South Wales Maintenance Treatment Clinical Practice Guidelines, 2006.

Appendix 17

Withdrawal States from Commonly Used Drugs

Drug class	Onset	Duration	Symptoms
Opioids	8-12 hours (short acting). Delayed for longer acting opioids.	Peaks 2-4 Ceases 7-10 days (short acting). Longer for long acting opioids.	Anxiety, muscle tension, muscle and bone ache, muscle cramps, sleep disturbance, sweating, hot and cold flushes, piloerection (goosebumps), yawning, lacrimation, rhinorrhea, abdominal cramps, nausea, vomiting, diarrhoea, palpitations, elevated blood pressure, elevated pulse, dilated pupils.
Alcohol	As blood alcohol falls, depends on rate of fall and hours after last drink.	5-7 days	Anxiety, agitation, sweating, tremor, nausea, vomiting, abdominal cramps, diarrhoea, anorexia, craving, insomnia, elevated blood pressure, elevated pulse, temperature, headache, seizures, confusion, perceptual distortions, disorientation, hallucinations, hyperpyrexia.
Benzodiazepines	1-10 days depending on half life	3-6 days	Anxiety, insomnia, muscle aching and twitching, perceptual changes, feelings of unreality, depersonalisation, seizures.
Stimulants	8-36 hours	Several days, occasionally 2-3 weeks	Lethargy, depression, irritability, hyperphagia, anhedonia, dysphoria, desire for sleep increased.
Cannabis	Usually days	Weeks	Irritability, anxiety, insomnia, anorexia, sweating, muscle spasms, headaches.

Note: Reproduced from the New South Wales Maintenance Treatment Clinical Practice Guidelines, 2006.

Appendix 18

ADS Opioid Pharmacotherapy Did Not Dose Form

Department of Health and Human Services		ALCOHOL AND DRUG SERVICES
 Tasmania Explore the possibilities	Alcohol and Drug Services Opioid Pharmacotherapy	
DID NOT DOSE		
To be completed by dosing site/Pharmacy at completion of daily dosing. (if clients fail to attend or issues of concern are identified.)		
Dosing site		
Name of dosing site/Pharmacy:		
Day: Date: / / 20.....		
Please list all clients that DID NOT dose today		
Client Name	Dose Details	Consecutive days missed
		Sign when updated in client history (ADS office use only)
Please report identified issues of concern of client instability		
.....		
Reporting pharmacist (print clearly):		
Pharmacist Signature:		
Please fax completed form to relevant Alcohol and Drug Service Office:		
Hobart: (03) 6230 7992		Launceston: (03) 6336 5567
Ulverstone: (03) 6429 8599		
THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE ADDRESSEE AND MAY CONTAIN CONFIDENTIAL INFORMATION If you are not the intended recipient please forward to the person identified, or if you have received this transmission in error please notify us immediately by telephone and destroy the original message.		



**Alcohol and Drug Services
Opioid Pharmacotherapy**

DID NOT DOSE

PLEASE NOTE: THIS SECTION IS FOR ADS USE ONLY

The requirement for missed dosing are as follows:

One missed dose:

The pharmacist should assess the client to determine their suitability for dosing. If the client is not intoxicated and there are no other identifiable risks or concerns then they should proceed with dosing by notify the service via the form overleaf that the client has missed a dose.

Two consecutive missed doses:

The pharmacist must not dose the client and should notify the treating service of the consecutive missed doses via the form overleaf. **They should inform the client that they are unable to dose them without the approval of the treating service and advise them that they should contact their case manager to arrange a case management review.**

Three consecutive missed doses:

The pharmacist must not dose the client and should notify the treating service of the consecutive missed doses via the form overleaf. **They should inform the client that they are unable to dose them without the approval of the treating service and advise them that they should contact their case manager to arrange a medical review.**

* These procedures for the management of missed doses are sourced from the *National Guidelines for Opioid Dependent People (2004)*



Contact
Alcohol and Drug Services
1300 139 641

Department of Health and Human Services
GPO Box 125
Hobart Tas 7001
www.dhhs.tas.gov.au