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| Pharmacy self-assessment checklist for pharmacotherapy service delivery |
| Completion mandatory for approval to provide opioid pharmacotherapy services. |
| OFFICIAL |

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| Pharmacy Name | Click or tap here to enter text. | | |
| Pharmacy Address | Click or tap here to enter text. | | |
| Phone Number Click or tap here to enter text. | | | Email Click or tap here to enter text. |
| Name of pharmacist completing assessment | | | Click or tap here to enter text. |
| AHPRA registration number | | | Click or tap here to enter text. |
| As the nominated pharmacist regularly and usually in charge (PRUIC) of pharmacotherapy service delivery at …………………………….. pharmacy, I declare that I have read and understand the self-assessment checklist set out below. I will ensure that any pharmacists working under my supervision are familiar with the content of the checklist. Those areas of practice to which I have responded “no” will be addressed in a timely manner, to ensure our pharmacy offers pharmacotherapy services at the professional level expected. | | | |
| Date assessment completed | | Click or tap to enter a date. | |
| Signature | |  | |
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# **Introductory notes**

Methadone and buprenorphine are the medications commonly in opioid replacement pharmacotherapy for the treatment of opioid use disorder and is variously known as Opioid Replacement Therapy (ORT), Opioid Agonist Therapy (OAT) and Medication-Assisted Treatment of Opioid Dependence (MATOD).

For reasons of consistency across the Victorian Department of Health (the department) documents, the term “pharmacotherapy” is used to refer both to this program, and the opioid replacement medications used by people enrolled on this program.

This document has been prepared by the department to assist pharmacists to understand both the legislative requirements and best practice policy that are applicable to pharmacotherapy service delivery.

Pharmacotherapy medications are Schedule 8 poisons under [The Poisons Standard](https://www.tga.gov.au/publication/poisons-standard-susmp). Victorian legislation sets out requirements in relation to scheduled poisons, including pharmacotherapy, in the *Drugs Poisons and Controlled Substances Act 1981* (the Act). The safe and secure storage, sale, supply, prescribing, administration and use of pharmacotherapy is facilitated under the Drugs Poisons and Controlled Substances Regulations 2017 (the Regulations).

## The regulations

Requirements under the Regulations for pharmacotherapy are the same as for other Schedule 8 poisons. In this document where the word “**MUST**” is used, it refers to a practice that is required by legislation.

## The policy

Victoria’s [Policy for maintenance pharmacotherapy for opioid dependence](https://www2.health.vic.gov.au/public-health/drugs-and-poisons/pharmacotherapy/pharmacotherapy-policy-in-victoria) (the policy) has been developed in accordance with input from health professionals with expertise in treating patients with opioid use disorder to minimise the risks associated with pharmacotherapy. It should be read in conjunction with the [National guidelines for medication-assisted treatment of opioid dependence](https://www.health.gov.au/resources/publications/national-guidelines-for-medication-assisted-treatment-of-opioid-dependence).

The policy contains general best practice advice, which is intended to assist health professionals 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** merely because a prescriber gives instructions to do so.

Pharmacists are advised to consider the “Principles of Pharmacotherapy Administration” (contained within Appendix 7 of the policy – Certification of pharmacists to administer doses) to support their clinical decision making in varying from the policy and situations that are not specifically addressed in the policy. Reasons for any actions that are not consistent with the policy should be documented.

In this document where the words “**SHOULD**” or “**RECOMMENDED**” are used, it refers to a practice that is best practice policy advice.

## Explanatory notes

This self-assessment checklist is designed to be read in conjunction with the Victorian policy for maintenance pharmacotherapy for opioid dependence.

**Methadone** applies to either of the 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.

**Buprenorphine** applies to either Suboxone® or Subutex® unless otherwise indicated.

**Long-acting injectable** **buprenorphine (LAIB)** apply to both Buvidal® and Sublocade® unless otherwise indicated.

Reference to the term prescribers apply to medical and nurse practitioners.

# Self-assessment checklist

## Reference material

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| Victorian guidelines  Refer to the [Pharmacotherapy policy in Victoria webpage](https://www2.health.vic.gov.au/public-health/drugs-and-poisons/pharmacotherapy/pharmacotherapy-policy-in-victoria) on the Department of Health website to access:   * Victoria’s Policy for maintenance pharmacotherapy for opioid dependence * Pharmacotherapy policy addendum - long-acting injectable buprenorphine * Long-acting injectable buprenorphine - Brief clinical guidelines   National guidelines  Refer to the [publications page](https://www.health.gov.au/resources/publications/national-guidelines-for-medication-assisted-treatment-of-opioid-dependence) on the Commonwealth Department of Health website to access:   * the National Guidelines for Medication-Assisted Treatment of Opioid Dependence   Key Contacts   * The [Drug and Alcohol Clinical Advisory Service (DACAS)](https://www.dacas.org.au/) is an addiction medicine specialist service available for health professionals. DACAS can provide clinical advice for pharmacotherapy management (Tel: 1800 812 804) * The [Pharmacotherapy, Advocacy and Mediation Service (PAMS)](https://www.hrvic.org.au/pams) is a service provider for consumers treated with pharmacotherapy. They can also provide assistance for pharmacists in resolving patient-related issues that might arise (Tel: 1800 443 844) * [DirectLine](https://www.directline.org.au/) is an Alcohol and other Drug (AOD) phone counselling and referral service provider. Directline can assist consumers in finding a suitable prescriber or pharmacy (Tel: 1800 888 236) | |
| Are electronic or printed versions of all reference material readily available to pharmacists at your pharmacy? | **Yes**  **No** |
| Are all pharmacists at your pharmacy aware of the key contacts that support pharmacotherapy service delivery in Victoria? | **Yes**  **No** |

## Training

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| The [Victorian Opioid Pharmacotherapy Program (VOPP)](https://www.psa.org.au/practice-support-industry/victorian-opioid-pharmacotherapy-program/) is a department-funded training module offered for free by the Pharmaceutical Society of Australia (PSA). It is **strongly recommended** that all pharmacists involved in pharmacotherapy delivery service complete this training at their earliest convenience.  Refer to the end of this document for information about the training required for pharmacist administration of long-acting injectable buprenorphine | |
| Have all pharmacists in your pharmacy been encouraged to complete the VOPP training module? | **Yes**  **No** |

### **Awareness of key treatment principles**

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| Pharmacotherapy 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.  The policy contains a *Certification Document* (Appendix 7) that summarises pharmacotherapy key principles, for ready reference by all pharmacists, including locums. | |
| Have all pharmacists read and signed a copy of the document “Certification of pharmacists administering doses” found in Appendix 7 of the policy? | **Yes**  **No** |

## Varying from the policy

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| The policy does not replace professional judgement in **individual** cases. If a variation from the policy is justified in an individual case, pharmacists should document reasons for the variation in patient notes. | |
| Have all pharmacists been advised that, if a prescriber requests 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 keep record of any variations from the policy that can be readily retrieved if called upon to justify decisions to authorities? (e.g. Medicines and Poisons Regulation, Pharmacy Board, Coroner) | **Yes**  **No** |

## Principles of pharmacotherapy – Stigma and substance use

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| People living with substance use or addiction issues often require long term support for these chronic, relapsing conditions. An understanding of this will help pharmacists form realistic expectations of patients.  Pharmacotherapy is the gold-standard medical approach for the management of opioid use disorder not only in patients who have been using illicit (street) opioids, but also in those experiencing problematic use of prescription opioids. It can prove valuable in assisting opioid-dependent people to manage physical dependence, drug craving and compulsive drug use successfully*.* Maintenance on a pharmacotherapy program has been demonstrated to significantly reduce the risk of accidental (fatal) opioid overdose.  Considering pharmacotherapy through the lens of harm minimisation means **not seeing it as a** **cure**, but rather as a public health intervention which aims to improve health, social and economic outcomes for both the community and the individual. It is a long-term program directed at normalising the patient’s life, treating them with respect, integrating them back into the community and retaining them in treatment as appropriate.  Substance Use Disorder is a highly stigmatised health condition, and the conscious and unconscious manifestations of this stigma can create barriers for people who need to access treatment. As health care professionals, the language we use can play an enormous role in creating a safe environment for the clients on our pharmacotherapy programs. It is essential that pharmacists and pharmacy staff are mindful of the language they use and ensure that conversations with clients are non-judgemental and person-centred. Resources such as [Language matters](https://www.nada.org.au/wp-content/uploads/2018/03/language_matters_-_online_-_final.pdf) and [The Power of Words](https://adf.org.au/resources/power-words/) are an excellent guide to the use of non-stigmatising language. | |
| Are all pharmacists at your pharmacy aware of the principles of pharmacotherapy and use of non-stigmatising language? | **Yes**  **No** |

**Co-occurring substance use or addiction and mental illness**

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| People living with substance use or addiction have a high co-occurrence of mental illness. People with mental illness experience more complications from drug use than the general population. Although a clinical assessment of “dual diagnosis” can result in a more complicated treatment regimen, outcomes are generally improved when both conditions are addressed appropriately.  Engagement in substance use may suggest poor treatment adherence, or even failure of psychiatric treatment. | |
| Are pharmacists aware that Substance Use Disorder commonly occurs alongside other mental health conditions, and that treatment of both conditions will generally improve patient outcomes? | **Yes**  **No** |

**Initiation of pharmacotherapy**

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| **Methadone:**  Initiating methadone treatment should take into consideration the associated risks of toxicity related to its long half-life and narrow therapeutic window.  A similar risk exists for patients who are ***resuming*** treatment – there is a risk of a reduction in tolerance to methadone if a patient misses ***four or more consecutive doses***.  Most common starting dose is 20-30mg - it is strongly recommended that an initial prescribed dose should not exceed 40mg daily. The prescriber should be consulted before administration of >40mg daily for new or resuming treatment and, if there are concerns, the pharmacist and/or prescriber may need to discuss the case with DACAS.  Dose should be increased gradually - 5-10mg every 3 days, subject to assessment.  This slow initial titration may result in some patients experiencing discomfort and withdrawal symptoms, which can incentivise multi-drug or alcohol use to manage the symptoms. *It is essential that the dangers of this combination be communicated effectively to patients starting on the program.* | | |
| Are pharmacists aware that methadone has a narrow therapeutic window, which requires a low initial dosage which is then slowly titrated up to the maintenance dose? | | **Yes**  **No** |
| Are pharmacists aware that patients who are stabilising on their methadone dose are at a high risk of overdose as a result of the withdrawal symptoms which can result from slow initial titration? | | **Yes**  **No** |
| Have all pharmacists been informed of the need to communicate with prescribers if a patient appears to be commencing **or recommencing** pharmacotherapy with a methadone dose that exceeds 40 mg daily? **Note**: This includes when a patient resumes after missing 4 consecutive doses. | | **Yes**  **No** |
| **Buprenorphine**  The partial agonist nature of buprenorphine means it has a ceiling dose of 32mg, above which it has little extra opioid agonist effect. Titration of buprenorphine to maximum tolerated dose can be safely achieved within a few days of the initial dose.  Although there is a lower risk of overdose with buprenorphine as a single agent, overdose risk is increased in the presence of other sedatives such as benzodiazepines and alcohol.  Buprenorphine possesses a significantly higher m-receptor binding affinity than other opioids; it will not only block the effect of other opioids taken at the same time, but if taken while a patient has other opioids in their system, it will bind preferentially and precipitate opioid withdrawal - a very unpleasant experience.  It is recommended that a patient take their first dose of buprenorphine pharmacotherapy when they are experiencing withdrawal from their opioid of choice. The exact period of time expected for withdrawal to occur will vary depending on the half-life of the opioid and the magnitude of the dose taken. | | |
| Are pharmacists aware that a patient needs to be experiencing mild-withdrawal symptoms before starting buprenorphine, to minimise the risk of precipitated opioid withdrawal? | | **Yes**  **No** |
| Are all pharmacists mindful of the fact that, while overdose risk is low when buprenorphine is used as a single agent, this risk increases significantly when used in combination with other sedating agents? | | **Yes**  **No** |
| **Driving**  Both methadone and buprenorphine have the potential to cause drowsiness and/or cognitive impairment.  The risk of these side effects are highest during treatment initiation, when a dose is being increased and at any time a substance with the potential for sedation is taken concurrently.  It is strongly recommended that patients do not drive if sedated – patients may need to be guided by their pharmacist to recognise the situations in which this risk is magnified.  Over time, tolerance to the sedative effects of these pharmacotherapeutic medications will increase, and patients should be able to drive safely while on methadone or buprenorphine treatment. The timeline for this varies greatly from person to person and should be judged accordingly. | | |
| Is it standard practice for pharmacists to counsel patients, especially those starting on pharmacotherapy, about the sedating potential of their medications where appropriate, and the commensurate risk this poses to an individual’s ability to drive safely? | **Yes**  **No** | |

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| **Counselling patients about overdose preparedness and overdose response**  Each client should be offered the “Starting methadone or buprenorphine” information leaflet   * Available in range of languages – can be found at the department Website. * Contains information about signs of overdose and use of naloxone   It is recommended that all patients on pharmacotherapy are also provided with naloxone, available on prescription or over-the-counter  The Pennington Institute website hosts a range of useful resources to assist overdose and naloxone counselling, such as the [Community Overdose Prevention Education](https://www.penington.org.au/resources/cope-overdose-first-aid/) program and their [Overdose Response Resources](https://www.penington.org.au/resources/overdose-response-resources/). | | |
| Have you and your pharmacists familiarised yourselves with the “Starting methadone or buprenorphine” information leaflet, and has it been established that this will be discussed with new clients on your program? | | **Yes**  **No** |
| Do you understand the place of naloxone in pharmacotherapy treatment, and are you confident in your ability to communicate this to clients on your program? | | **Yes**  **No** |
| Risks associated with new or returning patients Deaths associated with pharmacotherapy have been attributed to patients being dosed multiple times (with or without take-away doses) when transferring between dosing points. Multiple dosing is more likely if there is miscommunication or no communication between the dosing points involved in the transfer.  A patient may be absent from their pharmacotherapy program for a number of reasons – due to hospital treatment, a prison term, or even a period of illicit drug use. The reasons for this absence may not be known to all clinicians involved in that person’s treatment.  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.  There is also the possibility of a patient still being in possession of take-away doses, or an interim prescription issued by a prison health care provider.  Considerations when commencing a new patient – management strategies vary!   * Are they commencing ORT for the first time? * Are they resuming ORT after a period off the program? * Are they transferring from a new pharmacy? * ***If this is not clear you need to communicate with the prescriber to determine.*** | | |
| Have all pharmacists been informed that they should **always** communicate with the prescriber **(to determine whether a patient is commencing (or recommencing) pharmacotherapy or transferring from another dosing point)** before administering methadone or buprenorphine to a patient who is new to your pharmacy **or resuming after an apparent absence**? | **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** | |

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| **Patient identification**  Before administering pharmacotherapy, a pharmacist needs to be able to confirm that the patient is the same person for whom treatment was prescribed, using a photo which represents the patient’s current physical appearance, which needs to be **certified by the prescriber**, to confirm the person’s identity. | |
| Do you understand that you are required to make provision to keep certified photographs which actually look like the patient, or alternative identification standards for all current patients? | **Yes**  **No** |

# Prescriptions

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| **Schedule 8 requirements**  A pharmacist **MUST** have lawful instructions from a prescriber before administering a Schedule 8 poison.  A pharmacotherapy prescription **MUST** adhere to S8 prescription requirements, and additionally:   * The name of designated dosing point (pharmacy) is required * A script start date and expiry date is required, rather than a quantity of medication * The **dose of medication** **MUST** be expressed words as well as figures * Extra information informing dosing such as take-away or split doses may be necessary   The prescriber **MUST** provide instructions in writing (in the form of a prescription) or (in an emergency) verbally, with written confirmation of verbal instructions to be provided as soon as practicable. <https://www2.health.vic.gov.au/public-health/drugs-and-poisons>  **Note**: A faxed document should be used only to ***confirm verbal instructions -*** a faxed document **alone** does not represent lawful authorisation. | | |
| 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** |
| **Nominated Pharmacy**  The nominated pharmacy needs to be endorsed clearly on the prescription, to ensure that the patient is receiving treatment at only one dosing point at a time. | | |
| Have pharmacists been made aware that they should contact prescribers, to inform them of this responsibility, if they fail to endorse prescriptions in a manner that unambiguously identifies the dosing pharmacy? | | **Yes**  **No** |
| **Prescription expiration dates**  It is not uncommon to hear reports of pharmacotherapy patients who have received pharmacotherapy doses for a considerable time after their prescription expiration date has lapsed. This oversight can be avoided if 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. | | |
| Has your pharmacy established a system by which pharmacotherapy prescription expiry dates are regularly reviewed, and are all pharmacists aware of this system? | **Yes**  **No** | |

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| **Prescriptions from prescribers in another state or territory**  Although Victorian legislation requires prescribers in Victoria to obtain permits before prescribing pharmacotherapy medication, it has no jurisdiction over prescribers in other states or territories.  Because a pharmacotherapy prescription from another state or territory may still be valid in Victoria, there is a risk of a concurrent Schedule 8 permit being issued to a Victorian prescriber, since this interstate permit will not be tracked in SafeScript.  As a result, a pharmacist who is preparing to offer pharmacotherapy services to a patient on the basis of a prescription issued in another jurisdiction is required to notify MPR using the form [*“Notification of a temporary interstate transfer of a patient on opioid replacement therapy (ORT) to a Victorian Pharmacy”*](https://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 the prescriber to MPR when they undertake to provide ORT on the basis of a prescription issued in another jurisdiction? | **Yes**  **No** |

**SafeScript**

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| Pharmacists are required to use SafeScript upon receipt of **each pharmacotherapy prescription**, and use their everyday dispensing software (e.g. FRED, LOTS) to process the script – as is standard practice for any Schedule 8 medication.  As supply data is transmitted to the SafeScript server through the dispensing software, failure to process pharmacotherapy prescriptions in this manner results in no supply record for that medication.  Other electronic systems for recording pharmacotherapy doses such as Methsof or MethDA are not linked with SafeScript, so processing the prescription through the dispensing software remains necessary even with these systems in place.  **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 * SafeScript should be **checked** when necessary – especially when the patient’s treatment has been reviewed. This will include:   + Upon commencement of pharmacotherapy   + When transferring from another dosing point   + Upon renewal of an expired prescription (as described above)   + Any change in the prescription – medication, dose, number of take-aways   + Recommencement of treatment, including after discharge from hospital or prison   + If concern has been raised about the patient’s stability in treatment | |
| Are all pharmacists informed and aware of the SafeScript requirements for pharmacotherapy medications? | **Yes**  **No** |

## Pharmacotherapy records

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| **Patient attendance records**  Regular pharmacy attendance leads to less fluctuation in blood levels of medication and greater patient stability.  Irregular attendance may be indicative of aberrant drug use, or ongoing psychosocial or medical issues in the patient’s life which may benefit from counselling or treatment review.  Although a single missed dose may not be significant, the prescriber should be advised if a pattern of regularly missed doses begins to emerge.  Attendance records serve as a record of patient’s day-to-day dosing. They ensure that a patient cannot receive multiple doses on the same day and assist the pharmacist in reviewing a patient’s regularity of attendance  As a minimum, a patient attendance record should include:   * A certified patient photograph * A space for a copy of the current prescription * The prescription expiry date displayed prominently * A daily record for the patient’s dosing which includes:   + Date and time of dosing   + Patient signature   + Pharmacist signature   + An indication of whether the dose has been issued as a take-away   + An indication of whether a buprenorphine dose is a double or triple dose   + Clear and unambiguous contemporaneous notes     - Patient notes which are of a more sensitive nature should be recorded in a separate pharmacist communications book   **NOTE**:   1. The administering pharmacist **MUST** be identified on each occasion – unless they are 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. | | |
| Has your pharmacy established patient attendance records which fulfil the requirements outlined above? | **Yes**  **No** | |
| **Dose administration records**  A pharmacist **MUST** make a true and accurate record of all transactions, including the administration or supply of pharmacotherapy. Suggested formats are contained in Appendices 8 to 12 of the policy | | |
| Do the methadone administration records (for patients and total supply) at your pharmacy have a clear and consistent use of either milligram, millilitre or BOTH milligram and millilitre units 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** |

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| **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**.  *Some pharmacies record dose quantities in a separate record (another book or a spreadsheet) as they dispense throughout the day. This is acceptable, contingent upon the totals of each medication being recorded formally at the end of the day.* | |
| To ensure the **recorded** balance is **true** and **accurate**, it should be reconciled with the **actual** balance on a regular basis. This may involve a weekly stock check, or a stock check upon receipt of new stock.  **NOTE**: Any discrepancies in a Schedule 8 poison **MUST** be investigated immediately with any unresolved discrepancies reported promptly to MPR. [dpcs@health.vic.gov.au](mailto:dpcs@health.vic.gov.au) | |
| Has your pharmacy established a system of recording and reconciling the balance of your Schedule 8 pharmacotherapy medications which fulfils the requirements outlined above? | **Yes**  **No** |

# **Stock management considerations**

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| **Storage of pharmacotherapy medicines**  **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 ‘in-use’ methadone-dispensing container? | **Yes**  **No** | |
| **Dispensary access**  Some pharmacies have experienced situations where a person has reached over or around a dispensary barrier and take a bottle of methadone solution or packets of buprenorphine preparations. | | |
| Has a position been established for the methadone dispensing container and the ‘in-use’ buprenorphine preparations where a person with intent to misappropriate the drugs cannot reach them or walk to them without being obstructed? | | **Yes**  **No** |
| **Stability of buprenorphine preparations**  Buprenorphine sublingual preparations are packed under nitrogen into their immediate packaging (either blister packs or sachets), to ensure the stability and integrity of the drug. Both tablets and films should remain in the manufacturer’s immediate packaging until just before administration, to decrease the risk of degradation. | | |
| Do all pharmacists understand that it is necessary to leave buprenorphine preparations in the manufacturer’s immediate packaging until it is time to prepare a dose for administration? | | **Yes**  **No** |

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| **Advice about alternative approaches to pharmacotherapy dispensing**  It is **not recommended** to dispense **methadone** doses from a container other than the manufacturer’s original  It is **not recommended** to dilute **methadone** solution   * The stability of the medication cannot be guaranteed if it is diluted. * There is a risk of accidental overdose if solution concentrations are confused.   It is **not recommended** to prepare pharmacotherapy doses prior to the patients’ attendance   * The department recommends that each pharmacotherapy dose is prepared and administered by an **individual** pharmacist **at the time** the patient attends the dosing point to receive the dose * Dilution of pre-prepared doses of methadone prevents the administering pharmacist from checking the original dose of methadone liquid, and is therefore not recommended | |
| Do all pharmacists understand that methadone doses should **not** be diluted, and be dispensed whenever possible from the manufacturer’s original container? | **Yes**  **No** |
| Do all pharmacists understand that it is **not recommended** to prepare pharmacotherapy doses prior to the patient’s attendance? | **Yes**  **No** |

**Pharmacotherapy Administration Considerations**

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| **Administration containers**  For the purposes of hygiene, are disposable containers (e.g. plastic/paper cups) used for the administration of both methadone and buprenorphine doses? | **Yes**  **No** |
| **Methadone liquid considerations**  Is each supervised dose of methadone diluted with water or cordial before administration? | **Yes**  **No** |
| Is the administration of each in-store dose of methadone supervised to ensure that the patient has consumed the dose?  *A common approach is for the pharmacist to supervise the dose being drunk, and then engaging the patient in conversation, to ensure it is not being held in the mouth.* | **Yes**  **No** |
| 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** |
| Are all pharmacists aware that the prescriber **MUST** be contacted before a vomited dose can be replaced?  *If the veracity of the claim can’t be confirmed, it is difficult to rationalise a replacement dose.* | **Yes**  **No** |
| **Suboxone® film considerations**  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 to ensure that Suboxone® Films are genuinely applied within the mouth and not palmed for diversion? | **Yes**  **No** |
| Are patients supervised until the Suboxone® Films have adhered to the mucous membrane? | **Yes**  **No** |
| **Subutex® tablet considerations**  The policy states that **Subutex® tablets** should be broken into small pieces (resembling granules) and administered directly under the patient’s tongue.  ***Note****: The department advises that instructions from prescribers* ***not*** *to crush* ***Subutex® tablets*** *for specific patients are best interpreted as an instruction to* ***not crush the tablets into a fine powder****, as doing so can cause the dose to form a paste upon mucosal exposure, which can affect the extent to which it is 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** |

## Take-away doses of pharmacotherapy medication

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| **Authorisation of take-away doses**  Take-away doses are a key aspect of a patient’s pharmacotherapy program, representing many positives:   * A demonstration of trust from both the prescriber and the pharmacist * A greater degree of freedom within their week which can facilitate work, study, or family commitments   However, the association between methadone take-away doses and overdose deaths in the community means that authorising take-away doses for a patient is a significant clinical decision, and one in which **pharmacists should play a central role.** It is recommended that prescribers consult with the patients’ pharmacist when considering initial authorisation of take-away doses, or whether or not to increase the number or frequency of take-away doses. | | | |
| The broader scope of considerations required to assess whether or not to provide authorisation for take-away doses is explored in Appendix 4 of the policy. In particular, the pharmacist would consult on the following:  **Absolute contra-indications:** If in the last three months there has been   * Overdose of any substance reported. * Diversion of doses to others, sharing or trading doses. * No safe and secure storage facility available. * Concerns about risk of causing harm to self or others (for example, intentional poisoning).   **If there has been a continuous period of stability**   * This should **always** be considered **after** any absolute or relative contra-indications. | | | |
| **Patient responsibilities regarding take-away doses**  It is important for the pharmacist to engage with their patients about the responsibilities they are taking on when being authorised to have take-away doses. The documents mentioned can also be found [on the MPR website](https://www2.health.vic.gov.au/public-health/drugs-and-poisons/pharmacotherapy/policy-resources-pharmacotherapy).   * Patients receiving methadone take-away doses for the first time should be provided with a copy of the patient agreement found in Appendix 5 of the Policy document. * Patients receiving buprenorphine take-away doses for the first time should be provided with a copy of the patient agreement found in Appendix 6 of the Policy document. * The pharmacist should ensure that their patients understand the contents of these agreements and a copy of the relevant agreement should be signed by the patient and kept in their attendance record. | | | |
| Have all pharmacists been made aware of the steps which require consideration before authorising the supply of take-away doses? | | **Yes**  **No** | |
| Is a copy of [Appendix 4](https://www2.health.vic.gov.au/about/publications/policiesandguidelines/policy-for-maintenance-pharmacotherapy-for-opioid-dependence) (*“Checklist for assessing appropriateness of take-away doses”*) readily available 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 in circumstances which the pharmacist feels are not in accordance with the Policy, the pharmacist is required to make their own 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** | |
| **Secure storage of take-away doses by patients**  There is a significant risk presented if doses are consumed by someone other than the patient for whom they were supplied, which is magnified significantly in the case of children, people who lack tolerance for the drug and people who are concurrently using other drugs.  The absence of a **safe, secure storage facility** (such as a locked cupboard, a cashbox or a safe) is **one of four absolute contra-indications** to the supply of take-away doses.  **Note**: *There is no need to refrigerate methadone take-away doses– this may even increase the risk of a dose being taken by children or other household members*. | | | |
| Are pharmacists aware that they should periodically check the manner in which patients store take-away doses, as well as the need to ensure that take-away doses are stored securely, where they cannot be located or accessed by others, especially children? | | | **Yes**  **No** |
| **Labelling of take-away doses**  Please refer to the Policy for example labels (Part 4.5 Policy for Pharmacists: Take-away doses)  **Note:** *Pharmacists should use their professional judgment about the appropriateness of including other authoritative* ***recommendations****, including those contained in the APF, which recommends “Do not inject”.* | | | |
| Have all pharmacists been made aware of the packaging and labelling requirements for take-away doses? | **Yes**  **No** | | |

**Take-away doses of methadone**

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| The recommended maximum number of **methadone** take-away doses following **continuous periods of stability in treatment** can be found in Table 3.1 of the Policy. Policy amendments made during periods of emergency (such as during the Covid-19 pandemic) may override what is written in the original document. | |
| **Preparation of methadone take-away doses**  To minimise the risk of consumption of methadone take-away doses by persons other than the intended client, as well as to deter injection, each methadone dose should be diluted **with water** (not cordial) to a volume of 200ml. In addition, these doses have to be provided in a container with a child-resistant lid.  In no circumstances should multiple methadone take-away doses be included in the same container. **This represents an unacceptable risk.**  Take-away doses should **NOT** be diluted with cordial – cordial can increase the risk of microbial growth in the container, and the sweetened dose may also be more attractive to a child than its otherwise bitter counterpart. | |
| Is it standard practice at your pharmacy to dilute each methadone take-away dose to a volume of 200 mL? | **Yes**  **No** |
| Are all pharmacists aware that it is **unacceptable** to include multiple methadone take-away doses in the same container, even if directed to do so by the prescriber? | **Yes**  **No** |
| Is each methadone take-away dose supplied in a container with a child-resistant closure? | **Yes**  **No** |
| **Re-use of methadone take-away containers**  While tap water may be used to dilute methadone take-away doses, it is important to also consider the quality of the local tap water and that of the building’s plumbing when doing so.  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.  While it is common practice for pharmacies to re-use amber methadone take-away bottles for their clients, it is also necessary to adequately clean and sanitise these bottle before re-use.  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**

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| **Subutex® take-away doses**  **Subutex**® should only be authorised for take-away doses if the patient:   * Is pregnant or breastfeeding * Has a clinically documented allergy to naloxone (or to an excipient in Suboxone®) * Is reducing their dose below 2.0mg and require a supply of 0.4mg tablets. | |
| Have all pharmacists been informed that the Policy makes no provision for routine take-away doses of **Subutex**® tablets apart from the exceptions outlined above? | **Yes**  **No** |
| The recommended maximum number of **Suboxone®** take-away doses following **continuous periods of stability in treatment** can be found in Table 3.2 of the Policy. Policy amendments made during periods of emergency (such as during the Covid-19 pandemic) may override what is written in the original document. | |

## When to withhold treatment and when to contact the prescriber?

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| **Prescriber communication**  Regular communication with your patients’ prescribers is an essential aspect of running a professional opioid pharmacotherapy service. Consistency of dosing is key – a good rule of thumb is that it is worthwhile contacting the prescriber if a patient’s presentation is inconsistent. Familiarity with your pharmacotherapy patients will provide a good sense of what constitutes a person’s “regular” attendance or “usual/expected” behaviour. | |
| **Intoxication**  A patient may be intoxicated because of an excessive dose of pharmacotherapy medication, a combination of agents, or even a single agent which nevertheless poses an unacceptable risk if combined with the scheduled dose of pharmacotherapy.  Symptoms of opioid toxicity include (but are not limited to):   * Constricted pupils (tricky to assess, although familiarity with your patient could make this an easier task) * Excessive drowsiness * Confusion * Slurred speech – engaging your patient in conversation can help to get a sense of this symptom   **Remember – the pharmacist administering the dose has the final word on whether it is safe to provide that dose.** Use your clinical and professional judgement.   |  |  |  | | --- | --- | --- | | **Scenario** | **Considerations** | **Suggestion** | | Mild intoxication | Patient may be safe to dose, given some time | Ask the patient to return later in the day | | Moderate intoxication | May be difficult to ascertain when it is safe to dose next | Ask the patient to consult their prescriber | | Severe intoxication | Risk of overdose? | Instruct the patient to attend a hospital ED | | Patient refuses to leave without a dose | Safety of staff and customers | May be appropriate to administer a reduced or placebo dose | | Prescriber is unavailable | Clinical advice still necessary | Contact DACAS | |  | | | | |
| Have all pharmacists been informed that pharmacotherapy should **not** be administered if a patient appears to be intoxicated? | **Yes**  **No** |
| **Irregular dosing**  A pattern of missed doses or irregular attendance may indicate underlying issues for a patient which need to be addressed, especially if a patient has previously been stable  If a patient has also been issued take-away doses, if can become difficult to assess how many consecutive doses have been missed | |
| 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** |
| **Missing four or more consecutive doses**  Missing four or more doses of pharmacotherapy can reduce a patient’s tolerance to their medication and puts them at a risk of overdose if they take their previously-prescribed dosage. They may have also been using other drugs. **In such cases, the prescriber should consider reducing the recommencement dose.** | |
| Are all pharmacists aware that neither **methadone** nor **buprenorphine** is to be administered, without the prescriber’s authorisation, if a patient has missed doses on **four or more** consecutive days? | **Yes**  **No** |
| 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** |

## Contemporaneous notes

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| The inherent risks associated with the vulnerability of pharmacotherapy patients and the potential toxicity of pharmacotherapy medication make effective communication between pharmacists an essential component of a well-run pharmacotherapy program. Risks to patients are minimised when all pharmacists are aware of the key issues related to patient’s treatment. This can be addressed easily by readily retrievable contemporaneous notes, which are maintained in a consistent manner and location. | |
| Do all pharmacists have access to, and maintain contemporaneous notes about the patients on your pharmacotherapy program? | **Yes**  **No** |

## Long-acting Injectable Buprenorphine

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| **Long-acting injectable buprenorphine (LAIB) formulations**  Buvidal® and Sublocade® should be administered only by registered health practitioners who have completed the administration training and should **NOT** supplied to (or handled by) patients or carers.  Any pharmacy with approval to supply pharmacotherapy medications is authorised to supply LAIB to an external clinician for administration. In these circumstances, it will be necessary to arrange for the medication to be delivered to the clinic by a representative of the pharmacy, or for the medication to be collected from the pharmacy by a representative of the clinic.  Both products are formulated for **subcutaneous administration ONLY**.  It is expected that patients have been stabilised on a sublingual buprenorphine formulation for at least a week before transfer to the long-acting injection.  [Buvidal®](https://www.camurus.com/camurus/) is available as both weekly and monthly administration  [Sublocade®](http://www.indivior.com/) is available as monthly administration  [Clinical guidelines for long-acting injectable buprenorphine](https://www2.health.vic.gov.au/Api/downloadmedia/%7BC4D766A2-5113-4F8C-B181-8D8AC9DF346D%7D) can be found at the Department of Health [pharmacotherapy policy page](https://www2.health.vic.gov.au/public-health/drugs-and-poisons/pharmacotherapy/pharmacotherapy-policy-in-victoria), alongside addendums to the Victorian pharmacotherapy policy document. | |
| Are all pharmacists aware that LAIB formulations should **NOT** be supplied to (or handled by) patients or carers, and that supply to an external clinician for administration requires either delivery to the clinic by a representative from the pharmacy, or collection from the pharmacy by a representative of the clinic? | **Yes**  **No** |
| **Pharmacist qualification to administer LAIB on the order of a prescriber**   1. For **pharmacists** to administer LAIB on the order of a prescriber it is *expected* that: 2. They are familiar with and understand requirements for pharmacotherapy program delivery by:    1. Completing [Victorian Opioid Pharmacotherapy Program](https://www.psa.org.au/practice-support-industry/victorian-opioid-pharmacotherapy-program/) training developed by the Pharmaceutical Society of Australia (PSA); or    2. Working as a registered pharmacist in opioid replacement therapy delivery for at least five years 3. They understand requirements for injection administration by completing an immunisation course approved by the Department of Health (see [PSA](https://www.psa.org.au/practice-support-industry/programs/immunisation/) or [The Pharmacy Guild of Australia)](https://www.pharmacyguild.edu.au/immunisation/) 4. They understand requirements specific to LAIB by completing [LAIB Administration by Pharmacists](https://my.psa.org.au/s/training-plan/a110o00000AiHEN/longacting-injectable-buprenorphine-laib-administration-by-pharmacists) training developed by PSA 5. It is *expected* that pharmacists will consolidate this knowledge by administering LAIB to a patient while under the supervision of a clinician familiar with the use of the LAIB formulations. There is no expectation from the department that this supervision be documented, although your Quality Care Pharmacy Program may require some form of record of this procedure. | |
| Are all pharmacists aware of availability of LAIB formulations and the requirements for qualification to administer LAIB on the order of a prescriber? | **Yes**  **No** |

## Miscellaneous topics of importance to pharmacotherapy

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| **Deputised prescribers in the absence of the usual approved prescriber**  Any prescriber working at the same clinic as a pharmacotherapy permit holder may **deputise** for the pharmacotherapy permit holder in their absence, 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 | | | |
| Are all pharmacists aware that, in the absence of a patient’s usual prescriber, a prescriber at the same clinic can be deputised to maintain an existing prescription, in the circumstances outlined above? | | | **Yes**  **No** |
| **Pharmacy days of opening**  Only stable patients for whom the prescriber has authorised take-away doses may be accepted at a pharmacy which is open fewer than seven days a week unless special arrangements are made for dosing elsewhere on the days on which the pharmacy is closed. | | | |
| If your pharmacy is open fewer than seven days a week, will you only accept clients for treatment on your program for whom their prescriber has authorised take-away doses, unless special dosing arrangements are made for your pharmacy’s closed days? | | **Yes**  **No** | |
| **Pregnancy or breastfeeding while on pharmacotherapy**  Continued pharmacotherapy treatment essential for pregnant patients – the benefits of maintenance far outweigh the risks which treatment cessation poses to both mother and baby.  Prescribers are recommended to refer their patients to a specialist maternal pharmacotherapy prescribing service such as that found at the [Royal Women’s Hospital](https://www.thewomens.org.au/patients-visitors/clinics-and-services/pregnancy-birth/pregnancy-care-options/womens-alcohol-drug-service). Engagement with a pharmacotherapy program – especially if connected to a specialist maternal pharmacotherapy prescriber – affords a patient access to comprehensive ante- and postnatal care, important in addressing the risk of neonatal abstinence syndrome | | | |
| Are all pharmacists aware that maintenance on pharmacotherapy is essential for pregnant women who are established on the program, and that sudden withdrawal from pharmacotherapy has the potential to cause harm to both the mother and child? | **Yes**  **No** | | |

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