

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 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 must be performed on March and September of each year in accordance with clause 118 of the Regulation.
- When the loss or theft has occurred, Pharmaceutical Services of the NSW Ministry of Health 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 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 the 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. There is provision in the legislation that allows for this, provided the prescriber sends the original prescription within 24 hours and it is received by the pharmacist in no later than seven days.

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.
- 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 "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.

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.

5.1.4

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

5.1.5

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

5.1.6

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 written authorisation from the prescriber.

5.1.7

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.

5.1.8

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.

5.1.9

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 5.2).

5.2 Supply of Takeaway Methadone Doses

The *NSW Clinical Guidelines: Treatment of Opioid Dependence* 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.
- 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 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.

5.2.2

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.

5.2.3

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

Takeaway doses should not be diluted with water or anything else, unless specifically ordered by the prescriber on the prescription. Please refer to the current version of the Australian Pharmaceutical Formulary (APF) for guidance on dilution of takeaway doses and the use of an appropriate diluent and preservative.

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.
- 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).

5.3.2

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

5.3.3

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 authorisation from the prescriber.

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.

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.
- 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 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.

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.

7.7

Community pharmacists should be aware of the *NSW Clinical Guidelines: Treatment of Opioid Dependence*, available at: <http://www.health.nsw.gov.au/aod/Publications/nsw-clinical-guidelines-opioid.pdf>.

An abbreviated version of the NSW Clinical Guidelines provides a quick reference guide for practitioners but does not replace 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.

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