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 electing to register as a dosing point for the NSW OTP.

1. INTRODUCTION


The legislative requirements for the receipt, storage, 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 regarding methadone and buprenorphine under the OTP.

Adherence to this document will assist a pharmacist 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 50 (note that this does not include buprenorphine-naloxone patients in unsupervised dosing regimens who may present only weekly, fortnightly or monthly). 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 their pharmacy to participate in the NSW Pharmacotherapy Opioid Treatment Program should contact the Duty Pharmaceutical Officer, Pharmaceutical Services during office hours on (02) 9391 9944 or go to http://www.health.nsw.gov.au/pharmaceutical/pharmacists/Pages/OTP-pharmacists.aspx to download the application form.
The applicant pharmacist must be the proprietor of the pharmacy and 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.

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 the Pharmaceutical Services Unit as soon as possible in order to prevent any delay to dosing patients.

On completion of the registration process, the Pharmaceutical Services Unit 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 to treat drug dependence 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 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 is securely attached to the premises in compliance with clause 76 of the Regulation.
- They must remain in the safe except when in immediate use.
- They must be entered into the pharmacy’s Schedule 8 drug register on the date of receipt as per the requirements of clause 112 of the Regulation (see Section 6 below).
- Access to the safe is restricted to pharmacists and the key must be kept in the possession of the pharmacist at all times while the pharmacy is open for business.
- The keys should not be ‘hidden’ in the pharmacy overnight except in a separately locked key safe.

4. OTP PRESCRIPTIONS FOR METHADONE AND BUPRENORPHINE

Prior to a client 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 passport photo, the patient’s date of birth, the confirmed starting dosage and the first day of dosing, together with a valid prescription must be received by the pharmacist prior to the supply or administration of the first dose.

The passport photo and other documentation identifying the patient should always be kept with the current prescription. This is especially important when large numbers of patients are dosed or when locum pharmacists are employed.

Prescriptions should not be handed to patients. They should be sent directly to the pharmacy to avoid risk of alteration.

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, notwithstanding the 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, 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.
- Adequate directions for use (including clear directions regarding takeaway supplies, if any).
- The name, designation, address and contact details of the prescriber.
- It must be the only item on the prescription.

There are provisions to allow for computer generated prescriptions for. Please see http://www.health.nsw.gov.au/pharmaceutical/Documents/prescriptions-nonhandwritten.pdf for details. If clarification is required either for the pharmacist or the prescriber contact the Duty Pharmaceutical Officer, Pharmaceutical Services during office hours on (02) 9391 9944.

It is common practice for a prescriber to send a prescription 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 no later than seven days later.

4.2 Recording of a Prescription

On the first occasion that a prescription is to be used for the supply of a methadone or buprenorphine formulation 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 quite or private area of the pharmacy, but not in the dispensary area or where access to Schedule 4 or 8 medications is possible.

5.1 Supervised Methadone

5.1.1

Methadone must be accurately measured, preferably using a purpose specific device that is accurately calibrated and hygienically maintained (there are a number of commercially available manual or computerised pump systems available).

5.1.2

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

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

5.1.4

If the patient has missed three consecutive days of dosing or presents intoxicated by alcohol or another drug, then the pharmacist should contact the prescriber for further advice before dosing.

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

The patient must be carefully observed and can be given some water and asked to speak 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 authorisation from the prescriber.

5.1.8

The patient’s prescriber is the only person who may increase the dose or make changes to the dosing schedule e.g. addition of takeaways (see Section 5.2).

5.1.9

If a prescriber cannot be contacted the pharmacist may consider reducing or withholding the dosage with a clinically valid reason (e.g. intoxication). However the prescriber should be notified within 24 hours or as soon as practically possible.

5.2 Supply of Takeaway Methadone Doses

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

The NSW Clinical Guidelines for the Treatment of Opioid Dependence provides guidance on eligibility for takeaway supply. General principles include observing the patient regularly and limiting the number of takeaways a week to four.

5.2.3

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.

5.2.4

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.

5.2.5

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

5.2.6

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.

5.2.7

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.

5.2.8

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 (particularly 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).
5.3 Supervised Buprenorphine

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

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

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.

Buprenorphine sublingual film should be placed under the tongue and kept there until fully dissolved, which usually occurs within 4 to 8 minutes.

Patients must be closely observed at all times during these times to ensure correct administration and to prevent the risk of diversion.

5.4 Supply of takeaway buprenorphine

5.4.1

Single ingredient buprenorphine (Subutex®) should not be supplied as a takeaway dose unless in exceptional circumstance as determined by the prescriber.

5.4.2

The buprenorphine/naloxone sublingual film is reportedly 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 takeaway supply of buprenorphine under the NSW OTP.

5.4.3

It is expected that a pharmacist would make enquiries with a prescriber if a prescriber authorises Subutex® takeaways to be provided in preference to Suboxone®.

5.4.4

Takeaway doses of Suboxone® 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.

5.4.5

Takeaways of Suboxone® 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 Suboxone® film.
• 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).

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. However you are reminded that for methadone liquid it is mandatory to package each daily dose in an individual dispensing bottle (see Section 5.2.5).

For patients who meet certain criteria, the prescriber may issue prescriptions for weekly, fortnightly, or monthly supplies of unsupervised Suboxone®. In these cases the medication can be packed and labelled according to the requirements for any Schedule 8 dispensed medication.

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.

6.2

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

6.3

Drug register entries must include:

• the date of the entry (the day of the transaction),
• quantity of methadone or buprenorphine tablets 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 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 Sigma Methadone Syrup (manufactured by Aspen Australia Pty Ltd.) must have its 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 as set out by the requirements of the provisions of clause 112 of the Poisons and Therapeutic Goods Regulation 2008 (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 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 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 dispensed transferred to the register daily.
• The subsidiary drug register book must include 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 to an inspector from the Ministry of Health’s Pharmaceutical Services Unit. An inspector must identify themselves and produce a photo identification card.

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 to 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

Unless exceptional or unforeseen circumstances exist, all services participating in the opioid treatment program must comply with the clinical guidelines and community pharmacists have an important role in monitoring compliance with these guidelines.

Prescribers may, at times, in certain exceptional circumstances, elect to vary their clinical practice from that of the clinical guidelines. For example the provision of more
than four takeaways per week would constitute a departure from the guidelines and 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 opioid treatment program 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, Pharmaceutical Services during office hours on (02) 9391 9944.

This guide has been produced by:

Pharmaceutical Services Unit
Legal and Regulatory Services Branch
NSW Ministry of Health
Telephone (02) 9391 9944
Fax (02) 9424 5860
Email: pharmserv@doh.health.nsw.gov.au
Website: http://www.health.nsw.gov.au/pharmaceutical