

Pharmacotherapy self-assessment

For use by pharmacists providing opioid-replacement therapy

Pharmacy Name:

Introductory notes

The legislation that defines lawful actions in relation to scheduled poisons is contained in the *Drugs Poisons and Controlled Substances Act 1981* (the Act) and the *Drugs Poisons and Controlled Substances Regulations 2017* (the regulations). The regulations complement the Act by authorising actions that would otherwise be unlawful and define the outcomes required of lawful actions. For full details of legislative requirements, current versions of the Act and the regulations should be considered in concert and not read in isolation. These documents can be accessed at Victorian Law Today (www.legislation.vic.gov.au). A link to the Poisons Standard, which contains details relating to poisons schedules plus labelling and packaging requirements, can be found on the MPR website (at www2.health.vic.gov.au/dpcs).

This document has been prepared by Medicines and Poisons Regulation (MPR) to assist pharmacists in assessing their compliance with key regulatory and policy requirements associated with safe and lawful provision of opioid-replacement therapy (ORT). **Note:** For simplicity of reading, this document does not address all aspects of the requirements; pharmacists should refer to the regulations and Victoria's 'Policy for maintenance pharmacotherapy for opioid dependence' (the Policy) for full details. Documents relating to other key requirements and practitioners can be located on the MPR website (at www2.health.vic.gov.au/dpcs).

Explanatory notes

Examples of commonly accepted procedures have been included for guidance and clarification; they are not intended to represent the only manner in which compliance might be achieved.

Where 'Yes/No' responses are required, **bold** text is used to indicate the 'correct' or 'preferred' response.

Where **methadone** is mentioned in this document, the reference may be applied to either of the two available liquid formulations, which both contain 5 mg/mL of methadone hydrochloride. Methadone Syrup (Aspen) contains preservatives and other excipients; Biodone Forte® contains colouring and purified water.

References to **buprenorphine** in this document may be applied to either Subutex or Suboxone - unless otherwise indicated.

In addition to medical practitioners, references to prescribers are equally applicable to nurse practitioners whose registration endorsement and scope of practice are applicable to prescribing opioid-replacement therapy.

The regulations

Regulatory requirements associated with ORT are the same as for other Schedule 8 poisons. Failure to comply with the regulations renders a person liable to prosecution. In this document, the term '**must**' is used to emphasise regulatory requirements.

The Policy

The Policy has been developed in accordance with input from health practitioners with expertise in treating opioid-dependent patients to minimise the risks associated with ORT. It should be read in conjunction with the National Guidelines for Medication-Assisted Treatment of Opioid Dependence.

The Policy contains general advice, which is intended to assist health practitioners manage patients in a safe, appropriate and lawful manner. However, the Policy cannot address every clinical situation and is not intended to replace professional judgement in individual cases.

It is expected that pharmacists will generally act in a manner consistent with the Policy and will vary from it only if there is sufficient justification in an individual case.

A pharmacist is **not** obliged to vary from the **Policy** and **must not** vary from **regulatory requirements** simply because a prescriber gives instructions to do so.

In determining whether there is sufficient justification to vary from the Policy, or when dealing with a situation that is not specifically addressed in the Policy, pharmacists are advised to consider the “Principles of Pharmacotherapy Administration” (contained in Appendix 7 of the Policy) and to document reasons for any actions that are not consistent with the Policy. Pharmacists might also consider whether their actions are likely to satisfy the scrutiny of the Coroner in a worse-case situation.

Recent changes to the Policy

The current version of the Policy, which took effect in September 2016, is similar to previous versions of the Policy. Four key amendments have been highlighted in this document by yellow background shading rather than green. If this document has been printed in black and white, please refer to the website version to identify the sections with yellow background shading.

Self-assessment issues

Reference material

The Policy and the *National Guidelines for Medication-Assisted Treatment of Opioid Dependence* may be accessed on the department’s website at: www2.health.vic.gov.au/public-health/drugs-and-poisons/pharmacotherapy

Many useful contact details are contained in Appendix 2 of the Policy, including:

- The Drug and Alcohol Clinical Advisory Service (DACAS) for urgent clinical advice (1800 812 804)
- The Pharmacotherapy Advocacy and Mediation Service (PAMS) for advice and assistance in dealing with client-related issues that might arise (Tel: 1800 443 844)

Does your pharmacy have internet access, with the above website bookmarked for ready access by pharmacists, OR are printed versions of the corresponding reference material readily available?

YES / No

Are you confident that all pharmacists at your pharmacy are aware of and are able to readily access the emergency contacts listed in Appendix 2 of the Policy?

YES / No

Awareness by all pharmacists

ORT has inherent risks, associated with the vulnerability of the patients as well as the potential toxicity of the drugs – especially methadone. Those risks can be minimised when all pharmacists are fully aware of the key principles of treatment but can be heightened if some pharmacists are not fully aware.

The Policy contains a Certification Document (Appendix 7) that contains a concise summary of key principles, for ready reference by all pharmacists, including locums.

Are you confident that all pharmacists at your pharmacy are fully aware of and are complying with the Policy?	YES / No
Have all relevant pharmacists completed a Certification Document to confirm that they are familiar with the Policy?	YES / No
Are copies of the Certification Document available for reference by all pharmacists?	YES / No

Varying from the Policy

The Policy is not intended to replace professional judgement in **individual** cases. If a variation from the Policy is considered to be justified in an individual case, pharmacists are strongly advised to document fully the reasons for the variation. (Refer to the disclaimer on page 3 of the Policy)

Have all pharmacists been advised that, if a prescriber requests or directs them to vary from the Policy, the pharmacist is required to make a professional judgement and to be satisfied that the requested variation is safe and lawful before agreeing to implement the proposed variation?	YES / No
Have all pharmacists been advised to record any variations from the Policy in a prominent, consistent manner and in a form that can be readily retrieved if called upon to justify decisions to authorities? (e.g. Medicines and Poisons Regulation, Coroner)	YES / No

Patient identification

Before administering ORT, a pharmacist needs to be able to confirm the patient is the same person for whom treatment was prescribed. This is commonly achieved by reference to a photograph, which looks like the patient and which has been **certified by the prescriber**, to confirm the person's identity.

Commonly accepted examples:

- Photographs are securely attached to, or contained in, patients' attendance records.
- Photographs are scanned and displayed on the pharmacy computer.
- Computer software scans of irises and/or fingerprints are used to confirm identities.
- Replacement photographs are obtained if a patient's appearance changes significantly.

Are certified photographs, which actually look like the patient, or alternative identification standards held for all current patients?	YES / No
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Information for patients commencing Opioid Replacement Therapy

Appendix 1 of the Policy contains an information leaflet to explain key aspects and risks associated with the commencement of ORT. The leaflet is available in a range of languages.

The leaflet also contains references to the use of naloxone injections, which might be prescribed by the ORT prescriber, especially where methadone is the drug selected.

Note: Buprenorphine is generally safer than methadone during the induction phase, but the risks of poly-drug use and precipitated withdrawal still require caution during the induction period and while the maintenance dose is being established.

Have all pharmacists been made aware of the information leaflet and its contents?	YES / No
Note: Information about the use of naloxone injections is on page 20 of the Policy.	

Patients commencing or recommencing methadone treatment

During the initial stabilisation period, **methadone** blood levels take some days to plateau. There is a significantly greater risk of toxicity due to lack of recognition of the long half-life of methadone and the possibility of concurrent poly-drug use.

If the initial prescribed dose exceeds 40 mg daily, the prescriber should be consulted before administration. If there are concerns, the pharmacist and/or prescriber may need to discuss the case with the DACAS (1800 812 804).

Note: Buprenorphine is generally safer than methadone during the induction phase, but the risks of poly-drug use and precipitated withdrawal still require caution during the induction period and while the maintenance dose is being established.

Have all pharmacists been informed of the need to communicate with prescribers if a patient appears to be commencing or recommencing ORT with a methadone dose that exceeds 40 mg daily?

YES / No

New OR returning patients

In addition to the risks associated with a patient commencing treatment with higher doses of methadone, deaths associated with ORT have been attributed to multiple dosing (with or without take-away doses), when patients are transferring between dosing points. Multiple dosing is more likely if there is miscommunication or no communication between the dosing points involved in the transfer.

Similarly, when a patient returns to a pharmacy after an absence and dosing resumes on the basis of a prescription from a previous (or new) prescriber, the reason for the absence (e.g. hospital treatment, prison term, illicit drug use) might be known to the prescriber, the pharmacy, both or neither.

It is **not** acceptable to make assumptions. To ensure the patient's safety; precise details of the magnitude and timing of the most recent dose need to be determined and documented before a dose is administered. The possibility of take-away doses and/or an interim prescription, which might have been issued by prison health service provider, should also be considered.

Have all pharmacists been informed that they should **always** communicate with the prescriber **(to determine whether a patient is commencing (or recommencing) ORT or transferring from another dosing point)** before administering methadone or buprenorphine to a patient who is new to your pharmacy?

YES / No

Have all pharmacists been informed that they should **always** communicate with the previous dosing point **(to determine precisely when the previous dose was given; the magnitude of the actual dose; and whether any take-away doses were supplied)** before administering methadone or buprenorphine to a patient who is transferring to your pharmacy?

YES / No

Prescriptions from prescribers in another state or territory

Victorian legislation requires prescribers in Victoria to obtain permits before prescribing ORT but it has no jurisdiction over prescribers in other states or territories, whose prescriptions may still be valid in Victoria.

To prevent the possibility of a concurrent Schedule 8 treatment permit being issued to a Victorian prescriber, a pharmacist, who undertakes to provide ORT to a patient on the basis of a prescription issued in another jurisdiction, should notify MPR using the form "*Notification of a temporary interstate transfer of a patient on opioid-replacement therapy (ORT) to a Victorian pharmacy*", which may be downloaded from the MPR website at: www2.health.vic.gov.au/public-health/drugs-and-poisons/pharmacotherapy/pharmacotherapy-transfers-into-victoria.

Have all pharmacists been informed of the need to provide relevant details of the patient and

YES / No

the prescriber to MPR when they undertake to provide ORT on the basis of a prescription issued in another jurisdiction?

Patient attendance records

Attendance records are required to ensure that a patient cannot receive multiple doses on the same day and to assist pharmacists in reviewing a patient's regularity of attendance.

Commonly accepted examples:

- Patients are required to sign for each dose in a designated exercise book.
- Patients are required to sign for each dose on loose-leaf pages in a designated binder.
- Patients are required to sign for each dose on loose-leaf pages that are kept in designated drop folders.
- Patients' signatures or attendances are recorded electronically using computer software.

NOTE:

1. The administering pharmacist **must** be identified on each occasion – unless he/she is identified in the pharmacy's Administration Records (see below).
2. If the administering pharmacist is identified in the attendance records, rather than in the pharmacy's administration records, the attendance records **must** be retained for three years.

Dose administration records

A pharmacist **must** make a true and accurate record of all transactions, including the administration or supply of ORT. Suggested formats are contained in Appendices 8 to 12 of the Policy

Commonly accepted examples:

- Manual records on computer-generated day sheets
- Computer spread sheet
- Commercially developed computer software
- Manual records in a bound book with consecutively numbered pages
- Manual records in a Schedule 8 Drug Register (practical only for small numbers of patients)

Is the unit of measurement of methadone (mg or mL) clearly recorded to prevent misinterpretation by pharmacists?

YES / No

Is the supply of take-away doses recorded in a consistent and unambiguous manner that may be readily identified by all pharmacists?

YES / No

Are administration records kept in a manner that preserves patient confidentiality and ensures they may not be viewed by other patients?

YES / No

Recording & reconciling the balance of Schedule 8 poisons

With Schedule 8 poisons, including **methadone** and **buprenorphine**, a pharmacist **must** record the balance remaining after each transaction in a manner that ensures the record cannot be altered, obliterated, deleted or removed without detection.

NOTE: The minimum standard required to comply with this requirement involves recording the **calculated** balance in an appropriate form (e.g. Drug Register) **at least daily**.

Commonly accepted examples:

- The cumulative total, of doses administered or supplied during the day, is calculated in the Administration Records and transcribed to a manual Schedule 8 Drug Register with the remaining balance calculated and recorded **each day**.
- The computer software automatically calculates the remaining balance as each dose is recorded **and** records the balance in a computer file, which cannot be altered without making a separate record.
- The daily total is calculated and recorded in the Administration Records, which are in a bound book with consecutively numbered pages. The remaining balance is calculated **each day** and recorded in the same book.
- Each dose, administered or supplied during the day, is recorded in the Schedule 8 Drug Register with the remaining balance calculated and recorded after each dose (practical only for small numbers of patients).

To ensure the **recorded** balance is **true** and **accurate**, it should be reconciled with the **actual** balance on a regular basis.

Commonly accepted examples:

- Weekly or fortnightly physical stock checks are performed, with a separate entry made when it is necessary to adjust the recorded balance to show the actual balance.
- Physical stock checks are conducted when new stock is received, with a separate entry made when it is necessary to adjust the recorded balance to show the actual balance.

NOTE: Any discrepancies in a Schedule 8 poison **must** be investigated immediately with any unresolved discrepancies reported promptly to MPR.

Prescriptions

Pharmacists are required to use their everyday dispensing software (e.g. FRED, LOTS) to record details of **each ORT prescription** – in order to ensure that basic information relating to provision of ORT information will be transmitted to Victoria's monitored poisons database (SafeScript) – **regardless** of whether similar information is recorded using ORT-specific software (e.g. Methsof, MethDA).

Note:

- This requirement relates to each prescription; **not** to each dose that is administered or supplied.
- The patient's **date of birth must** also be recorded by the dispensing software.

Have all pharmacists been informed about this new requirement?

YES / No

A pharmacist **must** have lawful instructions from a prescriber before administering a Schedule 8 poison.

The prescriber **must** provide instructions in writing or (in an emergency) verbally, with written confirmation of verbal instructions to be provided as soon as practicable.

Note: A faxed document should be used only to confirm verbal instructions.

When receiving verbal instructions from a prescriber (to authorise administration in an emergency), is it your pharmacy's policy to request that the prescription is faxed to confirm those instructions?

YES / No

Following verbal instructions, is it your pharmacy's policy to seek further instructions from the prescriber, before administering further doses, if a prescription is not provided promptly?

YES / No

It is an offence for a pharmacist to administer a Schedule 8 poison without lawful instructions from a prescriber but such occurrences are not rare. In some cases, pharmacists have been found to have administered ORT for months after the prescription had expired and in circumstances where the patient had ceased consulting the prescriber.

Common examples of how prescription expiry dates are **prominently** recorded so that pharmacists and/or patients are aware of the need to obtain new prescriptions in a timely manner:

- The expiry date of the current prescription is prominently highlighted in the patient's attendance record so that both patient and pharmacist are aware that the expiry date is approaching.
- The current prescription is attached to the patient's attendance record with the expiry date prominently recorded. Pharmacists routinely remind patients that the expiry date is approaching (and make a note that they have done so), to allow the patient ample time to obtain a new prescription.
- The expiry date of the current prescription is prominently displayed on the computer screen when a patient attends. Pharmacists routinely remind patients that the expiry date is approaching (and make a note that they have done so), to allow the patient ample time to obtain a new prescription.

All prescriptions for Schedule 8 poisons **must** be retained for 3 years in a manner that enables them to be produced on demand.

Commonly accepted examples:

- Prescriptions that have expired (or that have been superseded by a subsequent prescription) are filed in clearly marked bundles on a regular basis (e.g. monthly) and are kept separate from prescriptions for other Schedule 8 poisons so that they are easier to locate if required.
- Prescriptions that have expired (or that have been superseded by a subsequent prescription) are retained in the designated file or drop folder for the corresponding patient; care is taken to ensure that the current prescription is clearly distinguished from earlier prescriptions.

Storage

ALL methadone and buprenorphine **must** be stored in a safe or Schedule 8 drug cabinet when not actually required for administration and **always** at the end of the day.

Does your pharmacy have sufficient storage capacity to accommodate all ORT drugs – including the methadone-dispensing container?

YES / No

Some pharmacies have experienced situations where a person has reached over or around a dispensary barrier to snatch a bottle of methadone solution or packets of buprenorphine preparations.

During the working day, is the methadone dispensing container and the “in-use” buprenorphine preparations located where a person cannot reach them or walk to them without obstruction to affect an opportunistic theft?	YES / No
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Stability of buprenorphine preparations

Buprenorphine sublingual preparations are packed under nitrogen, to ensure the stability and integrity of the drug. Tablets and Films should remain in the manufacturer’s immediate packaging until immediately prior to administration.

Are buprenorphine preparations left in the manufacturer’s immediate packaging until it is time to prepare a dose for administration?	YES / No
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Methadone dispensing container

Where pharmacies dispense **methadone** doses from a container other than the manufacturer’s original container, most use the solution in its original 5 mg/mL concentration; some choose to dilute the solution to a 1 mg/mL concentration. To avoid errors, it is essential that the dispensing container is labelled to identify its contents plus the strength of those contents accurately and prominently.

IF dispensed from other than its original container, is the container labelled to identify its contents prominently - including the concentration of the methadone solution?	YES / No
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Doses prepared in advance (if applicable)

The department recommends that each ORT dose is prepared by the pharmacist who is to administer the dose when the patient attends to receive the dose.

Do pharmacists at your pharmacy prepare doses prior to patients’ attendance? (If the answer is ‘no’, you need not complete the rest of this sub-section)	Yes / NO
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Where a pharmacy chooses to prepare doses in advance of patients’ attendance, additional matters should be considered to minimise the risk of errors.

Are pre-prepared doses placed in containers that have a secure closure?	YES / No
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Are pre-prepared doses placed in containers that are clearly & unambiguously labelled with the identity of the patient?	YES / No
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Do the pharmacy records clearly identify the pharmacist who prepared the dose in addition to the pharmacist who administers the dose?	YES / No
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Are pre-prepared doses of methadone diluted prior to the patient’s attendance? (This practice is not recommended because it precludes the possibility of re-checking the dose)	Yes / NO
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Administering methadone & anti-diversion strategies

Is each supervised dose of methadone diluted with water or cordial before administration?	YES / No
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Is the administration of each methadone dose supervised to ensure that the patient has	YES / No
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consumed the dose?	
Are all pharmacists aware that methadone is fully absorbed within 20 to 30 minutes of ingestion and that a dose might have been substantially absorbed if a patient claims to have vomited a dose after leaving the pharmacy?	YES / No

Administering buprenorphine & anti-diversion strategies

To address widespread reports of diversion and injection of Subutex®, naloxone was added to the formulation to deter injection and pharmacists were instructed to break tablets into smaller pieces to reduce the times required for absorption and supervision. Suboxone® Films were subsequently developed to further reduce the times of absorption and supervision.

For administration of **Suboxone® Films**, each sachet should be torn to allow the patient to remove (peel off) the strips and place one strip under each side of the tongue without overlapping. Some patients will be able to administer four doses concurrently, with the extra two Films being administered in the buccal cavities.

Have all pharmacists and patients been advised that buprenorphine preparations are to be administered sublingually and that Suboxone® Films should not overlap?	YES / No
Are patients supervised until the sublingual dose of buprenorphine tablets has been substantially absorbed or Suboxone® Films have adhered to the mucous membrane?	YES / No

The Policy states that **Subutex® tablets** should be broken into small pieces (resembling granules) and administered directly under the patient's tongue. **Note:** Crushing tablets into a fine powder may cause pasting in the mouth and actually slow absorption.

MPR recommends providing the dose of broken tablets to the patient in a dry disposable cup. If patients complain about the taste, bread is reported to be quite effective in eliminating the taste and, if it is a particular concern, patients can be advised to bring a slice of bread to eat once the tablets have been absorbed.

To minimise the possibility that Subutex® tablets might be diverted, are the tablets routinely broken into small pieces or granules before administration to each patient?	YES / No
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Some prescribers have directed pharmacists **not** to crush **Subutex® tablets** for specific patients. The department advises that this instruction is probably best interpreted as an instruction to not crush the tablets into a fine powder, an action that might affect the extent to which a dose is absorbed.

Commonly accepted options:

- If the pharmacist agrees that it is safe and appropriate to vary from the recommended process in relation to an individual patient, the reasons for the variation should be documented in the patient's records. In such cases, the sublingual tablets should be broken into smaller pieces and additional time should be allotted to supervise the patient in order to prevent diversion.
- If a prescriber is unable to satisfy the pharmacist that it is safe and appropriate to vary from the recommended process in relation to an individual patient, the pharmacist should inform the prescriber that he/she is not willing to agree to the variation. In such cases, the prescriber and the patient could be invited to transfer to another pharmacy.
- Suboxone® sublingual films may be suggested to the prescriber as an alternative formulation.

Administration containers

For reasons of hygiene, it is recommended that disposable containers are used for the administration of both methadone and buprenorphine.

Commonly accepted options:

- Disposable containers are used and are discarded into a designated waste container.
- Re-usable containers, labelled for specific patients, are thoroughly cleaned and sanitised after each use.

Authorisation of take-away doses

The supply of take-away doses is a significant clinical decision that requires thorough consideration of the risks and benefits of a patient having the privilege of take-away doses; see pages 30 to 42 of the Policy for a broad discussion of the many variables that should be assessed and considered.

Appendix 4 contains a check list to assist prescribers in assessing whether authorisation for take-away doses might be considered; it divides the numerous issues into four categories:

1. **Absolute contra-indications:** Take-away doses should **not** be supplied
2. **Relative contra-indications**
3. **Reasonable need**
4. **Continuous period of stability**

Note: Before authorising take-away doses, prescribers should communicate with pharmacists to confirm that patients fulfil the criteria for the supply of take-away doses; to ensure that pharmacists are not aware of any contra-indications; and to confirm or establish the duration of continuous, stable treatment – a key factor in determining the frequency with which take-away doses may be supplied.

Have all pharmacists been made aware of the relative importance of the four categories that are associated with the supply of take-away doses?	YES / No
Is a copy of Appendix 4 readily available (hard copy or bookmarked) for ready reference by pharmacists?	YES / No
Have all pharmacists been informed of the need to alert prescribers if the conduct of patients who have been receiving take-away doses, represents a contra-indication to the ongoing supply of take-away doses?	YES / No
Have all pharmacists been informed that, where a prescriber requests or directs them to provide take-away doses other than in accordance with the Policy, the pharmacist is also required to make a professional judgement about the safety and appropriateness of the variation?	YES / No
Have all pharmacists been advised that take-away doses that are claimed to have been lost or stolen are not to be replaced unless the prescriber's authorisation has been obtained; and that pharmacists should exercise professional judgment about the safety and appropriateness of providing replacement doses even if authorised to do so?	YES / No

Take-away doses - secure storage by patients

The absence of a safe, secure storage facility is one of four absolute contra-indications to the supply of take-away doses because of the significant risk if doses are consumed by someone other than the patient for whom they were supplied. This risk is magnified in the case of children, people who lack tolerance for the drug and people who are

concurrently using other drugs. In a number of inquests into deaths from ingesting take-away doses of methadone, the Coroner has raised concerns about the safe storage of take-away doses. To minimise these risks, it is essential that take-away doses are stored securely by patients.

Note: Take-away doses of methadone do not need to be refrigerated and doing so might increase the risk of a dose being taken by children or other household members.

Are patients periodically questioned about the manner in which they store take-away doses and reminded of the need to ensure that take-away doses are stored securely, where they cannot be located or accessed by others, especially children?	YES / No
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Take-away doses of methadone

A schedule, showing the recommended maximum number of methadone take-away doses following **continuous periods of stability in treatment**, is included in Appendix 4 of the Policy.

Less than 3 months	<ul style="list-style-type: none"> No take-away doses
3 to 6 months	<ul style="list-style-type: none"> Not more than 2 take-away doses per week
More than 6 months	<ul style="list-style-type: none"> Not more than 4 take-away doses per week Not more than 3 take-away doses on any occasion

Take-away doses of methadone represent a significant risk if consumed by someone other than the patient for whom they were supplied. This risk is magnified in the case of children, people who lack tolerance for the drug and people who are concurrently using other drugs.

To minimise these risks and to deter injection, **each** methadone take-away dose should be diluted **with water** to a volume of 200 mL and supplied in a container with a child-resistant closure. Take-away doses should **not** be diluted with cordial, as doses prepared in this manner may develop microbial growth.

Is each methadone take-away dose diluted to a volume of 200 mL?	YES / No
Is each methadone take-away dose supplied in a container with a child-resistant closure?	YES / No

MPR sometimes receives complaints alleging that pharmacists have re-used containers that were previously used for methadone take-away doses but have not been adequately cleaned and sanitised before being re-used and/or that tap water has been used to dilute take-away doses.

These issues relate to professional pharmacy standards rather than regulatory requirements but MPR offers the following information for consideration.

The use of tap water in diluting methadone take-away doses may be acceptable but pharmacists should consider the quality of local tap water and the fact that the concentration of preservatives in Methadone Syrup will also be diluted. Accordingly, the use of tap water for dilution of methadone take-away doses represents a minor risk that might be elevated if a take-away dose is not stored appropriately or consumed until several days after preparation.

The risks associated with the use of tap water might be less significant than the provision of methadone take-away doses in containers that have not been thoroughly cleaned and sanitised.

Have all pharmacists been informed of the need to ensure that containers used for take-away doses are not to be re-used for anyone other than the same patient and then only if they have been thoroughly cleaned and sanitised ?	YES / No
Have all pharmacists been advised to consider the proposed duration and conditions of storage of methadone take-away doses when determining whether tap water may be used to dilute take-away doses?	YES / No

Take-away doses of buprenorphine

Subutex[®] should **not** be authorised for take-away doses unless the patient is pregnant or breastfeeding; has a clinically documented allergy to naloxone (or to an excipient in Suboxone[®]); or where it is necessary to supply the 0.4 mg tablet to achieve a dose that is less than 2.0 mg.

Where take-away doses of **Suboxone**[®] are authorised, the patient should be transferred to Suboxone[®] for all doses, including the days when doses are supervised.

Have all pharmacists been informed that the Policy makes no provision for routine take-away doses of **Subutex**[®] and that take-away doses of **Suboxone**[®] should be limited as indicated other than as indicated above?

YES / No

A schedule, showing the recommended maximum number of **Suboxone**[®] take-away doses following **continuous periods of stability in treatment**, is included in Appendix 4 of the Policy.

Less than 2 weeks	<ul style="list-style-type: none"> No take-away doses
2 weeks to 2 months	<ul style="list-style-type: none"> Not more than 2 take-away doses per week
2 months to 6 months	<ul style="list-style-type: none"> Not more than 5 take-away doses per week
More than 6 months	<ul style="list-style-type: none"> Not more than 6 take-away doses per week

Minimal Supervision Regimens of Suboxone[®]

A small percentage of very stable, low-risk patients may be considered for provision of Suboxone[®] for longer periods than listed under low-level supervision - up to a maximum of 28 days' supply. Such permits, which will be different to other ORT permits, will generally be issued only to Fellows of the Australasian Chapter of Addiction Medicine (FACHAM) or prescribers with supporting advice from a Fellow.

Suboxone[®] take-away doses might be packaged and labelled as individual doses **OR** as multiple doses with different strengths in different containers. In either case, labelling **must** be accurate and unambiguous (see sample labels on the final pages of this document).

Suboxone[®] Films are to be retained in the manufacturer's immediate packaging - see page 53 of the Policy for related information

Take-away doses - labelling

Ad hoc reviews by MPR of labels on containers of take-away doses have revealed that a significant number of pharmacists failed to label containers in accordance with the Regulations or the Policy. Extracts from the Policy, showing sample labels for take-away doses have been included on the final pages of this document.

Have all pharmacists been made aware of the packaging and labelling requirements for take-away doses?

YES / No

Note: Pharmacists should use their professional judgment about the appropriateness of including other authoritative **recommendations**, including those contained in the Australian Pharmaceutical Formulary (APF), which recommends including the warning "Do not inject".

Irregular dosing

Are all pharmacists aware of the need to inform the prescriber when a patient's attendance becomes irregular – regardless of whether take-away doses have been authorised?	YES / No
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When not to administer ORT

The symptoms of methadone toxicity are similar to those of alcohol intoxication and may indicate that a patient has administered other drugs.

Have all pharmacists been informed that ORT is not to be administered if a patient appears to be intoxicated?	YES / No
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If a patient has ceased receiving ORT for a period, there is a risk that his/her tolerance to the drug might have diminished or that he/she has used other drugs. **In such cases, the prescriber should consider reducing the commencement dose.**

Have all pharmacists been informed that neither methadone nor buprenorphine is to be administered, without the prescriber's expressed authorisation, if a patient has missed doses on four or more consecutive days?	YES / No
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Have all pharmacists been informed that, if a patient recommences ORT after having missed doses on four or more consecutive days, safety precautions should be similar to those that apply when a patient initially commences ORT?	YES / No
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Refer to pages 3 and 4 of this document for details of issues relating to commencing or recommencing ORT.

Transfers & temporary absences

Deaths associated with ORT have been attributed to multiple dosing (with or without take-away doses), when patients are transferring between pharmacies. Multiple dosing is more likely if there is miscommunication or no communication between the two pharmacies involved in the transfer.

Similarly, when a patient returns to a pharmacy after an absence and dosing resumes on the basis of a prescription from a previous or new prescriber, the reason for the absence (e.g. hospital treatment, prison term, illicit drug use) might be known to the prescriber, the pharmacy, both or neither.

It is **not** acceptable to make assumptions. To ensure the patient's safety; precise details of the magnitude and timing of the most recent dose need to be determined and documented before a dose is administered. The possibility of take-away doses and/or an interim prescription, which might have been issued by prison health service provider, should also be considered.

Have all pharmacists been informed that they should always communicate with the prescriber (to determine precisely what has transpired) before administering methadone or buprenorphine to a patient who is returning to your pharmacy after missing doses on four or more consecutive days ?	YES / No
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Have all pharmacists been informed that they should always communicate with the previous dosing point (to determine precisely when the previous dose was given; the magnitude of the actual dose; and whether take-away doses were provided) before administering methadone or buprenorphine to a patient transferring to your pharmacy?	YES / No
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Contemporaneous notes

ORT has inherent risks associated with the vulnerability of the patients as well as the potential toxicity of the drugs – especially methadone. Those risks can be minimised when all pharmacists are fully aware of key issues relating to the management of a patient but can be heightened if some pharmacists are not fully aware, which is more likely if aspects of a patient's treatment rely on what is known by just one pharmacist. Readily retrievable contemporaneous notes, which are maintained in a consistent manner and location, are needed to address this issue.

Commonly accepted options:

- Contemporaneous notes are recorded in a designated section of each patient's attendance records – in a location that is not available for the patient to peruse.
- Contemporaneous notes are recorded in a designated section of each patient's file or folder – where the patient cannot peruse them.
- Contemporaneous notes are recorded in a computer file for each patient.

All pharmacists should be aware of the need to make contemporaneous notes of the following:

- Communications with prescribers in relation to variations from the Policy
- Communications with prescribers in relation to dose variations
- Communications with prescribers in relation to proposed & authorised take-away doses
- Communications with prescribers in relation to absences or irregular attendance
- Communications with other pharmacies where transfers are involved and where doses are to be administered from multiple dosing points
- Communications with DACAS in relation to the receipt of clinical advice
- Communications with prescribers or PAMS in relation to unacceptable behaviour or suspected diversion of doses
- Communications with MPR in relation to issues of concern, including suspected or confirmed diversion of doses

Prescribers who have not completed training and assessment

In recognition of the lesser risk of diversion and less complicated pharmacokinetics of **Suboxone**[®] use, any prescriber may prescribe **Suboxone**[®] (only) for up to 5 patients without completing the training or assessment required to prescribe other ORT drugs or formulations.

Prescribers who have not completed training and assessment should seek advice from an 'approved prescriber' (preferably in the same practice) or from DACAS before prescribing to a patient.

Have all pharmacists been made aware of the possibility of **Suboxone**[®] prescriptions from prescribers who have not completed training and assessment and who might not be familiar with all aspects of the Policy and relevant legislation?

YES / No

Prescribers who have not completed training and assessment may also **deputise** for an 'approved prescriber' to continue the treatment of a **stable** patient if the following circumstances are met:

- the deputising prescriber is practising at the same practice as the usual treating prescriber, **and**
- the usual treating prescriber holds a current permit, **and**
- the deputising prescriber is not re-starting treatment of a patient with pharmacotherapy (including where a patient has missed doses on four or more consecutive days), **and**
- the duration of the prescription is limited to the expected period of absence of the usual prescriber, **and**
- the prescription is endorsed to show that the prescriber is temporarily deputising for the usual prescriber

Sample labels for take-away doses

Each **methadone** take-away dose bottle should only contain a single dose of methadone.

The following example includes the key requirements for labelling a methadone take-away dose of 40 mg daily.

<p>METHADONE SOLUTION containing 40 mg in 200 mL</p> <p>This bottle contains a single daily dose of methadone to be taken on 15 June 2016 by John Citizen.</p> <p>Prepared on 14 June 2016</p> <p>KEEP OUT OF REACH OF CHILDREN</p> <p>Pharmacy Name</p> <p>Address & Phone Number</p> <p>Pharmacist ID</p>
<p>“This medication may cause drowsiness and may increase the effects of alcohol. If affected do not drive a motor vehicle or operate machinery.” <i>(commonly on an ancillary label)</i></p>
<p>“May cause death or injury if taken by another person” <i>(on an ancillary label or the main label)</i></p>

Buprenorphine/naloxone take-away doses may be packaged individually to contain only a single dose of buprenorphine. The following example includes the key requirements for labelling a buprenorphine/naloxone take-away dose as a single dose of 22 mg daily.

BUPRENORPHINE/NALOXONE FILM

This container contains a single daily dose of 22 mg of buprenorphine to be taken by John Citizen. Take the contents of this container as a single dose dissolved under the tongue on 15 June 2016.

Prepared on 14 June 2016

KEEP OUT OF REACH OF CHILDREN

Pharmacy Name

Address & Phone Number

Pharmacist ID

“This medication may cause drowsiness and may increase the effects of alcohol. If affected do not drive a motor vehicle or operate machinery.” *(commonly on an ancillary label)*

“May cause death or injury if taken by another person”
(on an ancillary label or the main label)

Alternatively, buprenorphine/naloxone take-away doses may be packaged for multiple days of unsupervised dosing. However, if the patient is required to take different strengths of preparation (i.e. a combination of the 2 mg and 8 mg films), the different strengths of films are to be packaged separately. Ensure that the patient is aware of the dosing instructions for both strengths of film to achieve the correct daily dose of buprenorphine.

The following example includes the key requirements for the labelling of buprenorphine/naloxone take-away doses of 22 mg daily packaged in two separate containers for multiple days of unsupervised dosing.

**BUPRENORPHINE/NALOXONE FILM 8 mg
(Qty 6)**

Dissolve under the tongue TWO films each day.

To be taken on 15 June, 16 June and 17 June 2016 by John Citizen.

**BUPRENORPHINE/NALOXONE FILM 2 mg
(Qty 9)**

Dissolve under the tongue THREE films each day.

To be taken on 15 June, 16 June and 17 June 2016 by John Citizen.

<p>(Please note: buprenorphine/naloxone 2 mg films are packaged separately)</p> <p>Prepared on 14 June 2016</p> <p>KEEP OUT OF REACH OF CHILDREN</p> <p>Pharmacy Name</p> <p>Address & Phone Number</p> <p>Pharmacist ID</p>	<p>(Please note: buprenorphine/naloxone 8 mg films are packaged separately)</p> <p>Prepared on 14 June 2016</p> <p>KEEP OUT OF REACH OF CHILDREN</p> <p>Pharmacy Name</p> <p>Address & Phone Number</p> <p>Pharmacist ID</p>
<p>“This medication may cause drowsiness and may increase the effects of alcohol. If affected do not drive a motor vehicle or operate machinery.” <i>(commonly on an ancillary label)</i></p>	<p>“This medication may cause drowsiness and may increase the effects of alcohol. If affected do not drive a motor vehicle or operate machinery.” <i>(commonly on an ancillary label)</i></p>
<p>“May cause death or injury if taken by another person” <i>(on an ancillary label or the main label)</i></p>	<p>“May cause death or injury if taken by another person” <i>(on an ancillary label or the main label)</i></p>

For information relating to induction, education and program development

Department of Health & Human Services (DHHS)

Harm Reduction and Pharmacotherapy Services

Maureen Chesler
Pharmacotherapy Development Officer
GPO Box 4057
Melbourne 3001

Phone: 03 9096 5057
Mobile: 0418 221 452
Fax: 03 9096 9170
Email: maureen.chesler@dhhs.vic.gov.au

For information relating to matters of compliance

Department of Health & Human Services (DHHS)

The Duty Officer Medicines and Poisons Regulation

GPO Box 4057
Melbourne 3001

Tel: 1300 364 545
Fax: 1300 360 830
Email: dpcs@dhhs.vic.gov.au
Web: www2.health.vic.gov.au/dpcs

For further information

Department of Health & Human Services (DHHS)

Medicines and Poisons Regulation

GPO Box 4057
Melbourne 3001

Tel: 1300 364 545

Fax: 1300 360 830

Email: dpcs@dhhs.vic.gov.au

Web: www2.health.vic.gov.au/dpcs

Key contact details

- For urgent advice, relating to Schedule 8 permits and previous treatment for specific patients, phone **1300 364 545** (Monday to Friday 10am to 4 pm) and select **option 3** and then option 3.
- To seek **legislative advice** about the Drugs Poisons and Controlled Substances Act & Regulations, please forward your query to MPR via Email (dpcs@dhhs.vic.gov.au) or phone **1300 364 545** (Monday to Friday 10am to 4 pm) and select **option 3** and then option 2.
- To obtain **clinical advice** from specialist consultants, registered health practitioners (only) may phone the **DACAS** at any time on **1800 812 804**.
- For 24-hour confidential **drug and alcohol counselling** and advice about available **treatment facilities**, patients, family or health practitioners may phone **Direct Line - 1800 888 236**.
- For information relating to prescribing under the Pharmaceutical Benefits Scheme (PBS), refer to the Medicare Australia website (at www.medicareaustralia.gov.au/provider/) or contact Medicare Australia on 132 290

Other possible sources of information

Victorian Pharmacy Authority

Web: www.pharmacy.vic.gov.au

Pharmacy Board of Australia

Web: www.pharmacyboard.gov.au

Australian Health Practitioner Regulation Agency (AHPRA)

Web: www.ahpra.gov.au

To receive this publication in an accessible format phone 1300 364 545, using the National Relay Service 13 36 77 if required, or email dpcs@dhhs.vic.gov.au

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