

NSW Clinical Guidelines: Treatment of Opioid Dependence – 2018



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About these guidelines

Purpose and scope

These guidelines provide clinical guidance and policy direction for opioid treatment in NSW. They align with national directions and recommendations, and incorporate the latest clinical evidence.

The guidelines aim to:

- improve access to opioid treatment by
 - supporting the expansion of the NSW Opioid Treatment Program (OTP) into the primary care sector
 - increase involvement of general practitioners (GPs), non-government organisations (NGOs) and community pharmacies
- personalise patient care by introducing a system that differentiates between those who have
 - low/moderate treatment needs and can be treated in community settings
 - complex/high treatment needs and should be referred to and treated in the specialist treatment sector
- support more effective coordination of care across health services.

The clinical recommendations are for medicines currently available in NSW and approved for use in the treatment of opioid dependence (e.g. oral methadone, sublingual buprenorphine, sublingual buprenorphine-naloxone, oral naltrexone).¹ Other medicines, that may be the subject of ongoing research, are not discussed here.

Audience

These guidelines are intended for use in generalist health settings (e.g. primary care, hospital, clinic or community settings) as well as specialised drug and alcohol/opioid treatment clinics. For generalists, these include acute care settings where some practitioners (e.g. anaesthetists) may have specialist skills in the pharmacology of opioid drugs, or in managing other health and medical conditions, but not the treatment of dependence. As such, the guidelines identify situations where it is considered appropriate to seek assistance from, or refer to, specialist addiction treatment providers.

In public health settings (e.g. specialist drug and alcohol services in local health districts and networks), local policies or procedures may be used in addition to the information provided in these guidelines.

As medical and health practitioners are the primary audience for this document, the term 'patient' rather than 'client' or 'consumer' is used. This document is also intended as a reference point for patients and other non-medical service providers.

The term opioid substitution treatment (OST) is not used in these guidelines as it is considered a misnomer because of its conflation of physiological dependence and compulsive behaviour – and its presumed equivalence in the use of medicines and illicit substances.² Instead, the term opioid agonist treatment (OAT) is used, except in relation to naltrexone, which is an antagonist.

1 'Methadone' in these guidelines refers to oral methadone. 'Buprenorphine' and 'buprenorphine-naloxone' refer to the sublingual forms of the medicine (i.e. excluding injections or patches). 'Naltrexone' refers to oral naltrexone.

2 Lauren M. Broyles PhD, RN, Ingrid A. Binswanger MD, MPH, Jennifer A. Jenkins MPH, Deborah S. Finnell DNS, PMHNP, Babalola Faseru MD, MPH, Alan Cavaola PhD, Marianne Pugatch MSW & Adam J. Gordon MD, MPH (2014) Confronting Inadvertent Stigma and Pejorative Language in Addiction Scholarship: A Recognition and Response, Substance Abuse, 35:3, 217-221, DOI: 10.1080/08897077.2014.930372

Structure

The guidelines are made up of four main sections.

<p>Section 1 Overview of opioid dependence and treatment of NSW</p>	<p>Why treatment of opioid dependence is important The types of treatment approaches available How treatment is coordinated</p>
<p>Section 2 Clinical guidelines and recommendations</p>	<p>Clinical guidelines and recommendations derived from Part A of the National Guidelines for Medically Assisted Treatment of Opioid Dependence with additional information specific to NSW including:</p> <ul style="list-style-type: none"> • matching patients and services within NSW service system (e.g. case flagging) • supervised and unsupervised dosing framework • child protection issues relevant to NSW policy context <p>Further information on the evidence base for these guidelines is available from the National Guidelines for Medically Assisted Treatment of Opioid Dependence: Part B Supporting information</p>
<p>Section 3 Regulatory, policy and governance framework</p>	<p>An overview of the NSW regulatory and governance framework for opioid dependence, including:</p> <ul style="list-style-type: none"> • Regulatory information (e.g. approval to prescribe S8 drugs) • Accreditation processes and professional development for service providers • Child protection requirements – when, where and how to report concerns regarding children of parents on the OTP who may be at risk of harm • Specialised settings (e.g. correctional, hospital and residential rehabilitation settings) • Prescriber-related information • The role of pharmacists • Other dosing information
<p>Section 4 Appendices</p>	<p>A. Definitions of opioid dependence B. Opioid withdrawal rating scales C. Product information D. Responding to an opioid overdose E. Clinically significant interactions between methadone, buprenorphine and other medicines F. Possible drug interactions with other psychoactive drugs G. Intoxication and withdrawal states from commonly used drugs H. NSW Health forms used in the administration of the OTP I. Prescriber and Patient matters J. Patient identification K. Drugs of addiction (Schedule 8 of the NSW Poisons List) L. Australian Treatment Outcomes Profile (ATOP) M. Detection times for selected drugs in urine N. Adverse effects</p>

An abbreviated version of these guidelines, any updates to these guidelines, and other alcohol and other drug guidelines are available on the NSW Health website:


www.health.nsw.gov.au

Grading of recommendations

Recommendations supported by research evidence are graded according to National Health and Medical Research Council (NHMRC) definitions, but with a 4-star rating system rather than letters.

Grade of recommendation	Description
★★★★	Body of evidence can be trusted to guide practice
★★★	Body of evidence can be trusted to guide practice in most situations
★★	Body of evidence provides some support for recommendation(s) but care should be taken in its application
★	Body of evidence is weak and recommendation must be applied with caution

We have used letters and symbols to further guide practice.

C	Recommendations based on consensus of clinical experience
S	Recommendations reflecting a standard of care that should be routine in competent clinical practice
R	Recommendations established by regulatory requirements
	Caution is required and specialist advice or referral is recommended

Development process

An expert reference group (ERG) representing the opioid treatment sector in NSW was established to guide the development of these guidelines. Membership was comprised of:

- Ministry of Health Pharmacotherapy Credentialing Subcommittee (PCS)
- Chapter of Addiction Medicine
- OTP managers – public/private clinics
- regional and rural opioid treatment prescribers
- allied health
- private opioid treatment prescribers
- Ministry of Health Pharmaceutical Regulatory Unit (PRU)
- Pharmaceutical Society of Australia (PSA) NSW Branch
- Royal Australian College of General Practitioners (RACGP)
- NGOs providing treatment for opioid dependency
- Justice Health and Forensic Mental Health Network (JH&FMHN)
- Patients receiving opioid treatment
- Medicare Locals (now Primary Health Networks).

Professor Nicholas Lintzeris, the then Chief Addiction Medicine Specialist, at the Mental Health and Drug and Alcohol Office of the NSW Ministry of Health led the NSW document review. Professor Lintzeris was also a key writer/editor on *the National Policy and Guidelines for the Medicine-Assisted Treatment of Opioid Dependency* released by the then Australian Government Department of Health and Ageing.

The direction of the National Guidelines to enhance access to opioid treatment in the primary care sector aligned with NSW's proposed direction, and it was also noted that the national document:

- provided succinct and comprehensive clinical information aiming to support the primary care sector in the provision of opioid treatment
- included evidence-linked clinical recommendations
- gave directions to improve consistency, safety and effectiveness of practice across Australia.

The Ministry has adopted the recommendations in [Part A of the national document](#) (with some NSW specific adaptations). [Part B of the national document](#) provides supporting evidence to the recommendations.

The **National Guidelines for Medically Assisted Treatment of Opioid Dependence** is available at <http://www.nationaldrugstrategy.gov.au/internet/drugstrategy/Publishing.nsf/content/ng-mat-op-dep>

Abbreviations and acronyms

ADIS	Alcohol Drug Information Service
ADR	Adverse drug reaction
ATOP	Australian Treatment Outcomes Profile
BPN	Buprenorphine
BNX	Buprenorphine-naloxone
CBT	Cognitive behavioural therapy
CHO	Chief Health Officer
CNS	Central nervous system
COWS	Clinical Opioid Withdrawal Scale
CPH	Centre for Population Health
CWU	Child Wellbeing Unit
CYP450	Cytochrome P450
DASAS	Drug and Alcohol Specialist Advisory Service
DMTA	Drug Misuse and Trafficking Act
DSM	Diagnostic and Statistical Manual of Mental Disorders
ERG	Expert reference group
GP	General practitioner
HCCC	Health Care Complaints Commission
HIV	Human immunodeficiency virus
ICD	International Classification of Diseases
IM	Intramuscular
IV	Intravenous
JH&FMHN	Justice Health and Forensic Mental Health Network
LFT	Liver function test

LHD	Local Health District
MATOD	Medication-Assisted Treatment of Opioid Dependence (National Guidelines)
MDT	Multidisciplinary team
NGO	Non-government organisation
NSAIDs	Non-steroidal anti-inflammatory drugs
NUAA	New South Wales Users and AIDS Association
OAT	Opioid Agonist Treatment
OTAC	Opioid Treatment Accreditation Course
OTL	Opioid Treatment Line
OTP	Opioid Treatment Program
PCS	Pharmacotherapy Credentialing Subcommittee
PRN	<i>Pro re nata</i> (as needed)
PRU	Pharmaceutical Regulatory Unit
PSA	Pharmaceutical Society of Australia
PTG	Poisons and Therapeutic Goods Act
QIT	Quality in Treatment Committee
QTc	Corrected QT interval
S3	Schedule 3 (pharmacist only medicines, available over-the-counter)
S4	Schedule 4 (prescription only medicines)
S8	Schedule 8 (drugs of addiction, controlled drugs)
SHN	Specialty Health Network
SOWS	Subjective Opioid Withdrawal Scale
TGA	Therapeutic Goods Administration
UDS	Urine drug screening

Section 1

Overview of opioid dependence and treatment in NSW

1.1 Introduction

1.1.1 What is opioid dependence?

Opioid dependence is a chronic and relapsing disorder that affects physical and mental health and social wellbeing and function: it is a complex biopsychosocial disorder. People affected feel a loss of control over their use of opioids. They continue regular and often heavy opioid use despite health, legal and relationship problems.

Some harm may occur with any opioid use, but problems (particularly dependence) are more common with regular use over long periods of time. Not everyone who takes opioids, even long term, develops dependence. Multiple risk and protective factors interact to determine the likelihood of dependence. These factors are biological, psychological, social and cultural.

1.1.2 Why treat opioid dependence?

Opioid dependence is a major focus of drug and alcohol treatment services because the harms are disproportionate to the prevalence of use. It is second only to alcohol as the drug of principal concern amongst people seeking treatment.

Less than 1% of the Australian population aged 14 years or older had injected heroin or another illicit drug in the previous year over the period 2001 to 2016.³ Despite the low prevalence of use, the economic and social cost of opioid drug use is relatively high due to:

- loss of life through fatal overdose, with opioid-related deaths occurring at a much younger age than deaths attributed to alcohol or tobacco
- medical and mental health consequences, including transmission of hepatitis C, hepatitis B and HIV
- social consequences to individuals and their communities, including the impact upon relationships, employment, education, housing, parenting, finances and crime

- cost to health and social services, law enforcement and judicial systems.

Over the past two decades, there has been an increase in use of pharmaceutical (prescription and over-the-counter) opioids for medical conditions, particularly chronic pain.³ As a consequence, an increasing number of patients have developed pharmaceutical opioid dependence. These patients need assistance in managing dependence as well as their underlying medical conditions (e.g. chronic pain conditions, depression).

1.2 Treatment approaches

1.2.1 Goals and expectations

The broad goal of opioid dependence treatment is **reducing harm** due to non-medical use of opioids. The term harm encompasses negative health, social and economic effects on both individuals and the community. To achieve this broad goal, the NSW OTP takes a patient centred approach – treatment programs incorporate patient preferences, needs and **realistic individual goals**.

There may be community expectation that ‘treatment’ for drug dependence results in people becoming and staying drug-free. While abstinence can be an important long-term goal, this expectation does not reflect the reality of drug dependence treatment in terms of complexity, the use of opioid agonist treatment or the extended duration of treatment needed by some people.

Opioid agonist treatment (OAT) can lead to psychological stability, improved control over drug use and eventual abstinence from opioid drugs. But there is strong evidence that longer-term treatment is needed. Improvements tend to become significant after three months of treatment, with the majority of benefit gained after one year. Benefits may be sustained beyond this point with continued treatment.

3 2017 National Drug Strategy Household Survey

An emphasis on abstinence to some extent devalues the other achievements that can be made through treatment. For most people entering treatment, short-term achievable goals are important, such as:

- staying alive;
- reducing non-medical drug use;
- reducing high-risk activities (e.g. overdose, disease transmission, suicide and self harm behaviour);
- improved physical and psychological health;
- improved psychosocial functioning, including improved relationships, finances, employment and parenting;
- reduced criminal behaviour.

Patient journeys

These goals represent steps along a continuum: from dependent drug use, through reduced safer use, to abstinence. Reduced or controlled use, stable relationships, employment or better health are important changes that may encourage abstinence in the future. 'Slip ups' or lapses are a normal part of changing any human behaviour. Every time they occur, a person can learn from the experience and develop better ways of dealing with a similar situation in the future.

People commonly seek treatment when they are in crisis. For example, their drug use may have escalated to a point of being out of control, they have been given an ultimatum from family, or they may have been charged with a criminal offence. In these crisis situations, people often develop a resolve to stop using drugs and change their lifestyle. They tend to seek short-term treatment, hoping that an attempt at withdrawal will be sufficient to stop drug use, without necessarily having considered all treatment options or realistic goals.

To respond effectively to opioid use, a treatment system needs to be able to provide a range of options. Some options need to be accessed quickly and there should be multiple points and levels of entry. To ensure the patient's broader needs are addressed, the treatment system also needs links to primary and other specialist health, welfare and social service providers.

1.2.2 Treatment interventions

Overview

Patients within the OTP include those who use illicit opioids, those taking pharmaceutical opioids for non-medical purposes, and those taking pharmaceutical opioids for medical conditions. However, to differentiate between categories of patient only further marginalises an already marginalised population even further. OTP interventions are provided to meet individual needs, preferences, level of stability and controlled behaviour – regardless of their pathway to opioid dependence.

A range of effective evidence-based interventions is available for the treatment of opioid dependence. (Figure 1) Each intervention has advantages and limitations. (Table 1)

Brief interventions

Brief interventions involve counselling the patient, usually one to three times with each session lasting 10–60 minutes. Brief interventions may be opportunistic, that is offered to individuals who are identified as having 'unhealthy use' of opioids when presenting for other health concerns.

Health professionals in a range of settings, have opportunities to deliver brief interventions. Settings include primary and community care, hospitals and needle syringe programs.

Non-dependent opioid users may benefit from a range of brief interventions (e.g. overdose prevention, safer injecting techniques, controlled drug use, medicine adherence) that aim to reduce potential harms associated with their opioid use (★★).

Brief interventions are generally ineffective in achieving long-term changes in drug use in dependent opioid users, and more intensive treatment approaches are usually required (★★). Brief interventions may nevertheless be appropriate in assisting dependent users who are ambivalent or uncertain of their treatment options to clarify treatment goals and facilitate treatment engagement. Brief intervention for dependent users can also reduce potential harms (overdose, injecting risks, etc) and should be encouraged.

Withdrawal interventions

Withdrawal interventions aim to help patients to safely and comfortably reduce and stop taking opioids. They also engage patients into longer-term treatment interventions. Withdrawal may be elective, or occur because of interrupted access to opioids (e.g. hospitalisation, incarceration, travel).

Figure 1. OTP intervention summary

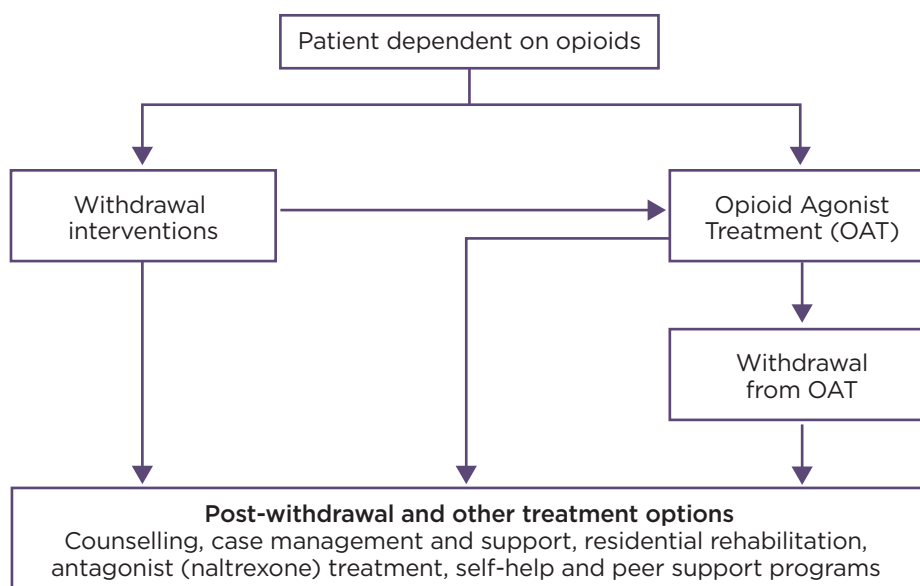


Table 1. Summary of evidence-based treatment approaches to opioid dependence

Type of treatment	Advantages	Disadvantages
Opioid agonist treatment	<p>Strong evidence of capacity to:</p> <ul style="list-style-type: none"> • reduce opioid use • decrease mortality • improve health and quality of life <p>Avoids withdrawal in people who are ill or unstable</p> <p>Capacity to retain patients in treatment</p> <p>Widespread availability (although gaps exist, so could be improved)</p>	<p>Expense to patient (for dispensing fee outside public clinics)</p> <p>Side effects</p> <p>Stigma</p> <p>Restrictions of supervised dosing (e.g. lifestyle, travel)</p> <p>Prolonged withdrawal profile on cessation</p>
Withdrawal interventions	<p>Short-term commitment</p> <p>Attractive to patient</p> <p>Low threshold for outpatient services</p> <p>Addresses non-elective withdrawal conditions (e.g. incarceration)</p>	<p>Poor long-term outcomes if stand-alone treatment</p> <p>Increased overdose risk following withdrawal (loss of tolerance)</p> <p>Can lead to destabilisation of other health conditions (e.g. chronic pain, mental health)</p>
Antagonist treatment (naltrexone)	<p>Effective in decreasing opioid use in highly motivated, well-supported people</p> <p>‘Opioid-free’ medicine</p>	<p>Poor retention for most patients</p> <p>Limited acceptance</p> <p>Side effects</p> <p>Complicates pain management</p> <p>Expense to patient</p> <p>Requires withdrawal prior to initiating naltrexone</p>
Residential rehabilitation	<p>Effective for those with complex needs, including physical and mental health issues, social problems and poor living skills.</p> <p>Some residential rehabilitation services accept patients on OAT.</p>	<p>Requires commitment of time and separation from home and community</p> <p>Long-term outcomes depend on aftercare</p> <p>Completion of withdrawal usually a requirement for entry</p> <p>Contributions from patients are required whilst undertaking these programs</p> <p>Often waiting lists</p>
Outpatient counselling (without medicine)	<p>Some effectiveness in substance misuse problems of lesser severity and early stages</p>	<p>Evidence indicates poor outcomes in dependent populations if stand-alone treatment</p> <p>High variability in quality of counselling services</p>

Withdrawal interventions can occur in different settings depending on patient needs. While most occur in ambulatory settings, hospital settings may be better for those with significant other medical or psychiatric problems. Residential withdrawal services are useful for those requiring structured social and housing supports.

Withdrawal interventions consist of:

- assessment;
- regular monitoring;
- psychosocial support (e.g. patient information, supportive care);
- medicine (most commonly reducing doses of buprenorphine-naloxone over 1–2 weeks);
- engagement with ongoing treatment services.

Withdrawal alone rarely results in long-term changes in opioid use. Better outcomes usually require longer-term treatment after withdrawal. There is an increased overdose risk following withdrawal due to loss of tolerance. Refer to Section 2.5 Naltrexone maintenance.

Post-withdrawal interventions

Counselling services

Counselling for opioid dependence can be delivered in individual (one-to-one) or group settings and many different approaches are used.

Motivational enhancement approaches can help ambivalent patients engage in treatment. Relapse prevention approaches help patients to identify situations associated with opioid use and to use appropriate cognitive and behavioural strategies to reduce risks and prevent a lapse from becoming a relapse.

However, the evidence suggests that counselling services on their own are generally not effective in achieving long-term abstinence in people who are opioid dependent (★★★).

Counselling is more effective when delivered after withdrawal, and/or in conjunction with other long-term treatment approaches (e.g. medicine-assisted treatment, residential programs). Some patients may also benefit from counselling for other issues, such as addressing mood or anxiety problems, unresolved grief or post-traumatic stress disorder.

For further information, see the **Drug and Alcohol Psychosocial Interventions Professional Practice Guidelines** available at http://www1.health.nsw.gov.au/PDS/pages/doc.aspx?dn=GL2008_009

Case management and support services

Many people with opioid dependence have problems related to other substance use, physical or mental health conditions, social circumstances and relationships. A case management approach allows for the identification of the patient's main concerns, their goals, available resources and develops an action plan to address these issues, with ongoing monitoring and support.

Case management can be provided by a range of health providers in different settings.

Residential rehabilitation

Residential rehabilitation programs offer intensive, structured interventions over a period of weeks or months. These include living/parenting skills training, case management and counselling to reduce or stabilise substance use.

Historically, these programs have been abstinence based. In recent years they have broadened to include people with complex needs who receive OAT during their stay, as well as those whose goal is to reduce off methadone or other opioids.

For further information, see the **NSW Health Drug and Alcohol Treatment Guidelines for Residential Settings** available at http://www1.health.nsw.gov.au/pds/Pages/doc.aspx?dn=GL2007_014

Naltrexone-assisted treatment

Naltrexone is an opioid antagonist medicine that blocks or reduces the effects of opioids. Naltrexone-assisted treatment involves the use of oral naltrexone medicine (usually 50 mg daily) in addition to counselling and regular monitoring.

Naltrexone treatment interventions have poor retention and, given the potential for overdose after relapse, are usually reserved for highly motivated patients with good psychosocial supports (★★★).

Unapproved naltrexone formulations (e.g. naltrexone implants) are not to be used outside clinical trial conditions (S).

Opioid agonist treatment

Opioid agonist treatment (OAT) refers to long-term treatment approaches that involve the regular provision of long-acting opioid medicine in addition to regular monitoring and psychosocial supportive care. OAT is a structured intervention with identified service providers and strategies to minimise the risk of misuse of opioid medicines (e.g. supervised dosing).

Approved medicines for this indication in Australia include:

- oral methadone;
- sublingual buprenorphine;
- sublingual buprenorphine-naloxone.

Regular use of these medicines prevents onset of opioid withdrawal, reduces cravings and reduces the effects of additional opioid use.

Evidence indicates that long-term OAT is an effective treatment approach for most opioid dependent users, enabling patients to stabilise their drug use, and to make the necessary changes in their substance use and lifestyle (★★★★).

Self-help and peer support programs

Self-help programs and peer-based interventions (e.g. [SMART Recovery](#)) can provide valuable support for patients, and patients should be encouraged to participate in such programs.

1.2.3 Engagement with services

Stepped and flexible care

Stepped care describes starting at a low level of intervention and then escalating the intensity of treatment depending on the individual's response to the first level.

Opioid treatment services need to be sufficiently varied and flexible to accommodate:

- the chronic relapsing nature of drug dependence;
- individual variability in personal circumstances
- the needs of patients (e.g. their severity of dependence, motivation and response to interventions);
- progression through the different stages of behavioural change.⁴

Patients' needs change as treatment progresses and they re-integrate with family, friends and community. Treatment journeys are not linear – patients progress through stages and relapses are common. Hence, continuous assessment and modification of interventions and services is necessary throughout the treatment journey.

There is no single best method, nor will one type of treatment work for everyone. Individuals seeking treatment for drug dependence will have different patterns of risk and protective factors, different psychological and social problems, and varying cultural backgrounds. People may need to try a number of options before finding one that suits them best. Also, a certain type of treatment may suit a person at one stage in their life, but may not be useful at another.

1.2.4 Treatment systems

Health services delivering drug and alcohol interventions

The NSW opioid treatment service system is designed to match patients with the level of care needed and resources available. Services are delivered in community, hospital and residential settings by specialist and primary care providers, often in shared care arrangements. Patients may transition across service providers as their circumstances and treatment needs change.

Generalist services

Generalist health services are important in providing:

- management of other health problems, which may or may not be related to the patient's opioid or other substance use;
- early identification and referral of individuals with problematic opioid use;
- safe and effective prescribing and dispensing of pharmaceutical opioid medicines by operating within a Quality Use of Medicines framework;
- specialist drug interventions in collaboration or in shared care arrangements with specialist service providers.

Specialist services

Specialist drug and alcohol services may be delivered by a range of public and private providers.

Public OTP services

The specialist public sector is targeted to patients with complex treatment needs (arising from their substance use, medical, psychiatric or social conditions).

Specialist public OTP services provide a multidisciplinary team (MDT) approach. Specialist medical, nursing, allied health and pharmacy professionals provide a mix of medical care (including prescribing), case management, counselling, dosing and monitoring services.

These services link to other drug and alcohol services, and specialist services (e.g. infectious diseases, mental health, chronic pain, the Justice Health and Forensic Mental Health Network, emergency departments).

Public clinics can also act as safety nets for private providers by re-admitting patients who cannot be safely or best treated in the community.

Specialist public OTP services may be supplemented by dosing in public hospital pharmacies or appropriate locations within the hospital for a limited number of patients where there are no other dosing facilities available and accessible.

Private OTP clinics

Private OTP clinics are less numerous than public services, but provide an important service, primarily as dosing facilities, particularly for patients who require more careful monitoring than can be provided in community or primary care settings. Some private clinics have access to a range of specialist services (e.g. psychiatrists, gastroenterologists, allied health professionals). There is a cost for patients at private clinics.

Primary care services

As opioid dependence is a chronic condition, general practitioners (GPs) are ideally positioned to deliver interventions, as well as provide continuity of care and coordinate services across multiple health providers.

As more nursing and allied health professionals become involved in primary care, the capacity for treatment increases in this setting. However, many GPs have limited training or resources to treat patients who are unstable or have complex treatment needs (and require multidisciplinary specialist services).

Primary care services should be able to:

- identify patients with opioid dependence through opportunistic or targeted screening and through regular assessment of patients using opioids for medical conditions (e.g. chronic pain);
- provide brief interventions;
- refer patients to appropriate services;
- provide support including coordination with other health and welfare service providers.

Some primary care providers also deliver opioid treatment interventions (e.g. withdrawal, opioid agonist treatment, counselling, naltrexone treatment) for dependent patients who do not have severe or complex treatment needs related to their substance use.

Community pharmacies

Community pharmacies play an important role in opioid treatment provision in NSW: the majority of patients in opioid agonist treatment programs are dosed in these settings.

Community pharmacies offer greater geographic accessibility and more accessible dosing hours than OTP clinics. However, patients pay dispensing fees for supervised dosing.

Dosing at a community pharmacy is most appropriate for patients who are progressing steadily in treatment. Patients who are regularly missing doses and/or presenting intoxicated may be more appropriately dosed in a public clinic/facility.

NGO services

Historically, many NGO-based drug and alcohol treatment providers excluded OTP patients from accessing their services. However, an increasing number now provide case management, welfare support, outreach and counselling services to patients on opioid treatment.

More residential rehabilitation services now cater for OTP patients, and provide services in which patients can remain on OAT, or can be assisted in completing OAT.

Shared care arrangements

Shared care arrangements between specialist and primary care providers offer better targeting of limited resources and a more holistic approach to health care for patients in OTPs. There are different models of shared care, but they generally involve a system that coordinates treatment across primary and specialist care settings and identifies each provider's role in the care plan.

Shared care models may include:

- co-location of clinical services;
- linkages through shared protocols, information systems and referral pathways;
- coordinated and cohesive professional development and clinical governance activities.

Shared care systems and networks can assist patients to move more easily between specialist and primary care settings according to their treatment needs.

Linkages with broader health and service systems

Drug use can be complex and often intertwined with many other health and social problems. To provide patients with appropriate supports and services that maximise treatment gains and enable re-integration into local communities, drug and alcohol treatment systems should be well integrated with other systems of care and social support.

Patients with complex treatment needs may require linkages and coordination across a range of services in addition to drug and alcohol services, including:

- primary health care services;
- mental health services;
- young people and older persons' services;
- specialist health services, including gastroenterology, infectious diseases, chronic pain;
- family and children's services;
- education and vocational services;
- legal services and criminal justice sector;
- financial services;
- housing services.

The severity of dependence, the nature and extent of physical and psychiatric comorbidity, and the nature and stability of social circumstances are all important when determining the most appropriate type and intensity of treatment. The treatment system should be responsive to individual needs, including cultural requirements, and recognise the rights of patients to choose preferred treatment options and be active in decision-making processes regarding their treatment.

Section 2

Clinical guidelines and recommendations


2.1 Assessment

2.1.1 General approach

A comprehensive biopsychosocial assessment and case formulation provides the basis for treatment planning, indicates additional service needs and the type of treatment likely to be appropriate (S). Assessment should cover the broad range of medical, physical and mental health conditions that frequently accompany opioid dependence (S).

The initial assessment of a patient using opioids should follow standard practice for assessment of a complex clinical condition, and incorporate collateral information where appropriate (S).

Applying privacy and confidentiality standards, collateral information may be obtained from other healthcare providers, family members, partners and carers, as well as regulatory and prescription monitoring systems. Refer to [The Health Records and Information Privacy Act 2002 \(NSW\) \(the HRIP Act\)](#) and for NSW Health staff, the [Privacy Manual for Health Information - Policy Manuals](#).

Assessment should be linked to the practitioner's skills, experience and available resources (S). Complex issues (e.g. high-risk behaviours, other substance use disorders, doctor shopping, serious comorbid physical or mental health conditions) make specialist addiction medicine advice or referral advisable. 

It is the practitioner's responsibility to ensure the patient has provided consent to treatment and that the patient is advised of all risks associated with opioid treatment. Specific risks should be communicated to the patient regarding:

- impact of using other drugs;
- possibility of altered tolerance levels and overdose potential; and
- intoxication and impact on capacity to drive.

2.1.2 Presenting complaint

Individuals come to the attention of treatment providers for a range of reasons. They may be seeking treatment for their opioid use or for other health or social problems (that may or may not be

drug related). The reason for presentation influences immediate treatment goals and the type of treatment that is acceptable and appropriate for the patient (S).

2.1.3 Assessing substance use and previous treatment

History

A comprehensive substance use history is essential. This involves assessment of all types of drugs used (i.e. illicit and pharmaceutical opioids, alcohol, cannabis, stimulants, benzodiazepines, tobacco), duration of use, quantity and frequency of recent use, route of use, and time of last use (C).

It should also cover any previous drug treatment attempted, the patient's perspective on what has worked before, and what treatment the patient is prepared to consider now.

Physical and mental state examination

General physical and mental state examination should be conducted based upon the medical history and presenting circumstances.

Assess for intoxication and withdrawal, taking account of reported last drug use (S). ([Table 2](#)) Intoxication with central nervous system (CNS) depressants such as benzodiazepines and alcohol increases the risk for overdose in combination with methadone or buprenorphine. Withdrawal severity indicates dependence severity. It may inform the timing and amount of first dose of medicine, as recent use of opioids increases the likelihood of withdrawal being precipitated by [buprenorphine](#) or naltrexone.

There are several scales available to measure withdrawal severity such as: [Subjective Opioid Withdrawal Scale \(SOWS\)](#), [Clinical Opioid Withdrawal Scale \(COWS\)](#) and [Objective Opioid Withdrawal Scale \(OOWS\)](#). ([Appendix B](#))


Examine peripheral sites (C), documenting any related complications (e.g. infections). Injecting into the groin or neck are indications of high-risk drug use that may benefit from specialist advice or referral (C).  (See also [Appendix G](#)).

Table 2. Features of opioid intoxication, overdose and withdrawal

Signs of opioid intoxication	Signs of opioid overdose	Signs and symptom of opioid withdrawal	
Constriction of pupils	Pinpoint pupils	Dilation of pupils	Lacrimation
Itching and scratching	Loss of consciousness	Anxiety	Rhinorrhoea
Sedation and somnolence	Respiratory depression	Muscle and bone ache	Abdominal cramps
Lowered blood pressure	Hypotension	Muscle cramps	Nausea
Slowed pulse	Bradycardia	Sleep disturbance	Vomiting
Hypoventilation	Pulmonary oedema	Sweating	Diarrhoea
		Hot and cold flushes	Palpitations
		Piloerection	Rapid pulse
		Yawning	Raised blood pressure

Investigations

Urine drug screening (UDS) is useful to corroborate patient history and establish recent opioid and other substance use. However, delays in obtaining results should not delay treatment initiation where the diagnosis can be clearly established (C). Be aware of the potential for an adversarial relationship with the patient if the use of UDS is poorly communicated (C).

Investigations for other conditions, either related to the presenting condition or to the patient's drug use (e.g. blood borne viruses, liver disease) should also be undertaken as needed.

Diagnosing substance use disorders

Establishing a diagnosis of opioid dependence is a requirement for opioid agonist treatment (R). The International Classification of Diseases (ICD) and Diagnostic and Statistical Manual of Mental Disorders (DSM) provide widely accepted definitions of dependence. (Appendix A)

Dependence on pharmaceutical opioids in the context of chronic pain can pose a diagnostic dilemma. Chronic use of high doses of opioids, such as morphine, oxycodone or codeine, will result in neuroadaptation (tolerance, withdrawal) in most patients, but this is not necessarily sufficient for a diagnosis of opioid dependence.

Features consistent with diminished control over opioid use (e.g. multiple dose escalations, non-medical routes of administration, use for reasons other than pain, difficulties in reducing opioid use) should be examined. Consultation or referral to a relevant addiction or pain medicine specialist may be advisable. See ACI Pain Management Network: <https://www.aci.health.nsw.gov.au/chronic-pain/painbytes>

2.1.4 Assessment of other health and social issues

Comorbid health and psychosocial conditions are likely to influence the preferred treatment approach, setting and broad (holistic) treatment plan, including the need for specialist advice or referral (S).

The clinician should target general health and wellbeing, and risk factor assessment within the context of the patient's substance use. Opioid and other substance use is commonly associated with a range of:

- physical conditions (e.g. chronic pain, liver, cardiovascular, injecting-related infections, endocrine);
- psychiatric conditions (e.g. anxiety, depression, cognition, sleep disorders);
- social problems (e.g. employment, housing, financial, relationships);
- high-risk behaviours (e.g. overdose, self-harm, child protection and domestic violence).

These conditions and risk factors should be assessed as appropriate for each patient. They may require assessment over a period of time and involve different health and welfare providers. As social situations are subject to change, they should be revisited regularly in the course of care.

The timing of assessment and investigation of other health issues should be tailored to the individual patient's presentation. For example, screening for blood borne viruses rarely needs to be conducted at the initial assessment. It may be better deferred until the patient has stabilised in treatment and is better able to engage in any pre- and post-test counselling.

2.2 Treatment planning

2.2.1 Identifying treatment options


As in other areas of chronic disease management, opioid dependence treatment planning should be a continuous process that:

- involves the patient (shared decision making) and reflect the patient's circumstances and case complexity (patient centred care);
- is based on coordinated care across service providers that addresses multiple domains;
- is documented in a way that is meaningful to the patient, their carers and other service providers (S).

The principles of shared decision making and informed consent should be observed in selecting and referring patients to treatment services (S). All types of treatment for opioid dependence should be considered in consultation with the patient, with decisions based on the patient's circumstances and treatment preferences (Table 3), and on evidence of effectiveness and safety of available options (S). (See [Patient journey](#), [Treatment interventions](#))

A [Stepped and flexible care](#) to treatment delivery suggests using less restrictive treatment approaches for those with low severity dependence (e.g. withdrawal interventions, counselling), increasing to more intensive treatment options (opioid agonist treatment, residential rehabilitation) for those with more severe and entrenched problems (C).

Appropriate referral should be made to a service where the treatment plan involves the decision to engage with a particular treatment approach that cannot be delivered by the assessing service.

Once diagnosis, consent to treatment and choice of modality are established, treatment should be commenced without delay (C). If there are concerns about initiating treatment safely and effectively, specialist referral is recommended. 

Opioid agonist treatment has specific requirements that need to be addressed in the treatment plan, including jurisdictional [approval to prescribe methadone or buprenorphine](#) and dispensing arrangements (R).

Table 3. Factors influencing treatment directions

Factor	Considerations
Medical and psychiatric conditions	Certain conditions (e.g. chronic pain, psychotic disorders, acute medical conditions such as infective endocarditis, HIV) can be destabilised during withdrawal and attempts at sustaining an opioid-free lifestyle; patients with these conditions are often better directed to OAT (C)
Pregnancy	Women who are opioid-dependent and pregnant should be directed to OAT due to the risk of antenatal complications associated with withdrawal, and high rates of relapse to heroin use with other treatment approaches (C)
Desire for abstinence	People with a preference for abstinence based interventions who are well supported and well motivated are more likely to respond to counselling with or without naltrexone (C)
Social instability	People with poor living skills and unstable social circumstances may benefit from residential treatment (C)
Use of other sedative drugs	People using other sedative drugs may be at increased risk of overdose during OAT induction and maintenance.

2.2.2 Level of treatment needs and coordinating treatment across providers

The effective delivery of opioid treatment requires the coordination of clinical and welfare services across a range of service providers. **Patient factors** and **service provider factors** both influence care planning. Patient factors are identified during initial assessment and subsequent review. (Table 4)

Table 4. Factors influencing planning

Patient factors	Service provider factors
Substance use Medical and psychiatric issues Social circumstances	Capacity to provide necessary components of care (e.g. Ability to regularly review and monitor patients during high-risk periods such as induction or instability) Ability to effectively communicate between service providers (e.g. Between prescriber and dispenser site) Having the relevant skills, training and expertise to deliver interventions

Coordinating OTP services

The components of OAT (i.e. assessment and monitoring, prescribing, case management, counselling, dispensing) should be tailored according to individual patient needs and available resources. These components may be delivered by a range of service providers, including specialist OTP services based in local health districts (LHDs), specialty health networks (SHNs) and private sector, Medicare funded medical, nursing and allied health in primary care, and NGO based treatment, case management and welfare services.

Coordinating other health and welfare services

Many patients also engage with a range of welfare services (e.g. education, employment, disability, guardianship, child protection, criminal justice) and other primary and specialist health providers for health problems not related to their substance use and treatment.

2.2.3 Matching patients to the treatment setting

General approach

Previous NSW guidelines recommended patients should commence OAT in a public or private clinic setting and only move to primary care settings when 'stable'. This may create unnecessary barriers to access and participate in treatment.

OAT can be safely and effectively initiated in primary care (GP and community pharmacy) settings provided:

- clinicians have adequate resources, particularly the ability to regularly monitor patients (e.g. at least every 2 or 3 days for methadone patients and every 3 or 4 days for buprenorphine patients during induction or periods of instability);
- clinicians and other team members (medical, nursing, pharmacy or allied health professionals) have adequate training and skills;
- there is effective communication between service providers, patients and carers;
- there are pathways for accessing specialist support if complications arise;
- the patient does not have severe or complex treatment needs including significant medical, psychiatric or social problems (Table 5).

Specialist services are more appropriate for conducting comprehensive assessments and initiating treatment for patients with complex treatment needs, or in circumstances where the primary care service providers (GP, pharmacist) do not feel adequately skilled or resourced to initiate treatment. Treatment plans can be reviewed after a period of stabilisation in a specialist clinic (Table 5).

Table 5. Categories of treatment needs

Category one - HIGH NEED	Category two - LOW NEED
High levels of polydrug use, particularly alcohol or benzodiazepine misuse or dependence.	Opioids are the primary problematic drug group. Other substance use not clinically problematic.
Serious or unstable physical and/or mental health issues. This may include recent overdose history, cognitive impairment, risk of harm to self or others.	No other serious health conditions requiring active interventions. Physical or mental health issues (if identified) stable and engaged in appropriate treatment.
Significant psychosocial issues such as homelessness, domestic violence, child protection concerns.	Stable social circumstances, with good supports No other risk factors identified (harm to self or others, domestic violence, child protection, homeless).
Patients who require more intensive services, assertive follow-up and/or coordination across a range of service providers due to: <ul style="list-style-type: none"> • recent release/discharge from custody* or hospital; • pregnancy or recent child birth; • engagement with multiple service providers requiring active case coordination, such as community services, drug court; • a history of poor engagement with services, with frequent missed appointments or non-attendance; and • significant cultural issues that may impact upon treatment (e.g. Aboriginal and Torres Strait Islander patients and culturally and linguistically diverse patients). 	

* People being released from correctional setting should be given priority access to dosing in public OTP services for several weeks upon release from custody, so a care plan for ongoing treatment can be established. See NSW Health Policy PD2005 313 [Dosing places - Availability for released inmates on substitution pharmacotherapies](#) www1.health.nsw.gov.au/PDS/pages/doc.aspx?dn=PD2005_313

Situations that influence treatment planning

Polydrug use

Polydrug use is common among people who are opioid dependent. Of particular concern is use of alcohol, benzodiazepines or other sedatives in conjunction with opioids because of an increased risk of overdose, particularly during methadone induction and during withdrawal attempts. (See [polydrug use and risk](#)). Amphetamine or other stimulant use may result in mental state changes and should be monitored.

Risks related to polydrug use should be assessed prior to and during treatment for opioid dependence. Referral to specialist services is indicated for patients with substance misuse of, or dependence to, multiple drugs or alcohol, but polydrug use should not be a reason to withhold OAT (C).

Acute medical conditions

Regular opioid use is associated with a range of health problems that may cause the patient to seek medical attention. This may provide an opportunity to initiate opioid dependence treatment.

Liver disease (viral infections and alcohol use) is particularly common and requires assessment and referral for specialist treatment as appropriate (e.g. treatment for hepatitis C infection). Long term antiviral treatment for hepatitis B, hepatitis C and HIV appears to be more effective for people who inject drugs engaged in OAT.

Seek specialist advice or referral for patients with severe or acute medical problems, including hepatic, renal or respiratory failure, cardiac arrhythmias, sepsis (C).

Psychiatric comorbidity

It can be difficult to establish whether opioid dependence is causing mood disturbance, or vice versa. Additionally, use of other substances (e.g. stimulants, alcohol) is associated with psychiatric problems including psychotic, affective and cognitive disorders. Treatment of opioid dependence should be initiated with regular reviews of the patient's mental health. Patients with persistent and/or severe presenting psychiatric problems (including risk of harm to self or others) may require more immediate assessment and treatment of their psychiatric condition, and specialist referral should be sought (C).

Chronic pain syndromes and pharmaceutical opioid dependence

In the past two decades, non-medical use of pharmaceutical opioids, including over-the-counter preparations, has increased. The boundary between chronic pain and addiction management is complex, with a continuum of presentations between some people using pharmaceutical opioids rather than heroin for non-medical reasons, and others commencing opioid use for management of chronic pain and then progressing to opioid dependence.

While both methadone and buprenorphine can be used effectively in treating patients with chronic pain and opioid dependence, a comprehensive treatment plan that addresses pain management is required. The evidence regarding long term use of prescription opioids for chronic non-malignant pain is limited. Specialist advice or referral is recommended for people with chronic pain and opioid dependence because of the potential complexity of managing both conditions (C).

People with a recent interruption to regular opioid use

This occurs in situations such as recent withdrawal, incarceration or hospitalisation. The interruption to regular opioid use lowers opioid tolerance, and if opioid agonist treatment is preferred, cautious dosing regimens should be used.

Some patients may not have recently used opioid drugs, but nevertheless have a history of opioid dependence and a high risk of returning to opioid use (e.g. following release from prison). It may be appropriate to offer opioid agonist treatment with methadone or buprenorphine even when neuroadaptation is not evident, after consultation with specialist services (S).

For people who have been incarcerated, it is important that there is a seamless referral from the closed custodial setting to community based treatment services (C).

With general hospital patients (including mental health admissions), any treatment of opioid misuse or dependence, or identified need for treatment, should be addressed through referral to addiction treatment services as part of the discharge processes. This should be accompanied by appropriate reporting to the patient's GP (C).

Child protection

Compared to the general population, people who are opioid dependent are relatively young – this increases the likelihood of children being involved. Also, people who are opioid dependent are more likely than the general population to have a history of neglect and abuse during their childhood. This makes it important to consider issues around child protection (R), and health professionals should be aware of mandatory reporting requirements. Refer to the [Mandatory Reporter Guide](#)

It also points to the value of facilitating the development of parenting skills as a way of breaking the cycle of abuse and neglect (S). (See [National MATOD Guidelines](#), page 138).

Difficulties attending dosing facilities

Temporary or long-term physical disability may make attendance at a dosing facility difficult. Alternative arrangements (including the possibility of home dosing) are desirable to retain the patient in treatment (C).

People who are itinerant (e.g. due to work) are likely to be unable to comply with the structure of opioid agonist treatment and alternative treatment options should be considered.

2.3 Withdrawal

This section focuses on managing withdrawal from heroin or non-medical use of opioids, including prescribed opioids. Withdrawal intervention in this context is the beginning of treatment. [Cessation](#) of methadone or buprenorphine at the end of a period of opioid agonist treatment is covered later.

2.3.1 Aims

The aims of withdrawal reflect the issues and needs of the patient (Table 6). Withdrawal in opioid dependence should always be considered as part of a structured treatment approach (C). The delivery of withdrawal services involves assessment and treatment planning; supportive care and provision of information, monitoring; medicine; and linkages to services for further treatment and support.

2.3.2 Settings for withdrawal

Selection of setting and approach to withdrawal should take into account the goal of the care episode, the purpose of withdrawal and timescale (S).

Table 6. Aims of withdrawal intervention

Aim	Rationale
Alleviate distress	An important reason for patients presenting for treatment is palliation of the discomfort of opioid withdrawal symptoms. This is one of the primary aims of withdrawal services.
Prevent severe withdrawal complications	Although opioid withdrawal on its own is rarely life-threatening, it can lead to serious problems such as: <ul style="list-style-type: none">• complication of other medical or psychiatric conditions (e.g. precipitation of an acute psychotic episode in a patient with schizophrenia in remission; dehydration in an individual with poor baseline nutritional status or diabetes)• risk of fatal and non-fatal overdose with resumption of opioid – due to the reduction in opioid tolerance that accompanies withdrawal, and to the combined sedative effects of opioids and medicines (e.g. benzodiazepines) used for the management of heroin withdrawal.
Interrupt a pattern of heavy and regular drug use	Many patients want treatment to end their opioid use completely during the withdrawal episode, intending to stay off opioids for a set period of time afterwards. However, giving up entirely is not the goal of every patient.
Provide linkages	Enrolment in a withdrawal program can help patients access linkages and enables engagement in ongoing treatment for their drug dependence.
Assist patients to get help with other problems	While some people are unwilling or unable to continue in ongoing drug treatment programs, they may need – and may appreciate – contacts with welfare services (e.g. accommodation), general support and case management services (e.g. outreach workers), or primary or specialist health services for co-existing medical and/or mental health problems.

Withdrawal may be conducted in a range of settings including:

- hospitals – particularly when people who use drugs have been admitted for other reasons;
- residential services – which provide a safe, supportive environment for withdrawal management, but a lower level of medical care than hospitals;
- ambulatory (outpatient and/or home-based services) – for those individuals with stable social settings and without significant medical or psychiatric complications or dependence to other drugs.

The pressures and strains of using drugs, key life events ('turning points') and the availability of social support are important factors impacting on the likelihood of successful withdrawal, the exact withdrawal technique used may be less important.

2.3.3 Supportive care and monitoring

Support

Psychosocial support during the withdrawal episode should be aimed specifically at supporting the patient through problems associated with withdrawal (coping with cravings, symptom relief, maintaining motivation) and in facilitating post-withdrawal links.

Monitoring

The treating team should review the patient regularly according to the patient's condition and treatment settings. Review should include risk assessment, assessment of withdrawal symptoms and severity, adverse events, other drug use and any patient concerns.

Structured withdrawal scales may be used to assist monitoring. ([Appendix B](#))

Patient information

Patients often have limited concentration during withdrawal. Information may have to be repeated or rephrased to be fully understood and absorbed. Written information is valuable in these circumstances, and is also recommended to support patients and their relatives.

The information provided should cover:

- the nature and duration of withdrawal symptoms;
- strategies for coping with symptoms and cravings;
- strategies to remove high-risk situations;
- the role of medicine and possible impact on capacity and fitness to drive.

2.3.4 Medication approaches for withdrawal

Major approaches

There are two major types of medication approaches used in managing opioid withdrawal:

1. abrupt cessation of opioid use and symptom relief using non-opioid drugs (e.g. antiemetics, benzodiazepines, clonidine, non-steroidal anti-inflammatory drugs and antispasmodics such as hyoscine butylbromide);
2. short course (usually less than 1 month) of reducing doses of buprenorphine or less commonly methadone. ([Table 7](#) and [Table 8](#))

Some non-opioid drugs are used off label for symptom relief and in such cases, patient informed consent is required. Both above approaches are well supported by evidence (★ ★ ★). However, the use of buprenorphine to manage withdrawal is associated with significantly better amelioration of withdrawal (than clonidine and supplementary medicines) and is the most flexible approach. It supports cessation of medication with minimal rebound withdrawal symptoms, and also enables transfer to naltrexone for relapse prevention treatment, or transfer to opioid agonist treatment if the withdrawal attempt is not successful. There is a reduced risk of non-medical use if buprenorphine-naloxone sublingual film is prescribed (compared to buprenorphine preparation alone).

The abrupt cessation of chronic opioid use without medicine is feasible, but typically associated with high failure rates and evidence does not support this as the routine approach. Due to reduced non-medical risks, buprenorphine-naloxone may be considered first line treatment for opioid withdrawal.

Unmedicated withdrawal is best reserved for people with lower levels of dependence in a setting with appropriate care and support, and the capacity to intervene if the level of discomfort becomes unacceptable to the patient. Control of vomiting and diarrhoea is particularly important to prevent dehydration, which can have serious consequences if left untreated.

Table 7. Sample 7-day inpatient buprenorphine dosing regimen for heroin withdrawal

Day	Buprenorphine dose (sublingual mg)	Common range of doses used
1	8 mg at onset opioid withdrawal. Additional 4 mg or 8 mg PRN for uncomfortable withdrawal	8-16 mg
2	Reduce total day 1 dose by 2-4 mg	6-12 mg
3	Reduce total day 2 dose by 2-4 mg [†]	4-8 mg
4	4 mg as morning dose [†]	2-6 mg
5	2 mg as morning dose [†]	2 mg
6	Cease buprenorphine 1-2 days prior to planned discharge to enable any rebound withdrawal to subside during admission period	0
7		0

[†]Review patient treatment plan. If plan is to continue buprenorphine following discharge (e.g. transfer to OAT), then increase buprenorphine dose to effective range (e.g. usually 8 mg or more) prior to discharge.

Table 8. Sample 14-day outpatient buprenorphine dosing regimen for heroin withdrawal

Day	Buprenorphine dose (sublingual, mg)
1	8 mg at onset of opioid withdrawal
2-4	Titrate dose so that patient is comfortable and not using additional opioids (e.g. heroin) Typically require doses between 8-16 mg daily
5-14	Review patient progress regularly and adjust dose Aim to reduce daily dose by 2-4 mg every 1-2 days [†] Aim for last 1-2 days of dosing to be on 2 mg dose

[†]Review patient treatment plan regularly. If plan is to continue buprenorphine in the post-withdrawal period (e.g. OAT), then increase buprenorphine dose to effective range (e.g. usually 8 mg or more).

Refer also to the NSW Drug and Alcohol Withdrawal Clinical Practice Guidelines:

http://www1.health.nsw.gov.au/pds/ActivePDSDocuments/GL2008_011.pdf

Other approaches (rapid detoxification)

Opioid withdrawal can also be achieved using opioid antagonists (naltrexone and/or naloxone). This is known as antagonist-induced withdrawal or rapid opioid detoxification.

Antagonist-induced withdrawal should only be considered as a means of facilitating induction of naltrexone to support relapse prevention treatment. Antagonist-induced withdrawal with minimal sedation is feasible, but the evidence base is weak and should only be done in accordance with the guidelines listed in the box below (★★). Specialist referral is strongly recommended.

Antagonist-induced withdrawal under heavy sedation or anaesthesia requires a hospital admission in NSW, and is generally not supported because of increased risk of serious adverse effects, lack of additional benefit, cost and use of scarce intensive care resources (★★★★).

Antagonist-induced withdrawal is not currently conducted in NSW's public sector and can only be conducted in private health facilities licensed for Rapid Opioid Detoxification as per the *Private Health Facilities Regulation 2010* under the *Private Health Facilities Act 2007*.

Refer to **NSW Health Guidelines on Rapid Opioid Detoxification** available at

http://www1.health.nsw.gov.au/PDS/pages/doc.aspx?dn=GL2011_009

2.3.5 Planning services after withdrawal

Withdrawal is associated with very high rates of relapse without structured ongoing treatment for dependence (★★★★). Withdrawal services should facilitate referral and engagement to ongoing treatment for each patient.

Suitable post-withdrawal treatment options include:

- outpatient counselling
- case management and support services
- residential rehabilitation
- naltrexone for relapse prevention.

Many patients will recognise the likelihood of relapse to opioid dependence following withdrawal and may seek to continue buprenorphine (or methadone) medicine used for withdrawal into longer-term OAT. This should be facilitated by the withdrawal treatment providers.

Many opioid dependent patients have a range of medical, psychiatric and social problems that may benefit from referral and engagement with relevant welfare services (e.g. accommodation), general support and case management services (e.g. outreach workers), or primary or specialist health services.

Withdrawal services should communicate with the patient's GP and other relevant health providers through a discharge summary (S).

2.4 Opioid agonist treatment

2.4.1 Choice of medicine

Overview

The choice between methadone or buprenorphine for OAT should be made in consultation with the patient, and informed by the patient's preference and goals. However, there are factors that indicate particular directions:

- It is easier to transition in and out of treatment with buprenorphine compared to methadone. This is both an advantage in terms of greater patient flexibility, and a disadvantage with lower rates of retention in treatment with buprenorphine (★★★).
- Whilst both buprenorphine and methadone typically have a range of opioid-like side effects, there is considerable individual variation in the experience of side effects with different opioids. If side effects are experienced with one medicine, it is worth trying the other. Some longer-term side effects (e.g. impact on sex hormones, sleep apnoea, prolonged corrected QT interval) are more common with methadone (★★).
- Drug interactions are more likely to be clinically relevant with methadone. In particular, interactions with medicines metabolised by the CYP450 hepatic system are clinically more relevant with methadone, with either induction of methadone metabolism (reduced methadone effects), or inhibition (increased methadone effects) that require monitoring of symptoms and may require dose adjustment. This can be particularly relevant for patients taking medicines for HIV or tuberculosis (★★★).
- Many patients say that methadone has greater impact upon cognition than buprenorphine, with stronger sedation and opioid-like subjective effects. This can be a therapeutic advantage for some patients with concurrent psychological distress. In contrast, many patients describe greater 'clarity of thought' with buprenorphine

– an advantage for many groups of patients (e.g. those in employment, parenting, studying or driving, the elderly, patients with other conditions affecting cognition, patients taking other sedative medicines) (★★).

- Buprenorphine should be the preferred medicine where there is limited opportunity for regular monitoring or supervision of dosing because methadone has greater sedating effects and is more commonly associated with overdose than buprenorphine, particularly
 - in the first two weeks of treatment as tolerance increases;
 - in combination with other sedatives (e.g. alcohol, benzodiazepines);
 - when used by individuals for whom the medicine was not prescribed (e.g. children and other opioid-naïve individuals) (★★★);
- Induction of opioid agonist treatment with buprenorphine is usually safer and easier, with maintenance doses reached more quickly than is the case with methadone (★★★). However, precipitated withdrawal can be an issue if buprenorphine is commenced too soon after the last use of a full opioid agonist, and this can be a barrier for some patients commencing treatment (★★).

2.4.2 Informed consent

It is the prescribing practitioner's responsibility to ensure the patient has provided informed consent to treatment and that the patient is advised of all risks associated with opioid treatment. Specific risks that should be communicated to the patient when commencing treatment include:

- the impact of using other drugs, whether prescribed or not;
- the possibility of altered tolerance levels and overdose potential when a stable dose is not maintained;
- risk of intoxication and impact on capacity to drive.

A checklist for prescribers when commencing treatment is provided in Appendix I.1.

2.4.3 Induction and stabilisation

Goals

The goal for the first 1–3 months of treatment is to safely achieve an adequate dose of medicine, stabilise the patient's opioid use, and to address co-existing conditions (C).

Other conditions that may need to be addressed early in treatment include advice on pregnancy and contraception, sexual health, child protection and domestic violence, blood-borne viruses, dental care, mental health (particularly suicide risk), sleep and nutrition, tobacco use and social services (e.g. housing).

Key objectives of the induction dose regimen are to safely achieve the following:

- reduction of withdrawal symptoms;
- reduction of cravings;
- reduced non-medical opioid and other drug use;
- patient satisfaction and engagement in treatment.

The differing pharmacological properties of methadone and buprenorphine mean that induction strategies are different. The greater risk of opioid toxicity and overdose during induction with methadone necessitates commencing at a low dose and a slow rate of dose increase (usually over weeks in outpatient settings). The partial agonist properties of buprenorphine (with less sedation and respiratory depression) allow for more rapid induction to a higher dose. Achieving an adequate dose of buprenorphine as quickly as possible (usually within several days) is associated with an improved rate of retention in treatment.

Methadone

Key principles

When using methadone for induction and stabilisation there are three key principles:

1. Methadone is sedating and can cause overdose in too high doses, particularly in those with low opioid tolerance, or in combination with other sedatives, or in those with altered pharmacokinetics (e.g. due to hepatic failure, drug interactions).
2. Methadone has a long half-life (20–36 hours) and accumulates in the plasma during induction. Steady state equilibrium on a dose is achieved after approximately five half-lives (4–7 days). Patients should be told to expect increasing opioid effects after each dose during this time.
3. Methadone has a delayed onset of action with peak effects achieved 2–3 hours after dosing. Patients should be cautious using other drugs (e.g. benzodiazepines, alcohol), particularly during initiation of methadone treatment. Patients should be assessed 2–3 hours after a dose to observe the peak effects of methadone (assessing for intoxication), and 24 hours after a dose to assess the extent to which methadone dose is preventing withdrawal.

For methadone product information, refer to Therapeutic Goods Administration (TGA) eBusiness Services – Product and Consumer Medicine Information:

- Methadone <https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2009-PI-00948-3&d=2016061416114622483>
- Biodone Forte <https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2009-PI-00726-3&d=2016061416114622483>

Transferring to methadone from heroin or non-medical pharmaceutical opioids


When deciding on induction of methadone, take account of pharmacy availability for supervision of dosing and monitoring of response. If seven-day pharmacy services are not available, it can be worthwhile timing the commencement of treatment so that induction is well underway before the first day of unsupervised dosing (Table 9). Also consider that applications for authorisation to Pharmaceutical Regulatory Unit should be received during business hours for processing, generally within two business days, and that the patient has sufficient funds to pay for pharmacy dispensing.


Transferring to methadone from prescribed opioids

There are some additional considerations when transferring a patient from prescribed opioids to methadone:

- The general principle for most patients is to taper off prescription opioid medicines (e.g. by 25% of total dose every 5–7 days), and taper onto methadone by an equivalent amount, with regular dose adjustments according to patient review.
- Where a patient has already discontinued their prescribed opioids (e.g. disrupted supply or treatment), or where the patient must suddenly discontinue their prescribed opioids, the general recommendations for methadone induction as per a heroin dependent patient apply. Consider specialist advice or referral under these circumstances.
- Prescribers need to apply for regulatory approval (authority) to prescribe for both drugs during the transition period. <http://www.health.nsw.gov.au/pharmaceutical/Documents/OTP-appln.pdf>

Table 9. Recommended outpatient regimen for transfer to methadone from heroin and/or pharmaceutical opioids (e.g. codeine, oxycodone, morphine)

Regimen	Recommendations and consideration
Patient supervision and review	<p>All doses of methadone should be supervised.*</p> <p>A clinician (doctor, nurse, pharmacist) should review the patient daily prior to dosing during the first week of treatment, which is the greatest risk period for methadone-related overdose.</p> <p>The review provides an opportunity to assess intoxication or withdrawal symptoms, side effects, ongoing cravings, other substance use and the patient's general wellbeing.</p> <p>Do not assume that what is being prescribed is what is being taken - patients may be using more or less than is prescribed.</p>
Starting dose of methadone	<p>Commence with 20–30 mg daily.</p> <p>Lower doses (<20 mg) are suited to those with low or uncertain levels of opioid dependence, with high-risk polydrug misuse (alcohol, benzodiazepines), or with other severe medical complications.</p> <p>Higher doses (30–40 mg) should be considered with caution if clinically indicated, at the discretion of the prescriber.</p> <p>Consultation with a specialist is recommended before commencing patients at doses greater than 40 mg because of the risk of over dose.</p>
Dose increase of methadone	<p>Increase methadone dose by 5–10 mg every 3–5 days after patient review if features of withdrawal suggest not enough methadone.</p> <p>Dose increments of 5–10 mg every 3–5 days will result in most patients being on doses of between 30 and 50 mg by the end of the first week, and 40 to 60 mg by the end of the second week.</p>
Goals of dose increase of methadone	<p>Gradually increase the dose to achieve:</p> <ul style="list-style-type: none"> • cessation (or marked reduction) in non-medical opioid use; • alleviation of cravings and opioid withdrawal features between doses; • minimal methadone side effects. <p>Daily methadone doses above 80 mg will also markedly reduce the effects of any ongoing heroin or other opioid use. However, the potential for opioid overdose still exists.</p>
When to consider specialist advice or referral	<p>If higher or more rapid dose increases are preferred/needed or where the patient must suddenly discontinue their prescribed opioids - this can be achieved in consultation with an addiction medicine specialist, and/or in inpatient settings with closer monitoring. </p> <p>If the patient has an unclear level of opioid tolerance, engages in high-risk polydrug use, has concomitant physical conditions and/or uses other medicines that may affect the metabolism of methadone.</p> <p>Where a patient has already discontinued their opioids (e.g. disrupted supply or treatment).</p> <p>If the patient has difficulty stabilising on a dose of methadone due to continued substance use, side effects or other complications, e.g. frequently missed doses, dose diversion or other aberrant behaviours at the pharmacy or with takeaway doses.</p>
*Check pharmacy availability	

- Published equivalent opioid doses may not be reliable for guiding dose transfers onto methadone (C), as they usually relate to short-term, not chronic opioid use, describe analgesic equivalence for single doses and not 24 hour dosing periods and have usually been determined with relatively low levels of opioid use (e.g. comparing 20 or 30 mg morphine). Multiple factors impact on dose conversion and specialist advice should usually be sought (C). 
- When transferring from buprenorphine to methadone
 - wait 24 hours after the last dose of buprenorphine before commencing methadone
 - an initial methadone dose of up to 30 mg is appropriate for patients transferring from daily buprenorphine doses of ≤8 mg, and 40–60 mg is appropriate for patients transferring from buprenorphine doses of ≥12 mg/day (C)
 - subsequent dose increments should occur after regular review, with dose increases of 5–10 mg every 4 to 7 days until the patient is comfortable.

The Faculty of Pain Medicine of the Australian and New Zealand College of Anaesthetists (ANZCA) have developed a free smart phone application designed to calculate [dose equivalence](#) of opioid analgesic medicines. Both [iPhone](#) and [Android](#) versions are available.

The Centre for Palliative Care Research and Education have developed [GP Pain Help](#) app and website.

Buprenorphine

Key principles

There are four key principles when using buprenorphine for induction:

- 1 Patients choosing buprenorphine should be commenced on the combination preparation (buprenorphine-naloxone) unless pregnant or with a proven allergy to naloxone (C). This is a misuse deterrent strategy, as buprenorphine-naloxone combination is less likely to be injected than buprenorphine preparations, and it is easier to supervise the dosing of buprenorphine-naloxone films than buprenorphine tablets (★★).
- 2 As a partial agonist, buprenorphine is a safer opioid than methadone with regards to potential for over-sedation, respiratory depression and overdose. As such, dose increases can be more rapid and, in general, most patients can achieve their target dose within two to three days (★★★).
- 3 Buprenorphine has higher mu opioid receptor affinity than most other opioids (including heroin, morphine, methadone, oxycodone). As such, it can cause precipitated opioid withdrawal symptoms if given too soon after a recent dose of a full agonist (it displaces the agonist but has lower activity as a partial agonist, which can be experienced as precipitated withdrawal) (★★★).
- 4 The general principle for safe induction is that the first dose of buprenorphine should be delayed until the patient is experiencing mild to moderate opioid withdrawal. Clinicians may want to use a validated scale or scales that assess both objective signs and subjective symptoms ([Appendix B](#)).

- a. Initiating buprenorphine for patients using short-acting opioids such as heroin, morphine (other than sustained-release preparations), codeine or oxycodone is usually not associated with severe precipitated withdrawal (C).
- b. Transfer from slow-release opioid preparations (sustained-release morphine, hydromorphone) to shorter-acting preparations for several days prior to transfer to buprenorphine is recommended (C). Unlike transfer from prescribed opioids (e.g. morphine) to methadone where a gradual taper from one to the other is recommended, transfer to buprenorphine requires cessation of the prescribed opioid prior to initiation of buprenorphine to avoid precipitated withdrawal (C).
- c. [Transfer from long-acting opioids](#) such as methadone can be more difficult due to risk of precipitated withdrawal.



For further buprenorphine product information, refer to the Therapeutic Goods Administration (TGA) eBusiness Services - Product and Consumer Medicine Information:

- Subutex® <https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2009-PI-00913-3>
- Suboxone® <https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2011-PI-01894-3>

Transferring to buprenorphine from heroin or short-acting pharmaceutical opioids

When commencing buprenorphine, take account of pharmacy availability for supervision of dosing and monitoring of response. Also consider that applications for authorisation to Pharmaceutical Regulatory Unit should be received during business hours for processing, generally within two business days, and that the patient has sufficient funds to pay for pharmacy dispensing. If seven-day pharmacy services are not available, the commencement of treatment should be timed so that induction is well underway before the first day of unsupervised dosing. With buprenorphine it is possible to prescribe a double dose on the first weekend of treatment as an alternative to a takeaway dose if there is no seven-day pharmacy service (Table 10).

Table 10. Recommended outpatient regimen for transfer to buprenorphine from **heroin and/or short-acting pharmaceutical opioids**

Regimen	Recommendations and consideration
Patient supervision and review	<p>Initial doses of buprenorphine should be supervised.*</p> <p>A clinician (doctor, nurse, pharmacist, drug and alcohol clinician within scope of practice) should review the patient within the first few days of treatment, during which the dose is stabilised.</p> <p>The review provides an opportunity to assess intoxication or withdrawal symptoms, side effects, ongoing cravings, other substance use and the patient's general wellbeing.</p> <p>On an ongoing basis, do not assume that what is being prescribed is what is being taken – patients may be using more or less than what is prescribed.</p>
Starting dose of buprenorphine	<p>Defer the first dose of buprenorphine until the patient is experiencing withdrawal (anxiety, abdominal or joint pain, dilated pupils, sweating) as measured by an objective scale such as the COWS.</p> <p>Most patients should have a day 1 dose of 8 mg buprenorphine:</p> <ul style="list-style-type: none"> • for the patient with moderate or severe withdrawal (e.g. COWS score >8) at the time of the first dose, an initial dose of 8 mg is appropriate • for the patient with mild opioid withdrawal (e.g. subjective symptoms but no signs of opioid withdrawal, COWS score of 4-8) at the time of the first dose, give an initial dose of 4 mg with an additional 4mg dose after 1-2 hours split dosing reduces the risk of precipitated withdrawal). <p>Lower doses (e.g. 2 or 4 mg total on day 1) are suited to those with low or uncertain levels of opioid dependence, with high-risk polydrug misuse (alcohol, benzodiazepines), or with other severe medical complications. Seek specialist advice if concerned (C). </p> <p>Some patients may require more than 8 mg buprenorphine day 1. This requires consultation with an addiction medicine specialist.</p>
Dose increase of buprenorphine	<p>The buprenorphine dose can be increased in 2, 4 or 8 mg increments, with upper limits of 16 mg on day 2 and 24 mg on day 3.</p> <p>Slower dose increments (as used for methadone) are not required, and dose increments that are too slow are associated with higher rates of treatment dropout (★★).</p> <p>Doses should be adjusted following review of the patient – assessing side effects, features of withdrawal (suggesting not enough buprenorphine) or intoxication (suggesting too much buprenorphine or other drug use), ongoing cravings and substance use.</p>
When to consider specialist advice or referral	<p>If higher or more rapid dose increases are preferred/needed or where the patient must suddenly discontinue their prescribed opioids – consult with an addiction medicine specialist, and/or in inpatient settings with closer monitoring. </p>
*Check pharmacy availability	

Transferring to buprenorphine from methadone or sustained-release pharmaceutical opioids

Transfer from methadone or sustained-release pharmaceutical opioids to buprenorphine may be suitable for patients withdrawing from OAT or for those who have problems with methadone (e.g. poor response, side effects or drug interactions). Transferring to buprenorphine may also allow greater flexibility if using buprenorphine-naloxone alternate day or unsupervised dosing.

However, such transfers are associated with complications including:

- precipitating withdrawal on initiating buprenorphine (See Buprenorphine - Key Principle 3 above)
- destabilisation of the patient during transfer (including opioid or other substance use, or their medical, psychiatric or social condition)
- side effects from buprenorphine
- failure to transfer and stabilise on buprenorphine.

Decisions regarding transfer should be made collaboratively by patients and service providers, and involve carers as appropriate.

The decision should include an examination of the potential benefits and risks of the transfer (C).


Patients at low risk of complications can be transferred to buprenorphine in outpatient (including primary health care) settings (Table 11). Patients need frequent monitoring and buprenorphine should be dispensed in multiple doses over the first 4 to 6 hours of the transfer – if this cannot be coordinated in a primary care setting, referral to specialist services is recommended. 

Table 11. Indicators of low risk of complications

Factor	Low risk indicator
Withdrawal	The patient experiences withdrawal with their current methadone dose and methadone dose is <60 mg/day
Drug use	No non-medical opioid use or unstable use of other drugs
Comorbidity	No severe medical or psychiatric conditions that may be destabilised during transfer
Social	Stable and supportive social conditions
History	No complications during any previous transfer attempts
Communication	The patient has a good understanding of the transfer process

Where possible, put in place strategies to address risk factors for complications during transfer. This may involve gradual methadone dose reductions, stabilising other drug use, and addressing health or

social problems, and may take several weeks or months to achieve. If the risk of complications cannot be reduced to an acceptable level, specialist referral is recommended.

Patients at high risk for complications should only be transferred to buprenorphine if there is capacity for:

- frequent monitoring under medical supervision
- supportive care
- regular doses of buprenorphine and symptomatic medicine as required
- transfer to an inpatient unit in the event of severe complications, or where appropriate supportive care is not available in an outpatient setting (for example, patients with unstable medical, psychiatric or social conditions).

Experience with methadone to buprenorphine transfers has shown that the key is delaying the first dose of buprenorphine until there is clear evidence of the onset of withdrawal, as determined by a validated assessment instrument (C). Withdrawal often does not occur until more than 24 hours after the last dose of methadone. The size of the last dose of methadone is less important than the time since the last dose, as determined by withdrawal.

Treatment setting, capacity for frequent monitoring and dosing, staff training and experience, ability to access specialist addiction treatment services or inpatient beds may also have a significant bearing on transfer decisions and outcomes (Table 12).

Table 12. Recommended outpatient regimen for transfer to buprenorphine from methadone

Regimen	Recommendations and consideration
Before transfer to buprenorphine	Where possible, the patient should be reviewed in the week prior to the proposed transfer date, preferably prior to their daily methadone dose to allow the assessment of withdrawal severity. Other factors affecting the risk of complications and the patient’s understanding of the process should be assessed at the same time, and plans for the transfer should be reviewed.
On the day of proposed transfer to buprenorphine	Prior to giving any medicine, assess the patient taking into account recent substance use, withdrawal severity and general health. Patients should be monitored (withdrawal severity, vital signs) regularly over a 4- to 8-hour period and buprenorphine administered when moderate withdrawal is apparent (COWS ≥ 13 ; SOWS ≥ 16).
Starting dose of buprenorphine*	The initial dose is 2 mg. An additional dose of 6 mg is administered 1 hour after the initial dose.
Supplementary doses	Supplementary doses can be administered every 1–3 hours according to withdrawal severity: <ul style="list-style-type: none"> • 0 mg if there is no or minimal withdrawal (COWS <6; SOWS <8); • 4 mg if there is mild withdrawal (COWS 6–12; SOWS 8–15); • 8 mg if there is moderate to severe withdrawal (COWS ≥ 13; SOWS ≥ 16) The maximum dose in the first 24 hours is 32 mg.

Table 12. (continued)

Regimen	Recommendations and consideration
Patient review	<p>Patients should be reviewed daily for the next 2–5 days, or until comfortable.</p> <p>Review should include assessment of withdrawal severity, recent substance use, adverse events and general progress, as well as address any concerns the patient may have.</p>
Adjusting the dose of buprenorphine	<p>Based on the review:</p> <ul style="list-style-type: none"> patients with moderate to severe withdrawal (COWS ≥ 13; SOWS ≥ 16) are given the total dose of buprenorphine from the previous day, plus 8 mg (up to a maximum of 32 mg) patients in mild withdrawal (COWS 6–12; SOWS 8–15) are given the total dose of the previous day, plus 4 mg (up to a maximum of 32 mg) patients with no or minimal signs of withdrawal (COWS 0–5; SOWS < 8) are given the total dose of the previous day.
Additional care	<p>Many patients will feel uncomfortable for the first 2–5 days on buprenorphine, with mild opioid withdrawal symptoms, headache, dysphoria, anxiety and sleep disturbances.</p> <p>During this time:</p> <ul style="list-style-type: none"> reassure the patient that symptoms tend to subside with time ensure the buprenorphine dose is adequate consider symptomatic medicines (NSAIDs, metoclopramide, hyoscine butylbromide, low-dose sedatives) for those patients not coping with persistent symptoms (typically only for a limited time of 1–3 days). <p>A minority of patients find buprenorphine unsatisfactory and will request transfer back to methadone.</p>
When to consider specialist advice or referral	<p>Specialist consultation is recommended if precipitated withdrawal is suspected. This is indicated by a sustained and marked increase in the severity of withdrawal symptoms within the initial 3 to 6 hours of the first buprenorphine dose (e.g. COWS increased by > 6, SOWS increased by > 8).</p> <p>The general approach to precipitated withdrawal is to continue buprenorphine dosing and consider symptomatic medicine (metoclopramide, NSAIDs, hyoscine butylbromide, low dose sedatives).</p> <p>Note that onset of withdrawal, or marked increases in withdrawal symptoms more than 6 hours after buprenorphine may reflect under-dosing rather than precipitated withdrawal.</p>
<p>* Experience suggests that most patients transferring from methadone doses > 20 mg will require buprenorphine doses of at least 8 mg on day 1 (often 16–32 mg), especially if transferring from higher methadone doses. Doses may need to be adjusted according to other substance use, side effects or other medical conditions, for which specialist advice is recommended.</p>	

2.4.4 Maintenance treatment

Optimising medicine dosing regimens

Patient input to treatment decisions, including determination of dosing levels, promotes a good therapeutic relationship by enhancing patient trust and responsibility. Doses should be tailored to each patient and adjusted based on:

- medicine effects – intoxication or sedation from too high a dose; withdrawal from an inadequate dose;
- side effects – many opioid side effects subside in the first 2–4 weeks of treatment, but some are persistent and may require dose adjustment (seek specialist advice if uncertain);
- continued drug use – increasing doses of methadone or buprenorphine is often an effective response to non-medical opioid use, but has a limited role in addressing use of other drugs (e.g. alcohol, cannabis, benzodiazepines, stimulants);

- patient report of dose adequacy and treatment goals;
- concerns about poor dosing attendance or dose diversion.



Methadone

Generally, methadone dose adjustment should occur only after review with a treating clinician (Table 13).

Methadone doses of ≥ 60 mg/day are more effective than lower doses in terms of retention in treatment, reduction in non-medical opioid use and associated high-risk behaviours (★★★★).

However, doses > 150 mg/day are generally associated with little additional benefit and may be associated with dose-related adverse events.

Table 13. Safe and effective adjustment of methadone dose

Adjustment	Recommendation
When to adjust dose	Dose adjustment should generally only occur after review with treating clinician. Usually allow at least 3 to 5 days between dose increases in outpatient settings (allowing steady state equilibrium to be achieved). More rapid dose increases may occur in an inpatient setting with closer monitoring, or following specialist consultation.
Size of adjustment	Adjust doses by 5-10 mg at a time, as needed.
Dose expected to achieve stabilisation	Most patients require methadone doses in the range 60-100 mg/day to achieve stabilisation, although some patients require higher (e.g. up to 150 mg/day) or lower (e.g. 30-40 mg/day) doses to achieve their treatment goals.
When to seek specialist advice or referral	Specialist referral is recommended for patients seeking methadone doses greater than 150 mg/day (C) for an investigation of the reasons for the high-dose requirement.  Doses above 200 mg require approval from the Pharmacotherapy Credentialing Subcommittee (See Section 3.2.1). See split dosing below.
Review	It is appropriate to review treatment of patients who have been on high doses of methadone (e.g. >120 mg) for long periods of time to determine whether that dose is still necessary. Assess patient stability, discuss treatment progress and actively monitor the implications of any dose reductions in terms of re-emergence of withdrawal symptoms, cravings or non-medical opioid use (C).
Split dosing	Some patients benefit from 'split' or multiple daily doses of methadone. These patients include those who are: <ul style="list-style-type: none"> • using methadone for combined chronic pain management and opioid dependence (they typically require methadone doses every 8 to 12 hours for effective analgesia) • rapid metabolisers of methadone due to genetic variation or interaction with medicines that induce CYP enzymes (see Table 27 Key drug-drug interactions) In these cases there is some role for therapeutic monitoring of methadone plasma levels, usually in consultation with an addiction medicine specialist • pregnant women experiencing rapid metabolism and/or vomiting methadone doses regularly. Safety issues, such as diversion of doses, injection of doses, and use of other drugs, must be considered prior to authorising split dosing, and a second opinion or specialist referral is recommended. 


Buprenorphine

Buprenorphine dose adjustment is more flexible than methadone, and can be done on a daily basis (Table 14).

Daily buprenorphine doses of 12 mg or more are superior to lower doses in terms of retention in treatment, reduction in non-medical opioid use, and associated high-risk behaviours (★★★★).

The characteristics of buprenorphine allow a wide range of dosing regimens, from several times daily to once every 2-3 days. The main reasons for considering reduced frequency dosing are convenience for patients, and reduced staffing requirements for supervised dose administration.

Table 14. Safe and effective adjustment of buprenorphine dose

Adjustment	Recommendation
When to adjust dose	Buprenorphine doses can be increased on a daily basis, although clinical review is recommended for patients making marked or rapid dose changes.
Size of adjustment	Adjust doses by 2-8 mg at a time as needed.
Dose expected to achieve stabilisation	<p>Most patients require daily buprenorphine doses in the range 12-24 mg to achieve stabilisation, although some patients require higher (e.g. up to 32 mg/day) or lower (4-8 mg/day) doses to achieve their treatment goals.</p> <p>Doses >16 mg are associated with increased duration of action, with little or no increase in the degree of respiratory depression or sedation, although there is evidence of increased 'blockade' and analgesic effects with higher buprenorphine doses (16-32 mg daily).</p>
When to seek specialist advice or referral	<p>32 mg is the maximum recommended daily dose of buprenorphine; prescribing above this level is beyond the licensed limit.</p> <p>If a practitioner wants to prescribe a daily dose of more than 32 mg buprenorphine, specialist referral and a separate approval from the PCS/PRU is required. </p> <p>Daily doses >32 mg may be associated with dose-related adverse events (e.g. hepatic inflammation). Patients requiring doses > 32 mg require monitoring (clinical titration, LFTs).</p> <p>Consider referral if other complications arise, e.g. frequently missed doses, dose diversion or other aberrant behaviours at the pharmacy or with takeaway doses.</p>
Review	<p>It is appropriate to review treatment of patients who have been on high doses of buprenorphine (e.g. >32 mg) for long periods of time to determine whether that dose is still necessary.</p> <p>Assess patient stability, discuss treatment progress and actively monitor the implications of any dose reductions in terms of re-emergence of withdrawal symptoms, cravings or non-medical opioid use (C).</p>
Less frequent dosing schedules	<p>Patients interested in attending less frequently than daily for dosing should first be stabilised on daily dosing (e.g. for 2 weeks) before trying alternate-day dosing.</p> <p>Alternate-day regimens involve attending the dosing facility for dosing on alternate days (i.e. every 48 hours).</p> <p>If this is successful, the patient can then be tried on a four-times-a-week regimen. This involves attending four times a week with 3 x 48 hour doses and 1 x 24 hour dose each week (e.g. Mon, Tues, Thurs, Sat) or seven-times-a-fortnight (e.g. Mon, Wed, Fri, Sun, Tue, Thurs, Sat).</p> <p>The dose dispensed for a 48-hour period is initially double the normal daily (24 hour) buprenorphine dose (usually to a maximum of 32 mg at a time).</p> <p>Occasionally, with multiple day dosing regimens patients may require doses >32 mg to remain stable across the inter-dosing period. For example, a patient who had been stable on 24 mg as a daily dose may require >32 mg as a 48 hour dose to be prevent withdrawal/cravings over that period. In these cases, clinical monitoring is required and specialist consultation is advised. However, with multiple day dosing regimens, application to the PCS/PRU for authorisation is not required unless the equivalent daily dose is >32 mg (See Table 38).</p> <p>Some patients may tolerate three-times-a-week dosing. This should be attempted once a 2-week trial on non-daily dosing has been shown to be successful. If the 24-hour buprenorphine dose is:</p> <ul style="list-style-type: none"> • <12 mg, the 3-day dose is three times the 24-hour dose • ≥12 mg, the 3-day initial 3 day dose should be 32 mg • If a patient cannot be stabilised on such dosing regimens due to the onset of withdrawal, cravings, side effects or features of intoxication, they should be returned to a more frequent dosing regimen.

The advantage of dosing four times a week is that the patient attends regularly each week, with less likelihood of attendance errors on the patient's part and dosing errors by the administering health practitioner. It also reduces inconvenience and cost of treatment.

When moving to alternate-day dosing, dispense double the normal daily (24 hour) buprenorphine dose (initially to a maximum of 32 mg as the alternate day dose). Then review the patient following the first or second 48-hour dose. Dose adequacy can be inferred if patients report being as comfortable on the second day as on the first, sleeping as well on the second night as on the day of dosing, and no more cravings on the second day than on the first.

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

Patients on low doses of buprenorphine may find that double the dose does not last for 48 hours. Patients on reducing doses of buprenorphine may need to switch to daily dosing as the dose becomes lower (i.e. <4 mg). Some patients are not comfortable with double dose when switched to less than daily dosing.

Clinical reviews and monitoring

Clinical review

Regular clinical reviews are an essential component of safe and effective OAT. The frequency of review depends on the patient needs. At each review, the following are assessed:

- patient's clinical circumstances
 - general health and wellbeing
 - quantity and frequency of any substance use since the last review
 - social circumstances
 - relevant risk factors (e.g. child protection, harm to self or others, domestic violence, overdose, blood-borne virus risk)
 - any recent investigations (e.g. UDS results)
- current treatment conditions
 - attendance for dosing
 - adequacy of medicine dose
 - side effects

- takeaways
- frequency of reviews
- monitoring and counselling services
- treatment plan including the patient's engagement with other health and social services.

A clinical review conducted by the patient's prescribing medical or nurse practitioner should review prescriptions to ensure they are correct, current and written for the appropriate time ahead.

Comprehensive treatment plan review

A longer comprehensive treatment plan review should occur at regular intervals (at least every 6 months), and may also need to occur following a significant change in the patient's circumstances (e.g. other health or social issues), or if there are concerns that the current treatment plan is not effective in adequately addressing the patient's goals.

This involves examining longer-term goals and treatment plans addressing broader health and social issues, screening and prevention activities, and consideration of cessation of medicine.

Monitoring

As with any chronic condition requiring long-term interventions, there are benefits in systematically monitoring patient clinical outcomes over time. There are specific instruments designed to aid in the assessment of response to treatment such as the Australian Treatment Outcome Profile (ATOP). These can be administered with the patient at periodic intervals (e.g. treatment entry, at subsequent clinical or comprehensive treatment plan reviews). These instruments can be useful in providing patient feedback, clearly charting progress over time, communicating with other service providers (e.g. shared care, transfer of care), and assisting in treatment care planning.

In multidisciplinary (e.g. specialist OTP services) or in shared care arrangements, reviews may be performed by suitably skilled nursing, pharmacy or allied health professionals familiar with the patient. Such services should hold multidisciplinary team clinical review meetings or case conferences to facilitate communication across the range of service providers, particularly for patient with complex treatment needs engaged with a number of health and welfare providers.

Categorising treatment needs (case flagging)

The frequency of clinical, medical and comprehensive treatment plan reviews will vary according to a range of clinical parameters. A categorisation system based upon case flagging principles can assist in grading patient’s clinical needs for treatment and support. ([Table 15](#))

There are three [case flagging categories](#):

- 1 High treatment needs – people in this group have considerable clinical complexity and require more intensive clinical reviews, care coordination and monitoring, and access to specialist drug and alcohol professionals. Where possible, patients with high treatment needs should be managed by multidisciplinary specialist opioid treatment services, possibly in conjunction with primary care services in the community.
- 2 Moderate treatment needs – people in this group have some degree of clinical complexity but their treatment needs are being adequately addressed, and have no recent high-risk presentations. Patients with moderate treatment needs should have regular case coordination and support, monitoring and reviews. They may be managed in specialist opioid treatment services, or in shared care arrangements with primary care providers (e.g. community pharmacy, general practitioner prescriber).
- 3 Low treatment needs – people in this group have no features of high-risk or problematic substance use, and where medical, psychiatric and psychosocial conditions exist, they are stable. These patients display good treatment adherence, with regular attendance for appointments. They should generally be managed in primary care settings, but may benefit from access to specialist services as required (e.g. specialist consultation, access to counselling services).

Table 15. Case flagging in OAT

	High treatment needs	Moderate treatment needs	Low treatment needs
Adherence to treatment conditions	Frequent high-risk presentations (e.g. intoxicated, missed doses) Poor treatment engagement (e.g. missed appointments) Complex OAT transfers	No (or infrequent) high-risk presentations Generally adherent with treatment conditions (e.g. dosing, appointments)	No high-risk presentations (e.g. intoxicated presentations, missed doses) Adherent with treatment
Substance use	High-risk or harmful polydrug use (e.g. misuse of, or dependence on alcohol, benzodiazepines, other opioids, psychostimulants)	Polydrug use identified but not high-risk (i.e. no intoxicated presentations or overdoses)	No significant use of alcohol or other substances
Mental and physical health conditions and cognitive impairment	Serious mental (including significant risk of harm to self or others), physical health or cognitive impairment issues that require specialist input, intensive care coordination and regular monitoring May include patients recently discharged from hospital	Issues generally stable, or being addressed in treatment care plan May include patients recently discharged from hospital	Generally stable
Pregnant	Pregnancy with significant perinatal risk factors	Pregnant without other significant perinatal risk factors	Not pregnant
Social circumstances	Significant issues (e.g. homelessness, domestic violence, child protection) May include patients recently released from custody	Stable but still need some assistance No significant child protection or domestic violence concerns May include patients recently released from custody	No significant concerns

The case flagging system provides a framework for matching components of care (service providers, clinical review and monitoring activities) according to the complexity and needs of each individual patient (Table 16).

Table 16. Matching treatment components according to treatment needs*

	High treatment needs	Moderate treatment needs	Low treatment needs
Treatment settings	Specialist OTP clinic or in shared care arrangement with primary care Specialist clinic dosing or use community pharmacy dosing cautiously	Specialist OTP, primary care or shared care arrangement Usually community pharmacy dosing	Primary care setting, or in shared care arrangement Usually community pharmacy dosing
Minimum clinical review frequency	Every month	Every 2 months	Every 3 months
Minimum medical review frequency	Every 2 months	Every 3 months	Every 6 months
Minimum comprehensive treatment review frequency	Every 3 months	Every 6 months	Every 6 months
Urine drug screening	As clinically indicated, and linked to clinical and medical review (e.g. every 1-2 months)	As clinically indicated, and linked to clinical and medical review (e.g. every 2-3 months)	As clinically indicated, and linked to clinical and medical review (e.g. every 3-6 months)
Supervised dosing conditions	Generally no takeaway or unsupervised dosing (special circumstances apply)	Generally limited takeaway doses available (e.g. 1-2 doses per week)	Generally greater number takeaways (e.g. 2-4 per week) or unsupervised dosing (buprenorphine-naloxone only)
*This is a guide. Treatments should be tailored to circumstances of the individual patient and service providers.			

Urine drug screening

Urine drug screening (UDS) is an essential component of OAT. It is a means of objectively identifying recent substance use, depending on the type of drug used and analysis conducted. Using UDS is an important way to:

- validate patient self-reported substance use
- identify substances not reported by the patient that may assist diagnosis and management (e.g. by identifying amphetamine or cannabis use in a patient developing features of psychosis)
- assist in determining eligibility for [takeaway or unsupervised dosing](#).

However, benefits should outweigh concerns such as false positive or false negative results, cost and damage to the therapeutic relationship. For example, UDS can be confrontational for patients who do not understand their purpose. Drug testing also places a burden on the privacy of those tested.

Commercial pathology laboratories in Australia typically comply with the Australian/NZ standard for urine testing of psychoactive drugs

(AS/NZS 4308:2008), a standard for medico-legal, workplace or court-directed purposes.

Components of this testing (in accordance with this standard) include:

- a statement as to whether the specimen complies with the national standard, including whether it has been collected according to this standard (i.e. including chain of custody)
- a statement regarding the creatinine level (to assist in assessing dilution)
- a qualitative screening test, usually an immunoassay test, across the following drug classes
 - amphetamines
 - barbiturates
 - benzodiazepines
 - cannabinoids
 - cocaine
 - methadone
 - opiates ([Table 17](#))
- a report of 'Not Detected', or an indication if further testing is required

- if any classes require further testing on screening, a confirmatory test, usually gas chromatography mass spectrometry or thin layer chromatography is performed. This may report quantitative levels as well.

However, for clinical practice, not all testing is required to adhere to this standard. For example, some laboratories will not report on all drug classes for the screening test (e.g. cannabis may not be reported). Not all laboratories will conduct confirmatory tests. Current routine laboratory drug testing is likely to be able to detect some particular substances only.

Table 17. Substances detected in UDS

Substances routinely detected	Substances not routinely detected
<ul style="list-style-type: none"> • Opiates (heroin, morphine, codeine) • Amphetamines type substances (methamphetamine, pseudoephedrine) • Cannabis • Benzodiazepines (diazepam, oxazepam, temazepam) • Cocaine • Methadone 	<ul style="list-style-type: none"> • Opioids (oxycodone, hydrocodone, buprenorphine, fentanyl) • Some benzodiazepines (alprazolam, clonazepam) <p>These substances may be detected by gas chromatography mass spectrometry or thin layer chromatography, but need to be asked for specifically.</p> <p>Laboratories may charge an additional fee for testing for these substances.</p> <p>Other substances not routinely detected by most commercial laboratories:</p> <ul style="list-style-type: none"> • Synthetic cannabinoids • Other new psychoactive drugs

In general, UDS can detect use of heroin or amphetamines in the prior 3–7 days, benzodiazepines in the prior 3–14 days (UDS can remain positive for benzodiazepines for longer than 2 weeks if patients are taking high doses of long acting benzodiazepines such as diazepam) cocaine in the prior 2–3 days, and cannabis usually for 3–14 days, although UDS can remain positive for cannabis beyond this period in frequent and regular cannabis users (e.g. 4–8 weeks). Consult with a specialist pathologist if uncertain on how to interpret results. Clinicians should check with their local pathology service for information on the screening test used and reference ranges.

As with any investigations, UDS use should be based on clinical indications, and not performed routinely due to ‘program rules’. It is nevertheless possible to identify broad levels of UDS frequency according to the case flagging categorisation presented in previous section.

An intermittent schedule of random testing may be applied in some settings, but may be difficult to do in primary care settings. Directly observed urine samples are intrusive and usually unnecessary. Other mechanisms, such as temperature or testing for non-human sources or dilution, are generally sufficient to ensure the sample is genuine. However, directly observed samples may be required in some legal situations.

The Medicare Benefits Schedule Item Number 66626 covers urine drug testing for patients in a drug treatment program. A maximum of 36 tests will be funded in a 12-month period.

For further information see the Australian National Council (ANCD) position paper: drug testing at <http://www.drugsandalcohol.ie/20368/>

Non-medical use of methadone or buprenorphine

Non-medical use of prescribed medicines, including methadone and buprenorphine, can occur in several ways, either by the person the medicine was intended for, or by others.

Due to the high opioid potency of opioid agonist treatment, especially methadone, significant risks occur if the medicine is consumed by someone not on an opioid treatment program, and especially if that person has low levels of opioid tolerance. A single dose of 30 mg methadone can be fatal to adults. Much smaller doses (less than 10 mg) can be fatal to children.

Diversion is a term that can be used to describe medicine being given, sold or exchanged from a patient on a treatment program to another.

Patients may not take their medicines as prescribed. This may include a range of behaviours (e.g. poor adherence, taking the medicine not at the time that day it was prescribed, missing a dose/s) to extra-

medical or non-medical use (e.g. storing multiple doses up, then taking them concurrently to achieve intoxication, injecting methadone or buprenorphine). There are risks to injecting OAT including phlebitis, septicaemia and infective endocarditis. These are issues that should be discussed with the patient, with strategies discussed to improve adherence.

For a range of reasons patients may not disclose non-medical use or methadone or buprenorphine or diversion of the medicines. Pharmacists may at times become aware and communicate this to the prescriber.

2.4.5 Takeaways and unsupervised dosing

Generally, treatment of opioid dependence with methadone or buprenorphine is based on daily, [supervised dosing](#) at a pharmacy or clinic. Access to [takeaway](#) or [unsupervised doses](#) is available according to individual patient circumstances.

Supervised dosing provides some benefits, but many patients find the requirements of daily supervised dosing intrusive and not compatible with community re-integration through activities such as work or study ([Table 18](#)).

Table 18. Potential benefits of different dosing regimens

Supervised dosing	Takeaways and unsupervised dosing
<ul style="list-style-type: none"> Greater adherence to the medicine regimen, with less diversion to others and less non-medical use (e.g. unsanctioned dose escalations, injecting) of medicine Less risk of overdose, with less risk of dosing of intoxicated patients, following missed doses (lowered tolerance), or use of excessive doses Daily structure and routine that can be important for many patients early in treatment. 	<ul style="list-style-type: none"> Improved re-integration into normal daily activities and routines by reducing the inconvenience of regular pharmacy attendance (particularly for workers, or in regional or rural areas) Reduced cost of treatment to patients by reducing dispensing fees (for unsupervised Suboxone® treatment) and travel costs Facilitates treatment engagement by enabling patients with travel difficulties, work or other commitments to maintain regular dosing Enhanced treatment outcomes, in which positive behaviours (e.g. regular attendance for appointments or dosing, cessation of other substance use) are linked to increased access to takeaway doses, consistent with the principles of contingency management Greater patient self-autonomy in the management of their medicine and treatment, consistent with the principles of chronic disease management Reduced stigma associated with regular attendance at pharmacies, or clinics, particularly where there are concerns regarding confidentiality for the patient

However, there are also potential harms associated with unsupervised or takeaway doses of opioid medicine to the patient, to others intentionally or accidentally (e.g. children) using opioid medicine, and to the broader opioid treatment program ([Table 19](#)).

Table 19. Potential harms associated with takeaway doses

Activity	Safety concerns	Methadone	BPN	BNX
Patient using takeaway dose whilst intoxicated on other drugs	Further intoxication, sedation, overdose	+++	++	++
Patient being dosed after period of several missed doses	Intoxication or overdose (if has reduced tolerance) on recommencing	++	+	+
	Precipitated withdrawal if recommencing BPN/BNX after recent opioid agonist use (e.g. heroin)	-	++	++
Poor medicine adherence (e.g. taking higher or lower doses than prescribed)	Intoxication and overdose Increased tolerance	++	+	+
	Reduced treatment effectiveness (e.g. running out of medicine early, relapse to other substance use, destabilised other conditions)	++	++	++
+++ indicates significant harm ++ indicates moderate harm + indicates safety concerns exist				

Table 19. (continued)

Activity	Safety concerns	Methadone	BPN	BNX
Use by non-prescribed routes (injected, intranasal)	Intoxication, overdose (higher peak plasma concentration)	+++	++	+
	Vein damage, infections, blood borne viruses	++	+++	++
Intentional or accidental use of opioid medicine by person for whom not prescribed	Intoxication and overdose risk Particular concern with children and others with low opioid tolerance	+++	++	++
	Opioid related harms, including adverse drug effects, route of administration, economic, legal and psychosocial consequences	++	++	++
Regular use of opioid medicine by person for whom not prescribed	Development of dependence to medicine	++	++	++
Illegal activities associated with selling, diverting or possession of medicines not prescribed to patient	Regulatory and legal and consequences	++	++	++
Poor reputation of opioid treatment from non-medical use of unsupervised medicine	Stigma against patients and treatment services	++	++	++
	Reduces attractiveness of treatment to target population, health providers and community	++	++	++

BPN buprenorphine; BNX buprenorphine-naloxone

NSW takeaway and unsupervised dosing guidelines

Takeaway guidelines reflect the need to individually tailor dosing conditions according to the relative benefits and risks for the patient, the service and the broader community. The guidelines aim to strike a balance between patient autonomy, practitioner duty of care and public concerns about diversion of medicine.

Dosing decisions are based on phase of treatment, medicine used and risk assessment (Table 20 and Table 21). Going outside of these guidelines is a clinical decision that requires documentation.

During the induction and stabilisation period supervised dosing is recommended. This is because of frequent dose adjustments, development of tolerance to medicines, development of a treatment care plan, and changing patterns of substance use, general health and living conditions. The risk of harms from takeaway doses is higher during this period.

Treatment with buprenorphine enables a faster and safer induction and stabilisation phase than methadone, accommodating earlier access to takeaways and unsupervised dosing of buprenorphine-naloxone.

Table 20. Summary of dosing recommendations

Treatment period	Dosing recommendation
Induction and stabilisation	<p>Induction and stabilisation phase of treatment should involve a supervised dosing regimen, with routine supervision of all doses</p> <p>Exceptions may apply for special circumstances (e.g. necessary travel or usual dosing site not being open 7 days a week)</p> <p>This period usually refers to the first 3 months for methadone, and 1-3 months for buprenorphine-naloxone treatment</p>
Maintenance phase	<p>Decisions regarding the level of supervised dosing should reflect:</p> <ul style="list-style-type: none"> • indication for takeaway or unsupervised dosing • risk assessment of the potential harms • strategies that aim to minimise potential harms

During the maintenance phase, when the patient has engaged in the treatment program to stabilise their dose and address other issues (e.g. substance use, medical, psychiatric and social problems), takeaway dosing may be considered. The level of takeaway dosing will depend on risk.

Table 21. Takeaway framework for NSW OAT

Methadone		
Induction and stabilisation Usually first 3 months of treatment	Supervised dosing No takeaway doses except special circumstances	
Maintenance phase Takeaway availability based on risk assessment	High risk	Supervised dosing No takeaway doses except special circumstances
	Moderate risk	0-2 takeaways per week Consider if takeaway doses should be non-consecutive*
	Low risk	2-4 takeaways per week
Buprenorphine-naloxone (Suboxone®)		
Induction and stabilisation period Usually first 1-3 months of treatment	Supervised dosing No takeaway doses except special circumstances Consider alternate day dosing to reduce attendance requirements	
Maintenance phase Takeaway availability based on risk assessment	High risk	Supervised dosing No takeaway doses except special circumstances
	Moderate risk	0-4 takeaways
	Low risk	Unsupervised (1-4 weeks dispensed)
Buprenorphine (Subutex®)		
Induction and stabilisation period Usually first 1-3 months of treatment	Supervised dosing No takeaway doses except special circumstances Consider alternate day dosing to reduce attendance requirements	
Maintenance phase Takeaway availability based on risk assessment	High risk	Supervised dosing No takeaway doses except special circumstances
	Moderate or low risk	0-4 takeaways

*See: Risk Mitigation Strategies section below

Indications for takeaway or unsupervised dosing

Takeaway or unsupervised dosing may be indicated for reasons such as:

- need for travel
- participation in activities that enhance social and community re-integration (e.g. study, employment, care of others, sporting, religious or recreational pursuits)
- associated costs of travel or supervised dosing
- accessibility of dosing and/or transport options (e.g. pharmacies or transport may not be available 7 days a week).

Other arrangements that avoid takeaway doses should be considered before authorising takeaway doses. Alternatives to takeaway doses include

alternative dosing sites, 2- or 3-day buprenorphine dosing, or the engagement of others (e.g. carers) in overseeing and enhancing medicine adherence.

Risk assessment for takeaway or unsupervised dosing

Prescribers should conduct and document regular risk assessments regarding the suitability of takeaway or unsupervised doses. When assessing the risk of takeaway or unsupervised dosing, harms to the patient, to others and to the broader OTP need to be considered.

A risk assessment for takeaway dosing can be performed using clinical information routinely obtained as part of regular reviews by the treating team. The use of structured clinical outcome instruments (e.g. [ATOP](#)) can assist in this process.

Risk assessments require communication and exchange of relevant clinical information between service providers, particularly between OTP providers in prescribing, dosing, psychosocial support and case coordination roles, and in some cases with other health, correctional or welfare agencies as required (Table 22).

The global risk rating for takeaway dosing recognises that each individual patient may have different levels of risk for different factors. It is recommended that prescribers should tend towards conservative takeaway prescribing, and where prescribers seek to prescribe a greater number of takeaways than is suggested within these guidelines, they should seek specialist advice, and clearly document their decision making.

Risk mitigation strategies

There are multiple strategies that aim to minimise potential harms associated with takeaway and unsupervised dosing. These include:

- Clear communication
 - with the patient and relevant others (e.g. carers, family members) regarding the conditions for unsupervised doses, and their responsible storage and use of their medicine

- between service providers, particularly where there are concerns regarding the safety of unsupervised doses
- regarding the roles and responsibilities of each person (Table 23)
- Use of safer opioid preparations
 - takeaway doses of buprenorphine are generally associated with fewer safety concerns than methadone, due to the lower risks of overdose and respiratory depression, the greater flexibility of dosing (e.g. safety of 'double dosing' with buprenorphine), and the fewer concerns regarding interactions with other drugs
 - the reduced injecting risk profile of buprenorphine-naloxone compared to buprenorphine or other opioids more safely enables unsupervised doses to be dispensed on a weekly, fortnightly or four weekly basis
 - patients with a history of injecting buprenorphine tablets should consider transfer to buprenorphine-naloxone or to methadone (with greater capacity for supervised dosing) in order to access takeaway doses
 - patients with a history of methadone injecting may have their risk mitigated by dilution of takeaway doses

Table 22. Risk assessment for takeaway or unsupervised dosing regimens

Risk factor	Low risk	High risk
Stability of opioid medicine	Stable dose with good attendance for dosing	Recent induction (within 1 month for methadone, 1 week for buprenorphine)
Adherence with medicine, particularly of takeaway opioid and/or other medicines	No significant adherence problems	Frequent missed doses or interruptions to treatment Significant use of higher doses than authorised, alternate route of administration (e.g. injecting), diversion to others
Adherence with other treatment conditions	Good adherence with appointments, and UDS monitoring	Poor adherence with appointments and UDS monitoring
Use of alcohol or other drugs	No significant use alcohol or other drugs	Frequent and heavy use of alcohol, illicit or pharmaceutical drugs, particularly sedatives
Other health or social conditions that impact upon medicine adherence and/or safety of takeaway doses	No significant medical, psychiatric, cognitive or social conditions that impair medicine adherence or safety of takeaway doses	Medical (e.g. respiratory or liver failure), psychiatric conditions (e.g. suicidal, severe anxiety or depression, psychosis), impaired cognition (e.g. impaired memory), homelessness, child safety concerns
After considering each of these factors, the overall risk rating for takeaway dosing is identified as one of three levels: <ol style="list-style-type: none"> 1. high risk - presence of one or more significant risk factors, 2. moderate risk - presence of some risk factors, but no significant high-risk factors 3. low risk - no significant risk factors identified 		

- Limiting the number of consecutive takeaway doses
 - Multiple consecutive doses of methadone, especially higher doses of methadone (e.g. >80 mg methadone daily) carry significant risks if used non-medically by a patient or if diverted to others, not on opioid agonist treatment. Limiting the number of consecutive takeaway doses provided in any week may be an appropriate way to reduce risk of poor adherence or non-medical use.
- Regular clinical reviews
 - patients receiving takeaways or unsupervised doses should have a formal clinical review at least every 3 months by a member of the multidisciplinary team (e.g. prescriber, nurse, allied health), and more frequently for patients with more complex treatment needs
 - patients in receipt of (or being assessed for) takeaway or unsupervised doses should also have regular UDS as part of the risk assessment process
 - structured reviews using instruments such as the ATOP enable clear documentation of key risk factors (e.g. recent substance use, injecting practice, social and health status)
 - if patients regularly miss scheduled appointments, the reason for missing appointments should be explored (may include problems with transport, child care, work). Patients at high risk (e.g. sedative use, risk of non-medical use of OAT) should have their dosing conditions reviewed. Also check on patient progress at community pharmacy dosing point, e.g. dosing debts, requests for additional takeaway doses directly to pharmacists only, shoplifting, aggression.
- Addressing use of medicines other than as prescribed
 - clinicians have a responsibility to address medicine not taken as prescribed, such as missed doses, running out early, using additional doses than prescribed, lost or misplaced medicines, diversion to others, unauthorised routes (e.g. injecting) or intoxicated presentations
 - due to the high opioid potency of methadone, overdose risks exist if a patient consumes multiple doses on the same day, or if the medicine is consumed by others not highly tolerant to opioids. Generally, 'lost' medicine should not be replaced. The patient should be informed that lost medicine will not be replaced prior to receiving takeaway doses. However the prescriber may, when clinically appropriate, decide if situations occur where replacement of lost doses is warranted. These may be supervised doses, additional monitoring of the patient may also be indicated.
 - aberrant behaviours or incidents require a review of the patient's dosing conditions, and are generally markers of the need for greater levels of supervised dosing and monitoring
- Clear documentation in medical records regarding the indications, risks and strategies put in place to mitigate identified risks.

Table 23. Roles and responsibilities regarding unsupervised doses

Prescriber responsibilities	Patient responsibilities	Pharmacists and other dosing staff responsibilities
<ul style="list-style-type: none"> • Authorising takeaway doses and clearly documenting dosing instructions on the prescription and communicating with dosing sites. • Regularly reviewing dosing conditions for each patient, involving regular assessment and documentation of the indications, risks and risk mitigation strategies. Specific attention should include a focus on safety and driving, and impacts of other psychoactive drug use. • Communicating takeaway guidelines and conditions to patients, enabling patients a clear understanding of decision-making processes regarding access to takeaway or unsupervised doses. • Regularly communicating with the patient regarding safe use and storage of unsupervised doses medicine. 	<ul style="list-style-type: none"> • Using medicine as prescribed and according to the instructions on dispensed medicine. • Safe storage of medicine, and ensuring that medicine is kept out of reach of children • Notifying treatment providers of any issues or concerns regarding medicine (including lost or misplaced doses, consumption by others, or use of the medicine not as prescribed). • Seeking emergency medical assistance in the event that medicine is consumed by others, particularly children or adults with low opioid tolerance, due to the risk of overdose and death. 	<ul style="list-style-type: none"> • Ensuring supervised and unsupervised doses are administered and dispensed as per prescription, unless there are safety concerns (such as providing unsupervised doses to intoxicated patients, or where patients have been routinely missing doses), in which case they should communicate with the prescriber. If a patient is intoxicated, the dosing staff are to advise the patient of the risks related to safety and driving. • Keeping accurate records regarding dispensed medicines. • Regularly communicating with the prescriber or other members of the MDT regarding factors that impact upon the safety of unsupervised doses, including intoxicated presentations, missed doses, attempts at not consuming supervised doses, or evidence of diversion to others. • Regularly communicating with the patient regarding safe use and storage of unsupervised doses medicine.

2.4.6 Psychosocial support in OAT

Psychosocial support should be tailored to the individual and identified in the broader treatment care plan for the patient (C). Psychosocial interventions are delivered as one-on-one and group sessions.

People who are opioid dependent often have complex issues. The first aim of treatment is stabilisation, which often requires early implementation of a range of psychosocial interventions (e.g. housing, welfare support, financial management, legal, overdose prevention, needle syringe programs).

There is also a range of counselling interventions that can play an important role in helping patients address substance use and related behaviours. These interventions include behavioural relapse prevention, cognitive behavioural therapy (CBT) and contingency management. These are described in NSW [Drug and Alcohol Psychosocial Interventions Professional Practice Guidelines](#), and can be delivered by suitably trained medical, nursing and allied health professionals. It is best to delay such counselling interventions until the patient's immediate needs have been addressed.

Similarly, there are a range of effective counselling and behavioural interventions that can address a range of other health and lifestyle concerns. These may target issues such as depression, anxiety, sleep disorders, post-traumatic stress, parenting, employment, finances. An OAT provider should be aware of such approaches and be able to make necessary referrals.

Some patients may benefit from more structured psychosocial services and supports. Increasingly, residential rehabilitation programs and outpatient day programs are becoming available in NSW to support OAT patients.

Participation in self-help groups (e.g. [SMART Recovery](#)) should be recommended to patients, but attendance should not be mandatory (C). The effectiveness of self-help groups is related to participation, not just attendance, and mandatory attendance can be counterproductive.

Psychosocial services should be made available to all patients although those who do not take up the offer should not be denied effective pharmacological treatment supported by regular clinical reviews and coordinated care.

2.4.7 Responding to continued substance use

For many different reasons, some patients continue to use alcohol or other drugs whilst in treatment. Although some patients may be able to do this with minimal impairment to their health and wellbeing, others find even low levels of drug use can be sufficient to cause significant medical, psychiatric or social harms. Addressing patterns of substance use that are related to poor outcomes and harms is an important aspect of safe and effective opioid treatment.

Some patients may inject buprenorphine or methadone in an attempt to stop injecting other opioids (e.g. heroin, non-prescribed fentanyl). In this situation patients should be supported to move away from injecting these medicines. (See section below Table 17: *Non-medical use of methadone or buprenorphine*)

It is important to establish a therapeutic relationship that encourages open disclosure by patients without fear of recriminations. As with the management of any chronic condition, a partnership approach to addressing substance use should be fostered. This requires that service providers recognise the validity of self-autonomy in patient decision-making, but also for the patient to recognise the responsibilities of the service provider to ensure the safety of treatment and their role to encourage improvements in the patient's clinical condition.

Substance use may be disclosed by patients and should be systematically addressed in clinical reviews. Structured instruments such as the [ATOP](#) can assist this process. UDS and breath alcohol monitoring can also identify undisclosed substance use.

Continued high-risk drug use may also be evidenced by:

- frequent presentations when intoxicated
- evidence of regular drug use on examination (e.g. breath alcohol, recent injecting sites)
- overdoses or other chaotic drug using behaviour
- deteriorating medical, mental or social wellbeing related to drug use.

Continued drug use can place the patient at risk of deteriorating health and social (e.g. relationship, employment, crime, financial) problems. Patients with regular and high-risk substance use may be more appropriately managed by a specialist service or multidisciplinary team (e.g. shared care arrangement) due to the increased safety concerns

and clinical review requirements, which may be difficult to coordinate in primary care settings.

Attempts should be made to stabilise such patients. A clinical review is required of the patient's goals regarding their substance use, precipitants to continued drug use, participation in psychosocial interventions and supports, and frequency of [clinical reviews and monitoring](#) (including UDS).

Medicine regimens should also be reviewed. This involves:

- ensuring an adequate dose of medicine is prescribed
 - increases in methadone or buprenorphine doses are beneficial in addressing additional opioid use, but less effective in addressing additional alcohol, benzodiazepine or stimulant use
 - patients on low methadone (<60 mg) or low buprenorphine (<12 mg) should be encouraged to increase their dose
 - there are fewer benefits however in dose increases in patients already on high doses (e.g. >150 mg methadone; >32 mg buprenorphine)
- ensuring the patient is taking the medicine as prescribed
 - [review takeaway or unsupervised dosing conditions](#)
 - patients with high-risk patterns of substance use may require a period of supervised dosing and restricting takeaway or unsupervised doses.

Consider change in medicines. Transfer [from buprenorphine to methadone](#) may be indicated if there is little or no response to high-dose buprenorphine treatment, and/or the patient is persistently diverting or misusing their buprenorphine medicine. Similarly, [methadone to buprenorphine transfer](#) may be indicated for patients with persistent concerns regarding the safety of methadone in combination with other sedatives (alcohol, benzodiazepines). Specialist consultation should be sought for advice as required.

If the patient's safety is not at risk from ongoing drug use in combination with their OAT, it will generally be in the patient's interest to persist with treatment. If the risks of combining methadone or buprenorphine with other drug use outweigh the benefits of opioid agonist treatment to the patient, arranging the patient's gradual withdrawal from methadone or buprenorphine may be indicated. Consult with specialist services when making such decisions.

Alcohol use disorders in OAT populations

Particular safety concerns arise in people with alcohol-use disorders, due to the increased risks of overdose, impaired memory and cognitive performance, and altered pharmacokinetics (e.g. liver disease). These concerns may apply more with methadone than buprenorphine, due to greater risk of sedation and overdose in combination, and concerns regarding altered hepatic metabolism of methadone.

Specific strategies should be considered in alcohol dependent patients, including:

- treatment interventions for alcohol dependence (withdrawal, counselling pharmacotherapies with acamprosate or disulfiram)
- increased monitoring by dosing staff (including consideration of the need for regular breath alcohol readings)
- increased frequency of clinical reviews and UDS
- restriction of takeaway or unsupervised dosing
- methadone or buprenorphine dose increases alone are often not effective in addressing alcohol use, and may indeed increase risks of over-sedation
- where there are persistent safety concerns in alcohol dependent methadone patients, transfer to buprenorphine may be indicated.

Benzodiazepine use disorders in OAT populations

Particular safety concerns arise in patients using benzodiazepines in high doses or erratically, due to the increased risk of overdose, impaired memory and impaired cognition. These concerns may apply more with methadone than buprenorphine (lower risk of sedation and overdose in combination, uncertain hepatic metabolism of methadone in severe liver disease).

The management of benzodiazepine use disorders in OAT patients is complex. Whilst it is estimated that approximately 30–60% of OAT patients have used benzodiazepines in the preceding year, only a minority (estimated at 10–20%) are high dose or erratic dependent users. These individuals may also experience complications from their benzodiazepine use such as increased anxiety, sleep disorders, intoxicated presentations for dosing, seizures, delirium, overdoses and hospital admissions.

It may take several consultations to comprehensively assess a patient's benzodiazepine use and how it affects OAT. (Table 24)

Table 24. Assessment of patients taking benzodiazepines

Aspect	Details
Pattern of benzodiazepine use	<p>This involves asking about:</p> <ul style="list-style-type: none"> • frequency and amount of use • how benzodiazepine use alters in relation to other substance use (e.g. opioid or alcohol withdrawal, missed OAT doses) • source of benzodiazepines (e.g. prescriber, 'grey' or 'black' markets) • extent of benzodiazepine dependence, including withdrawal phenomena such as seizures, perceptual changes, anxiety or sleep problems.
Adverse events or harms linked to benzodiazepine use	<p>Including:</p> <ul style="list-style-type: none"> • overdoses • high-risk behaviours whilst intoxicated (e.g. arguments, crime, injecting risk practices, falls, motor vehicle accidents) • memory and cognitive impairments • 'emotional blunting'.
Concurrent medical and mental health conditions	<p>Including:</p> <ul style="list-style-type: none"> • anxiety and depression • neurological conditions (e.g. epilepsy) • sleep disorders.
Review of OAT treatment conditions	<p>Including:</p> <ul style="list-style-type: none"> • frequency and attendance at appointments • UDS • missed doses or intoxicated presentations • level of dosing supervision • adequacy of the methadone or buprenorphine doses • participation in health and psychosocial services addressing comorbidities.
Collateral history	<p>From:</p> <ul style="list-style-type: none"> • other health providers • Medicare Australia's Prescription Shopping Information Service • Medicare and PBS claims information third party release • Check with PRU for authority if patient informs they are prescribed alprazolam or flunitrazepam. • Up-scheduling of alprazolam from Schedule 4 to Schedule 8 - Pharmaceutical Services.
Urine drug screening (UDS)	<p>UDS can assist in identifying patterns and types of benzodiazepine use, although caution is required when interpreting test results.</p> <p>Some benzodiazepines have active metabolites (e.g. diazepam may be excreted in the urine as nordiazepam, oxazepam and temazepam), making interpretation difficult.</p> <p>Contact local pathology service where queries are raised.</p>

For more information see **Prescribing drugs of dependence in general practice Part B**
<http://www.racgp.org.au/your-practice/guidelines/drugs-of-dependence-b/>

Is there a therapeutic role for benzodiazepines in OAT patients?

As with all medicines, potential therapeutic benefits must be balanced against potential adverse consequences, with recognition that risks are increased in particular subgroups. Particular caution should be shown in patients with:

- current or previous benzodiazepine-related problems
- concomitant conditions that increase the vulnerability to benzodiazepine-opioid interactions (e.g. cognitive or memory impairment, respiratory depression, use of other sedatives, and those with reduced hepatic clearance of benzodiazepines, such as in those with cirrhosis and the elderly).

Benzodiazepines are primarily used for short-term management of sleep disorders and anxiety disorders. These conditions are often chronic for many OAT patients hence they are unlikely to respond to short-term benzodiazepine treatment. As such benzodiazepines should generally be avoided in OAT patients, with greater emphasis upon alternative non-pharmacological (e.g. relaxation training and sleep hygiene strategies, CBT for anxiety disorders) or pharmacological approaches for anxiety disorders (e.g. selective serotonin reuptake inhibitors). Specialist assessment and treatment may be indicated for those individuals experiencing severe anxiety or sleep disorders.

A common request by patients is for benzodiazepines to assist in agitation and sleep problems associated with withdrawal from methadone or buprenorphine maintenance treatment. As OAT withdrawal symptoms tend to last weeks to months, the development of benzodiazepine dependence is a genuine concern if they are used for such prolonged

periods. Additional risks include overdose, in combination with benzodiazepines, in those who relapse to heroin use following OAT cessation.

Nevertheless, there are OAT patients without histories of problematic benzodiazepine use who may benefit from short courses (e.g. up to 2-4 weeks) of benzodiazepines, as an adjunct to psychosocial treatment approaches.

Managing benzodiazepine misuse in OAT populations

Here, benzodiazepine misuse describes high-dose and/or binge patterns of use that are associated with adverse events or harms (e.g. overdoses, intoxicated presentations), but not meeting criteria for significant benzodiazepine dependence.

There is a limited role for prescribing benzodiazepines in OAT patients with benzodiazepine misuse. Efforts should be directed to addressing concurrent psychiatric, medical and social conditions, and minimising the potential for harms arising from benzodiazepine-opioid interactions.

Generally, OAT treatment should not be discontinued for persistent benzodiazepine misuse. Instead, risk management strategies should be put in place (Table 25). A contingency management framework can be incorporated into treatment conditions.² For example, treatment conditions (e.g. takeaways, frequency of reviews) can be linked to benzodiazepine use (e.g. UDS results) and evidence of associated harms (e.g. intoxicated presentations).⁵ The degree of monitoring and multidisciplinary input required for such patients may be difficult to apply in primary care settings, and often such patients may benefit from specialist multidisciplinary services.

Table 25. Strategies for managing benzodiazepine misuse in OAT patients

Strategy	Action
Patient education regarding the potential adverse consequences of benzodiazepine use	This should target potential 'immediate' effects of benzodiazepine co-intoxication (e.g. impairment of memory, cognition and judgement, and how this can in turn lead to high risk behaviours and harms such as needle sharing, unsafe sex, violence, crime and driving offences), as well as longer-term disturbances in sleep and mood. Also, risk of seizure with sudden supply disruption for benzodiazepine-dependent patients.
<u>Regular monitoring and review</u>	
Dosing schedule	Ensure supervised dispensing of OAT and limit access to takeaway doses.
Dosage	Ensure an adequate OAT dose to prevent opioid withdrawal symptoms Consider reducing high methadone doses (e.g. >150 mg) as a means of reducing overdose risk in patients with frequent intoxicated presentations.
Medicine choice	Assess OAT medicine – buprenorphine in combination with benzodiazepines may carry less risk of respiratory depression than full opioid agonists ^{6,7} and buprenorphine may be a safer OAT agent than methadone in patients with a history of benzodiazepine-related overdose.

Management of benzodiazepine dependence in OAT populations

Different providers take different approaches managing benzodiazepine dependence in OAT populations – optimal management is unclear at present. Options include:

- not directly addressing benzodiazepine dependence as part of OAT treatment
- attempting long-term benzodiazepine ‘maintenance’ treatment
- attempting a gradual withdrawal or reduction regimen.

The concerns regarding maintenance benzodiazepine treatment include persistent additional benzodiazepine use (and related intoxication harms) and aberrant behaviours where medicines are not supervised (e.g. injecting, diversion to others). Additional concerns regarding long-term benzodiazepine dependence include long-term impairment of cognition, memory and psychomotor function (impacting upon activities such as employment, driving and parenting), mood effects (e.g. depression, emotional ‘blunting’) and tolerance resulting in deterioration of anxiety and sleep quality.

The concerns regarding graduated withdrawal include relapse to illicit or opportunistic benzodiazepine misuse or dependence. This may be more erratic than prescribed doses and associated with more drug-related harms.

The evidence at this stage is inadequate to recommend either strategy. However, given that a proportion of benzodiazepine-dependent patients (albeit a minority of one third or less) will successfully complete a gradual reduction, and there are no clear predictors of which patients will be successful, a trial of gradual benzodiazepine reduction regime is warranted. This is subject to certain conditions aimed at enhancing safety and success rates ([Table 26](#)).

The role of long-term ‘maintenance’ treatment with benzodiazepines for the management of benzodiazepine dependence remains unclear, due to concerns regarding chronic impairment of cognitive, memory, performance and mood. This is particularly the case in OAT patients, who may have a range of concurrent medical or psychiatric conditions that exacerbate these problems. A second opinion from a specialist is periodically warranted.

Table 26. Strategies for managing benzodiazepine dependence in OAT patients

Strategy	Action
Coordinate treatment providers	Ensure clarity as to which medical or nurse practitioner is prescribing. Patients not prepared to reveal the clinician from which they obtain benzodiazepine prescriptions are not good candidates, indicating ambivalence or poor motivation to change.
Address comorbidities	Including depression, mood and sleep problems through evidence based psychosocial (e.g. cognitive-behavioural) and pharmacological approaches. Treatment of benzodiazepine withdrawal should be seen as more than a prescription.
Stabilise on a long-acting benzodiazepine	Diazepam has been widely used for this purpose, although clonazepam and clobazam are less widely reported as benzodiazepines of misuse, and enable easier monitoring of additional benzodiazepine use by urinalysis. Dose conversions between benzodiazepines are unreliable, and it is important to differentiate the amount of benzodiazepines a patient may report to achieve intoxication, compared to the amount required to avert severe withdrawal. Doses of more than 40 mg diazepam daily are rarely required for the latter indication. Inpatient admission may be required to stabilise patients reporting very high or erratic benzodiazepine use.
Attempt gradual reductions	An 8-16-week reduction regime can be initially negotiated (up to 5 mg diazepam equivalent dose reduction every 1-2 weeks), with recognition that some patients require periods of stabilisation along the way. Reductions regimens may extend to more than 6 months, although this requires a review of treatment conditions and ancillary interventions. Such long-term prescribing should include periodic assessment of functional outcomes, such as cognition, memory, affect (depression, anxiety) and sleep.

Strategy	Action
Limit access to benzodiazepine medicines	Consider daily (or at least frequent) dispensing, along with OAT medicines. Patients should understand that prescriptions will not be provided to accommodate unauthorised dose escalations. Medicines are the patient's responsibility once dispensed, and lost tablets are not replaced.
Identify and address aberrant drug behaviours in the treatment plan	Clear understanding between patient and all clinicians that persistent severe aberrant drug behaviours may result in discontinuation of the treatment plan and cessation of benzodiazepine prescribing. Aberrant drug behaviours include use of additional benzodiazepines, intoxicated presentations, missed OAT doses, persistent use of other drugs that will precipitate benzodiazepine use (e.g. stimulants) or increase safety concerns (e.g. alcohol or heroin). Discuss the response to aberrant drug behaviours and document this discussion in the treatment plan.
Undertake regular patient monitoring	Including clinical reviews, communication with dispensing staff, and UDS, ideally with laboratory techniques (e.g. gas chromatography mass spectrometry) to differentiate benzodiazepine type. Prescription monitoring systems should be used where available.
Use contingency management principles regarding treatment conditions	For example, takeaway doses of OAT medicine and frequency of dispensing benzodiazepines may be linked to patients reducing their benzodiazepine dose and adhering to the treatment plan. Discuss the method of assessing the patient's suitability for takeaway dosing, and document this discussion in the treatment plan.
Document treatment decisions	There is minimal evidence supporting long-term benzodiazepine prescribing in this population, and given the high risk of adverse events, clinicians must be able to defend their decisions and prescribing practices in the event of severe harms such as overdose and death.

Cannabis use in OAT populations

Cannabis use by patients in OAT is common. When surveyed, around 40–50% of patients in NSW OTPs say they have used cannabis in the past month. Some patients report using cannabis to assist with comorbid conditions (e.g. pain management, sleep disorders), or as a means of assisting opioid dose reduction.

Although most patients do not identify any significant harms associated with their cannabis use, it can be associated with significant medical (e.g. respiratory problems), psychiatric (e.g. anxiety, psychosis, paranoia, memory impairment) or social (e.g. financial, legal) consequences. Often cannabis is mixed with tobacco. As a result, there is the increase risk of tobacco-related harm and a need to assist with nicotine dependence.

Clinicians should regularly assess their patient's use of other substances (structured approaches such as the ATOP is encouraged), and identify any harms that the patient may be experiencing from their substance use. Motivational counselling approaches may be used to encourage ambivalent patients to address cannabis use where harms are identified.

Cessation of cannabis use in dependent users can be associated with a clinically significant withdrawal syndrome (estimated to occur in about half of daily users and typically presents as sleep disturbance, cravings, agitation and low mood). However, symptoms are usually of short duration (1-2 weeks). There are currently no effective medicines specifically for cannabis withdrawal, although symptomatic management may have a role. Counselling (using CBT-based approaches) can be effective for some patients to address their cannabis use, and patients should be referred accordingly.

Clinical guidance and training resources

regarding the management of cannabis use disorders are available from <https://ncpic.org.au/>

Stimulant use in OTP populations

It is not uncommon for patients on methadone or buprenorphine in NSW to report using stimulants, particularly methamphetamine with estimates of 10-40% reporting recent use. Cocaine use is also reported, but far less commonly.

Methamphetamine use may be sporadic, infrequent or regular (including dependent use). As frequency of methamphetamine use increases so does the risk of health and social problems.

The most common problems seen with methamphetamine use are mental health problems, including a spectrum of problems such as anxiety, agitation, misperception, delusions, paranoia, magical thinking, hallucinations and psychosis. Depression is also common in regular users.

Methamphetamine, or other stimulant use, is not associated with increased risk of sedative overdose (contrasted with alcohol use or benzodiazepine use). However, regular or intensive users may be more exposed to at risk practices (e.g. risky injecting).

Common physical health problems include loss of weight, insomnia. Regular or intensive users may be at higher risk of blood borne virus or sexual health risks. Endocarditis can occur in injecting drug users. Other health problems can occur including cardiac (arrhythmias, ischaemia), CNS (haemorrhages, stroke) and hyperthermia.

Regular or intensive methamphetamine use is associated with behavioural problems in clinical settings, such as aggressive behaviour in patients attending for treatment. Strategies should be in place to clinically assess for methamphetamine use and prevent and manage behavioural incidents. (See [2.1 Assessment](#), and the [National Amphetamine Guidelines](#))

Some patients who use methamphetamines also use sedatives (e.g. cannabis, benzodiazepines, alcohol) to negate feeling over-stimulated or to reduce anxiety or insomnia. Screening for problematic use of sedatives in this population may be indicated.

Counselling is advised for patients experiencing problematic amphetamine use, including approaches using CBT and motivational interviewing. Patients who are dependent may require assistance with withdrawal.

Regular and dependent users experiencing mental health problems may require co-management with mental health services.

Smoking cessation

The prevalence of smoking is higher amongst the population of opioid users than in the general population and many patients find it particularly difficult to overcome. People in OAT are at heightened long-term health risks from smoking.

There is evidence that smoking cessation can enhance reductions in other substances in the short-term, rather than compromise the outcome of drug and alcohol treatments. Interventions for smoking cessation in the general population are also appropriate for OTP populations. However, people who are opioid dependent people may need more intensive treatment.

For dependent smokers, pharmacotherapy is proven to double the chances of successfully quitting. Pharmacotherapy options include nicotine replacement therapy (NRT) and anti-craving medicine (e.g. varenicline and bupropion). These can be prescribed for patients on methadone or buprenorphine for limited courses (12 weeks supply) and are subsidised by the Pharmaceutical Benefits Scheme.

Combining two forms of NRT (patches plus oral form such as gum or lozenge) has been shown to be more efficacious than a single form and is recommended practice. There is also evidence to support use of nicotine patch prior to smoking cessation, in preparation for a quit attempt. The TGA approved approach involves using either a 21 mg/24-hour patch or a 25 mg/16-hour patch for 2 weeks before quitting, then continuing to use the patch in the usual way for the quit attempt and adding oral NRT if needed. For further information, see <http://www.health.nsw.gov.au/tobacco/publications/managing-nicotine-dependence.pdf>

2.4.8 OAT Safety issues

Side effects

The [side effects](#) of methadone and buprenorphine are largely typical of opioid drugs. Those most troublesome to patients are excess sweating, dental caries, constipation, sleep apnoea, osteoporosis and reduction in sex hormones. It is important that patients are aware of these effects and their management.

Overdose

The risk of overdose is greatest with methadone, but the risk with buprenorphine is not insignificant. Methadone induction is associated with increased risk of overdose until achievement of a stable dose that reduces craving and the effect of any additional opioid use.

Use of CNS depressants (e.g. antidepressants, antipsychotics, benzodiazepines, alcohol) with methadone or buprenorphine is a significant risk factor in many overdose events. In the event of persistent high-dose benzodiazepine misuse, consider transferring the patient to buprenorphine to reduce the risk of overdose (C). Patients and their families should be given information on the signs of overdose and encouragement to seek medical assistance (C).

Driving a motor vehicle or operating heavy machinery

Driving or operating heavy machinery after dosing with methadone or buprenorphine is not associated with increased risk of accident or injury provided the patient is on a stable dose of the medication and is not using significant amounts of other psychoactive drugs (particularly alcohol, benzodiazepines or cannabis).

Assessing and managing short-term fitness to drive

Patients should not drive motor vehicles or operate heavy machinery until their commencing opioid agonist dose is stable and a steady state serum drug level has been achieved, and for several days following any subsequent significant dose increase.

Most patients initiating treatment with sublingual buprenorphine should be advised to not drive during the first two weeks of treatment. Patients should also be advised to be cautious in the 3 to 5 days after any dose change, or if attempting 'two or three day' dosing.

For patients initiating methadone treatment, patients should be advised to not drive in the first four weeks of treatment. Patients should also be advised to be cautious in the 3 to 5 days after any significant dose change (greater than 5mg).

All health professionals have a responsibility to advise patients of the effect methadone and buprenorphine may have on driving safety, and to advise patients to arrange alternate transport until a stable treatment dose and steady state are achieved.

If at any time a patient attends for treatment and is intoxicated, health professionals should address safety concerns (see Section 2.4.9 Intoxicated presentations) and advise the patient to not drive a motor vehicle. This should be documented in the patient's medical records. If a patient does intend to drive when intoxicated, then police may be contacted.

Assessing long-term medical fitness to drive

The law requires drivers to report to Roads and Maritime Services any permanent or long-term illness that is likely to affect their ability to drive safely.

All health professionals involved in a patient's treatment have a responsibility to assess and advise patients of their risk of impaired driving in accordance with the national Assessing Fitness to Drive - for commercial and private vehicle drivers standards.

The risk of impaired driving is likely to increase if:

- the patient is using alcohol or other prescribed or illicit drugs, particularly psychoactive medications such as benzodiazepines, antidepressants, pregabalin, or antipsychotics; or illicit drugs such as cannabis or amphetamines;
- the patient has other medical conditions that may impair driving, such as cognitive impairment, sleep disorders resulting in fatigue, severe pain, or seizures.

Prescribers should consider all relevant clinical information, bearing in mind the compounding effect each condition, medication or substance may have on the overall capacity of the patient to control a vehicle, to act in an appropriate and timely way for the road and traffic conditions, and to safely operate machinery.

Assessment in line with the Assessing Fitness to Drive standards should be completed at key points during opioid treatment.

At each driving safety assessment, prescribers should document their assessment and discussions with the patient, the reasons for their medical decision-making and any actions taken, including advice provided to the patient.

Key points where a driving safety assessment is warranted include:

- when commencing patients on treatment;
- when treatment doses are substantially increased; or
- whenever a health professional becomes aware that a patient may be at substantial risk of impaired driving (for example, where the patient is continuing to use other sedatives, or is not engaged consistently in treatment).

Patients rely on health professionals to advise them if a permanent or long-term injury or illness may affect their ability to drive safely. Prescribers should advise patients of their responsibility to report to Roads and Maritime Services if their long-term or permanent injury or illness may affect their ability to drive safely.

Health professionals also have an obligation to public safety, so if a health professional believes that a patient is not following advice to cease driving, the health professional may report directly to Roads and Maritime Services.

Roads and Maritime Services have the responsibility to make all decisions regarding the licensing of drivers.

If a patient does not meet the medical standards for an unconditional licence, they may meet the criteria for a conditional licence as outlined in Assessing Fitness to Drive.

See <http://www.austroads.com.au/drivers-vehicles/assessing-fitness-to-drive/for-health-professionals> and <http://www.rms.nsw.gov.au/roads/licence/health/fit-to-drive.html>


Medical conditions

Hepatic function

Conditions that affect hepatic function such as liver failure, alcohol dependence and acute hepatitis may require dose adjustment, transfer to buprenorphine, or in rare cases, cessation of medicine. Specialist consultation should be sought.

Respiratory conditions

Mild asthma and emphysema are not contraindications to opioid agonist treatment and changing the dose of substitute medicine is generally not necessary, but it is appropriate to review other factors that might contribute to respiratory distress (C).

Patients with severe impairment of respiratory function may require dose reductions, particularly with methadone. Patients may need to be transferred from methadone to buprenorphine if respiratory depression is a problem. If concerned, seek specialist advice or referral. 

Drug-drug interactions

A number of drug-drug interactions can affect the safety and effectiveness of methadone and buprenorphine treatments (Table 27). Medicines that are known to cause, or may potentially cause, clinically significant interactions when used in combination with methadone or buprenorphine should be avoided if possible (Appendix E & F). Where these drugs are necessary, patients should be monitored and medicine regimes adjusted as necessary. Consult with an addiction medicine specialist where there are concerns regarding safety or effectiveness of treatment.

Detailed information on the nature, biological basis and evidence of the clinical significance of interactions between buprenorphine, methadone and prescription medicines can be obtained from [Opioid Drug Interactions](#).

QT prolongation

The QT interval is the measure of time between the onset of ventricular depolarisation and completion of ventricular repolarisation. A delay in ventricular repolarisation (identified as a prolonged QT interval) can provoke arrhythmias, such as ventricular fibrillation and Torsade de Pointes (TdP), and is associated with sudden cardiac death. The QT interval varies depending on heart rate, age and gender and has a normal diurnal variation. (Table 28) To correct for heart rate variation, formulae (e.g. Bazett's correction), or a QT nomogram can be used. Heart rate corrected QT, or QTc, are generally used in peer reviewed literature.

Risk assessment of drug induced QT prolongation information available from www.nps.org.au/australian-prescriber/articles/risk-assessment-of-drug-induced-qt-prolongation

Prolongation of the QTc interval is a potential issue with methadone, but occurs less commonly with buprenorphine. Methadone and certain other synthetic opioids (e.g. levo- α -acetylmethadol) appear to prolong QTc interval, more than morphine or buprenorphine.^{8,9} Studies of clinical OTP populations suggest that 2-15% of methadone patients have significant QTc prolongation. QTc abnormalities are more usually seen following marked increases in plasma methadone levels, such as dose increases or with other drug interactions (e.g. [hepatic CYP inhibitors](#) increasing methadone plasma levels).

A number of other factors usually contribute to QTc prolongation in methadone patients, including:

- congenital long QT syndromes (family history)
- cardiac abnormalities (infective endocarditis, valvular lesions, cardiomyopathy, ischaemia)
- other [drug interactions](#), including medicines (atypical antipsychotics, TCAs, HIV medicines) and non-medical substance use (alcohol, caffeine, amphetamines, cocaine and other stimulants, tobacco)
- electrolyte or metabolic disturbances (including systemic infections, hypokalaemia, e.g. with vomiting and diarrhoea of alcohol or opioid withdrawal).

As with any medicine associated with prolonged QTc, the potential benefits of the use of the medicine must be balanced against the potential risks.

Table 27. Key drug-drug interactions

Drug	Effects in combination with methadone or buprenorphine
Other sedatives (opioids, alcohol, benzodiazepines, tricyclic antidepressants, sedating antipsychotics and antihistamines)	Sedation, respiratory depression, overdose and death There is a lower risk of sedative drug interactions with buprenorphine than methadone.
Other opioids Opioid antagonists (naloxone, naltrexone) Buprenorphine Methadone High doses of methadone (>60–80 mg) or buprenorphine (>12–16 mg)	May cause precipitated withdrawal if administered to a patient taking methadone or buprenorphine. Methadone and buprenorphine will have diminished effects in patients already taking naltrexone. May cause precipitated withdrawal if administered to a patient taking long-acting opioids such as methadone. Will have diminished effects if administered to a patient already taking buprenorphine. Will reduce the effects of additional opioid use (for recreational or analgesic purposes) This can make opioid analgesia more difficult to achieve.
Drugs that prolong QTc	Methadone can be associated with prolonged QTc interval, and may interact with other drugs (prescribed medicines, alcohol and illicit drugs such as amphetamines, cocaine) that also prolong QTc. Lists of medicines known to prolong QTc can be found at https://www.nps.org.au/australian-prescriber/articles/risk-assessment-of-drug-induced-qt-prolongation . QTc prolongation in methadone patients may also be mediated by medicines that increase methadone plasma levels (CYP450 enzyme inhibitors).
Medicines affecting hepatic CYP450 metabolism Methadone is metabolised by the hepatic cytochrome P450 enzyme system (notably 2D6, 2B4, 3A4) with marked genetic variation Buprenorphine is also metabolised by the CYP450 system, however there appear to be fewer clinically relevant drug interactions reported with buprenorphine than methadone	Inducers of CYP450 can accelerate the metabolism of methadone, lower methadone plasma levels and precipitate opioid withdrawal or undermine treatment effectiveness. Typically, hepatic enzyme induction effects are seen 1–2 weeks after changes in medicine. Inhibitors of CYP450 enzymes can slow the metabolism of methadone, increase plasma levels and produce opioid toxicity (sedation, overdose). Enzyme inhibition can occur immediately following changes in medicine. Specialist advice and caution are required if medicines affecting CYP450 are to be prescribed to patients receiving methadone. Patients require careful monitoring for dose effects, and careful titration of methadone doses (by up to 40% in some cases).

Table 28. QTc interval risks based on gender

Level	QTc interval in milliseconds
Normal range (low risk of cardiac arrhythmias)	Men ≤ 450 ms Women ≤ 470 ms
Mildly elevated	Men 450–500 ms Women 470–500 ms
Severe prolongation (high risk of cardiac arrhythmia)	>500 ms

Table 29. Recommendations regarding QTc

Assessing safety prior to initiating methadone treatment	
Electrocardiogram (ECG) screening	<p>There is limited role for routine ECG screening of all patients seeking to commence methadone treatment, due to the potential delays in initiating effective treatment, likely poor adherence and associated costs to services and patients.</p> <p>Patients who should be assessed (ECG) for QTc prolongation, prior to commencing methadone include those with:</p> <ul style="list-style-type: none"> • previous history of QTc prolongation (for any reason); • clinical manifestations of QTc prolongation or cardiac arrhythmias (syncope, palpitations, dizziness); • significant other risk factors for QTc prolongation (consider drug interactions). <p>Such patients should be informed of the potential risks of QTc prolongation and methadone, and the benefits of ECG assessment prior to commencing methadone.</p> <p>Clinicians should balance the risk of deferring commencement of methadone treatment if there are to be significant delays or other barriers (e.g. patient reluctance) in conducting an ECG assessment.</p> <p>Failure to initiate methadone treatment and treatment drop out may place the patient at greater risk of cardiac and other health problems due to remaining out of treatment.</p>
Echocardiography or genetic testing	Routine screening with echocardiography (to assess for structural heart disease) or genetic testing (for congenital long QT syndrome) is not indicated in OAT.
Assessing QTc prolongation in existing methadone and buprenorphine patients	
ECG	<p>Prescribers should periodically assess (clinical history) all OAT patient's risk factors for QTc prolongation, arrhythmias and sudden cardiac death.</p> <p>Patients with the following conditions should have an ECG:</p> <ul style="list-style-type: none"> • a previous history of QTc prolongation (for any reason); • clinical manifestations of QTc prolongation or cardiac arrhythmias (syncope, palpitations, dizziness, unexplained seizures); • significant risk factors for QTc prolongation (consider family history, methadone dose >120 mg, other drug interactions (including non-medical substance use), cardiac conditions, electrolyte or metabolic disturbances). <p>Whilst buprenorphine patients are at generally lower risk, clinically significant QTc prolongation has been reported in this group also, and patients with previous history, clinical manifestations or significant other risk factors should be investigated.</p>
Responding to elevated QTc prolongation	
In patients with mildly elevated QT interval (<500 ms) with no clinical manifestations (episodes of syncope, dizzy spells, palpitations or seizures)	<p>Discuss the implications of a prolonged QT interval with the patient, taking into account relevant clinical and family history. Consider Holter monitor use to assess risk over 24 hour period due to diurnal QT interval changes and assess using QT nomogram (www.nps.org.au/australian-prescriber/articles/risk-assessment-of-drug-induced-qt-prolongation). For further information see www.ncbi.nlm.nih.gov/pmc/articles/PMC5595951/.</p> <p>Methadone can be initiated or continued in these patients, but more frequent monitoring and reduction of other risk factors (such as the use of other drugs that are thought or known to be associated with prolongation of the QT interval) are recommended.</p> <p>If the QT interval remains prolonged, consider referral to an addiction medicine specialist or cardiologist, a trial of methadone dose reduction, or consider transfer to buprenorphine.</p>
In patients with severe prolongation of the QT interval (>500 ms) or where there are clinical manifestations of QTc prolongation	<p>Seek advice from an addiction medicine specialist and a cardiologist, and more intensive investigations may be warranted.</p> <p>Strong consideration should be given to a risk minimisation strategy (such as eliminating or minimising other contributing factors, reducing the methadone dose, transferring the patient to an alternative opioid medicine (such as buprenorphine or morphine in a hospitalised patient), or discontinuing methadone treatment).</p> <p>The treatment plan should take into consideration the effectiveness of methadone treatment for the patient, and likely impact of any significant treatment changes upon broader substance use and general health and welfare.</p> <p>Informed consent is important in ensuring patient adherence with the proposed treatment plan.</p>

2.4.9 Responding to clinical incidents

Intoxicated presentations

Patient safety is the key consideration in responding to those who present for dosing while intoxicated due to opioids, alcohol or other drugs. Patients should be made aware at the commencement of treatment that medicine will be withheld if a patient presents for dosing whilst intoxicated.

Patients should always be assessed by the person dispensing the dose (nurse or pharmacist) for [signs of intoxication](#) before the dose is given. Note that some conditions can appear as intoxication (e.g. head injury, stroke, liver failure, unstable diabetes). Medical assessment may be required when assessing intoxication or other changes in conscious state.

Patients who appear intoxicated with CNS depressant drugs should not be dosed or given a takeaway dose of methadone or buprenorphine. Patients can be asked to re-present later in the day (or the following day) for dosing. The prescriber should be notified and the patient assessed for evidence of intoxication prior to the next dose being administered.

Patients with a history of repeated intoxicated presentations for dosing should be reviewed by the treating team and the treatment plan reconsidered.

Missed doses

Missed doses (patients not taking their regular dose of methadone or buprenorphine) can be associated with reduced opioid tolerance, opioid withdrawal and/or use of other substances, which affect treatment safety and effectiveness. Discussion should occur with the patient to understand the reason for missed doses and ways to aid attendance in future.

When a patient misses more than three consecutive doses, a review or consultation must occur with the prescriber, or if not available, their delegate, or seek expert advice from the Drug and Alcohol Specialist Advisory Service (DASAS), before resuming treatment.

Patients who have missed 1–3 consecutive doses

The dispenser, prescriber, or if not available, their delegate, dosing clinician or experienced drug and alcohol clinician should review the patient prior to dosing. The review should include:

- the circumstances surrounding missed doses, including reasons for non-attendance

- other recent substance use and clinical presentation at dosing (including evidence of intoxication or withdrawal)
- any relevant medical, psychiatric or social issues.

The dosing clinician (pharmacist, nurse or prescriber) may resume normal dosing if there are no concerns regarding intoxication, significant withdrawal or other clinical concerns.

The dispenser should consult the prescriber, or if not available, their delegate, or seek expert advice from the DASAS if the patient presents intoxicated, in severe opioid withdrawal or has other significant medical or psychiatric concerns. Intoxicated patients should not be dosed with methadone or buprenorphine.

Patients who have missed more than 3 consecutive doses

Patients who recommence methadone after more than three consecutive missed doses are at risk of reduced opioid tolerance and of overdose, particularly if other sedative drugs have been used.

Patients recommencing buprenorphine after more than three consecutive missed doses are at risk of precipitated withdrawal if the patient has been using opioid agonists (e.g. heroin, morphine, methadone).

If 4–5 doses have been missed, the dispenser should assess the patient (as above) and attempt to contact the prescriber, or if not available, their delegate.

If the prescriber can be contacted, a dose of methadone or buprenorphine may be authorised subject to the prescriber being able to forward a legal prescription to the dosing site (faxed prescription or telephone orders may be used).

- Methadone patients: A prescription equivalent to either half the regular daily methadone dose or 40 mg (whichever is higher) should be issued for that day. Patients should be monitored by a clinician on subsequent days prior to dosing, aiming to return to the regular dose within 5–7 days, usually in increments of up to 20 mg per day.
- Buprenorphine patients: A prescription equivalent to either half the regular daily buprenorphine dose or 8 mg (whichever is higher) should be issued for that day. Patients should be monitored by a clinician on subsequent days prior to dosing, aiming to return to the regular dose within 2–3 days, usually in dose increments of up to 8 mg per day.

If the prescriber cannot be contacted or is unable to provide a valid prescription, the patient cannot be dosed. The patient should be referred to their prescriber for review and to re-initiate treatment.

Patients who have missed more than 5 consecutive doses

The prescriber must review the patient prior to re-commencing treatment. [Methadone dose induction](#) should commence with low doses (<40 mg), with careful subsequent titration.

Patients who repeatedly miss doses

A minority of patients have poor attendance for dosing. This may be due to ambivalence about treatment, access issues (e.g. transport, work, limited dosing hours) or medical issues (mobility problems, cognitive impairment). The treating team should consider options for enhancing treatment adherence, which may involve changes in dosing sites or takeaway conditions.

Safe re-induction remains important when re-commencing treatment for patients who repeatedly miss doses. The patient's average current dose (of doses presented for over a recent dosing period e.g. one week) may be a guide to an appropriate dose to recommence treatment.

Some patients who repeatedly miss doses may report that their methadone or buprenorphine doses are inadequate. It is recommended that regular attendance be encouraged prior to any dose increases.

Incorrect doses of medicine

Methadone

In the case of an accidental overdose, the critical issues that determine how clinicians should respond are the patient's level of tolerance and the amount of methadone given in error ([Table 30](#)).

In the first 2 weeks, patients who receive an overdose of any magnitude require observation for 4 hours. If signs of intoxication continue, more prolonged observation is required. This may involve sending the patient to an emergency department (ED).

Generally, patients who have been on a dose greater than 40 mg/day consistently for 2 months will tolerate a dose double their usual dose without significant symptoms. For an overdose with greater than double the usual daily dose, the patient will require observation for at least 4 hours. If signs of intoxication are observed, more prolonged observation must be maintained.

If patients are receiving regular takeaway doses, or if they do not attend daily, it cannot safely be assumed that they have been taking their daily dose and have a known level of tolerance. Therefore, such patients require observation in the event of overdose of more than 50% of their usual dose.

Patients in whom the level of tolerance is uncertain (dose <40 mg/day, or in treatment for <2 months) require observation for at least 4 hours if they are given a dose more than 50% higher than their usual dose.

Table 30. Methadone dosing error procedures

Magnitude of overdose	Procedure
Up to 50% of the normal dose	<p>Advise the patient of the mistake and carefully explain the possible consequences.</p> <p>Inform the patient about signs and symptoms of overdose and advise him/her to go to a hospital ED if any symptoms develop.</p> <p>The dispenser must advise the prescriber of the dosing error and record the event.</p>
Greater than 50% of the normal dose	<p>Advise the patient of the mistake and carefully explain the possible seriousness of the consequences.</p> <p>The dispenser must contact the prescriber immediately. If the prescriber is unable to be contacted consult a drug and alcohol medical specialist.</p> <p>If it is decided by the prescriber or addiction medicine specialist that the patient requires hospitalisation, the reasons should be explained to the patient and they should be accompanied to the hospital to ensure admitting staff receive clear information on the circumstances.</p> <p>If the patient has left before the mistake is realised, every attempt should be made to contact the patient.</p>
<p>Caution regarding inducing vomiting:</p> <ul style="list-style-type: none"> Inducing vomiting may be dangerous and is contraindicated if the patient has any signs of CNS depression. Emesis after the first 10 minutes is an unsatisfactory means of dealing with methadone overdose as it is impossible to determine if all of the dose has been eliminated. 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. Ipecac syrup is contraindicated as its action may be delayed. 	

Buprenorphine

The risks associated with an incorrect dose of buprenorphine are not as severe as with full opioid agonist medicines.

If an incorrect dose is administered:

- the dispenser should immediately notify the patient and the prescriber of the error
- the patient should be warned of the likely consequences (increased sedation or drowsiness may occur for several hours afterwards), and warned against any additional drug use, and driving or operating machinery, for the rest of the day.

If a higher than intended dose has been taken and any of the following circumstances apply, the patient should be monitored for at least 6 hours by trained health professionals or in the ED of a hospital:

- the patient is sedated following the dose (for any reason)
- the patient is new to opioid agonist treatment (within first 2 weeks)
- a buprenorphine dose of ≥ 64 mg was incorrectly administered (regardless of routine daily dose).

The patient should be reviewed by the prescribing medical officer or appropriate clinician prior to the next dose of buprenorphine. It may be that a lower dose, or no dose, is required the following day (in effect, a two-day dose has been administered).

Vomited doses

Methadone

Patients on methadone maintenance may vomit shortly after having their dose, which creates uncertainty about how much methadone has been absorbed. (Table 31)

Buprenorphine

Buprenorphine doses are absorbed sublingually within 2-3 minutes. Vomiting after this time makes no difference to the absorbed dose.

Patients with recurrent vomiting of doses

Patients who repeatedly vomit should be reviewed by their treatment team. Strategies to consider include:

- having a light meal or drink at least 10-20 minutes prior to dosing
- trying an alternate formulation of methadone
- consuming the dose slowly or as partial doses
- an anti-emetic (e.g. metoclopramide 10 mg oral or IM) at least 30 minutes prior to dosing.

Pregnant women who vomit a dose

Pregnant women may experience nausea and vomiting of medicines particularly in the first half of their pregnancy. Monitor pregnant patients who vomit their methadone dose closely – and give a supplementary dose (up to half usual dose) if necessary to avoid opioid withdrawal, which may be associated with foetal distress. Supplementary doses will require express permission of the prescriber prior to administration. Pregnant women may benefit from split methadone dosing with some of the dose (e.g. 30-50%) provided as a take away.

Overdose

Prevention

Overdose accounts for approximately one third of deaths in people who are opioid dependent. Overdose typically occurs on resumption of opioid use after periods of reduced opioid use and tolerance (e.g. following incarceration, hospitalisation or withdrawal), and/or following opioid use in combination with other sedative medicines (notably alcohol, benzodiazepines, sedating psychiatric medicines). Overdose is more common in older individuals (>30 years of age) than younger people who use drugs.

Participation in treatment for opioid dependence reduces the risk of overdose and mortality, however there are critical periods in treatment that are associated with increased overdose and mortality risk. These include:

- during induction into methadone treatment (particularly the first 2 weeks);
- following cessation of naltrexone treatment;
- following planned or unplanned withdrawal from opioids.

Overdose risk is increased with intravenous opioid use rather than by other routes (e.g. oral, smoked), and the use of particular types of opioids (e.g. injected fentanyl has greater risks than heroin, whereas injected buprenorphine has lower risks than injected heroin). However, fatal overdose can occur when opioids are used by any route of administration.

Treatment services should aim to reduce risk of overdose and mortality with risk mitigation strategies (Table 32).

Table 31. Procedures for vomiting after methadone

Timing	Action
Vomiting more than 10 minutes after methadone dose	Reassure patient that the majority of the dose will have been adequately absorbed. If there are concerns, the patient may represent for clinical review after 3–6 hours.
Vomiting less than 10 minutes after methadone dose	If a patient has been in treatment for ≥ 2 weeks is observed by dispensing or clinical staff to vomit within 10 minutes after dosing, a supplementary dose of up to half the patient's usual dose may be administered, subject to there being a valid prescription available. This will require communication with the prescriber prior to the administration of any supplementary dose. If a patient is in the first 2 weeks of treatment or there is some uncertainty about the event, review the patient 3–6 hours after dosing. If at this time the patient is experiencing opioid withdrawal, a supplementary dose of up to half the patient's usual dose may be administered, subject to there being a valid prescription available.

Table 32. Strategies to reduce risk of overdose and mortality

Strategy	Action
Patient education	Patients should be provided with information about: <ul style="list-style-type: none"> • overdose risks; • prevention of overdose; • how to respond to overdose (calling ambulance services, training in first aid). Education can be provided by suitably trained peer educators and/or health professionals.
Safe prescribing and dosing practices for patients in pharmacotherapy treatment	This includes safe induction and takeaway conditions, strategies to prevent dosing of intoxicated patients or following periods of missed doses, and attending to non-medical use of OAT (e.g. diversion, injecting medicines. See section below Table 17 entitled ' <i>Non-medical use of methadone or buprenorphine</i> ').
Safe storage	Patients should be advised how to store takeaway opioid and other sedating medicines safely.
Prescription of 'take home' naloxone (THN) to patients for reversal of overdose	THN involves the provision of education and supplies of naloxone to individuals to use in the event of an opioid overdose – similar in principle to the provision of adrenaline supplies for individuals at risk of anaphylaxis in the community. Patients who are opioid dependent can be prescribed naloxone ampoules (0.4 mg) to be administered by IM, SC or IV routes in the event of an overdose as part of an overdose response plan. Naloxone distribution requires patient and carer education regarding overdose prevention, emergency responses in the event of an overdose, and how to use naloxone in the event of an overdose. No special authority or training is required for doctors to prescribe THN. Naloxone ampoules can also be purchased over the counter from pharmacies, as it is now also a Schedule 3 medicine.
Planned procedures for overdose	All healthcare providers involved in treatment of opioid dependence need to have planned procedures for managing overdose. The response to an overdose will depend upon the severity and urgency of the situation but should, if necessary, include: <ul style="list-style-type: none"> • cardiopulmonary resuscitation; • calling for an ambulance (or the resuscitation team if associated with a hospital); • calling for urgent medical assistance • closely monitoring the patient • administering oxygen and naloxone (if indicated and possible).

Naloxone

The mu receptor opioid antagonist naloxone is the treatment of choice for opioid overdose, since it leads to almost immediate reversal of the overdose. Patients who are opioid dependent can be prescribed 'take home' naloxone (THN) for reversal of overdose as part of an overdose response plan for patients.

THN is effective in reducing opioid related mortality: widespread uptake of THN is estimated to reduce overdose related mortality by 30–50% at a population level, and it has been estimated that one death is prevented for every 164 THN interventions provided.

Naloxone is available both on prescription (S4), and as an over-the-counter medicine (S3) from a pharmacy. It is available as:

- ampoules (0.4 mg and 2 mg, Narcan, naloxone),
- pre-filled syringe (Prenoxad 1 mg/mL, 2mL).

Both are licensed for IV or IM administration for the reversal of opioid overdose in Australia. IM (or SC) naloxone may be preferred to IV route due to poor venous access in many long-term injectors, and less risk of precipitating severe or uncomfortable withdrawal.

In practice, over-the-counter availability is more expensive for most patients, which may serve as a barrier to uptake. Hence, OAT providers are encouraged to prescribe THN.

THN education can be delivered by any suitably skilled clinician (medical, nurse, pharmacist or allied health worker) or peer worker to opioid users and carers as a brief 15–20 minute intervention.

Core elements include:

- how to reduce the risk of overdose;
- identifying when someone may have overdosed;
- how to respond to a suspected opioid overdose – including calling an ambulance, recovery position, IM use of naloxone, and rescue breathing.

This information is summarised in the one page consumer information sheet 'Responding to an opioid overdose' (Appendix D).

When prescribing and dispensing THN, generally a 0.4 mg IM naloxone dose is effective to reverse most opioid overdoses, although a small proportion of individuals may require a second 0.4 mg dose (recommended if the overdose victim has not recovered within 5 minutes of the initial injection). Individuals are encouraged to attend ED following an overdose.

Note that effect of naloxone is shorter than effect of opioids. The plasma half-life of naloxone is 1–2 hours and the duration of effect from a single intravenous dose is as short as 45 minutes, compared to 4–6 hours for the physiological effects of heroin or morphine, and 24–36 hours for [methadone](#) or [buprenorphine](#).

Patients should be encouraged to return for additional supplies of THN if the naloxone is used or misplaced, or if approaching the 'use by' date.

For naloxone product information, refer to the Therapeutic Goods Administration (TGA) eBusiness Services – Product and Consumer Medicine Information:

- Naloxone <https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2010-PI-02490-3>

For more information and training resources, refer to <http://www.penington.org.au/>

Methadone and buprenorphine related overdose

Risks of methadone and buprenorphine related overdose

Methadone related overdoses typically occur during the first 1–2 weeks of methadone treatment (often around the third or fourth day of methadone dosing). Deaths commonly occur at home during sleep, many hours after blood methadone concentrations have peaked. Most overdose deaths involve other sedating drugs, particularly alcohol, benzodiazepines or other psychotropic medicines.

In a patient who is opioid tolerant, the risk of lethal overdose with buprenorphine is less than other opioid medicines, such as methadone. Nevertheless, overdoses with buprenorphine have been reported, particularly in combination with other sedating drugs (e.g. alcohol, benzodiazepines), in individuals with low-opioid tolerance, and following injection of buprenorphine products.

Signs and symptoms of overdose

Features of methadone and buprenorphine related overdose are similar to other forms of [opioid-related overdose](#). These include: pinpoint pupils, nausea, dizziness, feeling intoxicated, sedation/drowsiness, unsteady gait, slurred speech, snoring, hypotension, slow pulse (bradycardia), shallow breathing (hypoventilation), coma, frothing at the mouth (pulmonary oedema). Symptoms may last for 24 hours or more. Death generally occurs from respiratory depression.

Preventing methadone and buprenorphine-related overdose

In addition to the strategies mentioned above (Table 32), the following strategies should be routinely used to avoid methadone related overdose:

- the period of [OAT induction](#) requires daily review of the patient by dosing staff and review every 3–4 days by the prescriber, and usually prior to any dose increase;
- warn patients (and carers) of the risks of overdose associated with OAT, most notably use of other drugs, and also if methadone or buprenorphine is injected, or if opioids are used by an opioid-naive person;
- administer methadone in the morning so that methadone concentrations peak when patients are normally awake and other people may be around if overdose should occur;
- family members and carers should be warned that deep snoring during induction to treatment could be a sign of dangerous respiratory depression and should be reported to the prescriber. Heavy snoring during maintenance treatment may be associated with sleep apnoea and should also be reported.

Treating methadone related overdose

Patients who are thought to have taken a methadone overdose require observation by a health professional, usually in hospital, and usually for at least 24 hours. Patients may require ventilatory support and naloxone. Because of the long plasma half-life of methadone, naloxone should be given as a prolonged infusion when treating methadone overdose.

Treating buprenorphine related overdose

Treating buprenorphine related overdose usually requires inpatient hospitalisation, careful monitoring, and may require ventilatory support and naloxone. Due to buprenorphine's strong affinity for, and slow dissociation from mu opioid receptors, higher doses and prolonged infusion of naloxone may be required to reverse buprenorphine effects. Evidence suggests that many buprenorphine overdoses are reversed with usual naloxone doses (e.g. 2 mg IV or IM), however, much higher doses (e.g. 10–30 mg/70 kg) may be required if lower naloxone doses are not effective. 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.

2.4.10 Transfer of care

OAT is often long term, spanning months or years, and involves patients transferring their treatment between health providers over time. Safe and effective treatment requires coordination of care between providers through appropriate communication and clinical handover, and attending to necessary OAT authority requirements.

Clinical handover and communication between OAT providers

Relevant clinical information should be made available to the receiving clinical team when patients transfer between OAT providers.

Appropriate clinical handover should include:

- Patient identification details (See Appendix J);
- OAT details, including current medicine and dose, duration of current treatment episode and current dose, dosing conditions, and adverse events or significant aberrant behaviours associated with OAT;
- Recent substance use, including use of alcohol, pharmaceutical and illicit drugs;
- Relevant medical, psychiatric and social conditions, including other medicines, and results of recent investigations;
- Any high-risk conditions that may warrant assertive follow-up of patients who do not attend for treatment, including harm to self or others, child protection or domestic violence issues.

Where possible, clinicians should obtain informed consent from patients prior to communicating with other health providers regarding transfer of care. If patient consent is not given, disclosing information to another person or organisation involved in the ongoing care of the patient is possible, provided appropriate attention to confidentiality of this information is maintained.

Regulatory requirements in transferring OAT between providers

Transfer of dosing site

If a patient has not changed prescriber but is to transfer between dosing sites, the Pharmaceutical Regulatory Unit (PRU) is to be notified in writing of the change. To avoid the potential for double dosing, the prescriber should notify the previous dosing site and have them cancel all prescriptions.

Details of last OAT dose from previous dispensing site (including dose in mg and date of last dose) should be documented when initiating dosing at a new site.

For more information see [NSW Health Mandatory notifications](#).

Treatment exit form

When a patient exits an OTP, or transfers between prescribers, a treatment exit form (available from the PRU) must be completed and immediately forwarded to the PRU. Patients must be exited from treatment with one prescriber to begin treatment with another. This prevents patients being registered in two programs simultaneously and therefore being double dosed.

Transfer of care from custody to community settings

The transition from custody to the community involves risks that the patient may discontinue OAT, and/or resume non-medical opioid or other drug use. It is therefore vital that this transition is as well-managed as possible. For further details, refer to Table 40. *Strategies to ensure continuity of OAT.*

Refusal to exit a patient

No prescriber may refuse to complete exit procedures for a patient. Such an action would place the prescriber in breach of a condition of the authority to prescribe methadone or buprenorphine.

Refusing to exit patients has occurred in the past when money is owed to the service at which the patient has been dosed. A service in this position may pursue such civil remedies as are open to them to recover the debt. However, the patient must still be promptly exited to ensure further treatment is not blocked.

Persistent failure to exit patients may result in a review of approval to prescribe.

2.4.11 Cessation of opioid agonist treatment

Planning for withdrawal

For a patient, successful cessation of OAT involves the safe and comfortable withdrawal from opioid medicine without relapse into opioid or other substance use disorder. As with any chronic condition, premature cessation of treatment can be associated with relapse and/or deterioration in other aspects of the patient's health and wellbeing.

Information about cessation of OAT should be provided to patients expressing a desire to cease, and to those who have stabilised and may be considering cessation. Research indicates that most OAT patients are interested in discussing cessation of treatment issues with their opioid treatment providers. Some patients may want to discuss the long-term plan for ending treatment

quite early in their treatment program. Others are more focussed on stabilising immediate problems and these discussions can be deferred.

All patients and treatment providers should address issues regarding treatment cessation at regular intervals (e.g. every 6 months). As with other chronic disorders, periodic review of the need for medicine is appropriate, with destabilisation the key indicator of the need for resumption or continuation of medicine (C).

An understanding of the predictors of successful cessation of OAT can provide a framework for patients and clinicians to plan for this process (Table 33).

Successful planning for withdrawal should aim to assist the patient to stabilise their substance use and optimise their health and social conditions as a precursor for attempting withdrawal. Unfortunately, many patients will want to withdraw more quickly. The consequences of an unsuccessful withdrawal attempt can include relapse to opioid or other substance use, deterioration in the patient's physical and mental health and social conditions, and reverse gains made over months or years of treatment. Good patient understanding of how to approach withdrawal is central to informed decision making. All treatment providers (prescribers, pharmacists, nurses, case workers) have an important role in discussing issues regarding treatment cessation with patients, and in supporting patients during the process.

Some patients continue on low doses of medicine (<30 mg/day methadone or 2 mg buprenorphine) for long periods and may be resistant to further dose reductions or cessation of treatment. The key is stability. It is appropriate to discuss withdrawal strategies with the patient, and address any concerns or fears they may have. However, patients should be reassured that if they are stable and comfortable, there is no reason to push cessation of medicine, and there are good reasons to maintain the medicine.

Continuing care after ceasing OAT remains important, due to the risk of relapse and heightened opioid overdose risk after opioid tolerance reduces. Monitoring should continue to manage opioid withdrawal, assess any further opioid use, and manage other relevant health problems. Take home naloxone may be indicated (*See Table 32 - Strategies to reduce risk of overdose and mortality*).

Withdrawal procedures

The most commonly used treatment approach for ceasing OAT is to undertake an outpatient gradual taper of the medicine over several months. This enables time for patients to adjust to the necessary physiological, behavioural and social changes that arise during this process.

Withdrawal severity tends to increase as the dose approaches zero, with peak withdrawal discomfort usually described in the 1–4 weeks after cessation of dosing. Low severity symptoms (e.g. poor sleep, mood disturbances, cravings) often persists for several months. As with any attempt at gradual withdrawal of medicine, careful monitoring is required to identify a relapse or deterioration in the patient's condition, indicating the need to reconsider the treatment plan.

Methadone reductions

Most patients tolerate dose reductions of 5–10% decrements every 1 to 4 weeks (i.e. 5–10 mg reductions for doses >50 mg; 2.5–5 mg reductions for doses <50 mg). The rate of reduction may vary according to the indications and time frame for withdrawal, and the clinical stability of the patient.

Some patients may reach a dosing level (often between 20 and 60 mg) where they are unable to attempt further dose reductions on methadone and further dose reductions are not indicated, either due to uncomfortable withdrawal discomfort, increased use of other drugs, or deterioration in general health and wellbeing. Such patients may benefit from restabilising on a higher methadone dose, or consider transfer to buprenorphine, which may enable an easier withdrawal process for the patient.

Buprenorphine reductions

Many patients tolerate greater incremental dose reductions with buprenorphine than methadone. Dose reductions of up to 25% every 1 to 4 weeks are generally possible (i.e. 4–8 mg reductions for doses >16 mg; 2–4 mg reductions for doses <16 mg).

There is a practical challenge to reducing buprenorphine-naloxone formulations. The smallest formulation available is 2 mg film; and many patients find it difficult to cease from this level. Prescribing in terms of 'half a piece of film' represents off-label use and contravenes Australian regulations relating to the prescription and dispensing of medicines that require prescribers specify the dose of medicine to be dispensed. It also presents pharmacists with a range of administrative problems.

Furthermore, the film is not marked for cutting, and the manufacturer has not advised that buprenorphine is evenly dispersed through the film. One option is to dispense whole pieces of film as unsupervised doses to enable patients to cut the film and thereby manage a dose taper for themselves. Other options include using alternate day dosing or converting to buprenorphine tablets and dividing buprenorphine 0.4 mg tablets to reduce the dose below 2 mg.

Psychosocial supports

The principles of effective psychosocial support for patients undergoing withdrawal from OAT are:

- patient information and [engagement](#) in treatment decision making;
- supportive care, including [withdrawal counselling](#) (maintaining motivation, coping strategies, risk behaviours), [peer and self-help groups](#), community supports and stable living arrangements;
- regular monitoring and increased frequency of reviews is indicated for patients undertaking withdrawal.

Role for ancillary medicines

There may be a role for symptomatic medicine to assist in the management of withdrawal symptoms such as nausea, aches and pains, and diarrhoea. Caution should be used in using sedatives and other hypnotics such as benzodiazepines due to the long-term nature of the sleep problems (weeks to months), and the high risk of dependence or non-medical use of such medicine in opioid users.

The use of opioid antagonists ([naltrexone](#)) following cessation of OAT is discussed later. Rapid detoxification procedures using opioid antagonists are not recommended, and should only be undertaken under specialist care.

Residential settings

There are increasing numbers of residential rehabilitation programs that will assist patients in long-term withdrawal off OAT. They are particularly suited to those with unstable social conditions and limited social supports. It is important that these programs include a suitable period of support (weeks to months) after dosing cessation, to cover the peak period of withdrawal discomfort and relapse risk. Careful re-integration into the community (e.g. after care services, counselling) is important.

There is limited role for short-term residential inpatient withdrawal programs (less than 2 week admissions), as peak withdrawal and relapse risk occurs in the several weeks after discharge.

Table 33. Predictors of successful OAT cessation

Factor	Predictor of success
How withdrawal from OAT is attempted	Gradual dose taper over months, rather than rapid reductions (days or weeks) or sudden cessation. Good patient understanding of the process for withdrawal, and patient centrally involved in decision making. Participation in psychosocial approaches to withdrawal management addressing coping strategies, risk behaviours, support systems. Regular review of progress and plans.
Use of alcohol or other drugs	No unstable or problematic use of alcohol or other drugs.
Comorbidity	Stable medical and psychiatric condition, in particular, no comorbidity that may be destabilised by the process of withdrawal, such as mental health (depression, anxiety) or chronic pain disorders.
Social conditions	Stable social conditions, particularly having activities and supports (e.g. stable housing, family, friends, carers and other social networks, occupational, recreational activities).
Duration of treatment	Most patients take at least 1-2 years of continuous OAT to achieve these conditions, but some can achieve stability more quickly while others will not achieve this optimal state.

2.4.12 Involuntary transfer and discharges

In some circumstances, the relationship between the prescriber, dosing and/or other clinical staff or a pharmacist and the patient may become ineffective or compromised, and the prescriber may decide to transfer or discharge the patient from treatment.

In most instances, problems may be resolved by transferring the patient to another program, either temporarily or on a permanent basis, rather than discharging them from opioid agonist treatment. There should be an appropriate [clinical handover](#) between the treatment teams, in particular identifying any clinical risks for the patient and new service.

Involuntary cessation of treatment should be a last resort and only used in situations such as violence or significant threat of violence against staff or other patients.

Where possible, other treatment should be offered for the patient, due to the imminent and significant risk of severe opioid withdrawal as well as the risk of opioid overdose (with changes in tolerance and resumption of illicit opioid use). Options include:

- Transfer to another opioid agonist treatment provider;
- Managing the patient with alternative treatment approaches (e.g. withdrawal and post-withdrawal support such as counselling or residential treatment).

A management plan regarding alternative treatment options (e.g. counselling, rehabilitation programs) and/or subsequent readmission to the referring provider should be developed for each patient

involuntarily transferred or discharged from the program and recorded in the patient's case record.

Public pharmacotherapy clinics have additional resources compared to primary care or private clinics and should be considered for referral of unstable patients including patients with significant behavioural problems.

Other behavioural problems may warrant a change in the patient's prescriber and/or dosing point due to issues including: property damage, theft, or drug dealing on or near program premises.

A decision to transfer a patient to another service, or discharge a patient from OAT against their wishes should be considered carefully. Good clinical practice involves ensuring that the patient is adequately informed of decisions regarding their treatment and facilitating arrangements for the continuing care of the patient, including passing on relevant clinical information.

At the beginning of OAT treatment, patients should be provided with a copy of their rights and responsibilities in writing including the conditions under which their treatment may change or be withdrawn. In public settings, all patients should also have access to procedures intended to resolve conflicts between themselves and those responsible for their care. Clinical records should document reasons for ceasing or transferring treatment, including a consideration of the process for the patient re-engaging in treatment at the same site in the future, if this is to occur.

Where treatment is being discontinued with an involuntary discharge and cessation of OAT, the rates of dose reduction will depend on the circumstances, but a gradual taper of medicine is preferred if possible. Only where there are persistent and high level safety concerns should a rapid reduction occur (over 1–14 days based on risk assessment). Patients being involuntarily discharged must be warned about the risks of opioid drug use, of possible reduced tolerance to other opioids such as heroin, morphine and fentanyl, and informed of other treatment options. Consideration may also be given to overdose management and education, including the provision of naloxone.

2.5 Naltrexone maintenance

2.5.1 Pharmacology

Naltrexone is an antagonist at the mu opioid receptor. In doses of 50 mg/day, oral naltrexone will block the effects of opioid drugs. In naltrexone maintenance treatment, this blockade of opioid drugs provides support for relapse prevention treatment.

Sustained release and implant preparations of naltrexone are currently not registered in Australia and remain experimental. Refer to the [Australian National Council on Drugs: Sustained release naltrexone \(e.g. implants\) are not recommended for treating opioid dependence](#).

2.5.2 Effectiveness

The evidence on the effectiveness of naltrexone maintenance treatment is limited by low rates of retention in studies and the small number of comparable studies. Current evidence indicates no significant difference in treatment retention or abstinence for people treated with naltrexone, with or without adjunctive psychosocial therapy, compared to placebo or psychosocial therapy alone (★★).

2.5.3 Factors affecting treatment selection

Naltrexone is indicated as an adjunctive relapse prevention treatment in people who:

- have withdrawn from opioids;
- are seeking to remain abstinent;
- are capable of giving informed consent to naltrexone treatment.

Given the potential for overdose after relapse, naltrexone treatment is most likely to be useful for those with a reasonable chance of remaining abstinent.

Such groups include employed patients, those who have been using drugs for only a short time (e.g. younger patients) and those under threat of legal sanctions.

Naltrexone appears to be most useful when there is a 'significant other' to administer and supervise the medicine such as a family member, close friend or, in some cases, an employer.

Contraindications to naltrexone treatment are:

- current physiological dependence on opioids; those currently physiologically dependent should be offered withdrawal intervention or referred to specialist services;
- acute opioid withdrawal – there needs to be a drug-free interval before commencing naltrexone;
- opioid use for chronic pain states – this requires specialist assessment;
- acute hepatitis or liver failure as naltrexone can be hepatotoxic in high doses – the margin of separation between the apparently safe dose of naltrexone and the dose causing hepatic injury appears to be only fivefold or less;
- known adverse reactions or sensitivity to naltrexone.


Baseline laboratory tests should include liver function tests and regular retesting is advised. Patients with signs of acute or decompensated chronic liver disease (jaundice, encephalopathy) should not usually commence naltrexone.

Assessment by an addiction medicine specialist is recommended when considering prescribing naltrexone to:

- women who are pregnant or breastfeeding as naltrexone is classified as a [B3 risk](#) in pregnancy;
- patients concurrently dependent on multiple drugs;
- patients with impaired renal function, as naltrexone and its active metabolite are excreted in urine;
- patients with major psychiatric illness, including depression;
- children and adolescents, as the effects of naltrexone in the treatment of opioid dependence in these populations is also unknown.

2.5.4 Initiating treatment

Naltrexone is most likely to be used to treat heroin use as part of a comprehensive relapse prevention treatment intervention. The best approach to initiation of naltrexone maintenance treatment is to manage [withdrawal from heroin with small doses of buprenorphine](#) before commencing naltrexone.

Introduce naltrexone with caution if there is any uncertainty about time of last opioid use (C). An interval of 5 days between last buprenorphine and first naltrexone is recommended for generalist settings – if a faster transition is desired, seek specialist advice or referral. 

During naltrexone induction, UDS is of little use. The best approach is to advise the patient that the first dose of naltrexone may precipitate withdrawal if opioids have been used recently. Commence naltrexone at 25 mg per day for 3 days then increase to 50 mg per day if tolerated (C). Note that the onset of withdrawal triggered by naltrexone can be delayed following buprenorphine treatment.

2.5.5 Delivering safe and effective naltrexone treatment

Patients should be provided with information regarding risks associated with cessation of naltrexone and return to opioid use, particularly the increased risk of overdose. Some patients may wish to use naltrexone in an intermittent way. (Table 34)

Table 34. Intermittent use of naltrexone

Examples	Potential risks	Caution to patients
A patient may be abstinent, but when facing a high-risk situation, will take one tablet A patient may want to avoid opioid use most days, but want to take opioid drugs on weekends.	Overdose of opioids due to risk of misjudging level of tolerance. Precipitated withdrawal due to resumption of naltrexone following reinstatement of opioid dependence.	It is appropriate to caution people against irregular use of naltrexone. In some situations it may be prudent to discontinue naltrexone treatment if the patient's level of risk-taking outweighs any observed benefits of the treatment.

Many patients who have relapsed will express a desire to resume naltrexone treatment. However, these patients need to be cautioned that reinstatement of dependence occurs rapidly within days of regular heroin use, and therefore, somewhat unpredictably, resuming naltrexone can precipitate

Table 35. Naltrexone use after relapse

Situation	Action
More than 5 days since the last dose of naltrexone and the patient has used heroin each day since then.	Recommence on naltrexone as though a new patient requiring withdrawal.
Within 5 days of last naltrexone dose.	Restart naltrexone under medical supervision – patients may experience withdrawal, but this is usually not severe. <ul style="list-style-type: none"> Restart naltrexone in the morning, at least 24 hours after last use of heroin. Commence with 1/2 tablet (25 mg). Patients may need symptomatic medicine.

Clinical experience suggests that patients who relapse and return to naltrexone tend to remain in treatment a relatively short time. After multiple relapses, prescribers should seriously consider whether it is appropriate to continue naltrexone treatment, as it becomes increasingly likely that the patient will drop out. It is preferable to actively manage cessation of treatment than for people to drop out and be receiving no treatment. Alternative approaches such as residential treatment or methadone or buprenorphine maintenance treatment should be discussed.

2.5.6 Monitoring and review

Patients should be seen regularly while on naltrexone treatment. It is recommended that clinical reviews should be conducted weekly during the first month of treatment, then fortnightly or monthly as required.

Monitoring of compliance and progress should occur at each clinical review:

- Assess drug use, for both heroin and other drugs.
- Assess compliance with naltrexone regimen
- Assess changes in social functioning and relationships.

- Review whether the patient is involved in counselling.
- Monitor side effects especially mood.

Naltrexone treatment, or abstinence from heroin, may exacerbate or unmask psychiatric problems, particularly depression, in susceptible subjects. Identification and monitoring of depressive symptoms is desirable, and if there is concern about a patient's mood, psychiatric assessment may be helpful.

2.6 Issues affecting OAT

2.6.1 General approach

People who are opioid dependent frequently have a range of health concerns (e.g. dental problems, contraception, sexual health etc.). An integrated, coordinated care approach will ensure a holistic response addressing the issues on an individual basis (S).

Health practitioners and staff need to develop and maintain their cultural competence when treating Aboriginal patients, and migrants to Australia. This encompasses being aware of their own world view; developing positive attitudes towards cultural differences; gaining knowledge of different cultural practices and world views; and developing skills for communication and interaction across cultures.

Women are more vulnerable to the risk of domestic violence and sexual assault. They are also more likely to be involved in commercial sex work. They may need advice on sexual health, contraception and parenting skills, and are generally more vulnerable than men. Fear of losing custody of children can be a motivating factor, but can also deter women from seeking treatment.

2.6.2 Aboriginal People

To address the significant health burden affecting the lives of Aboriginal people it is important to consider their unique cultural and health needs when providing treatment and care.

The aim is to provide a variety of treatment options to reflect the diversity of Aboriginal people, to maximise their health, wellbeing and social functioning, as well as to reduce risk to community safety and health with a culturally safe approach. This is especially relevant given the substantially higher rates of mortality and morbidity experienced by Aboriginal people compared to other Australians.

Existing mainstream models of practice in the drugs and alcohol field have been developed primarily within western systems of knowledge and may ignore an Aboriginal 'worldview'. Application of these models to working with Aboriginal people can be detrimental, to the extent that some approaches can directly undermine cultural ways of working. This can affect Aboriginal people's engagement with and experience of the health system and impact on their decisions to seek support and treatment.

Models of drug and alcohol treatment, which are framed from within an Aboriginal cultural context and developed by Aboriginal people, are likely to be more effective. Such models respect the legitimate rights, values and expectations of Aboriginal people and acknowledge the diversity within and between Aboriginal communities living in remote, regional and metropolitan areas. These models:

- incorporate an Aboriginal holistic concept of health and wellbeing;
- are grounded in an Aboriginal understanding of the historical factors, including traditional life, the impact of colonisation and the ongoing effects;
- aim to strengthen Aboriginal family systems of care, control and responsibility;
- address culturally appropriate approaches to harm reduction; and
- work from within empowerment principles.

For resources on health issues for Aboriginal people, see www.healthinonet.ecu.edu.au

2.6.3 Pregnancy and breastfeeding

Maintaining or initiating OAT is the preferred approach to opioid dependence in pregnancy. Maintenance treatment with an opioid substitute can prevent the adverse effects on the foetus of repeated withdrawals and periods of intoxication.

Best practice advice regarding the management of drug use during pregnancy, birth and early developmental years of the newborn can be found in *GL2014_022 Guidelines for the Management of Substance Use During Pregnancy Birth and the Postnatal Period*.

Medicine selection

Overall, methadone and buprenorphine are equally effective in pregnancy (★★★). The choice should be made in consultation with the patient.

Methadone is safe and effective in terms of consistently better obstetric and perinatal outcomes compared with pregnancies in opioid dependent women not receiving OAT (★★★★).

If buprenorphine is used in pregnancy, the [Subutex®](#) preparation is preferable. While the absorption of naloxone is minimal when the combination preparation ([Suboxone®](#)) is administered sublingually, the effect of long-term naloxone exposure on the foetus is unknown. If buprenorphine is to be commenced during pregnancy and the risk of precipitated withdrawal is a concern, consider methadone as an alternative, or seek specialist advice. It is recommended not to attempt transfer from methadone to buprenorphine during pregnancy because of the risk of precipitated withdrawal (C).

The safety and efficacy of naltrexone and/or naloxone in pregnancy have not been established. Use of preparations containing naltrexone or naloxone should be ceased in advance of a planned pregnancy. For women who become pregnant while on naltrexone, the risks of ceasing should be balanced against the risks of remaining on naltrexone. Specialist advice is recommended. Caution should be advised regarding the use of naloxone during pregnancy as it may precipitate withdrawal in the foetus.

Risks

Withdrawal is risky in the first trimester due to risk of miscarriage and in the third trimester due to the risk of foetal distress and premature labour. Any potential benefit from withdrawal, or reduction of dose of medicine, must be balanced against the risk of relapse to uncontrolled drug use (C).

A structured attempt at withdrawal at some stage after pregnancy is preferred. Dose reduction after giving birth is currently a common practice, but the extent and timing of dose reductions has not been investigated in research studies. The maintenance dose should be reviewed in the early days following birth and regularly as indicated thereafter. The focus in reviewing the dose should be on supporting and enhancing the woman's stability, taking into account signs of withdrawal or intoxication, and risk of reverting to illicit drug use.

Outcomes for mother and baby are complicated by polydrug use.

OAT can be associated with neonatal abstinence syndrome (NAS), which occurs in newborns experiencing withdrawal as a result of the mother's dependence on drugs during pregnancy. NAS in

infants of mothers who are opioid dependent is characterised by signs and symptoms of CNS hyperirritability, gastrointestinal dysfunction and respiratory distress, and symptoms that include poor feeding, sleep-wake abnormalities, vomiting, dehydration, poor weight gain and occasionally seizures. This syndrome usually begins within 72 hours after birth, but may appear up to 2 weeks after birth.

NSW Health recognises that people with opioid dependence usually have simultaneous psychological, social and health problems that can be exacerbated in times of increased stress such as pregnancy. Pregnancy increases the importance of assessing the risk of domestic violence as well as the quality of parenting skills. Women who use drugs may not seek general health services until late into pregnancy and are therefore more vulnerable to medical and obstetric complications.

Many women are more motivated during pregnancy to make important health and lifestyle changes. This is an ideal time to engage, or more fully engage, a woman in care for her drug use and other problems. A range of services are required to work collaboratively in order to ensure optimal outcomes for both the mother and newborn. The aim is to minimise the likelihood of complications and to provide comprehensive antenatal and postnatal care in a non-judgemental, non-threatening environment.

NAS can be readily managed with withdrawal management and supportive care. If required or indicated, medicines such as tincture of opium or morphine can be titrated against severity of withdrawal symptoms.

For further information, see NSW Health Neonatal Abstinence Syndrome Guidelines http://www1.health.nsw.gov.au/pds/ActivePDSDocuments/GL2013_008.pdf

Breastfeeding

Mothers who are stable on OAT (methadone or buprenorphine) should be supported if they choose to breastfeed.

Women who are stable on an OAT, but occasionally use heroin in a 'one-off' pattern, should be advised that not using illicit substances is the safest option when breastfeeding. If they choose to use illicit substances, they should be advised to express and discard breast milk for a 24-hour period afterwards, then return to breastfeeding. They should also be encouraged to have a 'safety plan' in place for the infant on such occasions.

Mothers who are unstable, continuing to use opioids such as heroin, or using multiple drugs, should be encouraged not to breastfeed, and attention should be paid to assisting them to stabilise their lifestyle.

2.6.4 Age factors

Patients less than 18 years

In treating adolescents, the emphasis should be on psychosocial responses, harm reduction and family intervention approaches. But, pharmacotherapy may also be an important component of treatment for some young people (C).

Pharmacotherapy should only be used after careful assessment of risks and benefits, and in the context of a comprehensive treatment plan embracing various psychosocial approaches (C). The legal and regulatory requirements should be checked before prescribing methadone or buprenorphine to a patient less than 18 years of age. (Table 36)

If pharmacotherapy is used, buprenorphine may be preferred over methadone because of easier cessation. Doses may need to be adjusted from those used for adults.

Table 36. Requirements for patients less than 18 years

Patient age	Requirement
16-17 years	A second opinion (ideally from an addiction medicine specialist) in favour of treatment must be obtained before an authority for methadone or buprenorphine can be granted.
Less than 16 years	<p>Prescribing methadone or buprenorphine requires an exemption to the provisions of the <i>Children and Young Persons (Care and Protection) Act 1998</i> (NSW).</p> <p>The request for an exemption should include a second opinion from an addiction medicine specialist nominated by the LHD or SHN.</p> <p>To seek an exemption, the prescriber must apply in writing to the Director, Pharmaceutical Regulatory Unit.</p> <p>The request for exemption will be forwarded on behalf of the Director to the Department of Family and Community Services.</p>

Depending on their drug use history and social circumstances, adolescents may stabilise quickly on opioid agonist treatment enabling cessation of pharmacotherapy to be considered more quickly than would be the case with adults (C). However, as with adults, adolescent patients should be monitored for signs of destabilisation and opioid agonist treatment reinstated if necessary.

Older patients

The average age of patients in OAT is increasing, making it necessary to give consideration to issues for older patients. In this group, previous substance use, trauma and other factors accumulated from a drug-using lifestyle increase the likelihood of associated problems.

Issues around long-term use of high doses of opioids include an impact on the usual ageing process (osteoporosis and sex hormone deficiencies, particularly androgens in men), reduced cognition from repeated hypoxia, risk of falls, changes in pharmacokinetics and poly-pharmacy. Chronic hepatitis C, obesity and smoking-related issues are also likely in this population. Better coordination of care is needed to address the multiple issues.

There is no direct evidence about methadone dosing regimens for maintenance treatment in older adults. However, older people who use drugs are likely to metabolise drugs at a slower rate making lower opioid doses and slower dose titration of methadone advisable in older patients. Large doses of methadone (>150 mg/day) are not necessarily best for this group and should be reviewed in consultation with the patient (C).

2.6.5 Infectious diseases

Vaccinations for hepatitis B and tetanus are recommended. For Hepatitis B vaccinations, the recommended Australian infant schedule consists of a dose of monovalent hepatitis B vaccine given at birth, followed by 3 doses of a hepatitis B-containing combination vaccine, given at 2, 4 and 6 months of age, in accordance with [national guidelines](#).

Adults who are at risk for HBV and have not been administered HBV vaccination can be given hepatitis B vaccine at 0, 1 and 6 months.

Treatment of HIV, hepatitis C and chronic hepatitis B is as effective in people with a history of opioid dependence as in other population groups. In people with advanced HIV in whom there is ongoing opioid dependence, OAT is recommended in conjunction with antiviral treatment to facilitate treatment adherence and improve outcomes for both conditions.

Drug interactions between antiretroviral medicines and methadone, and to a lesser extent buprenorphine, need to be monitored and may necessitate adjustment of medicine regimens.

Testing and treatment for HCV using direct acting agonists should be a clinical priority for patients on OAT. Hepatitis C treatment with direct acting agonists is possible as these agents are available subsidised by the PBS. Current drug use or risk of re-infection does not preclude anti-viral treatment. Typically direct-acting antivirals can be used by people who inject drugs as drug-drug interactions with psycho-active drugs are rare (for most agents).

For more information see [Australasian Society for HIV, Viral Hepatitis and Sexual Health Medicine](http://www.asam.org/quality-practice/guidelines-and-consensus-documents/npg); <http://www.asam.org/quality-practice/guidelines-and-consensus-documents/npg>; and <http://www.gesa.org.au/resources/hepatitis-c-treatment/>

2.6.6 Management of pain

Acute pain

When managing mild to moderate acute pain in patients receiving methadone or buprenorphine, it is important not to assume that the maintenance dose of opioid agonist treatment will manage the pain.

Strategies for management of acute pain can be broadly divided into the following categories:

- Non-pharmacological;
- Manage cause/precipitant of pain (e.g. immobilise fractured limb);
- Simple analgesics (e.g. paracetamol, ibuprofen);
- Opioid analgesics;
- Adjuvants (e.g. antidepressants, gabapentinoids);
- Nerve blocks (e.g. local or regional blocks, epidural).


Generally, analgesic options should start with the first category above and work downwards. There are certain acute pain scenarios where there is evidence for specific treatments such as use of antivirals within 72 hours in herpes zoster or the use of indomethacin in paroxysmal hemicrania. It is also important to identify if specific treatments are contraindicated (e.g. opioids should be avoided in headache).

The Australian Faculty of Pain Medicine provides current evidenced-based [Acute Pain guidelines](#) to assist practitioners.

Approach to analgesia

Exploration of patient's fears and explanation about the condition and likely progress and outcome are important.

Consider the introduction of the simple analgesics (e.g. paracetamol and/or non-steroidal anti-inflammatory drugs [NSAIDs]) with due consideration of side effects and interactions. If an opioid is required, consider whether this is as an inpatient/outpatient, and the likely duration of treatment as this defines risk and options available.

Both buprenorphine and methadone have analgesic properties, but have shorter analgesic interdosing intervals (i.e. the analgesic effects of methadone and buprenorphine each lasts 8-12 hours). Consider splitting the OAT dose, increasing OAT dose, or add an opioid analgesic to the opioid agonist treatment regimen. Specialist advice is recommended (C). 

Practically, it may not be possible for patients to split the OAT dose if they are dosing in a community setting. In high-risk patients, it is inadvisable to add additional non-OAT opioids. The pain or underlying medical problem that has caused the patient to seek assistance may limit the patient's mobility such that the patient is unable to travel to the community dosing point.

Where opioid analgesics are being added to the opioid agonist treatment regimen in the outpatient setting, prescribers need to apply for regulatory approval <http://www.health.nsw.gov.au/pharmaceutical/doctors/Pages/default.aspx>

For information about the legal requirements in NSW of prescribing S8 drugs to patients in the OTP see [Authorisation to prescribe drugs of addiction](#).

Severe acute pain

Pain management should again consider options in categories above, as well as the patient's fears and explanation about the condition and likely progress and outcomes. However, severe acute pain typically requires opioid analgesia, usually administered in a hospital or specialist setting.

For non-opioid analgesia, consider simple analgesics (e.g. paracetamol and/or NSAIDs) or gabapentinoids with due consideration of side effects and interactions. Peri-operative gabapentinoids in the non-opioid dependent population may improve post-operative pain and reduce opioid requirements.

There is limited data in the opioid dependent patient, although 5 weeks of pre-treatment with gabapentin does improve experimental pain in methadone maintained patients, and this could be considered for elective surgery.

Ketamine is often used in an attempt to reduce opioid tolerance acutely. Close liaison with acute pain services around opioid management and local/regional/neuroaxial techniques is critical.

Methadone and major surgery or acute severe pain

In general, it is recommended that usual methadone is continued. If acceptable to the patient, the dose can be divided in two or three aliquots across the day, and this may improve analgesia.

Where patients cannot tolerate oral intake, methadone can be administered parenterally. A dose reduction to around 80% of the usual oral dose accounts for oral bioavailability. The parenteral methadone currently registered in Australia is available in a 10 mg/mL strength. Thus for higher doses of methadone, quite large volumes may need to be administered. This can be quite painful as SC or IM injections, and administering in divided doses across the day may be necessary to limit the volume administered.

Patients on methadone requiring additional opioid analgesic typically require larger doses of opioids than in the opioid naïve patient. Patient controlled analgesia is an acceptable mode of opioid delivery acutely. Differentiating tolerance from opioid induced hyperalgesia can be difficult in the clinical setting. A pragmatic solution is a trial of adequate additional opioid doses, and if unsuccessful a reduction of opioid could be trialled.

When the acute problem is resolving, longer-term planning about opioid management on discharge should progress. The likely need for increased opioid on discharge can be identified from consideration of the natural history of the disease process or post-operative healing.

Some patients may require additional opioid on discharge. Assessment of the patient to identify potential for harm to the patient and the community from additional opioid should be undertaken. Some patients may be safe for discharge with short duration of additional non-methadone opioid. Others may require an increase in methadone dose commensurate with the amount of additional opioid analgesic used.

Buprenorphine and major surgery or acute severe pain

The optimal management of the patient on buprenorphine maintenance in the peri-operative period is controversial. The options are to continue buprenorphine and add additional full agonist opioid, or transfer to methadone peri-operatively and continue as above. There is an increasing body of evidence supporting continuation of buprenorphine and addition of full agonist opioid.

In all situations, communication between hospital teams, community prescribers and GPs about analgesic plans and projected duration of pain and medicines is critical.

Chronic pain

Chronic pain in patients receiving OAT should be managed as for any other patient with psychosocial and non-opioid pharmacological approaches emphasised. However, there are some notable differences (C):

- Tolerance means that normal doses of opioids are likely to be less effective.
- When prescribing, be aware of the potential for aberrant behaviours and use appropriate strategies (monitoring and interval dispensing).
- Avoid use of other psychoactive medicines for which there is no evidence of effectiveness in pain relief (e.g. Benzodiazepines, antipsychotics).
- Exercise caution with the use of gabapentinoids as these medicines may be used non-medically, can produce intoxication, a delirium and a withdrawal syndrome.

- If concerned, seek specialist advice or referral.
- If prescribing opioids, be aware of relevant jurisdictional regulations and resources available to assist prescribers.

Use caution when continuing pain relief following discharge from hospital and avoid prescription of multiple opioid medicines (C). Vigilance is needed as acute and chronic pain can destabilise patients in OAT (C). Tailor the dose of buprenorphine in chronic pain as with any other medicine (C).

People with chronic pain conditions who experience dependence related problems may benefit from methadone or buprenorphine [maintenance treatment](#).

The patients with chronic pain for whom methadone or buprenorphine maintenance may be considered include those:

- Using illicit drugs (heroin) in addition to prescribed analgesics;
- Using large amounts of analgesics gained from multiple sources in a non-medical way;
- Unable to control their analgesic use (taking more and more) despite strategies such as having one nominated prescriber, dispensing small quantities of opioid each time, and dispensing frequently (e.g. daily or every second day).

A multidisciplinary team approach is required for these people, including collaboration with pain clinics and/or appropriate medical or nurse practitioners in drug and alcohol services.

Pain management is also important for people on opioid agonist treatment with a terminal illness. Collaboration with palliative care and specialist services is most likely to achieve the integrated care needed (C).

For further information see [National MATOD Guidelines](#), 2.6.10 Management of pain (page 149) and the [NSW Therapeutic Advisory Group \(TAG\) practical guidance](#).

Section 3

Regulation and governance of the Opioid Treatment Program in NSW

3.1 NSW regulatory framework and requirements for prescribing drugs of addiction

3.1.1 Regulatory bodies

Overview

Methadone and buprenorphine are Schedule 8 (S8) drugs of addiction. [Each state and territory has laws regulating the prescription and dispensing of these medicines.](#)

Regulation of OTP in NSW

Within the NSW Ministry of Health, the Pharmaceutical Regulatory Unit, Legal and Regulatory Services Branch, administers and enforces compliance with the Poisons and Therapeutic Goods (PTG) legislation.

Within the NSW Ministry of Health (The Ministry), the Centre for Population Health's Alcohol and

Other Drugs Branch provides policy and strategic directions and state-wide planning for the provision of drug and alcohol services. These include treatment services for opioid dependency.

The Centre for Population Health (CPH) is assisted by specialised committees such as the Drug and Alcohol Program Council (DAPC) and the Quality in Treatment Committee (QIT). The DAPC is a forum of drug and alcohol managers from the LHD/SHNs who meets to coordinate policy and service development on a state-wide basis.

The QIT Committee reports to the DAPC and the Centre for Population Health on matters related to improving clinical practice and quality of care. The QIT Committee consists of senior clinicians from the LHD /SHNs with representation from NGOs, the private prescribing sector, Justice Health and Forensic Mental Health Network, and nursing and allied health professionals.

Table 37. Organisational roles in OTP in NSW

Organisation	Role in NSW OTP
The Commonwealth Government Department of Health	Supplies methadone and buprenorphine to the dosing points (free of charge); Pays for services by prescribers working in the private sector (Medicare); Approves the formulation and registration of products by way of the Therapeutic Goods Administration (TGA), which is also responsible for recall of faulty products; Provides national policies and guidelines for the treatment of drug dependency with prescribed opioids such as methadone and buprenorphine; Provides national policies and guidelines on professional development and training for medical and nurse practitioners who prescribe/supply drugs of addiction, and pharmacists who dispense drugs of addiction.

Organisation	Role in NSW OTP
<p>NSW Ministry of Health, Pharmaceutical Regulatory Unit, Legal and Regulatory Services Branch</p>	<p>The PTG Act regulates:</p> <ul style="list-style-type: none"> • legal prescribing of S8 drugs by medical practitioners and nurse practitioners approved to prescribe drugs of addiction; • the review, amendment, and cancellation of the approval issued to medical practitioners or nurse practitioners to prescribe S8 drugs; • the licensing of private clinics; • licensing of wholesale distributors; • dispensing and dosing by pharmacists and dosing by nurses; • the investigation of complaints regarding prescribing and the professional behaviour of prescribers. <p>Processes applications under the <i>Poisons and Therapeutic Goods Act 1966</i> for authority to prescribe methadone and buprenorphine to individual patients on the OTP;</p> <p>Regulates supply by pharmacists of OTP;</p> <p>Maintains the database of accredited OTP prescribers, dosing points and registered OTP patients;</p> <p>Processes exit forms and transfers of dosing points;</p> <p>Produces guides to the Poisons and Therapeutic Goods legislation for medical practitioners and pharmacists, including guidelines for pharmacists dosing OAT.</p> <p>May undertake inspections of licensed private clinics and community pharmacies;</p> <p>Monitors the labelling, packaging, storage, prescription and supply of scheduled medicines under the PTG Act;</p> <p>Advises the PCS on any professional records and standing of prospective and current prescribers.</p>
<p>NSW Ministry of Health Alcohol and other Drugs Branch</p>	<p>Develops clinical guidelines for prescribing and dispensing opioid treatment drugs;</p> <p>Provides incentives for pharmacy-based dispensing;</p> <p>Formulates standards for services provided by opioid treatment clinics;</p> <p>Oversees the accreditation of prescribers and provides training to support accreditation. The Chief Health Officer (CHO) has the delegated authority of the Secretary of NSW Health to approve a medical or nurse practitioner as a prescriber of drugs of addiction in NSW;</p> <p>Oversees the accreditation of private OTP clinics;</p> <p>Formulates policies to improve access to opioid treatment for people in corrective settings and improve continuity of care post release;</p> <p>Liaises with local councils, police and community groups to handle issues of amenity in the vicinity of public and private clinics;</p> <p>Supports the Pharmacotherapy Credentialing Subcommittee (PCS), a subcommittee of the medical committee that assists the CHO by providing recommendations on applications for authority to become an approved OTP prescriber, and on applications to prescribe high doses of methadone and buprenorphine for individual patients;</p> <p>Receives input from the Opioid Treatment Line (OTL), which responds to complaints and provides advice to OTP patients, family members and services, and provides secretariat to the OTL committee comprised by representatives from the Health Care Complaints Commission, JH&FMHN, Centre for Population Health, Pharmacy Guild, Pharmaceutical Regulatory Unit and consumer groups.</p>
<p>Justice Health and Forensic Mental Health Network (JH&FMHN) (02) 9700 2101</p>	<p>Responsible for methadone and buprenorphine treatment for the prison population and for arranging continuity of care upon release;</p> <p>JH&FMHN provides prescriptions for patients for 3 weeks post-release for those who were in treatment prior to custody, and for 4 weeks for patients who were initiated onto treatment while in custody. JH&FMH also provides community prescriptions from time to time for patients on the Drug Court Program, and transition support for post-release OTP patients through the Connections Project.</p>

Organisation	Role in NSW OTP
The Health Care Complaints Commission (HCCC) 1800 0431 159	Acts to protect public health and safety by resolving, investigating and prosecuting complaints about health care; The Commission has a co-regulatory role with the Health Professional Council's Authority such as the Medical Council of NSW and The Nursing and Midwifery Council of NSW; May also refer matters to NSW Ministry of Health for investigation.
The Australian Health Practitioner Regulation Agency (AHPRA) 1300 419 495	Responsible for the implementation of the National Registration and Accreditation Scheme for health practitioners across Australia; In NSW, AHPRA's role in monitoring the health, performance, and conduct of health practitioners is delegated to the state councils (e.g. Medical Council of NSW, Nursing and Midwifery Council of NSW).
The Opioid Treatment Line 1800 642 428	Provides information to patients on access to prescribers; Provides information to prescribers on access to dosing points; Monitors complaints and provides support to patients; Reports complaints/issues to the Drug and Alcohol Unit, CPH to assist resolution and the development of proactive strategies to improve access and quality of care for people on opioid treatment.
New South Wales Users and AIDS Association (NUAA) 1800 644 413	Is a patient advocacy group; Provides support and advice to people who use drugs and other interested parties; Liaises with the Ministry's Drug & Alcohol Unit, the Opioid Treatment Line, the Health Care Complaints Commission, and the Justice Health and Forensic Mental Health Network to monitor patient satisfaction and plan ways to improve access to services for people who use drugs.
The Coroner's Court	Records and investigates unexpected deaths, including drug-related deaths; Refers matters to the Health Care Complaints Commission for further investigation, where appropriate; Refers matters to NSW Ministry of Health for consideration with a view to improve services or conduct further investigation if necessary.

3.1.2 Safety and quality framework

Clinical governance

Pharmacotherapy treatment benefits from quality improvement activities that aim to enhance the safety, effectiveness, and efficiency of services (S).

Accreditation of OTP clinics

An important quality assurance and improvement mechanism is the accreditation of services against standards. Services that hold a licence to supply buprenorphine or methadone under the *Poisons and Therapeutics Goods Act 1966* (NSW) are, as a condition of their licence, required to achieve accreditation and maintain an accredited status with an approved accrediting agency. Opioid treatment clinics operated by LHDs are required to achieve accreditation as part of the hospital/facility organisation-wide accreditation process.

Patient and carer participation in treatment

Safety and quality of OTP is improved by involving patients and carers (S) through:

- providing information to patients, including about treatment options and treatment risks;
- the obtaining of informed consent;
- having mechanisms to ensure participation of carers in the treatment process, according to different levels of patient consent;
- having accessible complaint and grievance procedures;
- having medical records, clinical information and data management policies, including mechanisms for ensuring patients' confidentiality with formal written consent if information needs to be shared or forwarded.

Data collection and reporting

Accurate data is required to monitor the effectiveness of treatment modalities and pharmacotherapies used in NSW to treat opioid dependence. Prescribers must comply with reporting requirements of the NSW Ministry of Health as a condition of being granted an authority to prescribe. This includes providing their full details on the application for authority to prescribe, and providing prompt advice in writing of any changes in their circumstances or in the circumstances of their patients including treatment cessation and particularly any changes in the dosing point.

3.2 Prescriber accreditation, authorisation, and professional development

3.2.1 Regulatory requirements

Prescribing methadone, buprenorphine and buprenorphine-naloxone

In order to prescribe opioids to up to 200-300 patients, prescribers are required to:

- complete the Opioid Treatment Accreditation Course (OTAC), either through attendance at a workshop or through the web-based course and successfully pass end of course examination;
- complete a workplace assessment (a 2-3-hour clinical placement).

Records that demonstrate the applicant has met the above requirements and the professional record of the practitioner are assessed by the Pharmacotherapy Credentialing Subcommittee (PCS) before an approval to prescribe is granted. Prescribing limits are generally for up to 200 patients who dose in community pharmacies or private clinics, or up to 300 patients who dose in public OTP clinics.

The Opioid Treatment Accreditation Course

This course aims to assist the development of knowledge, skills and practices to support the safe prescribing of opioid pharmacotherapies in NSW as per NSW regulatory and legislative framework.

Courses are held throughout NSW and include the following topics:

- Overview of opioid dependence and available treatment approaches in NSW;
- The pharmacologies of drugs for opioid agonist treatment;
- Recommendations for the effective delivery of methadone treatment based on clinical evidence;
- Recommendations for the effective delivery of buprenorphine-naloxone treatment based on clinical evidence.

The NSW Ministry of Health contracts with an external agency to provide the OTAC.

For course details or to enrol in the course, see the [OTAC website www.otac.org.au](http://www.otac.org.au)

3.2.2 Nurse practitioner accreditation process

In order to become endorsed as a nurse practitioner in Australia, registered nurses must be endorsed by the Nursing and Midwifery Board of Australia.

Once endorsed, nurse practitioners are able to prescribe in accordance with State and Territory Law. In NSW, this requires authorisation by the Secretary of Health (or delegate) in accordance with s17A of the *Poisons and Therapeutic Goods Act*. This process has been delegated to the Chief Nursing and Midwifery Officer. Nurse practitioners employed by NSW Health are authorised to prescribe within their scope of practice from the [NSW Nurse Practitioner Formulary](#) in accordance with policy directives [Nurse Practitioners in NSW](#) and [Nurse Practitioners in NSW Guideline for Implementation](#).

Nurse practitioners employed outside NSW Health, for example those employed by NGOs, GPs or who are self-employed are required to apply for authorisation to prescribe in NSW in accordance with s17A of the *Poisons and Therapeutic Goods Act*. This process occurs once credentialing requirements have been met.

Drug and alcohol nurse practitioners

The additional training and credentialing requirements for a drug and alcohol nurse practitioner to become a prescriber of opioid pharmacotherapies are identical to those required of medical officers (see [Regulatory requirements to be met by methadone and buprenorphine-naloxone prescribers](#)).

Nurse practitioners wishing to become a prescriber of opioid pharmacotherapies must demonstrate relevant experience and expertise within a scope of practice encompassing the drug and alcohol specialty.

Registered nurses employed in transitional nurse practitioner positions, or who are completing the requirements for endorsement as a nurse practitioner outside a transitional position, are not able to prescribe and cannot apply for approval until they have successfully completed the endorsement process.

3.2.3 Accredited and unaccredited OTP prescribers

Generally, medical practitioners and nurse practitioners prescribing methadone and buprenorphine on the NSW OTP are required to be accredited by the Pharmacotherapy Credentialing Subcommittee, as described previously.

Unaccredited medical practitioners

Methadone: Unaccredited medical practitioners may apply to the Pharmaceutical Regulatory Unit (PRU) for an individual patient authority to prescribe for up to ten (10) low-risk patients who are being transferred from an accredited prescriber. Unaccredited medical practitioners should engage with the previous accredited prescriber, or seek advice from DASAS if significant changes to treatment are required or the patient's risk assessment changes adversely. Unaccredited medical practitioners cannot initiate patients on methadone.

Buprenorphine and buprenorphine-naloxone (Suboxone®): Unaccredited medical practitioners may apply to the PRU for individual patient authority to initiate patients with buprenorphine or buprenorphine-naloxone. Unaccredited prescribers may be authorised for up to 20 buprenorphine or buprenorphine-naloxone patients. (Note: *Section 2.4.2 Induction and stabilization – Buprenorphine – Patients choosing buprenorphine should be commenced on the combination preparation (buprenorphine-naloxone) unless pregnant or with a proven allergy to naloxone (C). N.B. allergies to naloxone are rare.*)

To clarify, the total number of patients that an unaccredited prescriber may obtain authority to prescribe for, at any one time, is thirty (30) with a maximum of 10 of these patients being for methadone.

3.2.4 Authorisation to prescribe drugs of addiction

Pharmaceutical Regulatory Unit (PRU) of the NSW Ministry of Health administers the *Poisons and Therapeutic Goods Act 1966* (NSW) and *Poisons and Therapeutic Goods Regulation 2008* (NSW) and is responsible for issuing the authority to approved prescribers to treat individual patients with methadone or buprenorphine.

Prescribers should be aware that Clause 79 of the *Poisons and Therapeutic Goods Regulation 2008* (NSW) states that it is offence to prescribe a drug of addiction 'in a quantity or for a purpose that does not accord with the recognised therapeutic standard of what is appropriate in the circumstances'.

It is also an offence to prescribe an S8 drug to a drug dependent person without an authority issued under Section 29 of the PTG Act.

3.2.5 The Drug Misuse and Trafficking Act

The *Drug Misuse and Trafficking Act 1985* (the DMTA) includes a number of provisions that health professionals working in opioid agonist treatment and patients receiving methadone or buprenorphine on the OTP should be made aware of. The DMTA prohibits the manufacture, supply, possession and use of certain drugs. All prescription drugs of addiction listed in [S8 of the NSW Poisons List](#) are prohibited drugs under the DMTA. This includes methadone, buprenorphine, oxycodone, morphine, pethidine, hydromorphone, fentanyl and alprazolam.

The DMTA has relevance for patients undergoing OAT. It creates a number of summary offences:

- To forge or fraudulently alter a prescription;
- To fraudulently obtain a prescription for a prohibited drug;
- To induce a pharmacist to dispense such a prescription;
- To be in possession of such a prescription;
- To make any false representation to obtain or attempt to obtain a prohibited drug from a medical or nurse practitioner (e.g. To use a false identity or to forge documentation such as specialist letters or referrals);

- To obtain a prohibited drug from a medical or nurse practitioner without previously informing the practitioner of the quantity of that or any other prohibited drug for which prescriptions have been obtained within the preceding two months.

This last offence deals with, amongst other things, ‘prescription shopping’. When seeking a prescription for an S8 drug, a patient has a positive obligation to inform the prescriber of the quantity of any S8 drug that has been prescribed by another medical or nurse practitioner in the previous 2 months. This last offence also obliges a patient receiving methadone or buprenorphine under the OTP to disclose their quantity in the previous 2 months to another medical or nurse practitioner prior to oxycodone or morphine (or any other S8 drug) being prescribed.

The DMTA also makes it an indictable offence (i.e. a more serious offence) to supply, or knowingly take part in the supply, of a prohibited drug except in specified circumstances, including if licensed or authorised to do so under the *Poisons and Therapeutic Goods Act 1966*. For example, a patient diverting or ‘on-supplying’ methadone or buprenorphine (including a patient selling dispensed takeaway doses) is, therefore, committing an indictable offence under the DMTA.

3.2.6 Professional and workforce development

Clinicians working within the OTP should participate in ongoing professional development relevant to OAT and related health conditions (e.g. pain, hepatitis, mental health comorbidity). Education should also include effective communication and cultural sensitivity (S).

All sectors of the clinical and administrative workforce involved in the provision of OTP services should access professional development and training on the issue of stigma and discrimination for people who take drugs.

An online training resource entitled **Stigma, Discrimination and Injecting Drug Use** is available for the use by the NSW Health workforce through the Health Education and Training Institute (HETI).

3.3 Child protection

Child protection should be an ongoing consideration for clinicians and health workers involved in providing OAT to adult patients who are parents/carers or pregnant. Health workers working with adults who are expectant parents or have children in their care, and whose parenting capacity may be in question, should ensure that appropriate supports are in place for the whole family.

Evidence shows that people with drug and/or alcohol problems who have children in their care are at higher risk of neglecting or abusing their children. In a review of familial abuse-related deaths in NSW between 2004 and 2013, the NSW Ombudsman found that over half of the persons of interest had a documented history of substance use problems.

NSW Health policy directive PD2013_007 *Child Wellbeing and Child Protection Policies and Procedures for NSW Health* outlines the roles and responsibilities of NSW Health workers and provides tools and guidance for health workers in meeting their responsibilities under the *Children and Young Persons (Care and Protection) Act 1998*.

3.3.1 Recognising abuse and neglect

In the course of their work, health workers may see or hear something about a child, young person or adult patient that raises concerns about the suspected abuse or neglect of a child or young person. When considering whether a child or young person is at risk, health workers should consider contextual factors, such as the age and vulnerability of the child or young person, and whether issues affecting a parent/carer, such as problematic drug or alcohol use, are having a negative impact on their ability to provide a safe and nurturing environment.

The NSW [Mandatory Reporter Guide](#) can support health workers in making a decision about reporting safety, welfare and wellbeing concerns for a child or young person. Health workers can also contact the NSW Health Child Wellbeing Unit (CWU) if they have concerns about a child or young person.

NSW Health Child Wellbeing Unit (CWU) operates from 8:30am to 5pm Monday to Friday
Call **1300 480 420** (After hours leave a message)
Report Imminent Risk of Significant Harm to the Child Protection Helpline
Call **133 627**

3.3.2 Defining abuse and neglect

Abuse

There are different types of abuse:

- Physical abuse is a non-accidental injury or pattern of injuries to a child or young person caused by a parent, caregiver or any other person.
- Sexual abuse occurs when someone involves a child or young person in a sexual activity by using their power over them or taking advantage of their trust.
- Emotional abuse can occur if the behaviour of their parent or caregiver damages the confidence and self-esteem of the child or young person, which often results in serious emotional disturbance or psychological trauma.
- Domestic or family violence is any abusive behavior used by a person in a relationship to gain and maintain control over their partner or ex-partner. It can include a broad range of behaviour that causes fear and physical and/or psychological harm. If a child or young person is living in a household where there have been incidents of domestic violence, then they may be at risk of serious physical and/or psychological harm.

Neglect

Neglect is defined as continued failure by a parent or caregiver to provide a child with the basic things needed for his or her proper growth and development, such as food, clothing, shelter, medical and dental care and adequate supervision.

3.3.3 Concerns regarding a pregnant woman

When health workers consider that an unborn child may be at 'risk of significant harm' after birth, they should report their concerns to NSW Health Child Wellbeing Unit. Prenatal reporting can secure early support intervention for the pregnant woman, and reduce the likelihood that her newborn child will be placed in out-of-home care. The fact that a pregnant woman is receiving OAT is not sufficient reason in itself for a report to be made to Family and Community Services.

Best practice advice regarding the management of drug use during pregnancy, birth and early developmental years of the newborn can be found in [GL2014_022 Guidelines for the Management of Substance Use During Pregnancy Birth and the Postnatal Period](#).

3.3.4 Concerns regarding newborns

Opioid treatment providers (prescribers or dispensers) should work closely with other services involved in the care of the new mother to secure the best possible outcomes for her newborn child.

Health workers should consult the NSW Health Child Wellbeing Unit (details above) to determine what initial action should be taken to protect newborns in response to identified risks. This includes where the newborn child is likely to be exposed upon discharge from the maternity unit to abuse, neglect or domestic and family violence.

Table 38. Authorisation processes and contacts

Authorisation regulation	Contact
A prescriber must obtain authority for each patient by completing an Application for authority to prescribe methadone/buprenorphine form and faxing it to PRU at the NSW Ministry of Health.	Fax (02) 9424 5885
A patient must not begin methadone or buprenorphine treatment until approval has been given by PRU. (Note that an authority from PRU is not required to prescribe a drug of addiction to a person who is admitted to a hospital as an inpatient, unless the inpatient stay exceeds 14 consecutive days).	Approval may be checked by calling (02) 94245921
Prescribing a methadone dose above 200 mg or a daily buprenorphine buprenorphine-naloxone dose above 32 mg requires a separate approval from the PCS/PRU.	
Patients must be formally exited from treatment by the prescriber completing and submitting to PRU the Exit from Methadone and Buprenorphine Treatment form for each patient discharged from treatment or each patient transferred from the care of one prescriber to another.	
A medical practitioner or nurse practitioner must only prescribe a drug of addiction in accordance with Section 28 of the <i>Poisons and Therapeutic Goods Act 1966</i> . Specifically for patients who are drug dependent, authority is required prior to prescribing any schedule 8 drug of addiction.	Section 28 PTG

3.3.5 Consumption of methadone or buprenorphine by a child

Methadone and buprenorphine takeaway doses may be inadvertently taken or ingested by a child or deliberately administered to them by a patient or other person.

Ingestion of methadone or buprenorphine can be dangerous for children and can result in a potential life-threatening situation. Even the smallest amount can be fatal. Buprenorphine, while safer in adults, can pose a significant risk to children if consumed.

If a suspected opioid child poisoning occurs, it may warrant the NSW Ministry of Health to investigate the poisoning, the prescriber and their prescribing practices.

When presented with a suspected opioid ingestion by a child:

- Assess the level of consciousness and monitor this continuously until the child is in the care of an ambulance or qualified staff;
- Refer the child to a hospital emergency department without delay, providing the information available about the amount taken and the time;
- Administer oxygen if available;
- Consider naloxone administration if the child is showing signs of respiratory depression (document any treatment given);
- Notify the prescriber, the Pharmaceutical Regulatory Unit (PRU) and the Centre for Population Health (CPH) of the incident;
- Cease takeaways for the parent/guardian/patient immediately;
- If a child has ingested methadone or buprenorphine by any means, the child is at risk of harm and the authorities should be notified immediately;
- A report should be made to the Family and Community Services Child Protection Helpline: 133 627;
- The treating medical officer should discuss concerns for the child and next steps with the Health CWU and/or the hospital social worker (if available) prior to discharge.
- Police may be involved in exceptional circumstances.

Emergency departments

Under section 3.1.3 of the [NSW Health Incident Management Policy](#), when methadone or buprenorphine is associated with or potentially associated with a child's presentation or admission to hospital, a mandatory notification via a Reportable Incident Brief to the Ministry of Health is required, regardless of the Severity Assessment Code score.

3.3.6 Child protection checklist for opioid treatment providers

- Determine whether the adult patient is a parent or carer.
- Consider the impact that drug and alcohol use may be having on the safety, welfare and wellbeing of all children and young people concerned.
- Assess the level of risk to a child, young person or unborn child. Contact the CWU or report imminent risk of significant harm to the Child Protection Helpline on 133 627.
- Discuss your concerns with the adult patient so that they understand why you may need to talk with others and initiate referrals to other services (i.e. Whole Family Teams).
- Monitor risk and escalate concerns to senior managers/clinicians.
- Consider opportunities to share information and collaborate with other health professionals or support services to ensure the safety and wellbeing of a child or young person. For information regarding information exchange under Chapter 16A, refer to section 6 of PD2013_007 [Child Wellbeing and Child Protection Policies and Procedures for NSW Health](#).
- Consider opportunities to coordinate delivery of health services to parents/carers with complex needs. The CWU can assist health workers in planning and determining next steps.

Table 39. Key resources

Key resources	About	Contact
Mandatory Reporter Guide	Guides decision-making about whether or not a report to the Child Protection Helpline is appropriate applying the risk of significant harm (ROSH) reporting threshold.	https://reporter.childstory.nsw.gov.au/s/mrg
Child Protection Helpline	Report a child or young person suspected to be at imminent risk of significant harm.	Telephone: 133 627 (24 hours/7 days) http://www.community.nsw.gov.au/preventing-child-abuse-and-neglect/protecting-children
	For all other matters where the Mandatory Reporter Guide recommends 'Report to Community Services' an e-report can be made.	Register for first user access through the DoCS Connect portal: http://www.community.nsw.gov.au/welcome_to_docs_website.html Fax: 02 9633 7666 only if e-reporting is unavailable and after attempting a phone call and leaving a message advising that a faxed report will be made.
NSW Health Child Wellbeing Unit (CWU)	Telephone for advice, support and assistance in determining the level of risk of harm and in responding to the needs of vulnerable children, young people, pregnant women and families.	Telephone 1300 480 420 8:30 am–5.30 pm Monday to Friday, excluding public holidays. After hours please leave a message or use the After Hours Contact Form to provide some specific information about your concerns for a child or young person. The CWU will always respond on the next business day, using the contact details you provide.

3.4 Specialised settings

3.4.1 Correctional settings

Any patient on OAT who is in the correctional setting is managed by the Justice Health and Forensic Mental Health Network (JH&FMHN) Drug and Alcohol Services. A general principle of health care provision in correctional settings is that patients should have access to treatment as is available in community settings. This means that:

- Patients who are on an OAT program when they enter prison or a juvenile detention centre will have their treatment continued unless clinically contraindicated.
- Other people who are opioid dependent may begin OAT while in a correctional setting. The indications for treatment are generally the same as in the community setting, with recognition that prisoners may not have the same degree of regular opioid use and/or tolerance while in custody. More cautious dose induction procedures should usually be followed in comparison to those describing [induction in a community setting](#).

Transfer of care from community to custodial setting

Continuing a patient's OAT treatment following incarceration requires coordination between JH&FMHN services and community-based health providers.

OAT while in custody

Under Clause 83(2) of the *Poisons and Therapeutic Goods Regulation 2008* (NSW), an accredited medical practitioner or nurse practitioner may continue the treatment of a patient with methadone or buprenorphine if the patient was receiving that treatment immediately before the patient was taken into custody and another prescriber held an authority to prescribe to the patient under the Regulation. Wherever possible, patients should be included in decision making regarding their choice of OAT medicine and dose.

There may be circumstances when a JH&FMHN prescriber recommends substantial changes in the treatment plan compared to the community treatment plan, such as changes in medicine type (e.g. from buprenorphine to methadone) or exceeding maximum dose, based upon clinical findings identified during custody

(e.g. on reception into custody patients may disclose hazardous use of other substances that were not known to community treating team).

Changes of drug or exceeding maximum dose will require a new application for authority to the PRU.

Authority to prescribe from PRU

In general, community prescribers do not need to terminate their existing authority to prescribe methadone or buprenorphine with PRU for incarcerated patients to continue treatment. As the majority of incarcerated OAT patients serve short custodial sentences, there is often no need to disrupt the continuity of the community prescriber upon release from custody by terminating his/her authority.

However, there may be circumstances that warrant a transfer of authority to prescribe from community to JH&FMHN providers, such as:

- Relocation of community treatment upon release;
- Significant changes in the proposed treatment plan;
- Incarceration periods of more than 3 months;
- Significant patient complexity that warrants transfer to a specialist OTP service.

Community providers wanting to find out more information about the details of a patient's incarceration (e.g. likely duration or sentence) can contact JH&FMHN Drug and Alcohol Discharge Planning service on **9700 2101** or via email at dischargeplanning@justicehealth.nsw.gov.au

Coordinating transfer of care from community to custodial settings upon incarceration

JH&FMHN will notify PRU of details of the patient and incarceration date, and will continue to provide care during the period of incarceration. PRU will confirm details of community OAT providers to JH&FMHN. JH&FMHN Drug and Alcohol Services will contact the patient's dosing site (clinic or pharmacy) to confirm last dosing details and obtain patient's identification.

The community based dosing staff (clinic or pharmacy) are responsible for providing patient's ID and last dosing details in writing to JH&FMHN and for notifying the existing community prescriber (or OAT treatment team) of the patient's incarceration.

The community prescriber (or OAT treatment team) should facilitate clinical handover with the custodial treatment teams. This should include a summary of any relevant substance use, OAT details, medical or psychiatric conditions, or other psychosocial issues that may impact upon the patient's care whilst being managed by JH&FMHN Drug and Alcohol Services.

Clinical handover documentation should be emailed to: dischargeplanning@justicehealth.nsw.gov.au or faxed to 9700 3605.

The JH&FMHN Drug and Alcohol Central Office can be contacted on: (02) 97002101 for clarification or further information.

Transfer of care from custodial to community settings

The transition from custody to the community involves risks that the patient may discontinue OAT, and/or resume non-medical opioid or other drug use. The immediate period of return to the community following custody is associated with a high risk of overdose and death – particularly where OAT is unavailable upon release.

Following release from the correctional setting, patients should have priority access to a period of dosing for at least the duration of the JH&FMHN prescription at a public OAT program in the geographic area in which they are going to reside post-release, regardless of where they started on the OTP.

Many patients released from custody have complex substance use, medical, psychiatric or social issues (e.g. homelessness, domestic violence, child protection issues) and may benefit from continued treatment in a multidisciplinary specialist OTP clinic (subject to availability of treatment places) for an extended period of time beyond the JH&FMHN prescription.

Other patients will be suited to a community based (e.g. GP, community pharmacy) or private clinic provider. This is to be negotiated by the JH&FMHN medical team, the patient and community providers, including the Connections Clinical Support Workers where relevant.

Refer to **Dosing Places - Availability for Released Inmates on Substitution Pharmacotherapies**

Table 40. Strategies to ensure continuity of OAT

Strategy	Action
Coordinating transfer of care from custody to community settings	<p>High-risk sentenced patients on OAT with planned releases are eligible to access the Connections Project where a comprehensive post-release support plan is developed collaboratively between the JH&FMHN treatment team, the patient, community OAT providers and other service providers (e.g. mental health, housing) prior to release.</p> <p>These plans are formulated by the Clinical Support Workers and address health, family, social and financial needs and the patients are supported for the first 4 weeks post release.</p> <p>The JH&FMHN state-wide Drug and Alcohol Discharge Planning Service will, where possible, negotiate with the relevant community-based treatment program before releasing a patient on methadone or buprenorphine maintenance. Because of the way that the court system operates, in some instances a patient may be released directly from court without JH&FMHN staff being informed. This will result in an ‘unexpected release’, which will mean that no transfer of care has been prearranged.</p> <p>In these instances the community based provider should contact the JH&FMHN Drug and Alcohol Central office on: Telephone (02) 9700 2101 or via email address: dischargeplanning@justicehealth.nsw.gov.au, or via central fax number (02) 9700 3605 so that appropriate arrangements can be made for these patients.</p> <p>There should be appropriate clinical handover when transferring care from custodial to community based providers. This should include details of the patient and current OAT details, current health or social issues, and any risk factors that the community providers should be aware.</p>
Ensuring continuity of dosing	<p>After release from the correctional setting, patients should have priority access to a period of public dosing at a public OTP service to which they are released regardless of where they started their OAT (in a correctional centre or in the wider community, or whether they had a public or private point of entry to methadone or buprenorphine treatment).</p> <p>At a minimum, this should cover the period of the valid prescription written by the JH&FMHN prescriber (3 weeks if patient is already in treatment when they entered custody; 4 weeks if patient started treatment after entering custody). Community based dosing sites (e.g. pharmacies) may be used where OTP Clinics are unavailable.</p> <p>JH&FMHN prescribers can provide prescriptions on behalf of the authorised community prescriber for Drug Court patients who move in and out of prison due to sanctions.</p>
Ensuring continuity of OAT in the community	<p>It is essential that a patient’s OAT continues beyond the ‘bridging’ JH&FMHN prescription</p> <p>The location of community OAT is to be negotiated between the patient and community providers. In general:</p> <ul style="list-style-type: none"> • If the patient is returning to the same prescriber post-release and the community prescriber had not exited the patient from their program (using PRU Exit form), the community prescriber must: <ul style="list-style-type: none"> - contact the JH&FMHN Drug and Alcohol Central office on (02) 9700 2101 to confirm that the patient was not transferred to another community provider. This is to prevent the risk of double dosing (where the patient is dosed upon the JH&FMHN prescription at one site, and initiated on a second prescription by the community prescriber at another dosing site). • If the patient is transferring to a new community prescriber, the community prescriber must apply for an authority permit from PRU prior to the community based prescriber taking over prescribing. This may require the community provider to notify the previous prescriber to submit a PRU Exit Form, as advised by PRU.

Justice Health & Forensic Mental Health Network (JH&FMHN) OAT Prescriptions in the Community

JH&FMHN prescribers can only issue an OAT prescription that is valid for up to 3 weeks if patient is already in treatment when they entered custody as per legislative requirements; and up to 4 weeks if the patient started treatment after entering custody.

If a patient becomes clinically unstable after release and is still on a JH&FMHN prescription, then the community-based service provider should arrange transfer of care so that the treatment plan can be altered according to the clinical indications. A prescription can only be altered by the prescriber who has issued it.

3.4.2 Hospital settings

Managing inpatients

If a person who is opioid dependent is admitted to public or private hospital, prescribing methadone, buprenorphine or other opioid drugs may need to be considered, either as continuation of an OTP, as treatment of opioid withdrawal, or for pain relief.

Legal restrictions on prescribing drugs of addiction in hospital

Under the provisions of Section 28 of the *Poisons and Therapeutic Goods Act 1966* (NSW), a medical or nurse practitioner may not prescribe any drug included in [S8 of the Poisons List](#) for a person who in his/her opinion is a drug-dependent person without the approval of the PRU of NSW Health.

An exemption from this requirement is provided for inpatients of public hospitals and private health facilities, who may be prescribed an S8 for up to 14 days, even when the patient is known or suspected to be drug-dependent. This does not include the provision of take-home medicines upon discharge from hospital. See also http://www1.health.nsw.gov.au/pds/ActivePDSDocuments/PD2013_043.pdf

Treatment of an inpatient admitted on methadone or buprenorphine treatment

In general, methadone or buprenorphine treatment should continue in hospital. Discontinuation of OAT can result in significant opioid withdrawal discomfort, complicate analgesia and other medical or mental health conditions, and contribute to non-medical drug use or behavioural disturbances. OAT should not be withheld or withdrawal attempted without the specific consent of the patient.

The hospital/private health facility medical officer can take over prescribing the patient's OAT for up to 14 days for an inpatient without the authority from the community prescriber being transferred. Long-stay hospital inpatients should be discussed with the community prescriber and arrangements made with the PRU of NSW Health.

In the event of emergency department or non-admitted hospital attendance, it must be understood that a missed or delayed dose is not a medical emergency. It is generally not appropriate to prescribe methadone or buprenorphine in the emergency department, due to the potential for multiple dosing.

On admitting the patient, the admitting team should:

- Verify the patient's identity.
- Identify the authorised prescriber and the patient's dosing location (either through the patient, carers or by contacting the PRU of NSW Health on 02 9424 5921 during business hours).
- Contact the patient's dosing location to confirm the current prescribed dose, the date and time of the last dose, and whether the patient has been given any takeaway doses. The dosing information must be established prior to administering the first dose of OAT in hospital in order to avoid 'double dosing' and the risk of overdose. Written confirmation (e.g. facsimile of prescription and last dose) is ideal.
- Provided that no medical contraindication to the administration of an opioid exists, administer methadone or buprenorphine according to the dosage regimen of the patient's prescriber.
- Consult with the community prescriber regarding the patient's opioid treatment and relevant clinical history, and coordinate transfer of care back into the community. Advising the patient's prescriber of the approximate length of stay in hospital will prevent the patient being removed from the OTP through non-attendance.
- When a patient is discharged, inform the prescriber and the dosing location in advance to ensure that appropriate arrangements are made for the patient to continue methadone or buprenorphine treatment without interruption. Confirm the current dose and last dose given as an inpatient.
- Provide a discharge summary to the prescriber.

Where specialist drug and alcohol advice is required regarding OAT in hospital, or its implications for the admission, hospital staff can contact local [Hospital Drug and Alcohol Consultation Liaison Services](#), local drug and alcohol services, or [Drug and Alcohol Specialist Advisory Service \(DASAS\)](#).

Unable to verify community OAT on admission to hospital

If the patient is unable to provide the name of the prescriber and/or dosing location and contact cannot be made with the PRU (after hours, weekends, public holidays), specialist drug and alcohol services (e.g. [Hospital Drug and Alcohol Consultation Liaison Services](#), local drug and alcohol services, addiction medicine specialists or [DASAS](#)) should be consulted for an opinion on the advisability of methadone or buprenorphine treatment.

The decision to initiate methadone or buprenorphine treatment will depend upon multiple factors, including clinical condition of the patient, evidence of intoxication or withdrawal, and details of current OAT (type of medicine, dose, when last used). If the patient shows features of severe opioid withdrawal and neither the authorised prescriber nor the administration point can be contacted, the patient may be administered a small dose of methadone (e.g. 20 to 30 mg orally) or buprenorphine-naloxone (e.g. 4 or 8 mg sublingually), sufficient to alleviate significant opioid withdrawal, until such time as contact can be made with the regular prescriber or dosing location, or with specialist drug and alcohol services. Patients should be subsequently monitored for evidence of intoxication or withdrawal.

Patients with takeaway doses who are admitted to hospital

Patients who have takeaway doses for the days they are in hospital should be requested to hand the takeaway doses to the ward staff in accordance with the local hospital policy for patient's own medicines. The methadone or buprenorphine administered in hospital must be dispensed through the hospital pharmacy.

Takeaway doses must be stored by the hospital or removed from the hospital.

Patients who refuse or are unable to supply takeaway doses should be reviewed before deciding on the appropriate course of action. This may include not being given methadone or buprenorphine from hospital supplies, being given a reduced dose or full dose. Patients must not leave takeaway doses

in an unsafe or insecure place (e.g. their locker), as methadone and buprenorphine are S8 drugs and must be stored accordingly.

Responsibilities of the community OAT providers during hospital admission

Community-based prescribers and dosing staff should ensure appropriate clinical handover and continuity of care to and from hospital providers. This includes information regarding the patient's opioid treatment, relevant clinical history, and advice regarding the inpatient management of OAT (e.g. significance of any dose changes, analgesic requirements). When a prescriber is contacted regarding treatment, he/she must ensure that the dosing location has been notified.

The senior registered nurse or pharmacist at the dosing location should document that the patient has become an inpatient and is being dosed elsewhere.

To avoid double dosing, he/she should confirm that the patient has been discharged and confirm the date on which the patient last received a dose before recommencing dosing.

Treating opioid dependent hospital inpatients not currently in OAT

Opioid dependent people who are not in OAT may experience withdrawal during a hospital admission, which in turn can complicate analgesia and other medical or mental health conditions, and contribute to non-medical drug use or behavioural disturbances. Adequate treatment of opioid dependence in hospital minimises patient discomfort and simplifies patient management.

The admitting team should organise a comprehensive drug and alcohol assessment prior to initiating treatment, discuss treatment options, and obtain informed consent prior to embarking upon treatment options. Specialist drug and alcohol services should be contacted to assist in the assessment and treatment planning of such patients.

Options for the treatment of opioid dependence during hospital include:

- Short-term use of methadone or buprenorphine to manage opioid withdrawal whilst an inpatient, without continuation of OAT in the community.
 - This involves induction onto methadone or buprenorphine upon admission, and a rapid titrated reduction prior to discharge to the community.

- Most patients will experience withdrawal discomfort as the methadone or buprenorphine dose is reduced, and many will relapse to non-medical opioid use on return to the community. As such, longer-term OAT should generally be recommended.
- Initiation and stabilisation onto methadone or buprenorphine, with a view to continuation of OAT upon discharge to the community.
 - This requires identification and coordination of a suitable community based OAT provider before transfer to the community.
 - Hospital Drug and Alcohol Consultation Liaison Services can assist in coordinating transfer to the community.
- Use of symptomatic medicines for the management of opioid withdrawal.
 - Where methadone or buprenorphine is contraindicated, or where the patient does not consent to treatment with methadone or buprenorphine, [symptomatic withdrawal medicines](#) can be used.
- Where methadone or buprenorphine is being commenced, the hospital medical officer should liaise with appropriate drug and alcohol services or with an experienced OAT prescriber. As an inpatient,
 - [methadone can usually be safely initiated](#) at 10–20 mg twice daily (oral liquid) and gradually increased over subsequent days as necessary until the patient’s condition is stabilised.
 - [buprenorphine can usually be safely initiated](#) at 4 mg twice daily (sublingually) and gradually increased over subsequent days as necessary until the patient’s condition is stabilised.

Coordinating OAT and other S8 medicines for patients upon discharge to the community

Hospital medical officers can prescribe S8 drugs for inpatients in public hospitals or private health facilities for up to 14 days without PRU authority, however, hospital/facility medical practitioners require [appropriate authority from PRU](#) to prescribe any S8 medicines (including analgesic opioids) as discharge medicines for use in the community.

Application to PRU will need to be submitted well in advance of discharge and will generally require specialist support (pain management specialist and/or addiction medicine specialist) for the proposed regime. The need for analgesia and S8 medicines in the community should be discussed

with the community OAT providers and other primary care providers, and appropriate arrangements made prior to hospital discharge.

For more information see [NSW Health Pharmaceutical Services](#).

If the patient has been an inpatient for more than 14 days, the hospital/private health facility prescriber, in consultation with the community prescriber, may elect to apply for the authority.

- The hospital prescriber applying to take over should be an accredited OTP prescriber or a staff specialist from the drug and alcohol team
- This will require the permission of the current prescriber who must complete an exit form and return this to the PRU as soon as possible (OTP Application and exit forms are available from the PRU website)
- Prior to discharge of the patient the hospital prescriber and the drug and alcohol team are responsible for facilitating a seamless transfer of care to an accredited OTP prescriber and dosing point in the community.

Please note there is NO requirement in any of the above circumstances for a community prescriber to supply a prescription to the hospital. A direction on an inpatient chart satisfies the legal requirements for administration of methadone or buprenorphine in a hospital.

3.4.3 Patient information and perspective

The participation of an informed patient in the clinical decision-making process is essential in the treatment of all opioid dependence. It is particularly important when incorporating opioid medicines – such as methadone or buprenorphine – as part of the treatment plan.

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.

The following principles should apply:

- The free and informed consent of each patient to undertake treatment should be obtained in writing before treatment begins.
- Full disclosure of patient rights and responsibilities should occur at the commencement of treatment, but presentation of this information should not be a deterrent to treatment.

Patients should be given information on all aspects of treatment, including the costs of treatment,

frequency of appointments, and availability of support services prior to giving consent.

Table 41. Patient needs

Aspect of treatment	Need
Data security	There should be procedures in place for protecting patients' personal information.
Complaints and issues	There should be a formal mechanism, established at the local/clinic level, for resolving grievances between patients and those responsible for their treatment. Patients should have the right of access to these procedures and be informed of them at the commencement of treatment and on request thereafter.
Communication and education	Written information should be provided to each patient in a form that the patient can take away. Patients who cannot read should be read their rights and obligations at the time they enter the program. A competent interpreter should be used for patients who are not fluent in English, and where possible, information should be available in other languages. Such information should cover: <ul style="list-style-type: none"> • an overview of policies and procedures of the treatment program; • the cost of treatment, and possible arrangements to prevent cost becoming a barrier to participation in treatment; • the nature of the treatment; • any potential hazards and problems such as risks of overdose; • risks associated with ceasing treatment; • information about other relevant health issues (e.g. pregnancy and breast feeding, HIV, hepatitis C); • information about safe procedures for storing pharmacotherapies, particularly out of reach of children; • alternative treatment options; • confidentiality of treatment records.

Clinic confidentiality and consent

People whose mental state impairs their capacity to provide informed consent (e.g. those with an acute psychotic illness, cognitive impairment or a severe adjustment disorder) should receive adequate treatment for the psychiatric condition so that informed consent can be obtained before initiation of opioid agonist treatment.

The prescriber and dispenser and other members of the therapeutic team have a duty of care to the patient that may necessitate sharing of information but this needs to be balanced with patient rights to maintain confidentiality. Other clinicians who may see the patient should be informed of current treatment. The patient should ideally be seen on each occasion by the prescribing medical or nurse practitioner, or an informed colleague.

Occasionally, clinicians will need to communicate with pharmacists and other healthcare providers about the drug treatment of a particular patient (e.g. to verify a prescription). This requires clinicians who provide opioid agonist treatment to obtain

signed patient consent before disclosing individually identifiable treatment information to any third party (a patient's request not to share their information with other medical or nurse practitioners will be complied with wherever possible). It is particularly important to obtain patient consent. Clinicians should be aware of jurisdictional requirements concerning privacy and confidentiality, and safeguards regarding access with electronic prescribing.

OTP dosing options

The dosing hours for both public and private clinics are restricted and this is why the option of community pharmacy dosing offers more flexibility around dosing hours. Patients should consider this when making a decision about which clinic or GP to consult. Community pharmacy dosing can be an advantage in terms of mainstreaming healthcare for opioid dependent patients.

The majority of patients on the OTP in NSW make some form of regular payment for their daily dose. While treatment in a public clinic is free, once a patient has moved to a community pharmacy, dosing incurs a charge. This is to cover the time pharmacists spend on dispensing and the cost of e.g. takeaway bottles, labels, dosing cups. Some private clinics offer a weekly package deal where you pay less if you can afford to pay up front. Some pharmacies will also offer these deals however patients should remember that some dosing points will refuse to dose if no payment is made.

Patients should be advised that it is not always possible to be dosed on the day they present for treatment. The Ministry of Health requires that each patient receives an explicit authorisation in order to enter treatment. In some cases, this means that there may be a lag until their first dose. Patients should also be advised that during the first few weeks on treatment, appointments will be more frequent than they will be later in treatment.

Complaints

Each clinic should have a written description of the complaint mechanisms available at the local level. Should a resolution not be found using the local level procedure patients are able to approach the Opioid Treatment Line – 1800 642 428 for further advice.

Additionally, the [Health Care Complaints Commission](#) is an independent body that acts to protect public health and safety by dealing with complaints about health service providers in NSW.

The patient perspective

A strong therapeutic alliance is essential so that patients feel able to ask questions and to engage in their own treatment plan. In many instances, the anxiety patients' experience in the first few consultations may reduce their capacity to take in all of the relevant information, so it is important that essential information is emphasised. It may need to be repeated on several occasions.

There is a lot of information for patients to absorb in the initial phase of treatment. Nevertheless, it is important that specific safety concerns are highlighted and understood by patients and carers. In particular, signs and symptoms of overdose need to be emphasised regularly during induction to treatment (the first 7 days), and for patients and carers to understand how to respond to any such concerns.

During treatment, patients are assessed for suitability for takeaway doses. Patients should expect the rules for takeaway doses to be explained in detail, in particular the time points at

which access to more frequent takeaway doses can be assessed and the criteria used to assess suitability. Patients should be informed that appropriate use, including the safe storage of their takeaway doses, is an important criterion for ongoing access to further takeaways.

Urine drug screening is a controversial issue for many patients and the requirements in place at each clinic and dosing point must be clear and, in general, performed on a random basis to avoid a perception that an individual is being punished.

Support for consumers

Consumer engagement, advocacy and participation in the delivery of services are important dimensions in the provision of quality healthcare. An increasing feature of OTP services is the availability of consumer representatives and workers within services to support patients at an individual level (e.g. in accessing services, in working with health providers, in addressing complaints or grievances), and in representing consumer issues within the organisation's governance pathways (such as assisting in the development, implementation and evaluation of policies and procedures, service profiles, staff attitudes and approaches to working with consumers). See also http://www1.health.nsw.gov.au/pds/ActivePDSDocuments/GL2015_006.pdf

The [Opioid Treatment Line \(OTL\)](#) is a telephone helpline that provides opioid pharmacotherapy information, referrals, advice and a forum for pharmacotherapy concerns. Hours of operation: Monday to Friday, 9.30am to 5.00pm; Free call number: 1800 642 428.

A number of consumer based organisations can also provide support for patients engaged in opioid treatment, including support groups relevant to particular health conditions. These include:

- The [NSW Users and AIDS Association \(NUAA\)](#) is a not-for-profit NSW-based organisation advocating for people who use drugs, particularly those who inject drugs. The peak drug user organisation in NSW, NUAA was formed in 1989 in the face of a growing HIV epidemic. A group of people who use(d) drugs, their friends, families and supporters established NUAA as an independent, user-driven community-based organisation. Funded primarily by the NSW Ministry of Health, NUAA provides education, practical support, information and advocacy for users of illicit drugs and their friends. Most of NUAA's work is related to prevention of blood-borne viral

infections like HIV and hepatitis C. Staff can provide assistance in finding a treatment provider and support in managing a complaint. NUAA can be contacted on 8354 7300 or toll free on 1800 644 413.

- Viral Hepatitis: Resources and support services for patients with Hepatitis C and other forms of viral hepatitis can be found at Hepatitis NSW (www.hep.org.au, telephone 1800 803 990)
- Chronic Pain. Resources and support services for patients with chronic pain and carers can be found at the NSW Agency for Clinical Innovation (ACI) Pain Management Network, at www.aci.health.nsw.gov.au/chronic-pain.
- HIV. Resources and support services for patients with HIV and carers can be found at Positive Life NSW. Positive Life NSW works to promote a positive image of people living with and affected by HIV with the aim of eliminating prejudice, isolation, stigma and discrimination. They provide information and targeted referrals, and advocate to change systems and practices that discriminate against people with HIV, friends, family and carers in NSW. They can be contacted at www.positivelife.org.au, telephone 1800 245 677 (freecall).
- Mental Health. There are a number of support groups for patients (and carers) experiencing mental health problems. These can be accessed through sites such as www.beyondblue.org.au/ and www.blackdoginstitute.org.au/

Support for carers

Opioid dependence can have considerable impact upon family and other carers of patients in treatment. OTP service providers should ensure they have carer-friendly services, whilst respecting the privacy and confidentiality of patients. Specific support for carers for people with substance use problems can be found at:

Family Drug Support is a non-government and non-religious organisation primarily made up of volunteers who have experienced first-hand the trauma and chaos of having family members with drug dependency. They provide support for families and carers of people with drug dependence issues. They can be accessed at www.fds.org.au; or the 24 hour Support Line: 1300 368 186.

General information regarding support for carers with health conditions can be found at Carers NSW (www.carersnsw.org.au), which includes a directory of carer organisations. Carers may also be able to access support services through consumer organisations for other health conditions, identified in previous section (Support for Consumers).

3.4.4 Residential rehabilitation settings

Further to the release of the Drug and Alcohol Treatment Guidelines for Residential Settings (NSW Health, 2007) residential services have advanced in initiatives for individuals on methadone and buprenorphine maintenance programs. Stabilisation programs specific to complex needs individuals have been developed allowing them to remain on OAT during their length of stay in treatment addressing poly drug use, psychosocial issues, living skills, stabilisation of OAT along with mental and physical health needs.

Therapeutic community programs are now providing both stabilisation and withdrawal residential services offering the same structure as those services that have been historically abstinence based. These services can provide a longer stay in treatment giving more choice to the needs of the individual and clinical recommendations for their ongoing wellbeing. These services work closely with community prescribers and dispensing sites to ensure continuity of care.

Day programs have commenced in the community to support individuals receiving OAT and can offer aftercare options to those leaving residential treatment or alternatively those waiting to enter a residential setting or needing extra support whilst in the community. Prescribers, GPs and dispensing sites can make referrals for extra support for their OAT patients.

Aftercare and outreach services for individuals remaining on OAT to ensure supports are in place for the return to the community and for follow up.

For any advice on the ability to dispense OAT in a residential setting please contact the NSW Ministry of Health PRU via email pharmserv@doh.health.nsw.gov.au

3.5 Prescriber-related information

Intra/interstate & overseas transfer arrangements

The transfer of a patient's methadone or buprenorphine treatment within NSW, between states and overseas should be carried out by the prescriber (or his/her delegate). The necessary documentation for a transfer should be provided by the treating clinician and clinicians from the transfer destination.

The PRU does not require notification of temporary changes in administration point, but should be notified of overseas travel or transfers. For extended overseas stay (generally more than 30 days), prescribers should arrange for local dosing services at the destination.

Temporary transfers

Patients may require short term transfers of their dosing point for a range of reasons including: work, family commitments, holidays. Prescribers should assess any current risk factors for a patient prior to organising and commencing a temporary transfer. Patients who are at high risk may not always be suitable for takeaway doses while on temporary transfers. Liaison between the prescriber and pharmacist may be crucial during this period.

If overseas travel requires the patient to carry takeaway doses, the prescriber, as well as following the NSW policy regarding takeaway doses, must clarify with the consulates of the intended destinations their position on a foreigner entering the country in possession of methadone or buprenorphine. Methadone (Physeptone®) tablets, rather than methadone liquid, may be considered to avoid breakage or spillage.

The prescriber must comply with any special condition on the entry of a person possessing methadone or buprenorphine: providing a letter stating that the person is in possession of the drug to treat a medical condition in accordance with Australian laws is usually adequate.

If the destination requires a letter from the Australian Government this must be obtained from the TGA. Phone (02) 6270 4321. For more information, see the [TGA's leaving Australia](#) and [NSW Health OTP overseas travel](#).

During overseas travel, takeaway doses should be in their original packaging, with labelling. They should be carried in hand luggage and be declared at customs.

For information about travelling with methadone, see [Maintenance assistance point](#) (this site is for Europe and has a map) and [Travel Guide Index](#) (worldwide).

As with other S4 drugs, it is recommended that people using naltrexone obtain a letter from their prescriber to present to Customs. The letter should state that the drug is required for the treatment of a medical condition.

Prescriber availability

To support teamwork and maintain patient safety, prescribers should ensure that they are available to provide advice about their patients to the relevant dosing point within office hours (i.e. Mon - Fri, 8.30am – 5pm). This can be managed either by the prescriber providing their mobile phone number to the dosing point, or by allowing the dosing point to be given their number when dosing point staff contact their practice. Where possible, and at the prescriber's discretion, it is beneficial if this access can extend to weekends, so that, ideally, a dosing point can contact the prescriber whenever patients are being dosed. Many practices have an after-hours service that can link back to the prescriber.

It is recommended that prescribers do not give the patient their direct contact details, and that the pharmacy/dosing point also does not pass these details on to patients.

Locums

Prescribers who are going on leave and will not be available to their patients on methadone or buprenorphine must arrange for a locum prescriber, perform a handover and ensure that all scripts are up to date. A locum will ideally be experienced in the management of drug dependent patients. If possible, the locum should be an approved methadone and buprenorphine prescriber.

All locum arrangements should be notified to the Pharmaceutical Regulatory Unit (PRU). In the case of retirement or planned leave for more than 2 weeks, the PRU should be notified beforehand of the proposed arrangements, with all due notice given.

Notifications may be faxed to (02) 9424 5885 or emailed to: pharmserv@doh.health.nsw.gov.au

Locums should continue treatment according to the treatment plan, and the patient should be promptly reviewed by the authorised prescriber on their return to work. Changes to the patient treatment plan, such as prescribing benzodiazepines or increasing the frequency of regular takeaway doses, should not be initiated during short-term locum cover. Dose changes or prescription renewals should be written as short-term prescriptions valid only until the return of the authorised prescriber. Repeat locum prescriptions to cover brief periods of absence are not acceptable.

If an authorised prescriber is unavailable for more than 10 working days, the locum must accept responsibility for and be able to make all decisions relevant to patient care (including dose changes, provision of takeaway doses, management of concomitant conditions, dispensing point changes and transfers). Ideally the locum will be an authorised prescriber, and in this case the locum should ensure that he or she has not accepted responsibility for more than his or her authorised number of patients, or apply to the Pharmacotherapy Credentialing Subcommittee (PCS) for the necessary increase.

There will always be emergency situations. If there is no other practitioner in the practice who is authorised to prescribe pharmacotherapies for opioid dependence, it is appropriate for another GP who is in the practice and has access to the patient notes to write a prescription to cover the period during which the prescriber will be away, with no change in dose or takeaway doses. It is recommended that the duration of the prescription so written should not exceed 1 month.

Supernumerary places

In situations where transfer of care to another prescriber involves that prescriber in managing more than their authorised number of patients, the prescriber should apply to the PCS for the necessary increase.

Ceasing prescribing

It is important that when a prescriber decides to depart from their current OTP position, for whatever reason, their patients are transitioned smoothly to a new prescriber. The circumstances of such a situation can vary, for example:

- a planned process with due notice, such as retirement or pre-arranged resignation;
- a sudden unexpected event, such as a major health issue which precludes the prescriber from continuing work.

Retiring/resigning from prescribing (planned departures)

Prescribers intending to retire/depart from their current OTP position should write to the PRU indicating their proposed retirement date (the date on which they relinquish their authority to prescribe) and arrangements for the ongoing care of their patients. In most planned departures, a prescriber will be able to arrange the exit and transfer their OTP patients through PRU to another prescriber without the involvement of the Ministry's Drug and Alcohol Unit, or the local health district.

All doctors have overriding professional obligations for the continuity of care for all their patients, whether 'public' or 'private', on the OTP or as a general patient.⁴ Furthermore, the legal authority under the *Poisons and Therapeutic Goods* legislation remains with the prescriber until they exit the patient or transfer this authority by submitting an exit form to PRU, which they are required to do once they are no longer prescribing for the patient.

Where possible and with the patient's consent, information about the patient should be made available to the receiving prescriber or clinical service. If patient consent is not given, disclosing information to another person or organisation involved in the ongoing care of the patient is possible, provided appropriate attention to confidentiality of this information is maintained.

When a departing prescriber cannot find a replacement

In situations where a prescriber is unable to find a replacement prescriber for their OTP patients, the following action can be taken:

4 See Medical Board of Australia Code of Conduct, particularly 3.14, 4.3, 4.5 and 8.4.7.

It may be necessary for patients to be transferred in the interim to (an) existing public prescriber(s). The LHD/SHN's role includes assisting in the OTP to ensure that there are no gaps in service provision. The departing prescriber can work with the LHD/SHN, providing sufficient notice to allow a smooth transition and notifying all patients of transfer arrangements, both verbally and in writing.

- In general, the Drug and Alcohol Director and the OTP Public Clinic Manager are responsible for overseeing and coordinating OTP prescriber contingency plans at the local level.
 - An increase in the patient limit may be required for the interim prescriber, which the Secretary, NSW Health (or delegate) can approve when the circumstances are sufficiently urgent, under s28A (7) of the PTG Act.
- The departing prescriber should provide patient transfer details to PRU, which can arrange a bulk transfer of patients to avoid excessive paperwork.
 - The issue of resources for the additional urgent assessment, case planning and dosing for transferred patients may be addressed on a case by case basis between the LHD/SHN and the Ministry.
- Patients requiring an alternative prescriber are usually referred in the first instance to the public OTP clinic closest to their current dosing point.
 - The public clinic needs to be ready to support the patients when they present, particularly if there are a large number being transferred.
 - If capacity to assess and manage the patients becomes problematic, the possibility of having a visiting specialist assisting on a short-term basis to manage the transition can be considered.

Unplanned departures

When prescribers' departures are unplanned and they are no longer able to manage their patients, it is important that arrangements are put in place quickly to ensure continuity of treatment. In all but exceptional circumstances,⁵ the prescriber is expected to arrange the exit and transfer of their OTP patients through PRU to another prescriber.

If, because of exceptional circumstances, the departing prescriber is not able to arrange the transfer of their patients, it may be possible for the LHD/SHN to find a new prescriber through local connections, or by accessing such information from PRU. If only a small number of patients require transfer, the process can then proceed, with exit forms, patient information, etc. being dealt with by PRU according to the individual context.

If it is not possible to find a replacement private prescriber, patients may need to be transferred to (an) existing public prescriber(s), usually at the public OTP clinic closest to their current dosing point.

If a large number of patients require transfer, it may be necessary to develop a management plan, which can require the involvement of PRU, the public clinic, and/or the Alcohol and Other Drugs Branch, CPH. In exceptional circumstances, where patients are unaware of their prescriber's departure, PRU should provide the LHD/SHN with patients' dosing point contact details so that a standard letter can be sent to patients advising of the situation and any contingency arrangements. Verbal advice and a letter should also be provided to the pharmacy/dosing point to ensure consistent information is passed on to the patients.

The Alcohol and Other Drugs Branch, CPH can advise the Opioid Treatment Line (OTL) in advance that patients may contact OTL with concerns, or that patients may be seeking a replacement prescriber. The OTL can relay advice consistent with the LHD/SHN.

Writing prescriptions

Methadone and buprenorphine prescriptions must be written in accordance with the requirements for S8 prescriptions set down under [clause 80](#) of the *Poisons and Therapeutic Goods Regulation 2008* (NSW). See also:

<http://www.health.nsw.gov.au/pharmaceutical/Documents/drugsofdependence-controls.pdf>

<http://www.health.nsw.gov.au/pharmaceutical/Documents/prescriptions-nonhandwritten.pdf>

https://www1.health.nsw.gov.au/pds/ActivePDSDocuments/PD2013_043.pdf

5 Illness, death, or regulatory action (removal of authority, suspension)

3.6 The role of pharmacists in OAT

The majority of OAT is delivered in community pharmacies across NSW and other parts of Australia. Community pharmacy dosing is appropriate for:

- [Low-risk OAT patients](#) who do not require the high levels of supervision and monitoring provided by private or public OAT clinics, or where clinic dosing is unavailable (e.g. unable to geographically access clinics due to mobility or transport issues);
- OAT patients either already stabilised in treatment, or low-risk patients initiating OAT treatment in the pharmacy setting.

In NSW, the [Opioid Treatment Program's Community Pharmacy Dosing Point Protocol \(TG201/2\)](#) has been prepared for participating pharmacies to follow and compliance is mandatory.

Pharmacists play a key role in the provision of OAT, working collaboratively with prescribers and other OAT providers (e.g. case workers). Pharmacists are in regular contact with patients (often on a daily basis), and in many cases this contact is sustained for years, providing the opportunity for:

- The development of therapeutic relationship with the patient and carers,
- A contact point for patients to raise any concerns regarding their OAT (e.g. side effects, dose issues) or other health conditions;
- monitoring of patient's substance use, health and social issues over time;
- Communication of concerns regarding the patient to the prescriber/others in the treating team;
- Patient education regarding OAT and other medicines, and related health conditions;
- Coordination of health care in liaison with the prescriber and other health professionals as appropriate.

Discussion should occur between the prescriber and or clinic staff and pharmacists if there are significant changes in a patient's progress in treatment where observed in clinical or dosing settings.

3.6.1 Training and continuing professional development

Although accredited training for pharmacists in the delivery of OAT is not mandatory, individual pharmacists are encouraged to participate in training regarding OAT and relevant continuing professional development (CPD). CPD opportunities are available through PSA, the Pharmacy Guild of Australia, and local LHD-Primary Health networks. Training objectives should include:

- General requirements for setting up the pharmacy for the provision of OAT;
- Relevant clinical pharmacology of medicines used in OAT, including side effects and drug interactions;
- Procedures, protocol and guidelines regarding the safe and effective delivery of OAT, including assessing intoxication and withdrawal, supervised and takeaway dosing procedures;
- Setting up and maintaining relevant registers, records and patient profiles;
- Effective communication with patients, carers, prescribers and other health providers.

The Australian Pharmaceutical Formulary and Handbook (APF) is an essential reference text and should be accessed by pharmacists during the clinical assessment, reviewing, dispensing and counselling processes.

3.6.2 Starting up as a registered pharmacy to provide OAT

The regulatory framework for the dispensing of S8 drugs such as methadone and buprenorphine is the NSW *Poisons and Therapeutic Goods Act 1966*. To provide OAT services within NSW, a pharmacy must be registered with the PRU of NSW Health. The Duty Officer at the PRU provides applicant pharmacists with an information pack. See also [NSW Opioid Treatment Program \(OTP\) - Pharmacists](#)

On receipt of a signed undertaking of the pharmacist owner and staff to comply with legislative and policy regulations, arrangements are made for the pharmacotherapies to be made available to the applicant pharmacist (subsidised as S100 medicines by the Commonwealth Government).

The usual maximum number of patients in supervised OAT dosing (methadone and buprenorphine combined) at any one community pharmacy is 50 (note that this does not include buprenorphine-naloxone patients in unsupervised dosing regimens). This number is to minimise the potential for patients congregating in the vicinity of community pharmacies and contributing to local amenity concerns. There is provision for community pharmacies to get permission from PRU to increase above 50 patients (contact PRU for details and procedures).

3.6.3 Pharmacists working in collaboration with prescribers and the OAT treatment team

The success of OAT provision in the community pharmacy relies heavily on maintaining effective and regular communication between prescriber, other OAT health providers (e.g. clinic nursing unit managers, case workers), patient and pharmacist. The pharmacist should be proactive in contacting the prescriber or other OAT providers in the event of missed doses, intoxicated presentations, invalid or unclear prescriptions, or other concerns identified by the patient. The prescriber and/or caseworker should maintain regular contact with community pharmacists to assess the patient's adherence with dosing, general presentation and any identified concerns or issues.

A patient may be referred to a registered pharmacy by a prescriber or case worker after consensus is reached by all concerned parties (i.e. between patient, pharmacist and prescriber/nurse). Each patient should be made aware of:

- Dosing hours of the pharmacy, including weekends and public holidays;
- General procedures for dispensing of supervised and unsupervised (takeaway) doses;
- Procedures regarding missed doses, intoxicated presentation, invalid prescriptions and other issues;
- Dispensing fees and related procedures (e.g. Methods of collection, late fees);
- Any expectations or conditions regarding patient behaviour;
- Duty of care in communicating with prescribers and other health providers.

3.6.4 Guidelines regarding safe and effective OAT dispensing and administration of OAT

The PRU has developed [detailed guidelines](#) regarding the supply of methadone and buprenorphine in the treatment of opioid dependence by community pharmacists. These guidelines identify the legal and policy requirements for community pharmacists in NSW, including obtaining supplies, storage, prescriptions, drug registers, record keeping and documentation, administration of supervised doses, labelling and supply of unsupervised doses, and loss, theft and destruction of OAT medicines. Key points for staff involved in dispensing and administering OAT are:

- Routine administration of supervised OAT medicine.
- Dispensing unsupervised (takeaway) OAT doses.
- Conditions requiring communication with prescriber/other OAT provider:
 - commencing at a pharmacy;
 - intoxicated presentations;
 - missed doses/interruptions to treatment (including confirmation of last dosing details).

Administration of OAT

Routine administration of supervised OAT medicine in pharmacies

After careful patient identification and checking for signs of intoxication, methadone and buprenorphine must be administered by a pharmacist in compliance with the prescribed dose specified for that particular day. Doses should be prepared upon attendance of the patient, given to the patient and observed for absorption, followed by a drink of water. The patient is then asked to speak to ensure none of the administered dose is removed. The area where dosing is conducted should be private (but should not be in the dispensary).

Steps for dispensing and dosing opioid agonist therapy:

1. Establish a new or transferred patient record.
2. Identify patient and ensure the prescription is valid.
3. Assess whether the patient may be affected by alcohol or other drugs before dosing, or if they have missed doses.
4. Dose one patient at a time.
5. Record instances where a dose is withheld or declined, including criteria for withholding doses.
6. Record and refer instances where a patient fails to attend.
7. Record each dosing event to eliminate the potential for multiple supply.
8. Check to ensure correct dose amount.
9. Confirm the dose has been taken.
10. Check for Adverse Drug Reactions (ADRs)
11. Requirements for education and health information.
12. Requirements for record keeping.
13. Requirements regarding correct administration of OAT.

Dosing buprenorphine-naloxone (Suboxone®) sublingual film

The main formulation of buprenorphine used in Australian OTP programs is buprenorphine-naloxone sublingual film (in 2 and 8 mg doses). For further details regarding this formulation, refer to the Therapeutic Goods Administration (TGA) eBusiness Services – Product and Consumer Medicine Information: <https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2011-PI-01894-3>

One of the advantages of the sublingual film formulation is that it can quickly adhere to oral mucosa, reducing the time required for effective supervised dosing – and hence reducing inconvenience for both staff and patients. However, in order to optimise the muco-adhesion of the film, it is important that films are not ‘stacked’ (overlapping). Overlapping films markedly increase the time for films to adhere to mucosa, and increase the risk that film can be removed from the mouth after administration, or potentially accidentally swallowed (with reduced bioavailability).

Whilst the film formulation is licensed in Australia as a sublingual product, it has also been licensed in the USA as a buccal formulation, with comparable absorption to sublingual route. Consequently, it is recommended that for patients taking more than 1 film at a time, films are placed in the mouth side by side – not overlapping, using sublingual and/or buccal placement. This should reduce the time for adhesion and absorption of the dose, and enhance effective supervision.

Dispensing unsupervised (takeaway) OAT doses

Takeaway doses must only be provided on the day immediately prior to the first day of a scheduled absence of the patient from the pharmacy, and strictly as directed by the prescriber. Any verbal orders from the prescriber need to be faxed or emailed and the original received by the pharmacy within a week.

Ensure the takeaway is correctly labelled, including warnings of possible drowsiness/interactions with alcohol, and KEEP OUT OF REACH OF CHILDREN warning written in red. Liquid takeaway doses must be supplied in a container with a child resistant lid. Confirm the patient has safe storage arrangements for the takeaway doses before issuing.

Situations requiring communication with prescriber/other OAT provider

Commencing at a pharmacy

Prior to a patient dosing at a community pharmacy, the prescriber and/or the patient’s case worker should contact the community pharmacist to agree on the arrangements for the commencement of dosing, including checking on opening hours to plan takeaway doses, if appropriate.

Documentation including a recent passport photo, the patient’s date of birth, the confirmed starting dosage and the first day of dosing, together with a valid prescription must be received by the pharmacist prior to the supply or administration of the first dose. The passport photo and other documentation identifying the patient should always be kept with the current prescription. This is especially important when large numbers of patients are dosed or when locum pharmacists are employed. Prescriptions should not be handed to patients. They should be sent directly to the pharmacy to avoid risk of alteration.

Intoxicated presentations

If the patient presents intoxicated by alcohol or another drug, then the pharmacist should contact the prescriber for further advice about dosing.

If the prescriber cannot be contacted, the pharmacist may consider withholding the dosage with a clinically valid reason (e.g. intoxication). However, the prescriber should be notified within 24 hours or as soon as practically possible. See *under Section 2.4.8 re missed doses*.

Missed doses/interruptions to treatment (including confirmation of last dosing details)

After 1, 2 or 3 consecutive missed doses, the pharmacist, prescriber, or if not available, their delegate, should review the patient prior to dosing. The review should include:

- the circumstances surrounding missed doses, including reasons for non-attendance;
- other recent substance use and clinical presentation at dosing (including evidence of intoxication or withdrawal);
- any relevant medical, psychiatric or social issues.

The pharmacist may resume normal dosing if there are no concerns regarding intoxication, significant withdrawal or other clinical concerns.

The patient must not be dosed after missing more than 3 consecutive days of dosing, and doses should not be replaced for any reason unless authorised by the prescriber. When a patient misses more than 3 consecutive doses, a review or consultation must occur with the prescriber.

3.7 Other dosing information

3.7.1 Dosing arrangements for severely ill patients

Some patients may become temporarily or permanently unable to attend their usual dosing location. Options include:

- dosing at home;
- collection of doses by a responsible carer;
- using another dosing location that may be closer to the patient or provide easier access
- takeaway doses.

Dosing at home

The capacity to provide methadone or buprenorphine treatment to patients at home is limited by the resources available to the service provider. If dosing at home is to be offered:

- the nature and severity of the illness should be medically verified;
- the required medicine is to be dispensed as a takeaway dose by a pharmacist;

- a registered nurse and one other responsible person should administer the dose in the patient's home;

Before attending the patient's home, staff should carefully explore the extent to which their safety may be jeopardised during the home visit. If the administering staff are concerned about their personal safety in a particular patient's home, home dosing should not occur.

Service providers should have their own procedures for these matters.

Collection of doses by a responsible carer

Before allowing collection of doses by a responsible carer:

- The nature and severity of the illness should be medically verified;
- The patient, carer, prescriber, dosing point and other treating practitioners should all agree to this approach;
- Appropriate procedures for identification of the carer should be employed at the dosing point.

The patient and the dose collection process should be reviewed regularly.

Multiple dosing locations

Patients may receive methadone or buprenorphine from more than one dosing location in some circumstances. This can be useful, for example, in accommodating patients who work at a location remote from home. This arrangement can also be useful when a dosing location is closed on one or more days of the week.

However, administrative measures have to be carefully planned and monitored to prevent mistakes being made. If this is not done, patients may not receive doses at either site, or may be dosed at both sites on the same day. These procedures are to be followed:

- One site is nominated as the primary dosing site. This will usually, but not always, be the site attended by the patient more frequently, and preferably a private or public clinic rather than a community pharmacy. The agreement as to who will be the primary dosing site should be documented and available in the case notes at both sites.
- The primary dosing site is responsible for ensuring that the patient is dosed appropriately. This is the responsibility of the senior registered nurse, the prescriber, or the senior pharmacist.

- The days that the patient will be dosed at each site are nominated and generally will be fixed.
- The senior registered nurse of the primary clinic, the prescriber, or the senior pharmacist contacts the secondary dosing site at the beginning and end of each period for which the patient will be presenting at the secondary site.
- When patients are attending dual dosing locations on a permanent basis, each site must have full documentation, including a recent photograph. The days on which the patient is to be dosed at each site are to be clearly marked on the patient's card.
- The PRU should be advised of any permanent arrangements for dual dosing locations.

Generally, patients are not to be dosed at a dosing location other than on the designated day(s). The only exception to this is if the patient is unable to present to the usual dosing location. This may occur, for example, when a patient is not at work on his/her regular days due to illness or holidays. In the case of holidays this is to be arranged in advance.

In other cases, the patient is to contact the dosing location designated for the day and explain the circumstances. The pharmacist or senior registered nurse will then contact the other dosing location and enquire whether the patient could be dosed at that point for that day(s). A note is to be made on the patient's card that he/she is not to be dosed at the designated site that day.

The pharmacist or senior registered nurse at the dosing location at which the patient is to be dosed must verify the identity of the caller. This will usually be done by calling back.

If any doubt exists as to whether the change of arrangement may result in double dosing, the dose is to be withheld. Regular communication should occur between both dosing locations to ensure safety and monitor the patient's progress.

3.7.2 Patients under legal supervision

Public and private opioid treatment services are responsible for dosing any of their patients who are being held in police custody, except for patients held in cells where JH&FMHN nurses are formally rostered to provide health services. The police should inform the relevant service provider as early in the day as possible that a patient will require a dose of methadone that day.

For dosing in cells, the documentation that should be forwarded from the patient's regular methadone or buprenorphine provider to the service providing the patient's cell dose must include:

- patient identification, including photograph and/or physical description;
- a copy of the prescription/treatment chart for the patient;
- verification of the time and date of the administration of the patient's last dose;
- verification of the number of takeaway doses (if any) provided when the patient was last seen for dosing.

The dose should be administered by at least one registered nurse or pharmacist at the cells, who should carefully confirm the identity of the patient before administering the dose and closely observe the patient taking the dose to prevent diversion.

3.7.3 Urgent prescriptions due to unforeseen circumstances

In special circumstances a patient may require a prescription or an authorisation to receive a dose at a location other than their usual dosing site.

If the patient's regular prescriber cannot be contacted, a locum prescriber can be requested to provide a prescription to cover the special circumstances. If no details can be obtained about an individual claiming to be on methadone or buprenorphine from a prescriber or a dispensing site (public or private) then it is appropriate to refuse to prescribe or provide these drugs.

Section 4

Appendices



A. Definitions of opioid dependence

A.1 DSM-5 – Opioid use disorder

In DSM-5, substance use disorder combines the categories of substance abuse and substance dependence from DSM-IV into a single disorder. Each specific substance is addressed as a separate disorder.

Opioid use disorder diagnostic criteria

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

- Opioids are often taken in larger amounts or over a longer period than was intended.
- There is a persistent desire or unsuccessful efforts to cut down or control opioid use.
- A great deal of time is spent in activities necessary to obtain the opioid, use the opioid, or recover from its effects.
- Craving, or a strong desire or urge to use opioids.
- Recurrent opioid use resulting in a failure to fulfil major role obligations at work, school, or home.
- Continued opioid use despite having persistent or recurrent social or interpersonal problems caused or exacerbated by the effects of opioids.
- Important social, occupational, or recreational activities are given up or reduced because of opioid use.
- Recurrent opioid use in situations in which it is physically hazardous.
- Continued opioid use despite knowledge of having a persistent or recurrent physical or psychological problem that is likely to have been caused or exacerbated by the substance.
- Tolerance, as defined by either of the following:
 - A need for markedly increased amounts of opioids to achieve intoxication or desired effect.
 - A markedly diminished effect with continued use of the same amount of an opioid.
 - Note: This criterion is not considered to be met for those taking opioids solely under appropriate medical supervision.
- Withdrawal, as manifested by either of the following:
 - The characteristic opioid withdrawal syndrome (refer to Criteria A and B of the criteria set for opioid withdrawal, pp. 547–548).
 - Opioids (or a closely related substance) are taken to relieve or avoid withdrawal symptoms.
 - **Note:** This criterion is not considered to be met for those individuals taking opioids solely under appropriate medical supervision.

Specify if:

In early remission: After full criteria for opioid use disorder were previously met, none of the criteria for opioid use disorder have been met for at least 3 months but for less than 12 months (with the exception that Criterion A4, 'Craving, or a strong desire or urge to use opioids,' may be met).

In sustained remission: After full criteria for opioid use disorder were previously met, none of the criteria for opioid use disorder have been met at any time during a period of 12 months or longer (with the exception that Criterion A4, 'Craving, or a strong desire or urge to use opioids,' may be met).

Specify if:

On maintenance therapy: This additional specifier is used if the individual is taking a prescribed agonist medicine such as methadone or buprenorphine and none of the criteria for opioid use disorder have been met for that class of medicine (except tolerance to, or withdrawal from, the agonist). This category also applies to those individuals being maintained on a partial agonist, an agonist/antagonist, or a full antagonist such as oral naltrexone or depot naltrexone.

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

Coding based on current severity: Note for ICD-10-CM codes: If an opioid intoxication, opioid withdrawal, or another opioid-induced mental disorder is also present, do not use the codes below for opioid use disorder. Instead, the comorbid opioid use disorder is indicated in the 4th character of the opioid-induced disorder code (see the coding note for opioid intoxication, opioid withdrawal, or a specific opioid-induced mental disorder). For example, if there is comorbid opioid-induced depressive disorder and opioid use disorder, only the opioid-induced depressive disorder code is given, with the 4th character indicating whether the comorbid opioid use disorder is mild, moderate, or severe: F11.14 for mild opioid use disorder with opioid-induced depressive disorder or F11.24 for a moderate or severe opioid use disorder with opioid-induced depressive disorder.

Specify current severity:

- 1 305.50 (F11.10) Mild: Presence of 2–3 symptoms.
- 2 304.00 (F11.20) Moderate: Presence of 4–5 symptoms.
- 3 304.00 (F11.20) Severe: Presence of 6 or more symptoms.

See <http://dsm.psychiatryonline.org.acs.hcn.com.au/doi/full/10.1176/appi.books.9780890425596.dsm16#x29473.2670878>

A.2 ICD-10 – Opioid dependence

Opioid dependence is defined by the presence of three or more of the following features present simultaneously at any one time during the preceding year:

- a strong desire or sense of compulsion to take opioids
- difficulties in controlling opioid use
- a physiological withdrawal state
- tolerance
- progressive neglect of alternative pleasures or interests because of opioid use
- persisting with opioid use despite clear evidence of overtly harmful consequences.

See www.who.int/classifications/icd/en/

B. Opioid withdrawal rating scales

B.1 Subjective Opiate Withdrawal Scale (SOWS)

Patient's name						
Date	Time	Please score each of the 16 items below according to how you feel NOW (circle one number)				
	Symptom	Not at all	A little	Moderately	Quite a bit	Extremely
1	I feel anxious	0	1	2	3	4
2	I feel like yawning	0	1	2	3	4
3	I am perspiring	0	1	2	3	4
4	My eyes are teary	0	1	2	3	4
5	My nose is running	0	1	2	3	4
6	I have goose bumps	0	1	2	3	4
7	I am shaking	0	1	2	3	4
8	I have hot flushes	0	1	2	3	4
9	I have cold flushes	0	1	2	3	4
10	My bones and muscles ache	0	1	2	3	4
11	I feel restless	0	1	2	3	4
12	I feel nauseous	0	1	2	3	4
13	I feel like vomiting	0	1	2	3	4
14	My muscles twitch	0	1	2	3	4
15	I have stomach cramps	0	1	2	3	4
16	I feel like using now	0	1	2	3	4

Range 0-64.

Ref: Handelsman, L., Cochrane, K. J., Aronson, M. J. et al. (1987) Two new rating scales for opiate withdrawal, *American Journal of Alcohol Abuse*, 13, 293-308.

B.2 Clinical Opiate Withdrawal Scale (COWS)

Patient's name	
Reason for assessment	
Date	For each item, write in the number that best describes the patient's signs or symptom. Rate on just the apparent relationship to opiate withdrawal. For example, if heart rate is increased because the patient was jogging just prior to assessment, the increase pulse rate would not add to the score
Time	
Resting pulse rate: (beats per minute) Measured after patient is sitting or lying for one minute 0 pulse rate 80 or below 1 pulse rate 81-100 2 pulse rate 101-120 4 pulse rate greater than 120	GI upset: over last ½ hour 0 no GI symptoms 1 stomach cramps 2 nausea or loose stool 3 vomiting or diarrhoea 5 Multiple episodes of diarrhoea or vomiting
Sweating: over past ½ hour not accounted for by room temperature or patient activity. 0 no report of 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	Tremor observation of outstretched hands 0 No tremor 1 tremor can be felt, but not observed 2 slight tremor observable 4 gross tremor or muscle twitching
Restlessness Observation during assessment 0 able to sit still 1 reports difficulty sitting still, but is able to do so 3 frequent shifting or extraneous movements of legs/arms 5 unable to sit still for more than a few seconds	Yawning Observation during assessment 0 no yawning 1 yawning once or twice during assessment 2 yawning three or more times during assessment 4 yawning several times/minute
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	Anxiety or irritability 0 none 1 patient reports increasing irritability or anxiousness 2 patient obviously irritable anxious 4 patient so irritable or anxious that participation in the assessment is difficult
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 of joints/ muscles 4 patient is rubbing joints or muscles and is unable to sit still because of discomfort	Gooseflesh skin 0 skin is smooth 3 piloerection of skin can be felt or hairs standing up on arms 5 prominent piloerection
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 score (sum of all 11 items) Initials of person completing assessment

Score: 5-12 = mild; 13-24 = moderate; 25-36 = moderately severe; more than 36 = severe withdrawal

Ref: Wesson D.R. & Ling, W. (2003). The Clinical Opiate Withdrawal Scale (COWS). *Journal of Psychoactive Drugs* 35(2):253-259.

B.3 Objective Opioid Withdrawal Scale (OOWS)

Date	Time	Observe the patient for 5 minutes, then indicate a score for each of the opioid withdrawal signs listed below. Add the scores for each item to obtain the total score	
1	Yawning	0 = no yawning	1 = yawning
2	Rhinorrhoea	0 < 3 sniffs	1 = 3 or more sniffs
3	Piloerection (observe arm)	0 = absent	1 = present
4	Perspiration	0 = absent	1 = present
5	Lacrimation	0 = absent	1 = present
6	Tremor (hands)	0 = absent	1 = present
7	Mydriasis	0 = absent	1 ≥ 3 mm
8	Hot and cold flushes	0 = absent	1 = shivering/huddling for warmth
9	Restlessness	0 = absent	1 = frequently shifts of position
10	Vomiting	0 = absent	1 = present
11	Muscle twitches	0 = absent	1 = present
12	Abdominal cramps	0 = absent	1 = holding stomach
13	Anxiety	0 = absent	1 = mild to severe
Total score			

Range 0–3

Source: Handelsman L, Cochrane KJ, Aronson MJ, et al. Two new rating scales for opiate withdrawal. *Am J Alcohol Abuse* 1987;13:293–308.

C. Product information


For product information, refer to the [Therapeutic Goods Administration \(TGA\) eBusiness Services - Product and Consumer Medicine Information](#).

- Methadone Product Information: <https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2009-PI-00948-3&d=2016061416114622483>
- Biodone Forte Product Information: <https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2009-PI-00726-3&d=2016061416114622483&d=2016080916114622483>
- Subutex® Product Information: <https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2009-PI-00913-3>
- Suboxone® Product Information: <https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2011-PI-01894-3>
- Naloxone Product Information: <https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2010-PI-02490-3>
- Naltrexone Product Information: <https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2013-PI-01168-1>

D. Responding to an opioid overdose

For information on drug treatment call Alcohol Drug Information Service (ADIS) at any time on 9361 8000 (Sydney) or freecall 1800 422 599 for NSW regional and rural callers.

RESPONDING TO AN OPIOID OVERDOSE



When is the risk of opioid overdose increased?

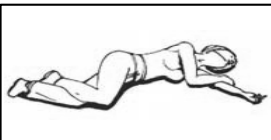
- Using again after a break with reduced tolerance (e.g. after hospital or drug-free treatment, detox, prison)
- Mixing opioids with other sedating drugs - such as alcohol or benzo's (e.g. diazepam, alprazolam).
- Using a greater amount (or purity) of opioid than usual.
- Injecting instead of other ways of using (e.g. swallowing, snorting, smoking)
- Having other health problems (e.g. a major infection, fever).
- Using alone - with no one able to call for help.

How to recognise an opioid overdose?

- Person is unconscious & does not respond to their name or physical stimulus (e.g. squeezing their shoulder).
- Person has blue lips, tongue and hands, cool pale skin
- Person is breathing infrequently, snoring or not breathing at all,
- 'Pinned' (small) pupils.

How to respond to an opioid overdose?

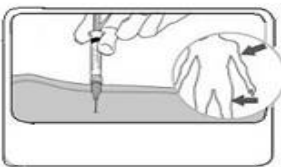
1. **Check the environment is safe** - clear away any uncapped needles or other sharp objects.
2. **Try to rouse the person** by calling their name or squeezing their shoulder. If no response:
3. Put them in the **recovery position**.



➔

1. Role person on to left side
2. Tilt head backwards
3. Turn mouth slightly downwards to allow drainage
4. Check their airway and clear any obstructions from their mouth or throat
5. Listen and look for normal breathing


4. **Call an ambulance:** Dial 000 & follow instructions
5. **Inject 1 ampoule naloxone**



➔


1. Unscrew mini-jet syringe cap
2. Screw needle into mini-jet
3. Remove needle cap
4. Insert needle into upper arm or outer thigh muscle
Needle should be at least 1cm deep
5. Push plunger all the way down to inject the naloxone
6. Note time the injection is given

6. If not breathing normally, roll the person onto their back & start '**Rescue Breathing**' until the person is breathing normally or the ambulance arrives



➔

1. Place one hand on forehead
2. Place other hand under chin
3. Tilt head backwards to open the airway
4. Put on breathing face mask
5. Pinch off nose
6. Seal your mouth over theirs and give quick breaths



7. **Second naloxone dose:** If person is still unconscious 5 minutes after first naloxone injection, a second dose of naloxone can be given – repeat step 5.

Naloxone is used to reverse opioid overdose (e.g. heroin, morphine, oxycodone, methadone).
It takes 2–5 minutes to start working and effects last about 20 minutes.

For information on drug treatment call ADIS 24 hours a day, 7 days a week on: 9361 8000 (Sydney) or free call 1800 422 599 for NSW regional & rural callers. **SESLHD D&A Services: 93328777**

E. Clinically significant interactions between methadone, buprenorphine and other medicines

This appendix lists some prescription medicines that are known to, or may potentially result in clinically significant interactions when used in combination with methadone or buprenorphine. The list is not exhaustive: if in doubt, seek specialist advice.

The list draws on information from www.opioiddruginteractions.com

In the tables, ++ indicates a strong clinical interaction, + indicates an interaction of less significance and ? indicates the potential for interaction with limited supporting evidence. All interactions should be avoided if possible, or patients should be monitored and drug regimens adjusted if necessary.

Increased sedative effects

The medicines in this group may increase the risk of overdose through additive CNS depression, or increased plasma levels of methadone or buprenorphine resulting from decreased metabolism or decreased urinary clearance.

Clinical significance for:		Medicine
Methadone	Buprenorphine	
++	++	Amitriptyline
	++	Atazanavir
++	++	Benzodiazepines (alprazolam, diazepam, triazolam)
?		Ciprofloxacin
++		Citalopram/escitalopram
?		Erythromycin
++	?	Fluconazole
+	?	Fluoxetine
++	+	Fluvoxamine
+	?	Indinavir
?	?	Ketoconazole
+		Moclobemide
?		Omeprazole
?	?	Ritonavir (avoid using in combination with atazanavir)
?		Sertraline
+		Urine alkalisers (e.g. sodium bicarbonate)
++	+	Zopiclone

Withdrawal symptoms or adverse effects

The medicines in this group may cause decreased plasma levels and withdrawal symptoms due to increased metabolism of methadone or buprenorphine, or may cause adverse effects through other mechanisms.

Clinical significance for:		Medicine
Methadone	Buprenorphine	
++		Carbamazepine
+	?	Cimetidine
+		Disulfiram (if used in conjunction with methadone formulations containing alcohol)
+	?	Hypericum perforatum (St Johns Wort)
+		Moclobemide
+		Nevirapine
	?	Nifedipine
++	?	Phenytoin
++	?	Rifampicin
++	++	Rifabutin
+	+	Urine acidifiers (e.g. ascorbic acid)Ketoconazole

Prolongation of QTc interval

These medicines may be contraindicated by the manufacturer for use in combination with methadone or buprenorphine due to their capacity to cause prolongation of the QTc interval.

Clinical significance for:		Medicine
Methadone	Buprenorphine	
+	+	Domperidone
+		Citalopram/escitalopram
?	?	Erythromycin
+	?	Thioridazine

Effects on other medicines

Methadone and buprenorphine may also impact adversely on the other medicines that may be used in combination.

Clinical significance for:		Medicine
Methadone	Buprenorphine	
++		Atazanavir (methadone may decrease serum levels)
++		Desipramine (metabolism decreased leading to increased plasma levels of desipramine)
++		Nifedipine (metabolism may inhibit methadone)
++		Zidovudine (metabolism is decreased leading to increased plasma levels of zidovudine. Symptoms of zidovudine toxicity can be misinterpreted as opioid withdrawal)

F. Possible drug interactions with other psychoactive drugs

Drug	Status of interaction	Effect	Mechanism
Alcohol	Clinically important	Increased sedation, increased respiratory depression. Combination may also have increased hepatotoxic potential	Additive CNS depression
Benzodiazepines	Clinically important	Enhanced sedative effect	Additive CNS depression
Barbiturates (e.g. phenobarbitone)	Clinically important	Reduced buprenorphine levels. Increased sedation. Additive CNS depression	Increased buprenorphine metabolism

G. Intoxication and withdrawal states from commonly used drugs

G.1 Acute intoxication states

Class of drug	Intoxication	Overdose
Opioids (e.g. heroin, morphine)	Miosis Itching Sedation/somnolence Lowered blood pressure Slowed pulse Hypoventilation	Unconscious Respiratory depression Pinpoint pupils Hypotension Bradycardia Pulmonary oedema
Stimulants (e.g. cocaine, amphetamines)	Hyperactivity Restlessness Agitation Anxiety/nervousness Mydriasis Elevated blood pressure Increased pulse Raised temperature Sweating Tremor	Panic Acute paranoid psychosis Seizures Cardiac arrhythmias Myocardial ischemia (rarely infarct) Hypertensive crisis Cerebrovascular accidents Hyperpyrexia Dehydration
Benzodiazepines (e.g. diazepam, oxazepam, flunitrazepam)	Disinhibition Sedation Drooling Incoordination Slurred speech Lowered blood pressure Dizziness	Stupor/coma Ataxia Confusion Respiratory depression
Cannabis	Relaxation Decreased concentration Decreased psychomotor performance Impaired balance Conjunctival injection	Paranoid psychosis Confusion Agitation Anxiety/panic Hallucinations
Alcohol	Relaxation Disinhibition Impaired coordination Impaired judgement Decreased concentration Slurred speech Ataxia Vomiting	Disorientation/confusion Respiratory depression Loss of consciousness Loss of bladder control

G.2 Withdrawal states

Drug class	Onset	Duration	Symptoms of withdrawal
Opioids	8-12 hours	Peaks 2-4 days, ceases 7-10 days	Anxiety, muscle tension, muscle and bone ache, muscle cramps, sleep disturbance, sweating, hot and cold flushes, piloerection, yawning, lacrimation, rhinorrhoea, abdominal cramps, nausea, vomiting, diarrhoea, palpitations, elevated blood pressure and pulse, dilated pupils
Stimulants	8-36 hours	Several days, occasionally 2-3 weeks	Lethargy, depression, irritability, hyperphagia, anhedonia, dysphoria, desire for sleep increased
Benzodiazepines	1-10 days (depending on half-life)	3-6 weeks (may be longer)	Anxiety, insomnia, muscle aching and twitching, perceptual changes, feelings of unreality, depersonalisation, seizures
Cannabis	Usually days	Weeks	Irritability, anxiety, insomnia, anorexia, sweating, muscle spasms, headaches
Alcohol	As blood alcohol level 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 and pulse, temperature, headache, seizures, confusion, perceptual distortions, disorientation, hallucinations, hyperpyrexia

H. NSW Health forms used in the administration of the OTP

Form	Use
H.1 Approval to prescribe pharmacotherapies	To register as a prescriber of methadone or buprenorphine treatment
H.2 Application for authority to prescribe methadone/buprenorphine	To enrol a new patient in opioid agonist treatment
H.3 Application form for methadone doses above 200 mg	To secure approval to prescribe a daily methadone dose above 200 mg
H.4 Application form for buprenorphine doses above 32 mg	To secure approval to prescribe a daily buprenorphine dose above 32 mg
H.5 Treatment exit	To exit a patient from an opioid treatment program
H.6 Application to become a registered methadone and/or buprenorphine dosing point	To enable a pharmacy to dose on the OTP
H.7 NSW opioid treatment program: notification of permanent change in dosing point	To notify of a patient's change in dosing point

*Note that the above forms may be subject to change.

H.1 Approval to prescribe pharmacotherapies

Secretary of Health
NSW Ministry of Health
C/o Secretary
Pharmacotherapy Credentialling Subcommittee
LMB 961
NORTH SYDNEY NSW 2059

ATTENTION: send completed scanned form by email to - PCS@doh.health.nsw.gov.au
NB: If you do not receive confirmation of receipt of your email within 3 working days, please resend.

Dear Sir/Madam

Re: Approval to Prescribe Pharmacotherapies

I wish to formally apply under the statutory requirements of the NSW Opioid Therapeutic Goods Act 1999 to be approved as a pharmacotherapy prescriber for the purpose of treating opioid dependent individuals.

I understand that as a prerequisite for approval I will need to successfully complete the Opioid Treatment Accreditation Course and demonstrate clinical competence in pharmacotherapy treatment.

I am interested in attending the Opioid Treatment Accreditation Course on ____/____/____, to be held at: _____

(location)
I have attached my Curriculum Vitae, which details my qualifications, employment history and other information relevant to my application.

Provider number _____ Prescriber number _____

Australian Health Practitioner Regulation Agency (AHPRA) Registration number _____

I understand that my application and supporting papers will be forwarded to the Pharmacotherapy Credentialling Subcommittee (PCS), and that my name will be passed to the Pharmaceutical Services Unit (PSU), and the Health Care Complaints Commission in accordance with any matters under investigation, and to the Australian Health Practitioner Regulation Agency (AHPRA) and the NSW Medical Board for advice as to any relevant matters relating to my professional conduct, performance or health. Also if appropriate, to equivalent bodies in other states for advice as to any relevant matters relating to my professional conduct, performance or health.

Correspondence regarding this application should be forwarded to:

(street address) Best telephone contact: _____

(suburb and postcode)

Or preferred email address: _____

To enable the Ministry to better manage the Opioid Treatment program, please complete the following:

Tick the box(es) that best describe your current title/qualification:

Registrar General Practitioner Physician Psychiatrist CMO VMO

Fellow Chapter of Addiction Medicine OTHER _____

and your current work setting: Public Clinic Private Clinic General Practice

Yours sincerely

Signature

Printed name

____/____/____
Date

Form 5B- Revised March 2015

H.2 Application for authority to prescribe

<http://www.health.nsw.gov.au/pharmaceutical/Documents/OTP-appln.pdf>



OTP03/18

Application for Authority to Prescribe Methadone or Buprenorphine under the NSW Opioid Treatment Program (OTP)

This form is available online in PDF format (<http://www.health.nsw.gov.au/pharmaceutical>) and should be filled in electronically using a computer. If completing the form by hand, please use BLOCK LETTERS and ensure that all details are legible. Eligible applications are generally processed within 2 business days.

Section A: Patient Details

Patient Name:

VOID

Also known as:

Patient Residential Address:

Suburb/Town:

Postcode:

Patient Date of Birth:

M

If patient is aged 16 years to under 18 years, provide a second opinion from an approved prescriber. A report from this prescriber **must** be attached to this application.

I confirm that I have positively identified the patient using appropriate form(s) of identification:

Y

N

Section B: Application details

1. This application is for:

Methadone

Buprenorphine

2. Indicate the patient's current status (tick one box only)

Currently on NSW OTP **VOID**

Not currently on NSW OTP but has previously been on NSW OTP

Never has been on NSW OTP

3. Is the patient of Aboriginal or Torres Strait Islander origin? (tick one box only)

Yes, Aboriginal

Yes, Torres Strait Islander

Yes, both Aboriginal and Torres Strait Islander

No, neither Aboriginal nor Torres Strait Islander

4. In which country was the patient born?

Australia

other, specify: _____

5. What is the patient's preferred language?

English

other, specify: _____

6. What is the patient's **primary opioid** drug of dependence? (tick one box only)

heroin

oxycodone

codeine

buprenorphine

methadone

morphine

fentanyl

hydromorphone

pethidine

other, specify: _____

7. What drug(s), **other than opioids**, does the patient perceive as being a concern? (tick the appropriate box/es)

no other drugs of concern

alcohol

benzodiazepines

cocaine

cannabis

amphetamine

MDMA (ecstasy)

methamphetamine

nicotine

non opioid analgesic

other, specify: _____

8. Who is the patient's current OTP prescriber? (tick one box only)

Patient is not currently on the NSW OTP **VOID**

I (the applicant) am the current prescriber

Justice Health

Other NSW community prescriber, specify full name: _____

Interstate or Overseas prescriber, specify (e.g. Vic): _____

Statement signed by the interstate prescriber showing the dose and date of last dose (including takeaways) is attached: Y

N

Patient's name:	
Section C: Dose information	
9. Date of last dose of methadone/buprenorphine: _____	
<i>Note: If the patient is transferring from another prescriber, specify the date of the last dose dispensed on the current prescription, including any takeaways.</i>	
10. Last dose of methadone/buprenorphine dispensed: _____ mg	
11. Proposed starting date: _____	
12. Proposed starting dose: _____ mg	13. Expected maximum dose: _____
14. Has treatment been commenced as an inpatient immediately prior to this application: <input type="checkbox"/> Y <input type="checkbox"/> N	
15. Proposed administration (dosing) point:	
Suburb/Town: _____	
<i>Note: Opioid Treatment line (OTL) 1800 642 428 can be contacted for registered dosing points in NSW</i>	
Section D: Prescriber declaration	
<p>I confirm that the information I have provided in this application is true and complete to the best of my knowledge. I declare I have read and agree to comply with NSW Clinical Guidelines for the Treatment of Opioid Dependence issued by the NSW Ministry of Health. The patient's opioid dependence has been established through current clinical practice and the patient has been assessed suitable for the OTP. Copies of i) Patients' rights and responsibilities and ii) Service provider/clinician responsibilities have been provided to the patient. The patient has been notified why their personal health information is collected, how it may be used, and who it may be disclosed to (see Privacy Statement below).</p>	
Prescriber's Signature: _____ Date: _____	
Prescriber Name: _____	
(first names) (family name)	
Name of Practice: _____	
Address: _____	
Suburb/Town: _____	Postcode: _____
Telephone: _____	Email: _____
AHPRA Registration No: _____	Pharmacist No: _____
HPI-I No (if known): _____	
<p>Privacy Statement: The information set out in this form is required by the NSW Ministry of Health for the issuance of an authority to prescribe a Schedule 8 drug as required under the law. The collection, use and disclosure of the information provided will be in accordance with privacy laws. The information collected may be disclosed to health practitioners when necessary to facilitate coordination of treatment and patient safety. Personal information will not be disclosed for any other purpose without prior consent, except where required by law or where otherwise lawfully authorised to do so. The application may not be processed if all information requested on the form is not completed. For further information on privacy visit http://www.health.nsw.gov.au/patients/privacy. For further advice or clarification please email pharmserv@doh.health.nsw.gov.au</p>	
<p>Fax completed form and supporting documentation to the Pharmaceutical Regulatory Unit: 02 9424 5885 For enquiries: Tel 02 9424 5921 during business hours.</p>	

H.3 Application for methadone doses above 200 mg

This form will be submitted to the Pharmacotherapy Credentialing Subcommittee for review.

This form should be accompanied by:

- A second opinion obtained from a prescriber who is a Fellow of the Chapter of Addiction Medicine, or a prescriber of equivalent training and experience as from time to time approved by the PCS.
- Current ECG giving corrected QT intervals (QTc)
- Recent urine drug screen (UDS)
- Current trough methadone levels

Patient's PSB Number DOB	
Current dose mg	
Clinical details	
Trough blood levels date use at time	
1. Observations 2-3 hours post dose	
2. Urine test. Other drugs present	
3. Reason for increased dose	
4. Current medicines including dosage	
5. Number of takeaways	
6. Relevant details of psychosocial situation e.g. chronic pain, psychiatric disorder	
Has the patient signed an HIC Privacy Release form so that information is available on the number of doctors visited in the last three months?	
<input type="checkbox"/> Yes <input type="checkbox"/> No (To obtain HIC form 'phone 1800 420 074)	
If this is a chronic pain case, have you addressed the issue of alternative methods of treatment? <input type="checkbox"/> Yes <input type="checkbox"/> No	
Have you submitted a high dose application to the committee previously?	
<input type="checkbox"/> Yes (date) <input type="checkbox"/> No	
Attachments:	
<input type="checkbox"/> Current ECG <input type="checkbox"/> Second opinion <input type="checkbox"/> Recent UDS <input type="checkbox"/> Trough levels	
Prrescriber name	Signature
Mailing Address	
Phone (W)	Phone (C)
Date	

Applications should be addressed to: Secretary, PCS, Centre for Population Health, NSW Health, LMB 961 North Sydney, NSW 2059. Ph: (02) Or email completed form to PCS@doh.health.nsw.gov.au

H.4 Application for buprenorphine doses above 32 mg per day

This form will be submitted to the Pharmacotherapy Credentialing Subcommittee for review.

This form should be accompanied by:

- A second opinion obtained from a prescriber who is a Fellow of the Chapter of Addiction Medicine, or a prescriber of equivalent training and experience as from time to time approved by the PCS.
- Current ECG giving corrected QT intervals (QTc)
- Recent urine drug screen (UDS)
- Current trough methadone levels

Patient's PSB Number DOB	
Current dose mg use applied for mg	
Clinical details	
1. Observations 2-3 hours post dose	
2. Urine test. Other drugs present	
3. Reason for increased dose	
4. Current medicines including dosage	
5. Number of takeaways	
6. Relevant details of psychosocial situation e.g. chronic pain, psychiatric disorder	
Has the patient signed a HIC Private Release form so that information is available on the number of doctors visited in the last three months? <input type="checkbox"/> Yes <input type="checkbox"/> No (To obtain HIC form 'phone 1800 420 074)	
If this is a chronic pain case, have you addressed the issue of alternative methods of treatment? <input type="checkbox"/> Yes <input type="checkbox"/> No	
Attachments: <input type="checkbox"/> Second opinion <input type="checkbox"/> Recent	
Attachments: <input type="checkbox"/> Current ECG <input type="checkbox"/> Second opinion <input type="checkbox"/> Recent UDS <input type="checkbox"/> Trough levels	
Prrescriber name	Signature
Mailing Address	
Phone (W)	Phone (C)
Date	
Subcommittee meetings are scheduled for the second Tuesday of every month and applications must be received one week prior to the meeting.	

Applications should be addressed to: Secretary, Centre for Population Health, NSW Health.
 LMB 961 North Sydney, NSW 2059. Ph: (02) 9391 9050. Or email completed scanned form to
PCS@doh.health.nsw.gov.au

H.5 Exit from methadone/buprenorphine treatment

<http://www.health.nsw.gov.au/pharmaceutical/Documents/OTP-exit.pdf>



Health

OTP03/18

Exit from Methadone or Buprenorphine Treatment under the NSW Opioid Treatment Program (OTP)

This form is available online in PDF format (<http://www.health.nsw.gov.au/pharmaceutical>) and should be filled in electronically using a computer. If completing the form by hand, please use BLOCK LETTERS and ensure that all details are legible. Exits are generally processed within 2 business days.

Section A: Patient Details

Patient Name:

(first name) (middle name) (family name)

Patient Residential Address:

Suburb/Town:

Postcode:

Patient Date of Birth:

Sex: M F

Section B: Current program details

1. Is the patient exiting a methadone or buprenorphine program? Methadone Buprenorphine

2. Date of entry to current program: ____/____/____
 (month) (year)

3. Date of last dose including any takeaways issued on current prescription: ____/____/____

4. Last dose of methadone or buprenorphine: ____

5. Name of last dosing point:

Suburb/Town:

6. Date commenced at dosing point: ____/____/____

7. Reason for Exiting Treatment (tick one box only)

- Patient did not commence treatment
- Treatment incomplete (by mutual agreement between prescriber and patient)
- Patient successfully completed treatment
- Patient ceased to pick up methadone/buprenorphine
- Treatment terminated involuntarily

Reason for involuntary termination (e.g. chronic or frequent illegal opioid use, violent or abusive behaviour towards staff, diverting methadone or buprenorphine): _____

Patient deceased Date of death: ____/____/____

Patient transferred to the Justice Health System

Patient transferred to another prescriber, specify name of new prescriber: _____

Other, specify: _____

Section C: Declaration

This patient has been discharged from methadone/buprenorphine treatment. I declare that I am the current authorised prescriber or I have permission of the current authorised prescriber to discharge the patient.

Name of person discharging patient:

(first and family name)

Signature of person discharging patient:

Designation:

Date: ____/____/____

Prescriber's Name:

Address:

Fax completed form and supporting documentation to the Pharmaceutical Regulatory Unit: **02 9424 5885**
 For enquiries: Tel 02 9424 5921 during business hours.

H.6 Application to become a registered methadone and/or buprenorphine dosing point



APPLICATION TO BECOME A REGISTERED METHADONE AND/OR BUPRENORPHINE DOSING POINT

I wish to apply for my pharmacy to become

- A registered methadone dosing point
- A registered buprenorphine dosing point
- A registered methadone and buprenorphine dosing point

This is a: New pharmacy

Date of registration with Pharmacy Council:

Existing pharmacy

- Change of ownership (Date of takeover:))
- Change of address
- New dosing point
- Addition of new dosing point

I and all registered pharmacists under my employ have read and have an understanding of the latest edition of the NSW Ministry of Health guideline TG 201 “Supply of Methadone and Buprenorphine under the New South Wales Pharmacy Only Drug Treatment Programs - Guidelines for Community Pharmacies”.

I hereby give an undertaking:

- that methadone and/or buprenorphine will be handled and administered by pharmacists at my pharmacy in accordance with the above-mentioned guideline, TG 201.
- that the retail pharmacy is located on premises at which a pharmacist is approved to supply pharmaceutical benefits under section 90 of the National Health Act 1953.

Pharmacy PBS approval number

Name* of applicant Pharmacist-Proprietor

(* Please print full name as registered with AHPRA)

Signature of applicant Pharmacist-Proprietor

..... Date

Names of other **Proprietors** (Please print full name as registered with AHPRA)

.....

.....

.....



Pharmacy Name

(If change of name, previous Pharmacy Name

Company or Proprietary Name (if applicable)

Pharmacy Address

Postcode

Telephone Number Fax Number

Dedicated Pharmacy Email Address

Please submit completed form by email to:

Chief Pharmacist
Pharmaceutical Services Unit
NSW Ministry of Health
Locked Mail Bag 961
North Sydney NSW 2060
Facsimile: (02) 9424 5866
Email: phmserv@doh.health.nsw.gov.au

Note:

- There may be a delay of up to five business days after receipt of your application at Pharmaceutical Services Unit (PSU) before you may order methadone and/or buprenorphine from your supplier.
- If you change premises, pharmacy name or wish to discontinue dosing in the future, please contact PSU without delay (Tel: (02) 9391 9944 during business hours). If you sell your pharmacy and are currently dosing, please have the new owner contact PSU approximately 10 days before takeover date and ensure there is enough OTP drugs in stock to last approximately 14 days.

Office Use Only
PSU Pharmacy Code.....
Pharmacists registered on APHRA w/o conditions?
Pharmacy registered on Council website?
Other.....
Approval.....

H.7 NSW opioid treatment program: notification of permanent change in dosing point

STRICTLY CONFIDENTIAL

PHARMACEUTICAL SERVICES

NSW MINISTRY OF HEALTH

NSW OPIOID TREATMENT PROGRAM: NOTIFICATION OF PERMANENT CHANGE IN DOSING POINT

Name of Person Completing the Notification:

Title/Position:

Name of Practice/Clinic:

Date:

Telephone:

Patient Ref No (if known)	Patient Name	Patient Date of Birth	Name of Previous Dosing Point (transferring from)	Name of New Dosing Point (transferring to)	Suburb/Town of Dosing Point	Date of Transfer

Fax to: Pharmaceutical Services
 NSW Ministry of Health
Fax: (02) 9424 5885

Postal Address: Locked Mail Bag 9611, North Sydney NSW 2059
 Telephone: (02) 9424 5921

I. Prescriber and Patient matters

I.1 Prescriber Checklist of issues to discuss with the patient when commencing treatment:

- Patient has had the treatment explained to them
 - Explanation of opioid treatment
 - Duration, cost, physical dependence
 - Consent to treatment
 - Discuss the impact of commencing or changing opioid treatment and the use of other drugs on ability to drive or operate heavy machinery in a safe way. This is to occur at commencement of treatment and where there is a substantial change in the opioid treatment medication or dose.
 - Agreed goals of treatment
 - Review of goals during treatment
 - During treatment
 - Clinical reviews
 - all risks associated with opioid treatment. Specific risks should be communicated to the patient regarding:
 - impact of using other drugs
 - possibility of altered tolerance levels and overdose potential
 - intoxication and impact on safety and driving.
 - Medical review – frequency, appointments
 - Investigations (e.g. drug screens)
 - Counselling (where relevant)
 - Travel arrangements and fitness to drive
 - Management of other health problems
 - Medicine
 - Dosing site, attendance, frequency
 - Medicine interactions
 - Safe storage, risks to children/others
 - Take away/non supervised dosing
 - Women’s health
 - fertility, contraception, OAT during pregnancy
 - partner violence
 - Where to get help support during treatment
 - E.g. Opioid Treatment Line (OTL), NSW Users and Aids Association (NUAA)
 - End of treatment
 - Withdrawal off treatment
 - When involuntary end of treatment occurs and what happens

I.2.i Patients' rights and responsibilities

Patients have the right to:

- receive health care given with consideration and respect, without bias or discrimination, thereby recognising personal dignity at all times.
- be assured of privacy at interview, and examination and that any further discussion or consultation is conducted with discretion and confidentiality.
- expect all communications and records pertaining to your care to be treated as confidential and that, in most cases, access to such records will be made available in the presence of a nominated health care professional of your choice.
- be advised by the attending clinician, in clear, concise terms which you understand, the complete and current information relating to your condition – including treatment, prognosis, risks, side or after effects and any alternate treatment or procedures.
- be advised of all risks associated with opioid treatment, and specifically regarding the impact of using other drugs, the possibility of altered tolerance levels and overdose potential, and intoxication and any impact on safety and driving.
- expect adequate information to be provided so that you are able to give informed consent for treatment and procedures. You have the right to refuse services from students and involvement in research.
- be offered the services of a trained interpreter, if required.
- be offered culturally appropriate support, when requested.
- know the identity (first and last names), professional status and qualifications of those providing care and to know which person is primarily responsible for your care.
- seek alternate health care or a second opinion; refuse treatment or withdraw consent at any time, to the extent provided by law.
- expect reasonable safety in both environment and practices and seek legal advice if it is perceived that harm has occurred as a result of negligence of the service.
- nominate a family member, friend, carer, or advocate to participate in the decisions regarding your health care.
- be given information and consultation regarding treatment costs before and throughout treatment.
- to make a complaint and be informed of the process for complaints management.

Patients have the responsibility to:

- work with your prescriber and treating clinicians towards your individual treatment plan
- work respectfully with your treating clinicians
- be aware that treatment cannot continue if clinical staff and/or other patients are exposed to violence or threats
- be aware that starting opioid treatment, changing opioid treatment medication or dose, or using other drugs or alcohol while on opioid treatment may affect your ability to drive safely, and to operate heavy machinery in a safe way
- to avoid driving or operating heavy machinery when informed by a health professional that you may be unsafe to drive for the period advised

I.2.ii Service provider / clinician responsibilities

It is the responsibility of the team treating the patient to:

- Obtain informed consent to methadone/buprenorphine treatment from the patient before he/she commences treatment.
- Develop and document an individualised treatment plan in collaboration with the patient following initial assessment.
- Develop a more detailed treatment plan in collaboration with the patient after 4 weeks in treatment, and review the plan at least every 3 months.
- Obtain NSW Health authority to provide opioid treatment and complete required forms for dosing transfer and exit.
- Provide competent care.
- Treat patients with dignity, respect and courtesy.
- Provide services that are free of physical and mental abuse, coercion, harassment and discrimination.
- Provide services that take into account the cultural, religious, social and ethnic needs, values and beliefs of patients.
- Identify and address any barriers that the patient may have to informed participation in methadone/buprenorphine treatment such as: literacy, non-English speaking, intoxication and disability.
- Provide takeaway doses only after careful assessment of a patient's stability and reliability.
- Advise the patient of the effect methadone and buprenorphine may have on driving safety, and to advise to arrange alternate transport until a stable dose is achieved. All health professionals involved in a patient's treatment have a responsibility for informing patients of the effect methadone and buprenorphine may have on driving safety and operating heavy machinery.

Health professionals also have an obligation to public safety, so if a health professional believes that a patient is not following advice to cease driving, he or she may report directly to the relevant Driver Licensing Authority.

- Provide education about overdose risk, particularly
 - the risk of combining other drugs (including alcohol) with methadone/buprenorphine; and
 - the strategies to avoid and manage overdose, including education about take-home naloxone.
- Act on evidence of client intoxication for the safety of the client and the public. This includes advising the client not to drive or operate heavy machinery, advising the client to arrange alternate transport, and notifying the client to a driver licensing authority and/or the police where necessary.
- Provide information and strategies to enhance the patient's capacity to successfully withdraw from methadone/buprenorphine.
- Support a client's right to make a complaint and have conflicts resolved by:
 - Providing all patients with information on and access to procedures for complaint handling and conflict resolution.
 - Being familiar with complaint procedures and best practice complaint handling.

J. Patient identification

Patient identity must be verified before a patient can be admitted to an opioid treatment program.

Group 1

Positive identification may be established by ANY ONE of the following:

- Passport;
- Photo licence;
- Gaol card showing photo, date of birth, MIN number and signature;
- Proof of age card.

Group 2

Identification may also be established by ANY THREE of the following:

- ATM card;
- Bank or credit union statements or passbook;
- Birth certificate;
- Credit card;
- Marriage certificate;
- Medicare card;
- Pay advice slip;
- Paid bills directed to the patient's current address (e.g. gas, telephone, electricity)

Note: Three ATM cards or credit cards are not acceptable.

Group 3

Identification may also be established by ONE item from this group and ONE item from GROUP 2.

- Gaol release slip;
- Methadone clinic patient ID, as used in transfers between clinics;
- Social security or pension card;
- Licence (no photo).

Note: Check that the signature on any document produced as proof of identity matches the signature on the consent section of the application for treatment.

K. Drugs of addiction (Schedule 8 of the NSW Poisons List)

For substances and preparations classified as drugs of addiction (Schedule 8 of the New South Wales Poisons List), please refer to the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP): <https://www.tga.gov.au/publication/poisons-standard-susmp>

Alternatively, contact the Duty Pharmaceutical Officer, NSW Ministry of Health during office hours on (02) 9391 9944.

L. Australian Treatment Outcomes Profile (ATOP)

ATOP Quick Reference Guide

(for comprehensive administration instructions refer to the ATOP Manual)

About the ATOP

The Australian Treatment Outcomes Profile (ATOP) is a simple set of questions to improve and simplify the review process and assist with on-going treatment planning and clinical handover. The answers to these questions will also provide data for measuring treatment outcomes.

Introducing the ATOP

- I'd like to spend a few minutes completing a short interview (called the ATOP) with you.
- The questions look at substance use, health risk and wellbeing over the last four weeks - some of them may not be relevant to you.
- We are asking all our clients to complete the ATOP.
- We use the information as part of the way we will plan your care and to evaluate how well the service is providing treatment to clients.
- It's important that you answer as accurately and truthfully as you can, but if you don't want to answer any of the questions say so and I'll move on.
- Once we've completed the ATOP we can look more in-depth at your needs and goals.

How to complete the ATOP

1. Carefully explain confidentiality (see box)

Don't assume that clients will be equally concerned or biased about confidentiality issues.

2. Enter:

Patient label (Name, MRN, date of birth and sex);

Your name;

Date of ATOP;

The stage at which the ATOP is being completed;

Main treatment type.

Principal Drug of Concern.

3. Frame the interview:

Use a simple calendar to clarify what you mean by the last four weeks and as a prompt to help the client think back across this period. Week 4=past 7 days (usually); Week 3=7days before that....

4. Enter client responses:

- **Nil drug/alcohol use** – enter “00” in the total box
- **Timeline** – invite the client to recall the number of days in each of the past four weeks on which they did something
- **Quantities** - The average amount used on a typical using day during the past four weeks. Agree unit of measure with your client.
- **Yes and no** – a simple tick for yes or no
- **Rating scale** – a 0-10 scale where “0” is poor and “10” is good. Together with the client, **CIRCLE** a number.
- **Refused/can't recall** – write “NA” (short for Not Answered) next to the total box, tick box or rating scale.

5. Section 1 notes:

Question a: Use the **Alcohol NHMRC Standard Drinks Chart** to calculate standard drinks.

Question f: Examples of Other opioids **include** oxycodone, MS contin, Codeine, Street Methadone, Street Buprenorphine. **Not included:** *Methadone and buprenorphine prescribed for the treatment of opioid dependence.*

Question k: Injecting equipment includes needle, syringe, water, spoon, or filter.

6. Section 2 notes:

- Refer to manual for definitions of homelessness and risk of eviction.
- Before asking **Items (f) to (h)** remind the client about confidentiality issues (**see box**)

7. Business Rules

WHEN

Start of Service Episode

All clients complete an ATOP at the start of a new service unless the client has completed one in the past 28 days and you have accessed a copy of that ATOP.

Progress Review – see manual for details

OTP: New/high needs=monthly; moderate needs =8wks; low needs= 3months.

Non-OTP: Every 3 months.

Discharge

All clients should complete a discharge ATOP within two weeks either side of the planned discharge date.

REFERRAL - when referring a client, for an additional service episode as part of the current treatment plan or to another service provider as part of discharge planning, send a copy of the most recent ATOP with the referral.

CONSENT - it is good practice to share information with the other service providers during the care plan review. It is important that information is shared according to local protocols and that client is informed of this practice. Client consent to share information is not required if all service providers involved are working in the same Local Health District.

Confidentiality

- The ATOP is treated in the same way as any other information held on your health record - it is protected by law from unauthorised access or use - any person who has access to this information is bound by a duty of confidentiality.
- **The courts may subpoena health records and Community Services may request information in child at risk investigations.**
- Where data is to be used to evaluate how well the service is providing treatment, the information pulled from the database will be presented in a format in which individual clients can't be identified.

Section 2: Items (f) to (h)

- I'd like to remind you that the answers you provide to these questions are held on your health record and that courts may subpoena health records and Community Services may request information at child at risk investigations.
- However, I am not asking for any details - just general information about whether you did certain things. Please just answer “yes” or “no”.

* This version of the form is for use with the temporary Access Database only. If you do not use the temporary access database, please use the general version of the ATOP.

ATOP

V5 Feb 2014

Surname: _____ MRN: _____

Given Names: _____

Date of Birth: ____/____/____ Sex: _____

Affix Patient Label here

ATOP DATE ____/____/____

CLINICIAN _____

Treatment stage: Start of service episode Progress review Discharge Post Discharge

Section 1: Substance use

Record number of days used in each of the past four weeks

	Typical qty on day used	Units	Week 4 (most recent)	Week 3	Week 2	Week 1	TOTAL	No answer
a Alcohol	<input type="text"/>	Std drks	<input type="text"/> 0-7	<input type="text"/> 0-7	<input type="text"/> 0-7	<input type="text"/> 0-7	<input type="text"/> 0-28	<input type="checkbox"/>
b Cannabis	<input type="text"/>		<input type="text"/> 0-7	<input type="text"/> 0-7	<input type="text"/> 0-7	<input type="text"/> 0-7	<input type="text"/> 0-28	<input type="checkbox"/>
c Amphetamine type substances (ice, MDMA etc.)	<input type="text"/>		<input type="text"/> 0-7	<input type="text"/> 0-7	<input type="text"/> 0-7	<input type="text"/> 0-7	<input type="text"/> 0-28	<input type="checkbox"/>
d Benzodiazepines (prescribed & illicit)	<input type="text"/>		<input type="text"/> 0-7	<input type="text"/> 0-7	<input type="text"/> 0-7	<input type="text"/> 0-7	<input type="text"/> 0-28	<input type="checkbox"/>
e Heroin	<input type="text"/>		<input type="text"/> 0-7	<input type="text"/> 0-7	<input type="text"/> 0-7	<input type="text"/> 0-7	<input type="text"/> 0-28	<input type="checkbox"/>
f Other opioids (not prescribed methadone/buprenorphine)	<input type="text"/>		<input type="text"/> 0-7	<input type="text"/> 0-7	<input type="text"/> 0-7	<input type="text"/> 0-7	<input type="text"/> 0-28	<input type="checkbox"/>
g Cocaine	<input type="text"/>		<input type="text"/> 0-7	<input type="text"/> 0-7	<input type="text"/> 0-7	<input type="text"/> 0-7	<input type="text"/> 0-28	<input type="checkbox"/>
h (i) Other substance	<input type="text"/>		<input type="text"/> 0-7	<input type="text"/> 0-7	<input type="text"/> 0-7	<input type="text"/> 0-7	<input type="text"/> 0-28	<input type="checkbox"/>
..... (ii) Other substance	<input type="text"/>		<input type="text"/> 0-7	<input type="text"/> 0-7	<input type="text"/> 0-7	<input type="text"/> 0-7	<input type="text"/> 0-28	<input type="checkbox"/>
..... i Daily tobacco use?	<input type="text"/>		Yes <input type="checkbox"/>	No <input type="checkbox"/>	Not answered <input type="checkbox"/>			

Record number of days client injected drugs in the past four weeks (if no, enter zero and go to section 2)

	Week 4	Week 3	Week 2	Week 1	TOTAL	No answer
j Injected	<input type="text"/> 0-7	<input type="text"/> 0-7	<input type="text"/> 0-7	<input type="text"/> 0-7	<input type="text"/> 0-28	<input type="checkbox"/>
k Inject with equipment used by someone else?	Yes <input type="checkbox"/>		No <input type="checkbox"/>		Not answered <input type="checkbox"/>	

Section 2: Health and Wellbeing

Record days worked and at college, school or vocational training for the past four weeks

	Week 4	Week 3	Week 2	Week 1	TOTAL	No answer
a Days paid work (incl. all paid work; not voluntary work)	<input type="text"/> 0-7	<input type="text"/> 0-7	<input type="text"/> 0-7	<input type="text"/> 0-7	<input type="text"/> 0-28	<input type="checkbox"/>
b Days at school, tertiary education, vocational training	<input type="text"/> 0-7	<input type="text"/> 0-7	<input type="text"/> 0-7	<input type="text"/> 0-7	<input type="text"/> 0-28	<input type="checkbox"/>

Record the following items for the past four weeks

c Have you been homeless?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Not answered <input type="checkbox"/>
d Have you been at risk of eviction?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Not answered <input type="checkbox"/>
e Have you, at any time in the past four weeks, been a <u>primary caregiver</u> for	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Not answered <input type="checkbox"/>
or <u>living with</u> any child/children	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Not answered <input type="checkbox"/>
f Have you been arrested?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Not answered <input type="checkbox"/>
g Have you been violent (incl. domestic violence) towards someone?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Not answered <input type="checkbox"/>
h Has anyone been violent (incl. domestic violence) towards you?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Not answered <input type="checkbox"/>

i Client's rating of **psychological health status** (anxiety, depression and problem emotions and feelings)

0 1 2 3 4 5 6 7 8 9 10 Not answered

Poor Good

j Client's rating of **physical health status** (extent of physical symptoms and bothered by illness)

0 1 2 3 4 5 6 7 8 9 10 Not answered

Poor Good

k Client's rating of **overall quality of life** (e.g. able to enjoy life, gets on well with family and partner, satisfied with living conditions)

0 1 2 3 4 5 6 7 8 9 10 Not answered

Poor Good

M. Detection times for selected drugs in urine

Drug	Time
Alcohol	4-24 hours
Amphetamine-like substances: including amphetamine, methamphetamine, ecstasy (MDMA)	2-4 days
Benzodiazepines - Short acting - Long acting (high level misuse)	1-3 days 1-2 weeks (up to 6 weeks)
Buprenorphine (sublingual)	1-2 weeks
Cannabis (50 g/L screen cut-off) -Occasional - Chronic, very heavy use	1-3 weeks 4-6 weeks (may be up to 12 weeks)
Cocaine metabolites	2-4 days
Monoacetylmorphine (heroin metabolite)	12-24 hours
Methadone	3-4 days
Opiates: codeine, morphine	2-3 days (metabolites 3-6 days)
Oxycodone	1-2 days

* Times are estimates only. Detection times for an individual may vary with specific drug, dose and metabolism.

Based on information supplied by SA Pathology, Frome Road, Adelaide

N. Adverse effects with opioid agonist treatment

An adverse drug reaction (ADR) is any undesired or unintended effect of drug treatment. An ADR may be predictable on the basis of the drug's known actions, or unpredictable (e.g. allergic drug responses, idiosyncratic drug reactions). It can be difficult to establish the causal agent in allergic reactions. Reported allergies need to be approached with caution because of the potentially serious consequences of severe reactions.

The reported side effects of methadone and buprenorphine are qualitatively similar to those of other opioid drugs.(Table O.1) Most people who have used heroin or other opioids will experience few side effects.

Table O.1 Common side effects with opioid agonist treatment

Side effect	Common causes	Things you can do
Feeling drowsy after taking dose	Dose too high	Lower the maintenance dose and review other medicines the patient may be taking.
	Other drug use (legal or illegal)	Review use of sedative and other drugs affecting cognition.
Withdrawal symptoms maximal before next dose	Dose too low	Raise maintenance dose.
	Changes in legal or illegal drugs that patient may be using	Review other drugs patient is taking.
Withdrawal precipitated by buprenorphine dose	Occurs early in treatment (or after absence from treatment) when buprenorphine dose administered soon after opioid use (e.g. heroin, methadone, morphine)	Transient effect. Aim to prevent by patient education. Delay buprenorphine dose until patient experiencing opioid withdrawal. Discourage use of on-top heroin.
Headache	Common in first week of buprenorphine treatment	Side effect is transient and generally mild. Consider aspirin or paracetamol.
	Other causes of headache	Consider other causes.
Nausea	Common early in treatment, particularly if buprenorphine dose high	Side effect usually transient (days). Avoid rapid dose increases. Consider dose-reduction if persistent.
Constipation	All opioids do this. Will be made worse by lack of dietary fibre, fluid intake or exercise.	Encourage fibre intake (fruit, cereals, vegetables), fluids, and regular exercise. Stimulant laxatives if necessary.
Poor sleep	Dose too low and causing withdrawal at night	Review maintenance dose and review other medicines.
	Dose too late at night, causing stimulation at time of peak effects Other drugs (particularly stimulants in the evening, such as coffee, nicotine, amphetamines) General anxiety or irregular sleep pattern Depressive illness	Follow sleep hygiene recommendations.
	Central sleep apnoea	

Side effect	Common causes	Things you can do
Weight gain, particularly for women	Fluid retention caused by opioids - more likely on high doses	Lower dose.
	Eating more while in treatment; high salt intake	Reduce fat and salt in diet, exercise regimen.
Amenorrhoea or oligomenorrhoea	All opioids can do this May be related to lifestyle, stressors, poor diet, and general poor health	Periods may return after cessation of heroin use, or following withdrawal from opioids. Address other causes.
Lowered sex drive	More common with a high dose through effect on sex hormones Can be many other psychological factors (such as anxiety, poor relationship with partner, etc.)	Review dose. Consider investigation for opioid-induced hypogonadism.
Dental problems	All opioids reduce saliva flow Poor diet, dental hygiene	Encourage oral hygiene, dental floss and use of sugar free gum. Dental check-up. Reduce intake of sugary drinks and sweet food.

Modified from Dunlop *et al.*, (1996). *Getting through methadone withdrawal*. Turning Point Alcohol & Drug Centre: Fitzroy, Melbourne.

Once on a stable dose, tolerance develops until cognitive skills and attention are not impaired.

Studies have identified insomnia, sweating, painful joints and bones, constipation and craving as the most common complaints of methadone maintenance patients. These complaints are experienced to some extent, by 40–50% of patients and to a severe degree by approximately 20%. Around one-third may experience withdrawal symptoms due to the methadone dose not ‘holding’ for the full 24-hour period.¹² A three-year prospective study in the USA of persons entering treatment with methadone identified increased perspiration as the only side effect that persisted.¹³ This study also identified adult onset diabetes, obesity and hiatus hernia (reflux oesophagitis) as being more common in the methadone-maintained population compared to untreated heroin users matched for age and years of addiction. In contrast, in the heroin-dependent populations, cutaneous ulcers, skin infections, bacterial endocarditis, burns and gunshot wounds were more common. Many specific components of immune function are severely compromised in heroin addicts. During opioid agonist treatment with methadone there is a steady and continuing improvement, with eventual normalisation of these components.¹³

Symptoms of constipation, sexual dysfunction and occasionally increased sweating can continue to be troubling for the duration of opioid agonist treatment with methadone¹⁴. People rarely develop tolerance to the constipating effects of opioids and patients on opioid agonist treatment may experience chronic constipation. Encourage the consumption of plenty of fruits and vegetables and non-alcoholic fluids each day, and stimulant laxatives if necessary. Central sleep apnoea can be a side effect of methadone and is exacerbated by the use of night sedation.^{15,16}

In large, multicentre trials of buprenorphine maintenance treatment, the most common adverse event (reported in over 30% of patients) has been opioid withdrawal symptoms, and these reports have been most common in patients on low doses of buprenorphine (e.g. 1 mg daily). Other commonly reported adverse events reported by the manufacturer are headache, constipation, insomnia, asthenia, somnolence, nausea, dizziness, and sweating, occurring in less than 10% of patients, particularly with doses of buprenorphine greater than 8 mg/day.

Elucidate the cause of any significant lethargy. Dose of medicine, particularly methadone, may need to be reduced.

For excessive sweating, try reducing the dose but this may not alleviate the symptoms. Sweating can also be a prominent symptom in withdrawal – careful history taking and observation of the patient prior to dosing may be necessary to assist in making the distinction.

Buprenorphine may be the optimal choice for those with renal dysfunction requiring maintenance treatment.¹⁷

Overdose

The major hazard associated with opioid agonist treatment is the risk of overdose, particularly with methadone. Induction onto methadone maintenance treatment is more hazardous than induction onto buprenorphine (★★). An analysis of 42,676 entrants to opioid pharmacotherapy treatment in New South Wales during the period 1985 to 2006, identified only one death during induction onto buprenorphine. This related to a crude mortality rate of 2.5 per 1000 person years, compared to 26.3 per 1000 person years for methadone induction during the same period.¹⁸

Methadone

The risk of methadone overdose is particularly high at the time of [induction to methadone](#) maintenance treatment and when methadone is used in combination with other sedative drugs. The relatively slow onset of action and long half-life mean that methadone overdose can be highly deceptive and toxic effects may become life threatening (overdose) many hours after ingestion. Because methadone levels rise progressively with successive doses during induction into treatment, most deaths in this period have occurred on the third or fourth day of treatment.

Signs and symptoms of methadone overdose:

- pinpoint pupils;
- nausea;
- dizziness;
- feeling intoxicated;
- sedation/nodding off;
- unsteady gait, slurred speech;
- snoring;
- hypotension;
- slow pulse (bradycardia);
- shallow breathing (hypoventilation);
- frothing at the mouth (pulmonary oedema);
- coma.

NOTE: Symptoms may last for 24 hours or more. Death generally occurs from respiratory depression.

Most deaths during stabilisation on methadone have involved other drugs, in particular, alcohol, benzodiazepines and antidepressants. Patients should be warned of the risks associated with using other drugs with methadone.

Death during methadone induction often occurs at home during sleep, many hours after peak blood methadone concentrations have occurred. Typically overdose occurs around the third or fourth day of methadone induction.

Given that many deaths occur during sleep, administration of methadone in the morning will ensure peak methadone concentrations occur when patients are normally awake and other people may be around if overdose should occur.

Naloxone promptly reverses opioid induced coma. However, a single dose of naloxone will wear off within one hour leaving patients at risk of relapse into coma due to the long lasting effects of methadone.¹⁴ Monitoring of the person's clinical state is important. Transfer to hospital is appropriate for determination of the need for prolonged infusion of naloxone.

Patients who are thought to have taken a methadone overdose require prolonged observation.

Family members should be warned that deep snoring during induction to treatment could be a sign of dangerous respiratory depression and should be reported to the prescriber. Heavy snoring during maintenance treatment may be associated with sleep apnoea and should also be reported.

Buprenorphine

The risk of lethal overdose in an opioid-tolerant individual on buprenorphine is substantially less than that associated with the use of other opioid medicines, such as methadone.^{19,20} This is due to the ceiling dose response effects of buprenorphine.

While overdose on buprenorphine is relatively uncommon, there is a greater risk when it is combined with other sedative drugs, such as alcohol, benzodiazepines, barbiturates, tricyclic antidepressants and major tranquillisers. Deaths due to the combination of buprenorphine and other sedatives have been reported.²¹⁻²⁴

Prolongation of QTc interval

The QTc interval normally varies depending on heart rate, age and gender. The QTc interval may be influenced by electrolyte balance, medicines, and ischaemia. There is evidence that QTc interval prolongation is associated with increased risk of cardiovascular comorbidities, including sudden cardiac death, with the degree of risk increasing with age^{25,26} and a range of other risk factors.²⁷

QTc interval prolongation is evident in 10-15% of people on methadone maintenance treatment, but not buprenorphine.^{8,9,28} Although the greatest prolongation of QTc interval has been observed²⁹ in men receiving higher methadone doses (110 to 150 mg) there is no clear evidence on the relationship between dose and QTc interval.

A number of other factors, in addition to methadone, appear to be important in QTc prolongation in opioid dependent people, including:

- congenital long QTc syndrome (family history, including family history of unexplained sudden death);
- cardiac abnormalities (infective endocarditis, valvular lesions, cardiomyopathy, ischaemia);
- other drugs, including medicines (atypical antipsychotics, tricyclic antidepressants, antiretroviral agents – link to drug interactions below and appendix 3) and non-medical substance use (alcohol, caffeine, amphetamines, cocaine and other stimulants, tobacco);

- electrolyte or metabolic disturbances (including systemic infections, hypokalaemia as may occur with vomiting and diarrhoea associated with alcohol or opioid withdrawal).

Drug interactions

Methadone and buprenorphine exert additional sedative effects when used in conjunction with other sedating medicines. These include other opioids, benzodiazepines, alcohol, tricyclic antidepressants, sedating antihistamines, and major tranquillisers.

As methadone has a more marked respiratory depressant effect, the interaction between methadone and sedative drugs is more significant. However, the combination of buprenorphine with benzodiazepines, alcohol and other sedatives has also been associated with fatal overdoses.

Other drug interactions may arise from effects on liver enzymes, either increasing or decreasing metabolism of methadone or buprenorphine or the medicine being used in combination with methadone or buprenorphine.

The most significant interactions are with drugs that inhibit the activity of the cytochrome system (particularly CYP450-3A), which results in decreased metabolism of methadone or buprenorphine and consequently increased blood levels.³⁰ Such interactions are most significant with methadone due to the potential for overdose.

Glossary

Abstinence	Not using a particular drug; being drug-free.
Addiction	A chronic, relapsing disorder characterised by compulsion to seek and take a substance, loss of control over substance use, and a negative emotional state when access to the substance is prevented. ³¹
Adverse event	Any untoward medical occurrence in a patient administered medicine and which does not necessarily have a causal relationship with this medicine.
Adverse reaction	A harmful or undesirable response to an agent/substance.
Affinity	The strength with which a drug binds to its receptor.
Agonist	A substance that binds to and activates the matching receptor.
Antagonist	A substance that binds to a receptor without activating it; a blocking agent.
Authority	An authority under the <i>NSW Poisons and Therapeutic Goods Act</i> for prescribers in NSW is issued by the NSW Ministry of Health and is legally required by a medical practitioner or nurse/midwife practitioner to prescribe or supply a drug of addiction. This State authority is distinct from, and independent of, any authority from Medicare Australia for Pharmaceutical Benefits (PBS) which is solely for the purpose of subsidising the cost of the medicine to the patient.
Aversive agent	Medicine that produces an unpleasant reaction, for example disulfiram (Antabuse) is aversive in combination with alcohol.
B3 risk	Under the system established by the Australian Drug Evaluation Committee, Pregnancy Category B3 drugs are those that have been taken by only a limited number of pregnant women and women of childbearing age, without an increase in the frequency of malformation or other direct or indirect harmful effects on the human foetus having been observed. Studies in animals have shown evidence of an increased occurrence of foetal damage, the significance of which is considered uncertain in humans. For more information go to http://www.tga.gov.au/ and search for the medicines in pregnancy database.
Buprenorphine	Derived from the opium alkaloid, thebaine; a partial opioid agonist with high affinity for the mu opioid receptor.
Clinical review	A direct 'clinical occasion of service with the patient' and possibly with other team members, advocates or carers present, where the patient's clinical circumstances, current treatment conditions and treatment plan are assessed and reviewed.
Combination preparation	Refers to preparations for sublingual administration containing buprenorphine and naloxone (e.g. Suboxone®).
Compulsivity	Elements of behaviour that result in perseveration in responding in the face of adverse consequences, perseveration in responding in the face of incorrect responses in choice situations, or persistent re-initiation of habitual acts.
Craving	Subjective experience of an urge or desire to use substances ³² that may be diverse in nature.
Dependence	A state in which drug use has become central to a person's thoughts, emotions and activities; stopping, or reducing the drug suddenly, can lead to physical withdrawal symptoms. See also Addiction. (See Appendix A)
Detoxification	Management of the signs and symptoms of withdrawal that occur on cessation of a substance on which a person is dependent. See withdrawal interventions.
Dissociation	A measure of the disengagement or uncoupling of a drug from its receptor.
Euphoria	Feeling of intense wellbeing – a 'high' or 'rush'.
Illicit	Not legal.
Impulsivity	A predisposition toward rapid, unplanned reactions to internal and external stimuli without regard for the negative consequences of these reactions to themselves or others.
Intrinsic activity	The degree to which a drug activates its receptors.
Lapse	Relevant only to abstinence-oriented programs where it is used to indicate an instance of alcohol or other drug use.

Methadone	A synthetic opioid agonist.
Naloxone	An antagonist at the mu opioid receptor with a short half-life that is used in the treatment of opioid overdose, but is also combined with buprenorphine to deter non-medical use and diversion.
Negative reinforcement	The process by which removal of an adverse stimulus (e.g. negative emotional state of drug withdrawal) increases the probability of a response (e.g. dependence-induced drug intake).
Opiate	One of a group of alkaloids, including morphine and heroin, derived from the opium poppy (<i>Papaver somniferum</i>) with the ability to induce analgesia, euphoria and, in higher doses, stupor, coma and respiratory depression.
Opioid	All drugs with morphine-like activity, both natural opiates and synthetic drugs such as methadone.
Opioid receptors	Brain structures that mediate the effects of opioid drugs.
Positive reinforcement	The process by which presentation of a stimulus, usually pleasant (e.g. the drug itself), increases the probability of a response.
Precipitated withdrawal	Precipitated withdrawal can occur when an antagonist (or partial antagonist, such as buprenorphine) is administered to a patient dependent on full agonist opioids. Due to buprenorphine's high affinity but low intrinsic activity at the mu receptor, the partial antagonist displaces agonist opioids from the mu receptors, without activating the receptor to an equivalent degree, resulting in a net decrease in agonist effect, thus precipitating a withdrawal syndrome.
QTc interval	That part of a person's electrocardiogram reading that begins at the onset of the QRS complex and extends to the end of the T wave. The QTc interval represents the time between the start of ventricular depolarisation and the end of ventricular repolarisation.
Rapid opioid detoxification	A general term for procedures involving the use of opioid antagonists to induce withdrawal from opioids.
Receptors	Brain structures which bind particular drugs; the effects of a drug are experienced when the drug has attached itself to its corresponding receptor.
Recovery capital	The sum total of all the personal, social, and community resources a person can draw on to begin and sustain his recovery from drug and alcohol problems. ³³
Relapse	Return to problematic use of alcohol or other drugs.
Supervised dosing	Refers to the direct observation of the patient taking their medicine by the administered dose and route, by an appropriate health professional.
Supervised dosing regimen	Involves routine supervision of all doses (exceptions may apply for special circumstances).
Takeaway dosing regimen	Describes a combination of supervised and takeaway doses routinely provided.
Takeaways	Dispensed doses of medicine to be taken from the dispensing point for later consumption by the patient.
Tolerance	Requiring higher doses of the drug to experience the same effects.
Treatment plan review	A comprehensive consultation that involves examining longer-term goals and treatment plans addressing broader health and social issues, screening and prevention activities, and consideration of cessation of medicine. It should also include consultation with other service providers involved in the treatment care plan, and may include the patient's carers or advocates.
Non-medical	Usually referring to use of drugs that is not in accordance with a medical prescription.
Unsupervised dosing regimen	Refers to the dispensing of medicine without regular or frequent (i.e. less than weekly) supervision of dosing. Unsupervised dosing is restricted to buprenorphine-naloxone treatment (methadone and buprenorphine routinely require some level of supervised dosing).
Withdrawal	Signs and symptoms associated with cessation of a substance on which a person is dependent.
Withdrawal interventions	Management of the signs and symptoms of withdrawal that occur on cessation of a substance on which a person is dependent.

Resources

National Drug Strategy www.nationaldrugstrategy.gov.au

National Pharmacotherapy Policy for people dependent on opioids <http://www.nationaldrugstrategy.gov.au/internet/drugstrategy/publishing.nsf/content/pharmacotherapy> Guidelines for pharmacists providing opioid pharmacotherapy services (Pharmaceutical Society of Australia)

Professional Practice Standards, version 4. Standard 18: Harm minimisation. (Pharmaceutical Society of Australia, 2010) [Currently under review] www.psa.org.au/downloads/standards/professional-practice-standards-v4.pdf

Guidance for the provision of a *Pharmacist Only* medicine: Naloxone (Pharmaceutical Society of Australia, 2016)

Opioid agonist treatment resource manual (The Pharmacy Guild of Australia) <https://www.guild.org.au/docs/default-source/nsw-branch-public/professional-services/dependency-care/pharmacotherapy/opioid-substitution-resource-manual.pdf?sfvrsn=0>

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