The Pharmacy Guild of Australia
NSW Branch

Opioid Treatment Program Resource Manual

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TABLE OF CONTENTS

DISCLAIMER

Important: All dosing of OTP patients should be in accordance with NSW Opioid Treatment Program Community Pharmacy Dosing Point Protocol (TG201/5); NSW Clinical Guidelines for the use of depot Buprenorphine (Buvidal® and Sublocade®) in the Treatment of Opioid Dependence-2019; and NSW Clinical Guidelines: Treatment of Opioid Dependence-2018. This manual is intended as a supplementary resource only.

INTRODUCTION

The Pharmacy Guild of Australia (NSW Branch) has developed this manual as a practical resource to assist pharmacies in the delivery of the Opioid Treatment Program.

Pharmacists delivering the service should have access to and knowledge of the following references and Legislation:

- NSW Clinical Guidelines: Treatment of Opioid Dependence-2018
- NSW Clinical Guidelines for the Use of Depot Buprenorphine (Buvidal® and Sublocade®) in the Treatment of Opioid Dependence-2019
- NSW Opioid Treatment Program-Community Pharmacy Dosing Point Protocol (TG201/5)
- Poisons and Therapeutic Goods Act 1966
- Poisons and Therapeutic Goods Regulation 2008
- Guidance for Accessing and Delivering AOD Services during Covid-19
- SafeScript NSW

Compliance with the current Community Pharmacy Dosing Point Protocol is mandatory for all pharmacies participating in the NSW Opioid Treatment Program. Adherence to the protocol will improve safety in delivering the program and maintain a consistent professional standard of service delivery for Pharmacies in NSW. Re-auditing regularly as part of continuous quality improvement is recommended. The self-audit should be completed every 6-12 months.

Opioid dependence is a complex health condition that often requires long-term treatment and care. Treating opioid dependence involves the user overcoming the compulsion of drug use, ongoing cravings, physical adaptation to chronic drug use as well as the social and psychological issues that may underlie their reasons for using drugs.

Opioid substitution treatment (OST) is well established in Australia as an effective treatment for opioid dependence. It is also referred to as medication assisted treatment for opioid dependence (MATOD), opioid replacement therapy (ORT), opioid pharmacotherapy or opioid agonist therapy (OAT). These terms may be used interchangeably, however the NSW OPIOID TREATMENT PROGRAM COMMUNITY PHARMACY DOSING POINT PROTOCOL (TG201/5) uses Opioid Treatment Program (OTP) as its preferred terminology. The ease of access and non-judgmental nature of community pharmacy makes it an ideal location to provide this service.

The pharmacist in charge is responsible for complying with relevant state regulation that governs the dispensing of the relevant pharmacotherapy in each state. The Proprietor Pharmacist must ensure that the premises and all relevant equipment (e.g. drug safe) meet state regulations and that there is sufficient staff with appropriate training and access to suitable references.

In NSW many people who are on pharmacotherapy programs obtain their treatment medications through their local community pharmacy. The provision of pharmacotherapy treatments involves integration of prescribers/drug treatment clinicians and community pharmacies working on a coordinated system of health care delivery. Many people in treatment obtain information, advice, and support in their treatment at their local pharmacy.

REGISTERING AS AN OPIOID TREATMENT PROGRAM DOSING POINT

Community pharmacies wishing to offer an Opioid Treatment Program must receive approval from the Pharmaceutical Regulatory Unit of NSW Health. The application to Become a Registered Opioid Treatment Program Dosing Point is available on the Pharmaceutical Services Website: https://www.health.nsw.gov.au/pharmaceutical/pharmacists/Pages/otp-pharmacists.aspx . The following requirements must be met:

- All owners of the Pharmacy must be on the application form
- The name of the Pharmacy included on the form appears on the Pharmacy Council of NSW Register of Pharmacies
- The Pharmacy must be approved to supply pharmaceutical benefits under Section 90 of the National Health Act 1953

PHARMACY INCENTIVE SCHEME

The NSW Opioid Treatment Program (OTP) seeks to reduce the social, economic, and health harms associated with opioid use1. This includes the delivery of pharmacotherapy and associated services through various sectors, including community pharmacy.

To support community pharmacies in their involvement with the NSW OTP through provision of pharmacotherapy, community pharmacies are able to register to participate in the NSW Pharmacy Incentive Scheme.

The Pharmacy Incentive Scheme is funded by the NSW Ministry of Health, and is administered by The Pharmacy Guild of Australia (NSW Branch).

It is a two-step process for community pharmacies seeking to be involved in the NSW OTP through the provision of pharmacotherapy, and the NSW Pharmacy Incentive Scheme.

Step 1: Register with the NSW Ministry of Health
The NSW Ministry of Health manages the registration and approval of NSW community pharmacies to supply methadone or buprenorphine (including buprenorphine-naloxone) under the NSW OTP. Applications are generally processed within 5 business days. Please note that methadone and/or buprenorphine cannot be ordered from a supplier until the registration process is complete.

Further information, including the application form for completion is available at:
http://www.health.nsw.gov.au/pharmaceutical/pharmacists/Pages/otp-pharmacists.aspx
Re-registration with NSW Health to supply methadone and/or buprenorphine under the NSW OTP is required in the following circumstances:

- Where there is to be a change in address
- Where there is to a chance in ownership (new proprietors or partners)
- Where there is to be a chance in the trading name of the pharmacy

When applying for approval as a dosing point the proprietor is signing an undertaking that they and all registered pharmacists under his/her employment have read and have an understanding of the latest edition of the NSW Ministry of Health's Guideline TG201 "NSW Opioid Treatment Program: Community Pharmacy Dosing Point Protocol. It is the proprietor's responsibility to ensure OTP is compliant with TG201 and to not assume the previous proprietor's system is compliant because they have been providing OTP for an extended period of time.

Step 2: Register with the Pharmacy Guild of Australia (NSW)
The Pharmacy Guild of Australia (NSW Branch) administers the Pharmacy Incentive Scheme, which is fully funded by the NSW Ministry of Health.

The Pharmacy Guild of Australia (NSW Branch) will contact your pharmacy following notification that your pharmacy has been approved to supply pharmacotherapy under the NSW OTP.

Once a pharmacy has dosed at least one patient for at least two months, they qualify for an Initial Incentive Payment of $1000 + GST. The pharmacy is required to complete a registration form and meet some quality assurance requirements in order to receive this payment.

Ongoing Incentives are paid twice yearly upon submission of the Six Month Declaration Form to the NSW Branch of the Guild. The Incentive payment is $50 + GST per patient being continuously dosed on the OTP (including Depot Buprenorphine) for at least two months during the reporting period. The incentive is capped at 40 patients or $2000. In addition to this, incentive payments for completing quality improvement activities related to the provision of the OTP by all pharmacy staff involved. The incentive payment is $50 + GST for every hour of CPD with at least 1 self-audit to be completed every six months to qualify for the payment (maximum of $500 + GST per six-monthly period). See Appendix 1 for "*Self-audit for community pharmacies providing OTP Service*".

REGULATORY REQUIREMENTS IN TRANSFERRING Opioid Agonist Treatment (OAT) BETWEEN PROVIDERS

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. *See Appendix 9 of this document and refer to "NSW Clinical Guidelines: Treatment of Opioid Dependence – 2018" (Page 56).*

MEDICATIONS USED IN NSW OPIOID TREATMENT PROGRAM

Methadone

Methadone is the most established medication used in OTP and accounts for 60% of OTP patients in Australia.

Methadone is a synthetic opioid agonist with a long half-life of around 24-48 hours. It is cross-tolerant with other opioid drugs, and provides a steady-state that allows the person to function normally. Upon oral administration, methadone is slowly absorbed, which results in less intoxication (compared to other opioids) and withdrawal symptoms.

Methadone is taken daily as an oral liquid, in a concentration of 5mg/mL (Aspen Methadone Syrup®, Biodone Forte®)

Tablet forms are also available (Physeptone®), however these are generally used for analgesia and are not indicated in the treatment of opioid dependence. Under special circumstances, in some jurisdictions they may be used for longer term take-away doses, such as when a patient is travelling.

Buprenorphine

Unlike heroin and methadone (which are full agonists), buprenorphine is a partial opioid agonist, and exerts weaker effects at opioid receptors.

Buprenorphine has two primary actions in the treatment of opioid dependence:

- It has a high affinity for opioid receptors, and therefore prevents the binding of other full agonists such as heroin, oxycodone and morphine. This reduces the patient's response if additional opioids are taken. It can also precipitate withdrawal by displacing other opioids from receptors.
- The opioid effects of buprenorphine reduce the physical symptoms of withdrawal. However, unlike methadone, the opioid effects of buprenorphine such as respiratory depression reach a ceiling, with higher doses not increasing the effect to a significant degree. This makes buprenorphine safer than methadone in overdose.

Buprenorphine has a longer half-life than methadone (approximately 35 hours) which allows the option of alternate-day dosing. Buprenorphine is available as a sublingual tablet (Subutex®) in 2mg and 8mg strengths. Patches (Norspan®) are not indicated in the treatment of opioid dependence.

Depot Buprenorphine is also available as a new, long-acting formulation of Buprenorphine for use in Opioid Pharmacotherapy. There are currently only two registered products of Depot Buprenorphine available on the Pharmaceutical Benefits Scheme (PBS) under a S100 opioid dependence listing: Budival® and Sublocade®.

Buprenorphine – naloxone combination

A combination of buprenorphine and naloxone is available in a film preparation, with a ratio of 4:1. When taken sublingually, the formulation acts as if it was buprenorphine alone. However if the preparation is injected, the naloxone reduces the effects of buprenorphine in the short-term, as well as precipitate withdrawal symptoms in individuals using other opioids. This makes the buprenorphine-naloxone film less desirable to inject, thereby limiting potential misuse and diversion.

Patients choosing buprenorphine as their preferred OAT should be commenced on the combination preparation, unless they have a proven allergy to naloxone.

Suboxone® is now more commonly prescribed than buprenorphine alone (Subutex®) in Australia, and its rate of use is increasing. It is available as a sublingual film as either 2/0.5mg or 8/2mg.

Buprenorphine – Long acting Injection

Depot Buprenorphine formulations provide further developments in the model of care for Opioid treatment therapy. Several potentially important benefits of the availability of these products in once-a-week and once-a-month depot injections will become evident and are expected to enhance current OTP treatment outcomes. These potential benefits include:

- Greater convenience for patients in that they will not have to attend dosing sites (pharmacies, clinics);
- Reduced treatment costs for patients and service providers;
- Less risk of diversion and non-medical use of the medication, enhancing community safety;
- Greater medication adherence and enhanced treatment outcomes for some patients who struggle to attend regularly with sublingual buprenorphine;

Budival® is a modified release formulation of Buprenorphine for administration by subcutaneous injection once a week (Budival® Weekly) or once a month (Budival® Monthly). Budival® Weekly is available in four dose strengths in prefilled syringes (8mg/0.16mL; 16mg/0.32mL; 24mg/0.48mL; or 32mg/0.64mL). Budival® Monthly is available in three dose strengths in prefilled syringes (64mg/0.18mL; 96mg/0.27mL; or 128mg/0.36mL).

Sublocade® is an extended-release formulation of buprenorphine for administration monthly by subcutaneous injection. It provides sustained plasma levels of buprenorphine over the monthly dosing interval. Sublocade® is available in two dose strengths (100mg/0.5mL and 300mg/1.5mL).

Adverse effects

The adverse effects of methadone and buprenorphine are similar to other opioid drugs. This includes:

- Excess sweating
- Dental caries
- Constipation
- Sleep apnoea
- Nausea
- Drowsiness
- Osteoporosis
- Sexual dysfunction

Additionally, adverse effects of depot buprenorphine relating to the injection of the drug include:

- Pain and/or swelling at the injection site
- Pruritus
- Induration
- Bruising
- Cellulitis
- Erythema

Many opioid adverse effects subside in the first two to four weeks of treatment, but others may persist throughout treatment.

Clinical review and monitoring

Patient safety is an important consideration when supplying OTP. Pharmacists should review the patient for signs of intoxication or withdrawal symptoms, particularly in the first few weeks of treatment, and contact the prescriber to discuss any identified issues. Issues and actions taken should be documented. Refer to the "Managing Driving Safety for at risk patients" in Appendix 10, if you have concerns about the patient's driving ability following review.

Intoxication:

- Stupor
- Drowsiness
- Slurred speech
- Unrousable snoring (Indicates respiratory depression-Medical Emergency)
- Poor balance
- Unsteady gait

Withdrawal:

- Anxiety, irritation, restlessness
- Dilated pupils
- Yawning, watery eyes and nose
- Hot and cold flushes, sweating, "goosebumps"
- Stomach cramps, vomiting
- Muscular pain, twitches, tremors

Interactions:

A range of clinically significant and potential drug interactions can occur with methadone and buprenorphine and other medicines. Refer to appendix E, F and G of the Clinical Guidelines ; and Appendix A of the *Clinical Guidelines for use of depot buprenorphine (Budival® and Sublocade®) in the treatment of opioid dependence* for more information.

PRACTICAL CONSIDERATIONS BEFORE PROVIDING AN OTP SERVICE

Community pharmacy provides a valuable service by offering OTP. For pharmacies that are considering offering the service, there are a number of factors which need to be considered to ensure that the service is professional, compliant with legislative requirements and fulfils a duty of care to patients.

Considerations include:

- Staff levels (both pharmacist and non-pharmacist staff)
- Training in pharmacotherapy
- Development of policies and procedures
- Appropriate equipment
- Recording and reporting requirements
- Storage requirements-Budival® and Sublocade®
- Current workload
- Opening hours

Staff and training

Pharmacies offering an OTP service should consider their staffing levels, ensuring they allow time for providing doses to OTP patients. Dispensing and supervision of doses of methadone and buprenorphine must be carried out by a pharmacist, not delegated to a pharmacy assistant or dispensary assistant.

It is important that the number of patients is at a reasonable level to ensure that there is no reduction in the service of care being provided to patients.

Ensuring that staff understand the benefits and processes involved in providing an OTP service is important to ensure that patients are safe and feel comfortable within the pharmacy. Discussing any staff concerns about an OTP service should be an important aspect of all training. This includes addressing and minimising stigma.

Policies and procedures

An OTP dosing service may be conducted in many different ways. It is therefore essential that all pharmacists supervising dose administration at the pharmacy have access to accurate and current policies and procedures. These should be readily available at the site of dosing.

A number of templates exist to assist pharmacies in producing their policies and procedures. Examples include:

- Quality Care Pharmacy Program (QCPP) Checklist for pharmacists dispensing methadone or buprenorphine

Appropriate Equipment

To ensure efficient and safe delivery and to meet regulatory requirements of the OTP service the pharmacy may require specialised equipment. Refer to "**Equipment for OTP Service**" on Page 9 of this manual.

Storage Requirements-Budival® and Sublocade®

Budival® Weekly and Monthly should be stored at room temperature (below 25°C)-do not refrigerate or freeze. Sublocade® demands cold storage requirements (2-8°C) but it may be stored at room temperature (below 25°C) for up to 7 days before use. Removal from cold storage is required for at least 15 minutes prior to subcutaneous injection.

Furthermore, the cold storage requirements for Sublocade® must meet the following requirements to comply with the Poisons and Therapeutic Goods legislation:

- The refrigerator must be in a room (which includes a part of a room or an enclosure) where there is no public access;
- The refrigerator, or any cupboard or receptacle in which the refrigerator is kept, must be locked securely at all times when not in immediate use;
- Any other items that are not a substance listed in Schedule 2, 3, 4 or 8 of the Poisons List or are not a therapeutic good must not be stored in this refrigerator

Once outside the refrigerator, Sublocade® injections must be kept apart from all other goods (other than cash or documents) in a safe which is securely attached to a part of the premises and kept locked at all times when not in use. Sublocade® should be discarded if left at room temperature for longer than 7 days.

Dosing area

When considering the pharmacy environment for dosing patients with methadone and buprenorphine, attention needs to be given to issues of both security and confidentiality. A discreet location, such as a private consultation room, for the administration of supervised pharmacotherapy doses is recommended for patient confidentiality.

While many pharmacies have designed specific dosing areas of the pharmacy for delivering methadone and buprenorphine doses, this is generally not a requirement. However, areas where dosing occurs should not be accessible to the general public.

Records

Records must be made for the receipt and supply of methadone and buprenorphine. In general:

- All legislative Schedule 8 recording requirements must be met
- A separate record should be maintained for each patient
- Avoid large, bold lettering of patient names on records to protect patient privacy
- A photograph of each patient must be kept with the patient record
- The initial presentation of each script should be recorded in the pharmacy software
- Accurate records must be maintained manually in the NSW Drug Register Book or in an approved electronic register. Records of all transactions MUST be entered into the register on the same day on which the transaction occurs. Excel spreadsheets are not acceptable. Subsidiary drug registers may help when there are multiple patients dosing on the day. A record must be kept on the premises where the drugs are stored.
- Details of communication with prescribers and patients are clearly and consistently maintained. Any changes in dose or take-away schedules must be confirmed in writing by the prescriber.
- In busy pharmacies with many staff members, consider keeping a dosing log that the patients confirms the receipt of the dose by signing, dating and recording the time of receipt of each dose, including take-aways. The pharmacist would countersign to identify the dispensing pharmacist. This is not a legislative requirement for pharmacies offering this service.

Opening hours

Some pharmacies close on weekends and public holidays. Where the pharmacy is not open seven days a week, only stable patients with authorised take-away doses should be accepted.

When the pharmacy does not open (e.g. for public holidays) it is important that alternative measures are taken so that there is no interruption to the patient's treatment.

Refer to the *NSW Guide to Poisons and Therapeutic Goods Legislation For Pharmacists* for more information.

MEETING QCPP REQUIREMENTS

The Australian Pharmaceutical Formulary (APF) Handbook (25th Edition) and The Pharmaceutical Society of Australia's Professional Practice Standards (Version 5 2017) have a series of indicators which act as a reference source for the requirements of the Quality Care Standard. The standard will be assessed against the Opioid Substitution Program Checklist (T3A). This kit is a resource kit to provide all the policies procedures and information required to meet the Standard. Use the Checklist T3A to assess whether the pharmacy has all elements in place to provide the professional service to patients.

The Opioid Substitution Program Checklist T3A and P3A example Opioid Substitution Program Procedure are available from Guild Membership Services staff or the QCPP Knowledge Hub.

All pharmacy staff involved in the delivery of the program should receive training appropriate to their level of involvement. Some example of appropriate training are:

Pharmacists:
- In pharmacy training on OTP procedures
- Read and fully understand the NSW Health Community Pharmacy Dosing Point Protocol
- Read and be familiar with the NSW Clinical Guidelines: Treatment of Opioid Dependence-2018
- CPD Activities relevant to this area of practise
- First Aid and CPR
- Treatment of Opioid overdose with Naloxone

Pharmacy Assistants:
- Basic principles of harm reduction
- Hand hygiene and Infection reduction principles
- In pharmacy training on OTP Procedures
- First Aid and CPR

All training should be recorded in each staff member's training plan (T15A) and record (T15B).

SUMMARY OF PROCEDURES TO MEET QUALITY CARE STANDARD

- All staff in the Pharmacy understand and apply the principles of the Community Pharmacy Service Charter
- A pharmacist will supervise the administration of all doses of methadone and buprenorphine
- The pharmacy will have in place a written procedure for delivery of the program, including the following elements:
  - » A procedure for the receipt and prompt storage of pharmacotherapies
  - » A procedure for dosing
  - » A procedure for the provision of take away doses
  - » A set communication procedure (written and verbal) for communication with prescribers and health care workers as appropriate and documentation of these communications
  - » A patient Identification form including photograph (As per Appendix 4 of this manual or Appendix J of the *NSW Clinical Guidelines: Treatment* of Opioid Dependence-2018).
  - » A pharmacy/patient agreement for all pharmacotherapy patients (Appendix 5 of this manual or Appendix I of the *NSW Clinical Guidelines: Treatment* of Opioid Dependence-2018)
  - » A standard fee for all transactions and actions for non-payment of fees
  - » A financial record system to verify patients' payment (Appendix 6 of this manual)
  - » Documentation of relevant discussions/observations with patients including:
    - ◊ Side effects (reported and observed)
    - ◊ Drug Interactions
    - ◊ Ability to drive or operate machinery
    - ◊ Supply and storage of take away doses
    - ◊ Inappropriate use of medicines/alcohol
    - ◊ Intoxication
    - ◊ Missed doses
    - ◊ Referrals

- The pharmacy will have in place a written privacy/confidentiality policy
- All staff have a signed agreement to the pharmacy's privacy/confidentiality policy
- All staff and patients are expected to behave in a responsible manner and understand their rights and responsibilities as outlined in Pharmacy/Patient Agreement
- Dosing of methadone/buprenorphine should be provided in private and discreet manner and be served in turn as per other customers/patients at the pharmacy
- All staff have training appropriate to their position and have this included in their training record
- The pharmacy meets all NSW Regulatory requirements including, but not limited to:
  - » Ordering of Schedule 8 medicines
  - » Storage of Schedule 8 medicines
  - » Recording all Schedule 8 transactions in approved Drug Register
  - » Schedule 8 prescriptions and supply
  - » Labelling and supply of Take away doses
- Maintenance and calibration record of any equipment used in program deliver, e.g. methadone pumps

Note: meeting Quality Care standards via the assessment process does not necessarily correlate to being fully compliant with TG201/5.

PRIVACY AND CONFIDENTIALITY POLICY

All pharmacy staff are required to maintain the confidentiality of information acquired about patients, families and others. Evidence is a signed Confidentiality Policy (e.g. P1A Confidentiality Policy) by each staff member as per QCPP Guidelines.

All pharmacy staff are to ensure that patient records, conversations with patients and professional consultations are conducted in a manner that preserves patient confidentiality.

Access to patient records and patient medical history is only to be made with the express approval of the pharmacist and/or the consent of the patient. Patient records are only to reflect the information required and associated with the provision of prescription or pharmacist only medicines.

Access to prescription records must be made available on request to authorised NSW Ministry of Health Inspectors or police officers under provision of the Poisons and Therapeutics Goods Act.

Pharmacy staff are to be mindful of any conversation held with any person outside of the pharmacy in either a social, professional or family setting so as not to inadvertently disclose any private, patient or confidential matter.

Any documentation detailing patient information is to be shredded or handed to the pharmacist for removal. Do not place such material in the general rubbish bins etc.

Should any staff member discover inappropriate disclosure of confidential patient information, the pharmacist in charge is to be notified immediately. The pharmacist in charge will deal with the matter appropriately.

Disclosure of confidential information is unethical and as such, any staff member who does not comply with this policy can be subject to disciplinary action, which may result in termination of employment.

EQUIPMENT FOR METHADONE/BUPRENORPHINE SERVICE

Methadone and buprenorphine are Schedule 8 medicines and must be stored in a locked drug safe that complies with clause 76 of the Poisons and Therapeutic Goods Regulation 2008. Containers of methadone and buprenorphine in use must be in a secure location and returned to the drug safe whilst not in use. You may need to consider the size of your drug safe before implementing an OTP program.

Pharmacies holding stock of Long-acting Injectable Buprenorphine (Sublocade(R) should consider having a secure refrigerator designed to meet NSW Health's storage requirements for Schedule 8 medicines that require refrigeration.

Other equipment required for dosing of methadone or buprenorphine includes:

Methadone

- Measuring device that is accurately calibrated and hygienically maintained
- Disposable cups
- Access to water
- Amber dispensing bottles with child-resistant closures for take-away doses
- Access to an appropriate diluent and preservative as referenced in the current version of the Australian Pharmaceutical Formulary (APF). Dilution must be clearly stated on the label of takeaway doses.

Buprenorphine

- Access to water (the patient may drink water before their dose to moisten the mouth)
- Cardboard dispensing box or plastic container for take-away doses

EQUIPMENT SUPPLIERS FOR METHADONE/BUPRENORPHINE SERVICE

Item	Supplier	Contact	Web
Subsidiary Drug Registers	Pharmacy Guild (NSW Branch)	02 9467 7100	https://www.guild.org.au/guild-branches/nsw/professional-services/pharmacy-incentive-scheme
Drug Registers	Stream Solutions	streamnswh_sales@stream.net.au	
Electronic Drug Registers	Modeus DD Book & MethDA	03 9867 2785	https://www.modeus.com.au/
	Easydose		https://easydose.net.au/
	Strong Room Ai	03 7065 4066	https://strongroom.ai/
Methadone Syrup	Symbion Sigma	1300 772 000 1800 500 760	https://www.symbion.com.au/our-businesses/community-pharmacy/symbion-wholesale/ https://sigmahealthcare.com.au/
Biodone Forte	Symbion	1300 772 000	https://www.symbion.com.au/our-businesses/community-pharmacy/symbion-wholesale/
Subutex & Suboxone	API Sigma Symbion		
Methadone Dispensing Pumps	Interpath Services	1800 626 369 sales@interpath.com.au	https://www.interpath.com.au/

Methadone Take-away Bottles with Child resistant lid	API Sigma Symbion Stirling Fildes Cospac	1300 651 118 sales@stirlingfildes.com.au 02 9820 8999 nsw@cospak.com.au	

Note: Equipment should be regularly cleaned and checked for accuracy of dose delivery and recorded for QCPP purposes in the Equipment Calibration and Maintenance Schedule and Record.

GENERAL OTP DOSING GUIDELINES

Further guidelines about the OTP can be obtained from NSW Health's "NSW Opioid Treatment Program Community Pharmacy Dosing Point Protocol"; "NSW Clinical Guidelines: Treatment of Opioid Dependence 2018" and "Clinical Guidelines for the use of Depot Buprenorphine (Budival® and Sublocade® in the Treatment of Opioid Dependence 2019".

PROCEDURE FOR PHARMACISTS TO DISPENSE METHADONE

IDENTIFY PATIENT by referring to Patient Record and photo attached to ID sheet.

CHECK PRESCRIPTION IS THE LATEST VALID PRESCRIPTION. Completed, superseded or outdated prescriptions must be clearly marked as cancelled and stored separately from the patient file and retained for 2 years.

ENTER ANY NEW PRESCRIPTION INTO OFFICIAL PHARMACY RECORDING SYSTEM.

SPEAK TO PATIENT BEFORE DOSING. If the patient is intoxicated they should not be dosed and pharmacists should notify the prescriber of intoxicated presentations to prompt a clinical review of the patient. If unable to contact the prescriber, delay dosing and ask the patient to return later and re-assess. If still intoxicated the dose should be refused for safety reasons. Discuss driving risk if applicable.

REFER TO PATIENT'S PRESCRIPTION AND CONFIRM THE CORRECT DOSE TO BE MEASURED. NOTE that methadone scripts usually have doses written in milligrams, but it is dispensed as a syrup containing 5 mg/ml. Thus a 30 mg dose is given as a 6 ml of syrup.

MEASURE THE REQUIRED DOSE into a disposable cup, using the syringe, pump, or dispensing measure.

MAKE AN ENTRY IN THE SCHEDULE 8 DRUG REGISTER of the total amount dispensed to patient. Take care that takeaway doses are clearly and separately marked and/or identified, whether this is in the Schedule 8 Drug Register or in the Subsidiary Drug Register.

PREPARE TAKE AWAY DOSES IF AUTHORISED, in new clean bottles with child resistant caps, label each dose appropriately, and affix No 1 cautionary label.

RE-CHECK DOSE AND PRESCRIPTION.

CONFIRM THE DOSE WITH THE PATIENT by making a statement such as "here is your dose of xx mg." Or ask the patient "what is your dose" to confirm quantity being given.

GIVE THE CUP TO THE PATIENT together with a jug of water or juice, for the patient to consume the dose.

OBSERVE that the patient swallows the dose and follows it with a drink of water and then ask the patient to speak to you.

HAND TAKE AWAY DOSES if authorised, to the patient.

If you are not using a subsidiary drug register ; make entry in the Schedule 8 drug register as for any other S8 item.

When using a Subsidiary Drug Register or approved Electronic Register calculate the total amount dispensed for all patients and make one entry in the drug register or approved Electronic Drug Register at the completion of the day.

DOSING DIRECTIONS MUST BE STRICTLY FOLLOWED - NO EXCEPTIONS. The dose and takeaway instructions must comply with the Patients' valid/current prescription.

Takeaway dose dilutions must be in accordance with a prescriber's instructions, such dilution of a takeaway must be clearly indicated on the label and prepared in a new bottle with child resistant closures and with appropriate label.

Takeaway doses label must include: "Keep out of the reach of Children" in red on a white background, Name, strength and quantity of drug; Direction and date for daily dose consumption; Prescription number; date of dispensing (if not incorporated in prescription number); Patient's name, Pharmacy name, address and phone number, Advisory Label 1.

SUPERVISED PHARMACY DOSES MUST BE CONSUMED IN THE PHARMACY. TAKE AWAY DOSES can only be given on the days specified on the script (the day prior to the scheduled dose) and recorded in the Subsidiary Drug Register.

LOST TAKE-AWAY DOSES CAN NOT be replaced without specific written authority from the prescriber.

IF A PATIENT MISSES A PARTICULAR DAY'S DOSE it means the loss of that dose. It cannot be supplied retrospectively. Similarly doses cannot be replaced for any reason (e.g. vomiting) without specific written authorisation from the prescriber.

IN CASE OF PROBLEMS INSTRUCT THE PATIENT TO: Contact their prescriber for further assistance and information.

IF A PATIENT HAS MISSED ONE-THREE CONSECUTIVE DAYS OF DOSING they should be reviewed by the dosing pharmacist, and if there are no clinical contraindications (e.g. intoxication, significant illness), the usual dose should be provided, and the prescriber notified of the absence.

IF A PATIENT HAS MISSED FOUR-FIVE CONSECUTIVE DAYS OF DOSING they should be reviewed by the dosing pharmacist, and the prescriber should be contacted. If there are no contraindications (e.g. intoxication, significant illness) then the prescriber may authorise a reduced dose.

IF A PATIENT HAS MISSED MORE THAN FIVE CONSECUTIVE DAYS OF DOSING they should be referred to the prescriber for re-induction into treatment.

For further details of what to do in the event of missed doses, please refer to the "*NSW Clinical Guidelines: Treatment of Opioid Dependence-2018"*

Contact details for prescribing and/or case worker should be recorded in the patient's record.

PROCEDURE FOR PHARMACISTS TO DISPENSE BUPRENORPHINE

IDENTIFY PATIENT by referring to ID sheet and photo attached to ID sheet

CHECK THAT THE PRESCRIPTION IS MOST RECENT, VALID PRESCRIPTION. Completed, superseded or outdated prescriptions must be clearly marked as cancelled and removed stored separately from the patient file (retained for 2 years)

ENTER ANY NEW PRESCRIPTION INTO OFFICIAL PHARMACY RECORDING SYSTEM

SPEAK TO PATIENT BEFORE DOSING If the patient is intoxicated they should not be dosed and pharmacists should notify the prescriber of intoxicated presentations to prompt a clinical review of the patient. If unable to contact the prescriber, delay dosing and ask the patient to return later and re-assess. If still intoxicated, the dose should be refused for safety reasons. Discuss driving risk if applicable.

REFER TO PATIENTS' PRESCRIPTION AND CONFIRM THE CORRECT DOSE TO BE ADMINISTERED

RECORD THE DOSE in a Subsidiary Drug Register or Schedule 8 Drug Register.

COUNT AND CHECK the number and strength of the buprenorphine tablets or films to be administered

RE-CHECK DOSE AND PRESCRIPTION

CONFIRM THE DOSE WITH THE PATIENT by making a statement such as "here is your dose of xx mg". Or ask the patient "what is your dose" to confirm quantify being given.

Buprenorphine should be dispensed as multiples of whole tablets or films and only removed from packaging immediately prior to administration

Place the tablets in a clean, dry medicine measure or medication vial or small disposable cup

Tablets may be partially broken into small fragments to assist sublingual absorption and reduce risk of diversion
PATIENT INSTRUCTIONS:

TABLETS:

Tip the medication directly under the tongue without handling the tablets

Tablet can be kept in place under the tongue by tilting head slightly forward

Do not chew or swallow the tablets

Do not swallow the saliva until tablets have dissolved (2-10 minutes depending on dose)

Do not talk while dissolving the tablet under the tongue as this usually causes the tablet to be dispersed in the mouth with poor absorption

Most patients can dissolve 2 or 3 partially broken 8mg tablets as a single administration. Once given to the patient the dose is their responsibility and no replacement dose will be provided

OBSERVE closely that the patient place the dose sublingually and to avoid diversion

Check that the patient has consumed the dose prior to leaving the pharmacy by speaking or opening mouth

FILMS:

Place the film(s) under the tongue or inside the cheek

Do not chew or swallow the film

Keep the film under the tongue or inside the cheek for 4 to 8 minutes

A glass of water may be given prior to dosing to assist dissolution of the film

Once the dose is given to the patient, it is their responsibility and no replacement dose will be given

OBSERVE closely to ensure correct administration and to avoid diversion

Check the patient has consumed the dose prior to leaving the pharmacy by speaking or opening their mouth

MAKE ENTRY IN THE SCHEDULE 8 DRUG REGISTER of the total number of tablets or films in each strength dispensed to the patient.

If using Subsidiary Drug Register, calculate the total number of each strength tablet/film dispensed for all patients and make one daily entry in the Schedule 8 drug register.

DOSING DIRECTIONS MUST BE STRCTLY FOLLOWED - NO EXCEPTIONS The dose must comply with the Patients' *VALID/ CURRENT* prescription.

SUPERVISED PHARMACY DOSES MUST BE CONSUMED IN THE PHARMACY

Double or triple dosing (maximum 32mg as single daily dose) can only be administered in accordance with the prescription.

LOST TAKE-AWAY DOSES CAN NOT be replaced without specific written authority from the prescriber.

IF A PATIENT MISSES A PARTICULAR DAY'S DOSE, it means the loss of that dose. It cannot be supplied retrospectively. Similarly doses cannot be replaced for any reason (e.g. vomiting) without specific authorisation from the prescriber.

IF A PATIENT HAS MISSED ONE-THREE CONSECUTIVE DAYS OF DOSING, they should be reviewed by the dosing pharmacist, and if there are no clinical contraindications (e.g. intoxication, significant illness), the usual dose should be provided, and the prescriber notified of the absence.

IF A PATIENT HAS MISSED FOUR-FIVE CONSECUTIVE DAYS OF DOSING, they should be reviewed by the dosing pharmacist, and the prescriber contacted. If there are no clinical contraindications (e.g. intoxication, significant illness), then the prescriber may authorise a reduced dose.

IF A PATIENT HAS MISSED MORE THAN FIVE CONSECUTIVE DAYS OF DOSING, they should be referred to the prescriber for re-induction into treatment.

For further details of what to do in the event of missed doses, please refer to the *NSW Clinical Guidelines: Treatment of Opioid Dependence-2018*.

Contact details for prescriber and/or case worker should be recorded in the patient's record.

PROCEDURE FOR PHARMACIST TO DISPENSE BUPRENORPHINE LONG-ACTING INJECTION

Pharmacists should contact the manufacturer of either product to confirm the ordering process. Buvidal (R) - Camurus australia@camurus.com and Sublocade(R) - Indivior 02 9025 0200.

Delivery from an S8 lincensed pharmacy via a prescription for a named patient

1) Arrangements should be made with the pharmacy before beginning to prescribe. A prescriber will contact your pharmacy to arrange ordering and delivery of the medicine to the health practitioner or their delegate.
2) Receive copy of a valid prescription via fax and original by post. **As with other OTP prescriptions it should not be given to the patient.**
3) Pharmacy to deliver the depot to the medical practice. Depot buprenorphine **must never be dispensed to a patient.** Pharmacy delivery of depot buprenorphine requires medical and nurse practitioners to maintain a drug register and secure storage for the medicine. Pharmacies can charge a dispensing and delivery fee.

Orders for depot buprenorphine should be placed for immediate/imminent administration to a patient-within a day or two. The companies involved have indicated that they are able to arrange a delivery within 24-48 hours for most areas.

USING SUBSIDIARY DRUG REGISTERS

The usual method is to record each dose daily as given, one patient per line, in a form as set out by the requirements of the provisions of Clause 112 of the Poisons and Therapeutic Goods Regulation, 2008 (drug register).

When a pharmacy has multiple patients receiving OTP, a daily dosing subsidiary drug register book having the format outlined below may be used. The Subsidiary Drug Registers supplied by the Pharmacy Guild of Australia (NSW Branch) at no cost to pharmacies meets these criteria.

- such a subsidiary drug register book may be used only as an adjunct to a correctly maintained register and must, like the register, be kept for a minimum of two years from the date of the last entry therein,
- the book must be in bound form with the pages numbered consecutively,
- the cover of the book must describe its contents and indicate the period covered,
- each page must have a clear heading,
- entries must be made in the book daily, summarised in a clear and unambiguous way, and the daily total quantities of medicine dispensed transferred to the register daily,

- together, the book and the register must provide a clear history of medicine usage (by patient, strength and quantity) and must be able to readily reveal the current theoretical balance of methadone syrup on hand,
- the records to be entered in the subsidiary drug register must include patient's name, prescription number, quantity of methadone dispensed to each patient, the date each dose is supplied, the dispensing pharmacist's signature, the name of the prescriber provision for a daily total quantity of methadone supplied, and an indication of the days for which takeaway doses have been supplied.

The following Subsidiary Drug Registers (SDR) are available at no cost to NSW Opioid Treatment Program pharmacies from the Pharmacy Guild of Australia (NSW Branch):

- Methadone SDR
- Buprenorphine SDR
- Buprenorphine/Naloxone SDR

Orders can be made online at: https://www.guild.org.au/guild-branches/nsw/professional-services/pharmacy-incentive-scheme/subsidiary-drug-register-orders

APPENDIX 1
SELF-AUDIT FOR COMMUNITY PHARMACIES PROVIDING OTP SERVICE

This resource is a quality improvement tool for pharmacies providing OTP services. It highlights the involvement of pharmacists to optimise patient safety when providing care. Measures relate to quality of practice for individual patients as well as general pharmacy procedures. Use the results to address identified areas for improvement (e.g., documentation practices, staff training and process refinement).

Re-audit regularly as part of continuous quality improvement. It is recommended that you complete the self-audit every 6-12 months, or more often if staff turnover is high. **Complete the QUALITY MEASURES checklist for at least 15% of patients (a minimum of 3 patients) receiving OTP dose administration at your pharmacy.**

Patient identifier: _____ Date of audit: _____ Name of auditor: _____

QUALITY MEASURES There should be **evidence** or **documentation** of the following for each patient audited		**Y/N**
1	Direct communication with the prescriber to facilitate initiation and shared management of the patient. Matters that should be discussed include: ( ) first day of dosing ( ) prescriber contact details and preferred methods of communication ( ) obtaining prescriptions (should not be handled by the patient) ( ) arrangements for takeaway doses ( ) arrangements for missed doses ( ) intoxication management ( ) any medicines (OTC or prescribed) that should not be provided without confirming with prescriber ( ) other (e.g., current concomitant medicines and comorbidities) specify _____	
2	Patient identification and a recent photograph to be kept with the current prescription	
3	A valid prescription, compliant with Schedule 8 regulatory requirements (must not be back-dated, with clear dose instructions and individually authorised takeaway doses if applicable)	
4	Discussed concomitant drug and alcohol use with the patient	
5	Discussed the safe use and storage of takeaway doses with the patient (if applicable)	
6	Discussed procedures and legal requirements around missed doses with the patient (e.g., if more than 5 doses missed, referral to prescriber for re-induction required)	
7	Discussed driving safety and intoxication with the patient (consider providing written information)	
8	Details of inter-professional communication for matters affecting treatment (e.g., to discuss adherence, reports of intoxication, multiple prescribers and concomitant drug use of concern)	
9	Discussed with the prescriber any instances where prescribing represents a clear and clinically significant deviation from the Clinical Guidelines. Recorded justification for variance should be documented in patient notes (e.g., number of takeaways prescribed)	
10	Full prescription details to be recorded in dispensing software (includes all of the following) ( ) a unique prescription number ( ) name of the prescriber, address of prescriber and contact telephone number ( ) date of the prescription ( ) name and address of the patient ( ) dose of methadone or buprenorphine and provisions for takeaway doses as individually authorised on the prescription ( ) date of supply ( ) name of pharmacist	
Total number of 'N' responses (considered gaps in practice)		**/10**

+ **Review your PHARMACY PROCEDURES.** Date of audit:_____Name of auditor: _____

PHARMACY PROCEDURES, record keeping, storage and other legislative requirements		**Y/N**
1	Suitable area for dosing (quiet or private area of pharmacy)	
2	Ready access to current therapeutic resources i.e. NSW Clinical Guidelines: Treatment of opioid dependence-2018, NSW OTP Communitypharmacy dosing protocol (TG201/5), consumer resources (eg, yourroom, self-care cards)	
3	Documented procedures for supervised dosing (must be a registered pharmacist using adequately maintained equipment for accurate measurement of doses and single use cups)	
4	Documented procedures and provisions for the safe supply of takeaway doses, including ( ) each takeaway dose labelled as described in section 5.2.7 of the current TG201 Protocol, including auxiliary label 1 ( ) new child resistant containers (methadone)/cardboard dispensing box or plastic container (buprenorphine)	
5	Compliance to legislative requirements for ordering, storage and receipt of methadone and buprenorphine in a compliant safe	
6	Hard copies of original prescriptions kept on the premises for 2 years ( ) kept separately from other prescriptions, as per all S8 and anabolic steroids ( ) cancelled/superseded prescriptions separate from current prescription to avoid dosing from an old script	
7	Proper use of an approved drug register, kept on the premises for 2 years ( ) if using approved subsidiary drug registers (SDR), a separate SDR used for each formulation of OAT, all fields completed correctly, recording dosing details using one line for each patient. Excel spreadsheets are NOT approved. ( ) balance transferred every day from SDR'	
8	Regular stock checks at the end of every bottle or monthly (whichever is sooner) ( ) reporting of loss or theft of drug of addiction to the Pharmaceutical Regulatory Unit ( ) reconcile any 'overage'	
Total number of 'N' responses (considered gaps in practice)		**/8**

+ **Document corrective and planned actions to address gaps identified** (suggested format)

Patient id	Quality measures: Corrective and planned actions	completion date
Pharmacy procedures: Corrective and planned actions		completion date

APPENDIX 2
EXAMPLES* OF SEDATING AGENTS THAT MAY REQUIRE INTERVENTION IF CO-PRESCRIBED FOR PATIENTS ON OAT

Drug class	Drug name
Opioids	codeine, dextropropoxyphene, dihydrocodeine, fentanyl, hydromorphone, morphine, oxycodone, pentazocine, pethidine, tapentadol, tramadol
Benzodiazepines	alprazolam, bromazepam, chlordiazepoxide, clobazam, clonazepam, diazepam, flunitrazepam, lorazepam, midazolam, nitrazepam, oxazepam, prazepam, temazepam
Other drugs for anxiety and sleep disorders	buspirone, diphenhydramine, doxylamine, melatonin, suvorexant, zolpidem, zopiclone
Sedating antihistamines	alimemazine (trimezaprine), brompheniramine, cyclizine, cyproheptadine, dexchlopheniramine, pheniramine, promethazine
Monoamine oxidase inhibitors	phenelzine, tranylcypromine
SSRIs**	citalopram, escitalopram, fluoxetine, fluvoxamine, paroxetine, sertraline
Tricyclic antidepressants	amitriptyline, clomipramine, dosulepin (dothiepin), doxepine, imipramine, nortriptyline, trimipramine
SNRIs**	desvenlafaxine, duloxetine, venlafaxine
Other antidepressants	agomelatine, mianserin, mirtazapine, moclobemide, reboxetine, vortioxetine
Antipsychotics	amisulpride, aripiprazole, asenapine, brexpiprazole, chlorpromazine, clozapine, droperidol, flupentixol, fluphenazine, haloperidol, lurasidone, olanzapine, paliperidone, periciazine, prochlorperazine, quetiapine, risperidone, trifluoperazine, ziprasidone, zuclopenthixol
Barbiturates	phenobarbital (phenobarbitone), primidone
Other antiepileptics	acetazolamide, brivaracetam, carbamazepine, ethosuximide, gabapentin, lacosamide, lamotrigine, levetiracetam, oxcarbazepine, perampanel, phenytoin, pregabalin, sulthiame, tiagabine, topiramate, valprOTPe, vigabatrin, zonisamide
Antihistamine/anticholinergic	azatadine, buclizine, cetirizine, chlorpheniramine, levocabastine, pizatofen, triprolidine
Centrally acting muscle relaxant	baclofen, dantrolene
Anticholinergic	benztropine, dimenhydrinate
Sedating antihypertensive	clonidine
Opioid antidiarrheal	diphenoxylate
Chemotherapy	gemcitabine
Opioid cough suppressant	ethylmorphine, pholcodine
Dopamine agonist	rotigotine
Cannabinoids	tetrahydrocannabinols, dronabinol
Others	Ketamine, Esketamine

* As determined by an expert panel based on co-prescribed medicines identified during an OTP safety review conducted in 2018 by the NSW Ministry of Health.

**Expert consensus that these drug classes are less sedating

APPENDIX 3
NEW PATIENT BOOKING FORM

Today's Date		
Patient's Name		
Contact made by (and role)		
Patient's Phone number		
Date Dosing to Commence		
Prescriber will be:		
Phone number:		
Preferred contact method:		
NB: Interstate Prescribers may not be authorized to prescribe in NSW		
Always ask these questions during the initial contact conversation:		
1. Has the patient dosed at this pharmacy before	Yes	No
2. Is the patient currently considered as a stable patient?	Yes	No
3. What comments would the contacting person like to make about the patient? Comorbidities/other medications etc		
4. What take-away arrangements are expected?		
5. What procedures are required for managing Intoxication?		
6. What procedures are required for missed doses?		
5. How will the paperwork be transferred to your pharmacy? Note: Prescriptions should not be handled by the patient.		
6. How will you manage the transfer of a patient to your pharmacy from another dosing site? If the prescriber has not changed, the PRU needs to be notified in writing of the change. Refer to the *NSW Clinical Guidelines: Treatment of Opioid Dependence-2018.*		
Any General Comments:		

Completed form to be retained in Patient's File

CHECK LIST					
Fax received:	Yes	No	Original script received	Yes	No
Labels created:	Yes	No	Script dispensed	Yes	No
Contact	Yes	No			
ID Page	Yes	No			
Dosing Record page	Yes	No			

APPENDIX 4
PATIENT IDENTIFICATION FORM

Attach Patient Photo Here

Pharmacy Details	
Pharmacy Name	
Address 1	
Address 2	
Phone	
Email	

Patient Details	
Surname	
Given Names	
Date of Birth	
Address 1	
Address 2	
Phone	
Email	

Description of Patient	
Height	
Weight	
Build	
Eyes	
Hair	
Dist Features	
Mother's Name	
Signature	

Treatment Details	
Prescriber Name	
Address	
Phone	
Fax	
Email	
Case Manager	
Phone	
Prev Dose Point	
Dosing Start Date	
Initial Dose	

Agreement Explained		Agreement Signed	
Fees Explained		Fees paid and Recorded	
Script Received		Script Dispensed	

APPENDIX 5
PHARMACY/PATIENT AGREEMENT

Patient Name: _____

Pharmacy Name: _____

The following Agreement details the conditions associated with receiving Opioid Substitution Treatment at this dispensing site. Please tick the box against each point to ensure that you have read and understood each part of the Agreement.

- ☐ Each dose of methadone or buprenorphine must be consumed under the pharmacist's supervision as per Program policy and prescription instructions. It is your responsibility to satisfy the pharmacist that the dose has been properly consumed before leaving the pharmacy. The pharmacist may request that you remain in full view and follow all instructions to satisfy them that you have taken the medication in the appropriate manner. The pharmacist can provide you with information on how to best take your medication to achieve maximum benefit.
- ☐ Diversion of your methadone or buprenorphine will result in restriction or cancellation of dispensing and possible termination of treatment.
- ☐ Medication will not be dispensed to you if the pharmacist believes that you may be under the influence of alcohol and/or drugs.
- ☐ Vomited doses will not be replaced unless the pharmacist has seen you vomit *and your prescriber authorises a replacement dose in writing*
- ☐ You must attend for dosing at the times agreed to. If you present outside of these times you will not be dosed.
- ☐ You can only be dosed at this site on the days/dates arranged by the prescriber in accordance with a valid prescription. It is important to keep appointments as scheduled by your prescriber. It is your responsibility to beaware of the dates and times of these appointments to continue dosing here.
- ☐ If you miss more than three consecutive doses of your medication you cannot be dosed without the approval ofyour prescriber.
- ☐ Takeaway doses can only be provided in accordance with NSW Regulations and where a valid prescription authorises takeaway doses. Once in your care, takeaways are your responsibility. Broken bottles, lost or stolen doses will not be replaced.
- ☐ After consuming your dose, remove all labels and dispose bottles/packages safely and appropriately.
- ☐ Dispensing fees apply at this dispensing site. Accurate records of fee payments will be kept and the pharmacistcan refuse to provide doses where fees are not paid. The pharmacist reserves the right to amend the charges relating to the provision of this service with 30 days notice being provided to you.
- ☐ To behave in a responsible manner to all staff and other patients. Rudeness, theft, disruptive or threatening behaviour will result in restriction or cancellation of dispensing and possible termination of treatment.
- ☐ Any acts of violence, suspicion of drug dealing or other criminal activity on or within the vicinity of these premises will result in the police being called.
- ☐ Should this dispensing site refuse to continue dosing you it is your responsibility to find another dispensing site,and to arrange for a new prescription from your prescriber.
- ☐ The pharmacist, prescriber, case manager (or other authorised health practitioner) have authority to exchange information concerning your medical history, social wellbeing and/or any other relevant information related toyour participation in this treatment Program.

The pharmacist will endeavour to provide this service in a safe, confidential, prompt and efficient manner and provide ongoing staff training to ensure the quality provision of the service to you.

If you are have any concerns or are experiencing any difficulties with your treatment please discuss these with your pharmacist, prescriber or case manager.

The daily supervised dispensing fee for methadone/buprenorphine is $ _____

The fee for takeaway doses of methadone/buprenorphine is $ _____

Pharmacy Dosing Hours:

Monday to Friday: _____ AM to_____PM

Saturday: _ AM to_____PM

Sunday: _ AM to_____PMPublic Holidays: _

_____ AM to_____PM

Patient Signature:_____Date_____/_____/_____

Pharmacist Signature:_____Date_____/_____/_____

A copy of this Agreement should be retained by both the pharmacist and the patient.

APPENDIX 6
PATIENT PAYMENT RECORD

Patient Name	Weekly Amount to be paid

Date of Payment	Date paid to	Amount Paid	Signature

APPENDIX 7
PATIENT NOTES RECORD

Patient Name	Prescriber

Date	Issue/Action	Pharmacist

APPENDIX 8
PATIENT REVIEW FORM

Patient Name: _____	Prescriber: _____
DOB: _____	Pharmacist: _____
Address: _____	Case Manager: _____
_____	_____

Current Treatment: Methadone ( ) Buprenorphine ( ) Buprenorphine/Naloxone ( ) Depot Buprenorphine

Current Dose: _____ Take away doses per week: _____

Current Medications used by patient with potential to interact with or affect Methadone or Buprenorphine:

_____

_____

_____

Number of patient intoxicated presentations in the last month: _____

Number of doses missed in the last month: _____

Pharmacist or staff concerns about patient behaviour: _____

_____

The patient presented with any of the following Clinical symptoms: Sleep disturbance ( ) aches or pains ( ) teeth/ dental problems ( ) reduced libido ( ) lethargy ( ) excessive sweating ( )

Any known issues/problems with illicit drug use? : Yes ( ) No ( )

If yes, details: _____

Any known patient related issues which may be relevant to their treatment (Health, family, social, financial, emotional): Yes ( ) No ( ) _____

Would you like the prescriber to contact you? : Yes ( ) No ( )

Pharmacist Name and Signature: _____

Pharmacist Phone Number: _____

Pharmacist Email: _____

Pharmacy Stamp or Label:

_____

APPENDIX 9
NOTIFICATION OF CHANGE TO DOSING POINT FORM

Prescribers are responsible for notifying the Ministry of Health of any permanent change to a NSW OTP patient's dosing point. The *NSW Opioid Treatment Program: Notification of Permanent Change in Dosing Point can be used for this purpose* and can be accessed at: https://www.health.nsw.gov.au/pharmaceutical/Documents/OTP-dosing-point.pdf

Treatment with:

- Methadone
- Buprenorphine
- Buprenorphine/Naloxone
- Depot Buprenorphine

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: ..... Date: .....

Name of Practice/Clinic: ..... 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 New Dosing Point**	**Date of Transfer**

Fax to: Pharmaceutical Services
NSW Ministry of Health
Fax: (02) 9424 5885

Postal Address: Locked Mail Bag 961, North Sydney NSW 2059
Telephone: (02) 9424 5921

1/15

APPENDIX 10:
MANAGING DRIVING SAFETY FOR AT RISK PATIENTS (EXAMPLE)

Critical issues:

- Prompt identification of withdrawal or intoxication
- Minimise the risk of complications
- Manage related symptoms
- Stabilise medical and psychiatric conditions
- Clients initiating opioid agonist therapy (OAT) should be advised that driving is unsafe until dosing is stable. Wherever possible, an alternative option to driving should be discussed with the client (see NSW Clinical Guidelines: Treatment of Opioid Dependence)
- Driving safety discussions should be regularly revisited and documented throughout treatment
- Consider the impact of other sedating medications and substances on driving safety for all clients, regardless of whether they are on OTP

Clients assessed to be a potential risk to themselves or others should be **encouraged to remain** on the premises for clinical observation and monitoring

⇩

If client refuses ongoing management or observation and **intends to drive a vehicle**/evidence that they may be in charge of a vehicle
(e.g. are carrying car keys or a motorbike helmet)

⇩

STEP 1
Inform client that driving is a **safety issue** and you have a **duty of care** to take all reasonable steps to ensure that this does not occur

⇩

STEP 2
Assist the client in developing an **alternative plan**
(safety advice needs to be accepted and acted on by client)

⇩

STEP 3
If the client continues to ignore advice/refuses to stay, **call the local Police Service or 000**
(inform the client and provide relevant information to Police e.g. description of the vehicle and registration number if known)

PRACTICE POINTS

- Ensure situation is recorded in medical notes and communicated to managing health practitioners
- Seek support from colleagues in managing these situations
- *Safety considerations extend to individuals using a bicycle or horse on a public road

Alternative options to the client driving [EXAMPLES, TAILOR TO LOCAL SETTING]:

a. Offer to call a friend or family member to come and collect the patient
b. If safe to do so, organise alternative transport e.g. taxi (+/- cab voucher) / Mission beat / other local service
c. If available, refer client to a safe place for continued observation
d. If client's clinical presentation requires emergency medical support and monitoring the senior medical practitioner should be contacted for further advice or an ambulance should be called.

Adapted from Medically Supervised Injecting Centre (MSIC) 1.21 Management of Intoxicated Clients in Stage 3] Procedure – [Dec 2016] and NSW Drug and Alcohol Withdrawal Clinical Practice Guidelines - NSW - GL2008_011

APPENDIX 11:
NSW OPIOID TREATMENT PROGRAM-
COMMUNITY PHARMACY DOSING POINT PROTOCOL

PURPOSE

This document has been prepared for Community Pharmacists to follow when supplying methadone and buprenorphine preparations under the New South Wales Opioid Treatment Program (OTP).

Compliance with this protocol is mandatory for all pharmacies participating as a dosing point for the NSW OTP.

1. INTRODUCTION

This protocol should be read in conjunction with the *Poisons and Therapeutic Goods Act 1966* (the Act) and the *Poisons and Therapeutic Goods Regulation 2008* (the Regulation) (available on the internet at www.legislation.nsw.gov.au) and the *NSW Clinical Guidelines: Treatment of Opioid Dependence* (http://www.health.nsw.gov.au/aod/Publications/nsw-clinical-guidelines-opioid.pdf).

The legislative requirements for the receipt, storage, and supply of methadone and buprenorphine under the OTP are, at a minimum, the same as for any other Schedule 8 medication. However, the specific monitoring and supervisory requirements of the OTP imposes additional obligations.

Adherence to this document will assist pharmacists in complying with the legislative and policy obligations regarding the supply of methadone and buprenorphine on the OTP. Compliance with the protocol provides proper accountability, minimises the risks associated with the program, and protects the health and safety of patients.

2. COMMUNITY PHARMACY REGISTRATION

New pharmacies applying to participate in the program are required to be Pharmaceutical Benefits Scheme (PBS) approved community pharmacies.

In accordance with clause 92 of the Regulation, the maximum number of patients in supervised OTP dosing at any one community pharmacy is 65. Patients assessed by the prescriber to be stable and who attend supervised dosing only once a week or less frequently i.e. supplied takeaway doses weekly, fortnightly or monthly are not to be counted toward this limit of 65. The limit aims to minimise the potential for patients congregating in the vicinity of community pharmacies and contributing to local amenity concerns.
Pharmacists interested in registering a pharmacy to participate in the NSW OTP should complete the application form available at:

http://www.health.nsw.gov.au/pharmaceutical/pharmacists/Pages/otp-pharmacists.aspx

This form is also used to notify the Pharmaceutical Regulatory Unit (PRU) of changes of ownership, change of pharmacy name and/or relocation of pharmacy premises.

This process of registration may take up to five working days to complete. Accordingly, any new applications, changes of ownership, change of pharmacy name or relocation of pharmacy premises should be communicated to PRU as soon as possible in order to prevent any delay to dosing patients.

The applicant pharmacist must be the proprietor of the pharmacy. They must ensure that all registered pharmacists employed at the pharmacy have:

- **Read and understand the current version of this protocol; and**
- **will comply with the legislative and policy requirements contained within.**

On completion of the registration process, PRU will notify wholesalers that the pharmacy is permitted to receive supplies of methadone and buprenorphine preparations. The
Commonwealth Department of Health provides methadone and buprenorphine preparations free of charge to the pharmacy under Section 100 of the *National Health Act 1953* for the treatment of Opioid Dependence.

Details of the formulations of methadone and buprenorphine available as a Section 100 PBS medication on the

OTP can be found at:
http://www.pbs.gov.au/browse/section100-md

3. ORDERING, STORAGE AND RECEIPT OF METHADONE AND BUPRENORPHINE

As with any Schedule 8 medication the usual legislated requirements of Part 4 and 8 of the Regulation apply to methadone and buprenorphine formulations, specifically:

They may only be obtained from a licensed wholesaler on the basis of a written signed order by a pharmacist.
On receipt of the order it must be checked to confirm the integrity of the product and that the quantity received is as indicated on the invoice.
They must be immediately secured in the locked drug safe, which must comply with clause 76 of the Regulation.
They must be entered into the pharmacy's Schedule 8 drug register on the date of receipt in accordance with clause 112 of the Regulation (see Section 6 below).
They must remain in the safe except when in immediate use.
An inventory stock check must be performed, at a minimum, in March and September of each year in accordance with clause 118 of the Regulation.
When loss or theft has occurred, PRU must be immediately notified without delay via the online notification form available at:
http://www.health.nsw.gov.au/pharmaceutical/Pages/lost-stolen-drugs.aspx
They may not be destroyed unless carried out in accordance with clause 125(2) of the Regulation.

Where a key is used to unlock the drug safe, it must be retained by a registered pharmacist at all times while the pharmacy is open for business. Keys should not be 'hidden' in the pharmacy after-hours unless they are retained in a safe/key safe to which only a registered pharmacist has access.

Where a code or combination is required to unlock the drug safe, this must only be known to authorised registered pharmacists.

4. OTP PRESCRIPTIONS FOR METHADONE AND BUPRENORPHINE

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.

Documentation including a recent clear photograph of the patient, 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 photograph 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 handled by patients. The prescription should be sent directly to the pharmacy by the prescriber to avoid risk of alteration.

4.1 Form of Prescription

Methadone and buprenorphine must only be supplied in accordance with a valid prescription.
Pharmacists should implement a system to ensure that valid prescriptions are obtained prior to the expiry of the current prescription used to prevent interruptions to ongoing treatment.

To supply methadone or buprenorphine without a valid prescription is an extremely serious matter and may constitute an offence under the *Drug Misuse and Trafficking Act 1985* as well as the *Poisons and Therapeutic Goods Regulation 2008*. There are also potential harms posed to the patient with the increased risk of double dosing.

Breaches of the Poisons and Therapeutic Goods legislation may lead to prosecution or to a complaint of professional misconduct being lodged with the Health Care Complaints Commission.

As for all Schedule 8 medications, prescriptions for methadone and buprenorphine on the OTP must comply with the requirements of clause 80 of the Regulation, and include:

- The date of issue, and the name and address of the patient.
- The name, strength and quantity of drug (expressed in words and figures).
- *Note: for OTP it is acceptable for the quantity to be supplied to be indicated by a clearly defined duration of treatment represented by a date range; and in the case of buprenorphine, the strength to be supplied indicated by a clearly defined daily dose.*
- It must be the only item on the prescription.
- *Note: It is acceptable to have different strengths of buprenorphine or buprenorphine/naloxone formulations stipulated on the one form in order to achieve the clearly defined daily dose.*
- Adequate directions for use (including clear directions regarding takeaway supplies, if any).
- The name, designation, address and contact details of the prescriber.

There are provisions to allow for computer generated prescriptions. For details see:
http://www.health.nsw.gov.au/pharmaceutical/Documents/prescriptions-nonhandwritten.pdf

It is common practice for a prescriber to send a prescription electronically to a pharmacy initially by fax or email. In accordance with clause 81 of the Regulation, in an emergency, an authorised prescriber may direct the supply of a drug of addiction orally, by telephone, by electronic mail or by facsimile. The prescriber must immediately make out a prescription and must send the prescription without delay (and in any case within 24 hours) to the pharmacy.

If such a prescription is not received within seven days after the drug is supplied, the pharmacist must report that fact to PRU in accordance with subclause 96 (2)(b) of the Regulation. Please send the notification via email to MoH-PharmaceuticalServices@health.nsw.gov.au. In your notification, please include a copy of the faxed or emailed prescription and outline any communication made with the prescriber.

4.2 Recording of a Prescription

On the first occasion that a prescription is to be used for the supply of methadone or buprenorphine on the OTP a full record of the prescription must be made in the pharmacy's dispensing program. The details to be recorded must include:

- A unique prescription number. *(Note this prescription number remains for life of the prescription)*
- The name of the prescriber.
- The date of the prescription.
- The name and address of the patient.
- The dose of methadone or buprenorphine and the provisions for takeaway doses, if any.
- The date of supply.
- The name of the pharmacist.

The pharmacy name and address, the original prescription number and the original date of supply should be endorsed on the prescription.

When the prescription has expired or is no longer valid, the prescription must be endorsed with the word "CANCELLED" in ink across the prescription, and then stored separately from other prescriptions for a period of two years from the date of the last supply (i.e. as for all Schedule 8 prescriptions).

5. DISPENSING AND SUPERVISED ADMINISTRATION

Dispensing and administration of methadone and buprenorphine must be carried out by a pharmacist in accordance with a valid prescription. It must not be delegated to a pharmacy assistant. The methadone and buprenorphine must be consumed under strict and direct supervision dependent on the specific type of formulation. Ideally, dosing should take place in a quiet or private area of the pharmacy, but not in the dispensary or where access to Schedule 4 or Schedule 8 medications is possible. Supervised dosing enhances safety and medicine adherence, reduces risk of diversion to others and enables better monitoring.

All health professionals involved in a patient's treatment, including pharmacists, have a responsibility to inform patients of the effect methadone and buprenorphine may have on driving safety and operating heavy machinery. Pharmacists should recommend that patients arrange alternative transport until a stable dose and steady state are achieved.

Patients must be dosed at the pharmacy. If the collection of doses by a carer is required, a signed written authority must be received from the prescriber. The patient, the carer, prescriber, dosing point and other treating practitioners should all agree to this approach before any doses are dispensed by the pharmacist. Further information on dosing arrangements for severely ill patients, please refer to Section 3.7 of the NSW Clinical Guidelines: Treatment of Opioid Dependence.

5.1 Supervised Methadone

The formulations of methadone available on the OTP are Biodone Forte™ (manufactured by Biomed Aust Pty Limited) and Aspen Methadone Syrup™ (manufactured by Aspen Pharma Pty).

5.1.1 Particular care needs to be taken in correctly identifying patients. Reference to the current prescription and the patient photograph must occur at each dosing (especially important for pharmacies that employ multiple pharmacists)

5.1.2 Intoxicated patients should not be dosed and pharmacists should notify the prescriber of intoxicated presentations to prompt a clinical review of the patient.

5.1.3 Doses should be prepared at the time of the patient's attendance and not be pre-prepared or stored in open cups or in any other receptacle.

5.1.4 Methadone must be accurately measured, preferably using a purpose specific device that is accurately calibrated and hygienically maintained. For further information on methadone pumps, contact The Pharmacy Guild of Australia.

5.1.5 Supervised methadone doses may be diluted with water in a clean, new disposable cup. The disposable cup is not to be reused.

5.1.6 Patients must be closely observed at all times and can be given some water and should be asked to ensure the prescribed dose has been consumed.

5.1.7 If a patient misses a particular day's dose, it means the loss of that dose. It cannot be supplied retrospectively. Similarly, doses cannot be replaced for any reason (e.g. vomiting) without specific signed written authorisation from the prescriber. The authorization should be attached to the original prescription.

5.1.8 Patients who have missed 1-3 consecutive days of dosing should be reviewed by the dosing pharmacist, and if there are no clinical contraindications (e.g. intoxication, significant illness), the usual dose should be provided, and the prescriber notified of the absence.

5.1.9 Patients who have missed 4 or 5 consecutive days should be reviewed by the dosing pharmacist, and the prescriber should be contacted. If there are no contraindications (e.g. intoxication, significant illness) then the prescriber may authorize a reduced dose.

5.1.10 Patients who have missed more than 5 consecutive doses should be referred to the prescriber for re-induction into treatment.

For further details of what to do in the event of missed doses, please refer to the *NSW Clinical Guidelines: Treatment of Opioid Dependence 2018.*

The patient's prescriber is the only person who may change the dose or make changes to the dosing schedule, e.g. addition of takeaways or changes to takeaway days (see Section 5.2). Any changes should be in writing and signed by the prescriber.

5.2 Supply of Takeaway Methadone Doses

The *NSW Clinical Guidelines: Treatment of Opioid Dependence 2018* provides the framework for takeaway provision for methadone based on the treatment phase and on risk assessment.

General principles for provision of methadone takeaway doses include:

- Regular assessment and documentation of patient presentation.
- No takeaway doses during induction and stabilisation phases of treatment (usually the first 3 months of treatment for methadone).
- No takeaway doses for high risk patients during maintenance phase except in special circumstances.
- Limiting the number of takeaways doses of methadone to a maximum of four per week, except in special circumstances
- Consideration of whether takeaway doses should be consecutive.

5.2.1 Methadone takeaway doses may only be supplied as indicated on the prescription. Any changes to the dosing schedule, e.g. the provision of additional takeaways, can only be authorized by the prescriber, not a case worker, nurse, receptionist or other staff of a public or private clinic. Any verbal authorization must also be confirmed in writing, be signed and dated by the prescriber, and should be attached to the original prescription.

5.2.2 Authorised takeaway doses my only be supplied on a day immediately prior to the first day of a scheduled absence of the patient from the pharmacy. An observed dose should be given prior to any supply of authorized takeaway doses.

5.2.3 Once a patient has been provided with a methadone takeaway dose for a specific day, an observed dose must not be given if they present at the pharmacy on the day the takeaway dose was intended.

5.2.4 Under no circumstances can methadone takeaway doses be accepted back into pharmacy stock.

5.2.5 Each daily takeaway dose should be individually packed in a new, clean, amber dispensing bottle with an approved child-resistant closure. Containers or bottlers must not be recycled or reused.

5.2.6 Dilution of takeaway doses must be specifically ordered by the prescriber on the prescription. Takeaway doses should not be diluted with water. Please refer to the current version of the Australian Pharmaceutical Formulary (APF) for guidance dilution of takeaway doses and the use of an appropriate diluent and preservative. Dilution must be clearly stated on the label of takeaway doses.

5.2.7 Takeaway doses must be labelled as for all other dispensed Schedule 8 medications, including:

- "Keep out of the reach of children" in red on a white background.
- The name, strength and quantity of methadone supplied.
- Adequate directions for use including the date the dose is to be consumed.
- The original prescription number and the date of dispensing/preparation
- The patient's name.
- The name, address and telephone number of the pharmacy.
- The mandatory driving hazard warning label (e.g. Label 1).

It is mandatory to package each daily dose of methadone in an individual dispensing bottle.

5.3 Supervised Buprenorphine

The formulations of buprenorphine available on the OTP are buprenorphine-naloxone sublingual film (Suboxone® film) and buprenorphine sublingual tablets (Subutex®). For comprehensive information regarding the administration of each specific formulation please consult the full prescribing information from the sponsor Indivior.

The prescribed dosage of buprenorphine may often consist of different strengths of formulations (e.g. 12mg = one 8mg tablet/film and two 2mg tablets/films).

5.3.1 Particular care needs to be taken with correctly identifying patients. Reference to the current prescription and the patient photograph must occur at each dosing (especially important for pharmacies that employ multiple pharmacists), regardless of how well the patient is known to pharmacy staff.

5.3.2 Intoxicated patients should not be dosed and pharmacists should notify the prescriber of intoxicated prescriptions to prompt a clinical review of the patient.

5.3.3 Buprenorphine tablets should be placed under the tongue for sublingual absorption. The tablets should not be chewed or swallowed by the patient. Depending on the dosage prescribed the tablet/s may take between 2 to 10 minutes to fully absorb.

5.3.4 Buprenorphine sublingual film should be placed under the tongue for sublingual absorption and placed on the inside of the cheek for buccal absorption. The film should not be chewed or swallowed by the patient and should be kept there until fully dissolved, which usually occurs within 4 to 8 minutes.

The patient may be instructed to drink a glass of water prior to administration to moisten their mouth to help the film dissolve more easily.

5.3.5 Patients must be closely observed at all times to ensure correct administration and to prevent the risk of diversion. Patients should be asked to open their mouth or asked to speak to ensure the tablet/film has fully dissolved.

5.3.6 If a patient misses a particular day's dose, it means the loss of that dose. It cannot be supplied retrospectively. Similarly doses cannot be replaced for any reason (e.g. vomiting) without specific signed written authorisation from the prescriber. The authorisation should be attached to the original prescription.

5.3.7 Patients who have missed 1-3 consecutive days of dosing should be reviewed by the dosing pharmacist, and if there are no clinical contraindications (e.g. intoxication, significant illness), the usual dose should be provided, and the prescriber notified of the absence.

5.3.8 Patients who have missed 4 or 5 consecutive days should be reviewed by the dosing pharmacist, and the prescriber should be contacted. If there are no contraindications (e.g. intoxication, significant illness) then the prescriber may authorise a reduced dose.

5.3.9 Patients who have missed more than 5 consecutive doses should be referred to the prescriber for re-induction into treatment.

For further details of what to do in the event of missed doses, please refer to the *NSW Clinical Guidelines: Treatment of Opioid Dependence.*

The patient's prescriber is the only person who may change the dose or make changes to the dosing schedule e.g. addition of takeaways or changes to takeaway days (see Section 5.4).

5.4 Supply of Takeaway Buprenorphine and Unsupervised Dosing

The *NSW Clinical Guidelines: Treatment of Opioid Dependence* provides the framework for takeaway provision for buprenorphine, dependent on the treatment phase and risk assessment.

General principles for provision of takeaway doses include:

- Regular assessment and documentation of patient presentation.
- No takeaway doses during induction and stabilisation phases of treatment (usually first 1-3 months of treatment).
- Consideration of alternate day dosing to reduce attendance requirements.
- No takeaway doses during maintenance phases for high risk patients except in special circumstances.
- Limiting the number of takeaway doses of buprenorphine to a maximum of four per week for moderate risk patients.

The buprenorphine-naloxone sublingual film is less prone to diversion. If injected the naloxone component produces marked opiate antagonist effects and opiate withdrawal, thereby deterring intravenous abuse. Accordingly, Suboxone® film is the approved formulation for unsupervised dosing of buprenorphine under the NSW OTP.

There are greater restrictions on takeaways for buprenorphine (Subutex®) than the combination buprenorphine-naloxone (Suboxone®) product. Low to moderate risk patients may receive no more than 4 takeaways of Subutex® per week.

Subutex® should not be supplied for unsupervised dosing unless in exceptional circumstances as determined by the prescriber, e.g. for pregnant or breastfeeding women.

5.4.1 Buprenorphine takeaway doses may only be supplied as indicated on the prescription. Any changes to the dosing schedule e.g. the provision of additional takeaways can only be authorised by the prescriber, not a case worker, nurse, receptionist or other staff of a public or private clinic. Any verbal authorisation must also be confirmed in writing, be signed and dated by the prescriber, and should be attached to the original prescription.

5.4.2 Authorised takeaway doses must only be supplied on a day immediately prior to the first day of a scheduled absence of the patient from the pharmacy. An observed dose should be given prior to any supply of authorised takeaway doses.

5.4.3 Once a patient has been provided with a buprenorphine takeaway dose for a specific day, an observed dose must not be given if they present at the pharmacy on the day the takeaway dose was intended.

5.4.4 Under no circumstances can buprenorphine takeaway doses be accepted back into pharmacy stock.

5.4.5 Takeaway doses and unsupervised dosing of buprenorphine must be supplied in the original child resistant sachets in a cardboard dispensing box or plastic container. Supply of takeaway doses in envelopes or loose plastic bags is not considered appropriate and does not comply with Australian Standard AS2216-1997, *Packaging for Poisonous Substances*.

5.4.6 Patients in the maintenance phase of treatment and considered low risk by the prescriber may be issued prescriptions for Suboxone® intended for unsupervised dosing (1-4 weeks dispensed doses). An observed dose should be given prior to any supply of authorised unsupervised dosing of buprenorphine, unless specified on the prescription.

In these cases, the medication can be packed and labelled according to the requirements for any Schedule 8 dispensed medication (see 5.4.7 below).
It is expected that a pharmacist would make enquiries with a prescriber if they authorise unsupervised dosing of Subutex® in preference to Suboxone®.

5.4.7 Takeaway doses and unsupervised dosing of buprenorphine must be labelled in accordance with the requirements for the labelling of all dispensed Schedule 8 medication, including:

- "Keep out of the reach of children" in red on a white background.
- The name, strength, and quantity of buprenorphine supplied.
- Adequate directions for use including the date(s) the dose is to be consumed.
- The original prescription number and the date of dispensing/preparation
- The patient's name.
- The name, address and telephone number of the pharmacy.
- The mandatory driving hazard warning label (e.g. Label 1).

5.4.8 Pharmacists should use their professional judgement in determining whether to package each day's takeaway dose individually or not, depending on the number of takeaways authorised, the dose prescribed and the capacity of the individual patient to understand the dosage instructions.

6. DRUG REGISTERS AND SUBSIDIARY DRUG REGISTERS

As per section 3, the recording of the receipt and supply of all Schedule 8 drugs applies to methadone and buprenorphine on the OTP. Specifically that:

6.1 The drug register must be in the form of a bound book whose pages are consecutively numbered, or in the form approved by the Secretary, NSW Ministry of Health.

6.2 Entries into a drug register must be made daily on the day the methadone or buprenorphine is received or supplied.

6.3 Entries for a drug register must include:

- the date of the entry (the day of the transaction).
- quantity of methadone liquid (mL) or buprenorphine tablets/films received or supplied.
- the name and address of the supplier of methadone or buprenorphine received.
- the name and address of the person to whom the methadone or buprenorphine was supplied by the pharmacy.
- the original prescription reference number.
- the name of the prescriber.
- the balance of methadone or buprenorphine in stock after each transaction.
- the signature of the pharmacist making the entry.

The different strengths and formulations of buprenorphine **Subutex®** and **Suboxone®** must be individually entered on separate pages of the drug register. Similarly, the two different brands of methadone formulations **Biodone Forte™** (manufactured by Biomed Aust Pty Limited) and **Aspen Methadone Syrup™** (manufactured by Aspen Pharma Pty Ltd) must have their own page in the drug register.

6.4 Subsidiary Drug Registers

The standard method of recording each dose daily as given is one patient per line, in a form compliant with the provisions of clause 112 of the Regulation (the drug register).

However, in the situation where a pharmacy may be dosing a number of methadone or buprenorphine patients, it is acceptable to maintain a daily dosing subsidiary register. ***The Ministry of Health strongly advises that if a subsidiary register is used, then it is the one provided free of charge by the Pharmacy Guild of Australia (NSW Branch), as it complies with the all the required fields.*** Otherwise the following minimum mandatory requirements are required for a compliant subsidiary register:

- Separate subsidiary drug register books should be used for Aspen Methadone syrup™, Biodone Forte™, Subutex® tablets and Suboxone® films.
- The book must be in bound form with the pages numbered consecutively.
- The cover of the book must describe its contents and indicate the period covered.
- Each page must have a clear heading and be ruled up in a consistent fashion with a heading for each column/line, as applicable.

- Entries must be made in the book daily, summarised in a clear and unambiguous way, and the daily total quantities of methadone or buprenorphine dispensed transferred to the drug register daily.
- The subsidiary drug register book must include the patient's name, prescription number, the actual quantity dispensed to each patient on that particular day (including takeaways), the date each dose is supplied, the dispensing pharmacist's signature, the name of the prescriber, provision for a daily total quantity of drug supplied, and an
  indication of the days for which takeaway doses have been supplied.
- Together, the subsidiary register and the main drug register must provide a clear history of methadone usage (by patient and quantity) and must reflect the actual balance of methadone or buprenorphine held.
- A system should be put in place to identify the pharmacist responsible for dispensing each dose, given many pharmacies have more than one pharmacist working on any day.

The entry of the daily totals in the subsidiary register must be entered into the main drug register at the end of each day.

7. GENERAL PRINCIPLES

7.1 All records required to be made under the provisions of the Poisons and Therapeutic Goods Legislation must be retained on the premises of the pharmacy for a period of two years from the date of the latest transaction.

7.2 All records must be legible, written in English, and able to be easily produced.

7.3 To ascertain if the provisions of the Poisons and Therapeutic Goods legislation are being complied with all records must be made available for inspection on request of a PRU inspector.

7.4 Pharmacists should be vigilant in protecting the confidentiality of all pharmacy records. The stigma often associated with drug addiction and its treatment makes protecting confidentially a particularly important issue for OTP patients. General privacy principles apply including the Privacy and Personal Information Protection Act 1988 and the Health Records Information Privacy Act 2002.

7.5 Before empty bottles of methadone are discarded they should be rinsed out and the labels removed or defaced (for security purposes and to avoid them being used illegally).

7.6 It is expected that community pharmacists will communicate with the prescriber and/or case worker on an ongoing basis regarding the patient's adherence to dosing and any other clinically significant presentations e.g. intoxication, missed doses, or matters affecting the patient's treatment. *Please note:* only the prescriber is able to make changes to treatment.

7.7 Community pharmacists should be aware of the NSW Clinical Guidelines: Treatment of Opioid Dependence-2018, available at: http://www.health.nsw.gov.au/aod/Publications/nsw-clinical-guidelines-opioid.pdf .
The NSW Clinical Guidelines for use of depot buprenorphine (Budival® and Sublocade®) in the treatment of opioid dependence-2019 available at: https://www.health.nsw.gov.au/aod/Publications/full-depot-bupe-interim-gl.pdf

An abbreviated version of the NSW Clinical Guidelines: Treatment of Opioid Dependence-2018 provides a quick reference guide for practitioners but does notreplace the full Guidelines is available at:
https://www1.health.nsw.gov.au/pds/ActivePDSDocuments/GL2018_018.pdf

Unless exceptional or unforeseen circumstances exist, all services participating in the OTP must comply with the clinical guidelines. Community pharmacists have an important role in monitoring compliance with these guidelines.

Prescribers may, in certain exceptional circumstances, elect to vary their clinical practice from that of the clinical guidelines. For example the provision of more than four takeaway doses of methadone per week would constitute a departure from the guidelines. A community pharmacist would be expected to confirm this with the prescriber and reference the guidelines. The advice from the Ministry of Health to any prescriber or OTP provider is that any departure from the clinical guidelines needs to be recorded in the patient notes with the justification or qualification for the variance from the guidelines to be clearly documented.

If any clarification on the content of this document or further information is required, contact the Duty Pharmaceutical Officer during office hours on (02) 9391 9944.

This guide has been produced by:
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APPENDIX 12: CLINICAL CARE STANDARDS – PRACTICE PRINCIPLES OF CARE AND SERVICE DELIVERY

NSW Health's Clinical Care Standards – Alcohol and Other Drug Treatment lists the principles of practice that underpin all levels of Alcohol and Other Drug care and service delivery.

PRINCIPLE	PRACTICE
Principle 1 **Services are person centred**	Services are provided within a trusted, inclusive and respectful culture that values and promotes a beneficial partnership between clients, their significant others and staff. The service respects diversity and is responsive to clients' needs and values. The experience of clients and their families is reflected in the service system
Principle 2 **Services are safe**	Services are continuously improving outcomes by giving regard to the physical, psychosocial and cultural wellbeing of all clients, and minimising the risk of harm.
Principle 3 **Services are accessible and timely**	The service system is visible, accessible from multiple points of entry, equitable and timely. Clients experience care as welcoming, accepting, non-judgemental and responsive to their needs.
Principle 4 **Services are effective**	Services are holistic, evidence-based and supported by NSW Health endorsed standards, policies and guidelines. The service system attends to the diverse medical, psychological and social needs of clients. The continuum of care is integrated across NSW Health, primary care and non-government organisations to reduce fragmentation and optimise outcomes.
Principle 5 **Services are appropriate**	The service system provides a range of approaches to meet the diverse needs of clients. The experience of clients and their significant others is reflected in the service system. Clients are informed about and engaged in influencing, services, treatment and options in a clear and open way. The right evidence-based care is provided by the right providers to the right person, in the right place and at the right time, resulting in optimal quality care.
Principle 6 **Services use their resources efficiently**	Services maximise the use of available resources to deliver sustainable, high-quality care. Services ensure close alignment and integration across services and sectors to avoid duplication or omission of service
Principle 7 **Services are delivered by a qualified workforce**	The workforce has the requisite skills, knowledge, values and attitudes to respond to clients' needs, and a capability and willingness to work across disciplines and sectors.

APPENDIX 13
RESOURCES

The following are links to useful resources for pharmacies providing OTP

- NSW Opioid Treatment Program Community Pharmacy Dosing Point Protocol
  https://www.health.nsw.gov.au/pharmaceutical/Documents/OTP-protocol-pharmacists.pdf

- NSW Clinical Guidelines: Treatment of Opioid Dependence 2018
  https://www.health.nsw.gov.au/aod/Publications/nsw-clinical-guidelines-opioid.pdf

- QCPP https://www.qcpp.com/

- Alcohol and Drug Foundation
  https://adf.org.au/

- Safe Script NSW
  www.safescript.health.nsw.gov.au

- Lifeline Substance Abuse and Addiction
  https://www.lifeline.org.au/get-help/topics/substance-abuse-and-addiction

- NSW Health OTP
  https://www.health.nsw.gov.au/pharmaceutical/pharmacists/Pages/otp-pharmacists.aspx

- Pharmacy Incentive Scheme
  https://www.guild.org.au/guild-branches/nsw/professional-services/pharmacy-incentive-scheme

- Your Room
  https://yourroom.health.nsw.gov.au/Pages/home.aspx

- Managing driving safety for at risk clients (example template)
  https://www.health.nsw.gov.au/aod/professionals/Pages/driver-safety-example-template.aspx

- NSW Drug and Alcohol Specialist Advisory Services (DASAS)
  (02) 9361 8006 or 1800 023 687
  www.svhs.org.au/our-services/list-of-services/alcohol-drug-service/drug-alcohol-specialist-advisory-service

- NSW Clinical guidelines for use of depot buprenorphine Budival® and Sublocade® in the treatment of opioid dependence
  https://www.health.nsw.gov.au/aod/Publications/full-depot-bupe-interim-gl.pdf

- NSW Guide to Poisons and Therapeutic Goods Legislation For Pharmacists
  https://www.health.nsw.gov.au/pharmaceutical/Documents/guide-pharmacists.pdf

- St Vincent's Hospital Sydney Drug & Alcohol Specialist Advisory Service
  https://www.svhs.org.au/our-services/list-of-services/alcohol-drug-service/drug-alcohol-specialist-advisory-service

- Safe Script NSW Clinical Advice Line
  https://www.svhs.org.au/our-services/list-of-services/alcohol-drug-service/safe-script-nsw-clinical-advice-line