

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)
- [NSW Clinical Guidelines: Treatment of Opioid Dependence](#)
- [Clinical guidelines for use of depot buprenorphine \(Buvidal® and Sublocade®\) in the treatment of opioid dependence](#)
- [Opioid Treatment Program Section 100 Highly Specialised Drugs Program](#)

The legislative requirements for the receipt, storage, and supply of methadone and buprenorphine (also referred to as Opioid Dependence Treatment or ODT) under the Opioid Treatment Program (OTP) are, at a minimum, the same as for any other Schedule 8 medicine. However, there are additional obligations under this protocol in relation to monitoring ODT supply and administration, including supervised dosing.

Adherence to this document will assist pharmacists in complying with the legislative and policy obligations regarding the supply of ODT. 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 number of patients supplied or administered methadone or buprenorphine on any day at any one community pharmacy must not exceed 65. If a person is supplied with methadone or buprenorphine once a week or less, the person is not counted towards the limit of 65. The limit aims to minimise the potential for patients congregating in the vicinity of community pharmacy and contributing to local amenity concerns.

Pharmacists interested in registering a pharmacy to participate in the NSW OTP should submit a completed application to the Pharmaceutical Services Unit (PSU). Applications are generally processed within 5 business days. The form is available at

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

The following requirements must be met before an application will be considered:

- all owners of the pharmacy must be listed on the application form
- the name of the pharmacy entered on the application form must match the Pharmacy Council of NSW Register of Pharmacies
- the pharmacy listed on the application form must be approved to supply pharmaceutical benefits under section 90 of the *National Health Act 1953*.

The proprietor(s) must have local policies and procedures in place to ensure that all pharmacists including locum pharmacists employed at the pharmacy:

- read and understand the current version of this protocol and
- comply with the requirements contained within, in addition to the legislative requirements under the Act and Regulation.

A new application form to supply methadone or buprenorphine is required when there is a change in the address, ownership, or the trading name of the pharmacy.

3. ORDERING, STORAGE AND RECEIPT OF METHADONE AND BUPRENORPHINE

As with any Schedule 8 medicine the provisions relating to storage, labelling, packaging, prescribing, supply, administration, record keeping and destruction under the Regulation apply to methadone or buprenorphine, specifically:

- Methadone and buprenorphine may only be obtained from a licensed wholesaler based on a written signed order by a pharmacist.
- On receipt of the order, it must be checked to confirm the integrity of the products and the quantity received is as indicated on the invoice.
- Methadone and buprenorphine must be immediately secured in the locked drug safe or refrigerator, which must comply with clause 76 of the Regulation.
- Methadone and buprenorphine must be entered into the pharmacy's drug register on the date of receipt in accordance with clause 112 of the Regulation (see Section 6 below).
- Methadone and buprenorphine 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. Pharmacies providing a large volume of medicines should consider conducting and recording stock checks more frequently e.g. fortnightly/monthly as this provides a regular baseline to assist reconciliation in the event of any discrepancy.
- When loss or theft has occurred, the Pharmaceutical Services Unit (PSU) 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>
- Following initial notification to PSU, if further details become available about the incident, a notification form should be resubmitted to include the additional details.
- Methadone and buprenorphine may not be destroyed unless carried out in accordance with clause 125 or clause 125A of the Regulation.

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

has access.

Where a code or combination is required to unlock the drug safe, this must only be known to pharmacists employed or engaged at the pharmacy.

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 date of 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. See example prescription on:

<https://www.health.nsw.gov.au/aod/Pages/otp-transition-s100-hsd-program.aspx#communityprescribers>

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.

As for all Schedule 8 medicines, 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, date of birth and address of the patient
- the name, strength and quantity of drug (expressed in words and figures)
- adequate directions for use (including clear directions regarding takeaway supplies, if any)
- the number of repeats authorised if the prescription is to be dispensed more than once and, if repeats are ordered, the time interval for repeats
- the name, designation, address and contact details of the prescriber
- methadone or buprenorphine must be the only item on the prescription.

There are provisions to allow for computer generated prescriptions. For details see TG184/12 Criteria for printed computer-generated prescriptions, available at <http://www.health.nsw.gov.au/pharmaceutical/Documents/prescriptions-nonhandwritten.pdf>

Note that the handwriting requirement in section B(4) of TG184/12 does not apply to prescriptions issued for methadone or buprenorphine for patients enrolled in the NSW OTP, provided that the prescription is sent directly to the patient's dosing supply point and is not provided to the patient.

Electronic prescriptions (e-prescriptions) are highly recommended for prescribing methadone or buprenorphine, as they can improve safety and compliance by reducing transcription errors. It is common practice for a prescriber to send a prescription 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 PSU in accordance with subclause 96 (2)(b) of the Regulation. Please send the notification via email to MOH-PharmaceuticalServices@health.nsw.gov.au. In the 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

In accordance with clause 113 of the Regulation, a pharmacist who supplies methadone or buprenorphine on prescription must record the following details:

- the details required by clause 80(1) of the Regulation to be included in the prescription,
- a unique reference number for the prescription,
- the date on which methadone or buprenorphine was supplied,
- the name of the pharmacist who supplied methadone or buprenorphine.

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 been superseded or the last supervised/takeaway dose has been supplied to the patient, 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 medicines is possible. Supervised dosing enhances safety and medicine adherence, reduces risk of diversion to others and enables better monitoring.

All health practitioners 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. For further information on dosing arrangements for severely ill patients, please refer to Section 3.7 of the NSW Clinical Guidelines: Treatment of Opioid Dependence (https://www1.health.nsw.gov.au/pds/Pages/doc.aspx?dn=GL2018_018).

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 with correctly identifying patients. Reference to the patient photograph must occur at each dosing (especially important for pharmacies that employ multiple pharmacists and locum pharmacists), regardless of how well the patient is known to pharmacy staff. The pharmacist must refer to the current original prescription at each dosing just like in the dispensing of any medicines.

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

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.

5.1.7

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

5.1.8

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. Any verbal authorisation must be confirmed via email or in writing signed and dated by the authorised practitioner. The confirmation should be attached to the original prescription.

5.1.9

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.

5.1.10

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 and/or request the patient present for clinical review depending on the clinical circumstances.

5.1.11

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 available at https://www1.health.nsw.gov.au/pds/Pages/doc.aspx?dn=GL2018_018

5.2 Supply of Methadone Takeaway Doses

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 5.2.1).

The *NSW Clinical Guidelines: Treatment of Opioid Dependence* (https://www1.health.nsw.gov.au/pds/ActivePDSDocuments/GL2018_018.pdf) provides the

framework for takeaway provision for methadone based on the treatment phase and on risk assessment. For further information, refer to Table 10 of the NSW Clinical Guidelines.

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. Any verbal authorisation must be confirmed via email or in writing signed and dated by the authorised practitioner. The confirmation should be attached to the original prescription.

5.2.2

An observed dose should be given prior to any supply of authorised takeaway doses. 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 unless authorised by the prescriber in writing.

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 for resupply. The returned medication can be accepted by the pharmacist, recorded in the drugs for destruction section of the drug register and stored in the drug safe clearly marked for destruction.

5.2.5

It is mandatory to package each daily takeaway dose individually. Each daily takeaway dose should be individually packed in a new, clean, amber dispensing bottle with an approved child-resistant closure. Bulk packaging of methadone takeaway doses is not permitted. Containers or bottles must not be recycled or reused.

5.2.6

Dilution of takeaway doses must be specifically ordered by the prescriber on the prescription. Dilution of takeaway doses should be in accordance with the Product Information (PI) of each formulation. Dilution must be clearly stated on the label of takeaway doses.

5.2.7

Takeaway doses must be labelled in accordance with the Regulation requirements, as for all other dispensed Schedule 8 medicines, 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).

5.3 Supervised Oral Buprenorphine and Buprenorphine/Naloxone

The oral formulations of buprenorphine available on the OTP are buprenorphine/naloxone sublingual film (Suboxone®) and buprenorphine sublingual tablets (Subutex®). For comprehensive information regarding the administration of each specific formulation please consult the full Product Information (PI) 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). A separate prescription is required for each strength of the medicine.

5.3.1

Particular care needs to be taken with correctly identifying patients. Reference to the patient photograph must occur at each dosing (especially important for pharmacies that employ multiple pharmacists and locum pharmacists), regardless of how well the patient is known to pharmacy staff. The pharmacist must refer to the current original prescription at each dosing same as the dispensing of any medicines.

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 or 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

minimise 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. Any verbal authorisation must be confirmed via email or in writing signed and dated by the authorised practitioner. The confirmation 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* (https://www1.health.nsw.gov.au/pds/ActivePDSDocuments/GL2018_018.pdf).

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 oral takeaway doses of buprenorphine and buprenorphine/naloxone

The *NSW Clinical Guidelines: Treatment of Opioid Dependence* (https://www1.health.nsw.gov.au/pds/ActivePDSDocuments/GL2018_018.pdf)

provides the framework for takeaway provision for buprenorphine and buprenorphine/naloxone based on the treatment phase and risk assessment. For further information, refer to Table 10 of the NSW Clinical Guidelines.

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 use. 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.

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 be confirmed via email or in writing signed and dated by the authorised practitioner. The confirmation should be attached to the original prescription.

5.4.2

An observed dose should be given prior to any supply of authorised takeaway doses. 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 unless authorised by the prescriber in writing.

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 for resupply. The returned medicine can be accepted by the pharmacist, recorded in the drugs for destruction section of the drug register and stored in the drug safe clearly marked for destruction.

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 resealable bag. 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 (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 medicine can be packed and labelled according to the requirements for any Schedule 8 dispensed medicine (see 5.4.5 and 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 sublingual buprenorphine must be labelled in accordance with the requirements of the Regulation for the labelling of any dispensed Schedule 8 medicine, 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.

5.5 Administration of depot buprenorphine

5.5.1

Pharmacists in NSW may administer depot-buprenorphine if it is within their scope of practice and professional competency. Pharmacists and proprietors offering this service must be satisfied that the medicine will be administered safely to the patient.

Accredited training is available for all NSW pharmacists through the [PSA Training Plan: NSW long-acting injectable buprenorphine administration by pharmacists](#).

5.5.2

Minimum requirements for administration of depot buprenorphine in community pharmacy:

1. Be a registered dosing point with NSW Ministry of Health
2. Pharmacist holds vaccination accreditation
3. Administration area and equipment must comply with the [NSW Pharmacist Vaccination Standards](#)

5.5.3

You must practice in accordance with the NSW Pharmacist Vaccination Standards (<https://www.health.nsw.gov.au/immunisation/Documents/pharmacist-new-standard.pdf>) and

PSA Guidelines for pharmacists administering medicines by injection <https://my.psa.org.au/s/article/Guidelines-for-pharmacists-administering-medicines-by-injection> or Pharmacy Guild Guidelines for Conducting Immunisation Services within Pharmacy (https://www.guild.org.au/data/assets/pdf_file/0020/92072/Guidelines-for-Conducting-Pharmacist-Administered-Vaccination-Services-V5.0.pdf).

5.5.4

If a pharmacist is dispensing depot buprenorphine for administration by a health practitioner, arrangements should be made to deliver the product directly to the clinic, it should never be supplied to the patient.

6. HARDCOPY 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. Requirements are as follows:

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 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 or depot buprenorphine received or supplied,
- name and address of the supplier of methadone or buprenorphine received,
- name and address of the person to whom the methadone or buprenorphine was supplied by the pharmacy,
- original prescription reference number,
- name of the prescriber,
- balance of methadone or buprenorphine in stock after each transaction,
- signature of the pharmacist making the entry.

Different strengths and formulations of buprenorphine Subutex®, Suboxone®, Buvidal® and Sublocade® 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 each 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 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. A spreadsheet does not meet these requirements and must not be used.
- 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.

6.5 Electronic drug register/ ODT dosing program

If an electronic drug register is used in conjunction with an ODT dosing program, the pharmacist must ensure it complies with the Framework for Use of an Electronic Drug Register Requiring Single Signature (TG216/1), see

<https://www.health.nsw.gov.au/pharmaceutical/Documents/framework-edr-single.pdf>.

All pharmacists involved in the provision of methadone or buprenorphine, including any part-time or locum pharmacists, must be familiar with how to correctly record and supply methadone or buprenorphine using an electronic ODT dosing program.

7. GENERAL PRINCIPLES

7.1

All records required to be made under the provisions of the Poisons and Therapeutic Goods legislation must be retained at the pharmacy at all times for a period of two years from the date of the latest transaction.

7.2

All hardcopy and electronic records must be legible, written in English, and be readily reproducible.

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 PSU inspector.

7.4

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

7.5

It is expected that pharmacists will communicate with the prescriber regarding any concerns e.g. intoxication, missed doses, takeaway doses, uncertainty between the prescribed number of doses not aligning with the dosage window, polypharmacy including the prescribing of centrally acting drugs by non-ODT prescribers. It is advisable to document any conversations and outcomes discussed with the prescriber.

7.6

Unless exceptional or unforeseen circumstances exist, all services participating in the OTP must comply with the clinical guidelines.

7.7

Other resources for OTP are available at

- <https://www.health.nsw.gov.au/pharmaceutical/pharmacists/Pages/otp-pharmacists.aspx>
- <https://www.health.nsw.gov.au/aod/Pages/community-pharm-nsw-otp.aspx#depotbupe>
- <https://www.psa.org.au/resource/opioid-dependence-treatment-odt-resources/>

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:

Pharmaceutical Services Unit (PSU). Legal and Regulatory Services Branch NSW Ministry of Health

Telephone (02) 9391 9944

Fax (02) 9424 5860

Email MOH-PharmaceuticalServices@health.nsw.gov.au

Website <http://www.health.nsw.gov.au/pharmaceutical>