

Pharmacy Instructions

In this section you will...

- *Understand the role of pharmacies who participate in the opioid pharmacotherapy program; and*
- *Gain an overview of the requirements of pharmacies who participate in the opioid pharmacotherapy program.*

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Pharmacists are an essential component of the opioid pharmacotherapy treating team. Patients can receive opioid pharmacotherapy treatment either from the Alcohol and Drug Service (ADS) or private prescribers. Many patients receiving opioid pharmacotherapy treatment from the ADS are dosed at the onsite pharmacy (Alcohol and Drug Service Pharmacy), particularly during stabilisation. However, the majority of opioid pharmacotherapy patients in Tasmania are dosed at community pharmacies. Access to a community pharmacy that dispenses methadone and buprenorphine means that many patients can conveniently dose near their home or work location.

The participation of pharmacists in the program is voluntary. Therefore, the role of the ADS includes supporting community pharmacies to register for, and provide services to opioid pharmacotherapy patients.

Due to the nature of dosing, pharmacists have regular ongoing contact with patients, and are able to provide critical information to the treating team about the progress of the patient on the program. The pharmacist's role includes:

- developing a positive rapport with the opioid pharmacotherapy patients;
- monitoring patients' progress on the program;
- monitoring daily levels of intoxication or withdrawal;
- observing patient behaviour whilst in the pharmacy;
- communicating with patients after dose to ensure that the dose has been consumed;
- encouraging the patient to take the dose at approximately the same time each day;
- maintaining regular contact with the prescriber and treating team; and
- working with the ADS, prescriber and treating team to ensure the best outcome for the patient.

16.1 Approval and Accreditation to Dose

To become a dosing site for opioid pharmacotherapy, a pharmacy requires approval from the ADS. In addition, each pharmacist involved in the provision of dosing is required to obtain accreditation. The ADS can assist pharmacists and pharmacies with this process.

16.1.1 Pharmacy Approval

Pharmacy approval is coordinated by pharmacists at the ADS, who are contactable on (03) 6230 7984 or (03) 6230 7983. The key criteria for obtaining pharmacy approval to dose are:

- all pharmacists involved in dosing are accredited within Tasmania; and
- the pharmacy has a designated area in which dosing can occur.

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An ADS pharmacist is available to provide the pharmacy with:

- the paperwork required to commence dosing;
- general support to discuss the practicalities of dosing;
- onsite support on the first day of dosing if required; and
- staff training.

When establishing a dosing service, the provision of a suitable dosing environment to enable private and confidential consultation is essential. The pharmacist in charge of this service at the location needs to ensure the provision of a private, safe and confidential dosing site for patients. Further information can be obtained from the Pharmacy Board of Australia's Codes and Guidelines on at their website:

<http://www.pharmacyboard.gov.au/Codes-Guidelines.aspx>

Once approval is obtained, the ADS will inform the pharmacy's nominated wholesaler(s) of the approval as an opiate pharmacotherapy dosing site. Consequently, the dosing medication (methadone liquid/syrup, Subutex® and Suboxone®) and associated dosing cups and takeaway dose bottles are supplied to the pharmacy.

16.1.2 Pharmacist Accreditation to Dose

Accreditation to undertake opioid pharmacotherapy dosing requires each pharmacist to undertake a short professional development program and complete a short exam. The ADS recommends that all pharmacists complete their accreditation to dose opioid pharmacotherapy during their intern year. Dosing without accreditation can result in the pharmacist working outside accepted standards of practice and this is not recommended.

For pharmacists not already accredited, successful completion of "open book" exams for both methadone and buprenorphine are required. ADS will supply the exams and corresponding resource material in electronic format. Completed exams can be faxed to (03) 6230 7950 for marking and accreditation by the ADS. For alternative ways to submit exams contact the ADS Pharmacy on (03) 6230 7984 or (03) 6230 7983. Participants will be notified of results. Pharmacists coming from interstate also need to complete the training.

If a pharmacy is undergoing Quality Care Pharmacy Program (QCPP) certification and a pharmacist(s) has misplaced their accreditation letter, ADS will supply written confirmation that the pharmacist is on the accreditation register. ADS can be contacted on (03) 6230 7984 or (03) 6230 7983.

16.1.3 Service Delivery Changes

ADS should be informed in advance if a dosing pharmacy changes ownership. The preference is always for the pharmacy to continue dosing. If this is not possible, ADS requires four weeks notice to arrange alternative dosing sites for patients and to negotiate an approval process for the change of ownership.

Due to the impact on patients and their dosing schedules, pharmacies should also provide the ADS with adequate notice (4 weeks) if:

- they no longer want to be part of the opioid pharmacotherapy program;

- they change their operating hours, including a change of opening days;
- a pharmacy no longer wants to continue dosing a particular patient; or
- they no longer want to provide a particular opiate replacement pharmacotherapy.

Alcohol and Drug Services should be informed as soon as possible when a pharmacy no longer wants to continue dosing a particular patient or they no longer want to be part of the opioid pharmacotherapy program.

16.1.4 Ongoing Training and Support

The ADS has a wide range of resources that can be made available to dosing pharmacies. This includes regular newsletters and information sheets about topical issues.

The ADS pharmacy can also provide the following supports:

- training for pharmacy staff (either one-on-one, group, written or verbal formats);
- providing advice & resources for the dosing pharmacy to set up a safe dosing process; and
- supportive learning environment to pharmacists, intern pharmacists, and student pharmacists with onsite visits to the ADS Pharmacy (situated in Southern Tasmania).

The ADS pharmacy is open every day (with reduced hours on weekends & public holidays), and is available to provide advice to dosing pharmacies at any time. Contact details are available on pageE XX or Appendix XX.

Contacting prescribers or case managers

As part of the extended treating team, it is important that pharmacists contact ADS or the patient's private prescriber when there is evidence of poor compliance, illicit drug use or drug seeking and other inappropriate or unacceptable behaviours. This includes:

- frequent missed doses;
- suspected or confirmed dose diversion;
- requests for CNS active over the counter (OTC) medication;
- repeated requests to the pharmacist to provide takeaway doses outside of prescription instructions;
- presenting with prescriptions for CNS active medications (that are restricted) not prescribed by the patient's pharmacotherapy doctor;
- erratic or aggressive behaviour;
- presenting intoxicated; or
- worrisome physical appearance or psychological health.

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16.2 Patient Orientation to a Community Pharmacy

The process for accepting new patients will vary between pharmacies. After discussing a prospective patient with the ADS or a private prescriber, it is recommended that the patient attends the pharmacy for an interview. The following topics should be discussed during the interview:

- supervised dosing procedures;
- maximum number of patients that can be in the pharmacy at the one time;
- opening times and dosing hours;
- code of conduct and acceptable behaviour (see also below);
- consequences of diversion or attempted diversion;
- procedures for takeaway doses (if applicable);
- cost of dosing;
- requirements and cost for ancillary medication dosing; and
- payment procedures.

At the time of the interview the patient should sign a contract. An example of such a contract can be found in Appendix XX.

16.3 Dosing Procedure

Dosing procedures will vary between pharmacies. The following procedures are recommended for supervised dosing and takeaway doses.

16.3.1 Supervised Doses

All supervision of opioid pharmacotherapy must be done by the pharmacist. Furthermore, patients are encouraged to attend the pharmacy at the same scheduled time. Routine attendance not only helps the patient achieve a steady state of medication in their system, it also helps develop a consistent routine for accessing their medication. For patients in the induction phase (the first 1-2 weeks of treatment), patients should be dosed at approximately the same time every day, and a divergence of more than 12 hours from this scheduled time should be avoided.

Pharmacists can help patients establish a dosing routine. Patients should be dosed at approximately the same time each day during the induction phase.

Prior to attending the pharmacy, patients should be informed that:

- only the patient can pick up their dose;
- the patient must enter the pharmacy alone;
- no bags or containers are allowed in the dosing area;

- the patient's hands and mouth must be visible to the pharmacist at all times;
- the dose must be consumed in direct view of the pharmacist without turning of the head;
- the dose must be consumed directly from the cup or spoon;
- for buprenorphine, the dose must be placed under the tongue; and the patient must remain in full view of the pharmacist until the crushed tablets are dissolved under the tongue;
- the empty cup or spoon must be shown to the pharmacist before discarding it;
- the patient must speak to the pharmacist, open their mouth, and have a drink of water or cordial after dosing if asked to do so; and
- the patient must leave the pharmacy area and clinic vicinity as soon as they have dosed.

For buprenorphine and methadone (including supervised and takeaway doses), the pharmacist should:

- ensure that each patient has an identification sheet containing the patient's name and a photo;
- confirm the patient's identification when they present for dosing. Use photo ID, confirmation of date of birth, address and normal dose. Also compare signature with that from the previous day;
- observe the patient for signs of intoxication (see Section X);
- check that the prescription is valid and not expired;
- if using a dosing program ensure the patient's file is open on the computer and the correct dose listed;
- check the last recorded dose and any communication notes;
- record the dose on the "Medication Administration Chart" and complete details for that day. Items include dose, quantity/volume, time, signature dosing pharmacist and patient;
- ensure the patient signs and pays for the dose before they receive it; and
- prepare the dose.

For methadone:

- to minimise nausea, it is recommended that the dose is given after the patient has eaten;
- check the dose in both mg and mL;
- measure the dose using a disposable syringe or an approved pump;
- double check the dose against the prescription (or photocopy) and then check the amount measured again;
- do not confuse mg & mL;

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- place in a clean disposable cup and dilute (with cordial or water) to a final volume of 100 mL of the liquid (this can either be in one cup all diluted or the one cup part diluted with a second cup of liquid);
- give the preparation to the patient to drink;
- ask the patient to drink again after the dose; and
- ask the patient to see the empty cup and to speak clearly with the pharmacist (this helps ensure the entire dose has been taken).

For buprenorphine sublingual tablets:

- give the patient diluted lemon cordial to drink prior to dosing. This causes salivation and speeds up dose absorption;
- check if the prescription is for Subutex® or Suboxone® - these brands are not interchangeable;
- check the number of each strength required;
- count the tablets into a pill crusher (crush different strengths separately) or break into rough pieces;
- crush tablets until they resemble coffee grounds. (Crushing the dose is recommended to discourage the diversion of the dose. Studies indicate that crushing does not cause significant loss of potency (Simojoki et al., 2010))
- DO NOT crush tablets into a fine powder;
- use a different tablet crusher for Subutex® and Suboxone®;
- tip the dose into a disposable spoon or cup and give to the patient;
- observe the patient placing the dose under their tongue - this is when diversion is most likely to occur;
- do not allow the patient to swallow the dose or talk while the dose is dissolving;
- maintain pharmacist supervision until the dose is dissolved; and
- once the dose is dissolved, the pharmacist should check the patient's mouth for any undissolved pieces. Ask the patient to lift their tongue and pull back their cheeks.

For buprenorphine sublingual film:

- advise the patient not to eat immediately before dosing (as it may interfere with absorption). Also advise not to smoke, drink caffeinated beverages (coke, coffee), clean teeth or use a mouth wash prior to dosing (as these can dry the mouth and effect absorption);
- ensure the patient has clean and completely dry hands;
- give the patient some water to moisten the mouth;
- check the number of each strength of sachet required. Half doses cannot be administered as the film should not be cut;

- the pharmacist must fold the sachet along the dotted line and tear down at the slit as indicated on the packaging. Do not open the sachets until time of administration;
- hand the film to the patient (either in the original sachet or in a transparent medicine cup);
- the patient must hold the film between two fingers by its outer edges and place it sublingually (under the tongue) one film at a time. If multiple films are needed, the first two (and strongest strengths) are placed under the tongue either side of the frenulum and any remaining are placed in the inside of the cheeks. (Buccal administration is an off-licence method of use, but the bioavailability of sublingual and buccal administration are similar);
- observe the patient placing the dose under their tongue - this is when diversion is most likely to occur;
- once the film has been placed in the mouth, the patient must not attempt to move the film, nor chew or swallow the film until fully dissolved (usually 2 to 5 minutes);
- if the film accidentally sticks to another part of the mouth the patient should be reassured that the dose will be absorbed, but they must keep their mouth closed so mucus membranes can be in contact with the dose;
- the film adheres to mucus membranes within seconds and it is difficult to remove 30 to 60 seconds after application. Under normal circumstances, post-dose supervision by the pharmacist need not exceed 1 minute. It is important that the film is not allowed to overlap in the mouth as this will impair mucosa adherence and prolong supervision time.

Note: Adapted from Suboxone Sublingual Film, Product Information, TGA Product and Consumer Medicine, 2011. Retrieved September 22, 2011, from <https://www.ebs.tga.gov.au/ebs/picmil/picmirepository.nsf/PICMI?OpenForm&t=&q=buprenorphine&r=/>

Double & Triple Buprenorphine Dosing

Whilst buprenorphine dosing (either as Subutex® tablets, Suboxone® tablets or Suboxone® film) is initially daily, when patients are stabilised they can be dosed every second or third day. The dose is usually doubled to cover a 48 hour period and tripled to cover a 72 hour period (to a maximum of 32mg dosed at any one time). Because of the limitations of the maximum dose, some patients will be unsuitable for this regimen. Of those patients eligible, some will not be comfortable and will need to be changed back to daily dosing. The procedure for dosing is the same as described above. For more details on alternate day dosing schedules see Section 8.7.

Pharmacists are reminded that:

The registration of buprenorphine in Australia specifies that a maximum dose of 32 mg can be prescribed per day.

This restriction applies whether it is a daily, double, or triple dose.

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16.3.2 Takeaway Doses

To receive unsupervised (takeaway doses), patients need to be assessed by their prescriber as meeting clinical stability criteria (see section 8). The prescriber is required to specify authorisation of unsupervised (takeaway) doses on the prescription, and details should be recorded in the patient record. Misuse of takeaway doses poses serious risks to both the patient and the general public: hence, patients are only provided with takeaway doses if they demonstrate clinical stability. Furthermore, only prescribers can authorise takeaway doses (see Section 8). Providing takeaway doses outside of prescriber authorisation is against legislation and can place the pharmacist's registration at risk.

Most new patients on opioid pharmacotherapy treatment require daily supervised doses for a period of time before becoming eligible for takeaway doses. The pharmacy is pivotal in ensuring the prescriber is kept up to date with how the patient is presenting over time, and contributes to the overall assessment of the patient's stability.

Only prescribers can authorise takeaway doses. Providing takeaway doses outside of prescriber authorisation is against legislation and can place the pharmacist's registration at risk.

Changes to takeaway doses

Patients may present to the pharmacy requesting a change to their takeaway dose regimen.

Patients need to contact their prescriber directly to negotiate changes to takeaway doses.

A pharmacist can only nominate the day the takeaway is collected (in consultation with the patient) if it is not allocated on the prescription.

The following changes cannot be made by the pharmacist and require written approval by the prescriber:

- changing the day that the takeaway dose can be collected when the prescription specifies the day;
- changing the number of takeaway doses;
- providing an extra takeaway dose;
- providing a takeaway from “next week's” doses;
- changing the way in which the takeaway dose is supplied, for example, providing two consecutive takeaway doses when two non-consecutive takeaway doses have been prescribed; and
- change the dilution volume of the takeaway dose from a final volume of 100mL.

Child-resistant containers

All takeaway doses must be provided to the patient in child-resistant packaging, as stated in national legislation (*Therapeutic Goods Act 1989*, Therapeutic Goods Order No. 80). A separate container is required for each day's takeaway dose. The takeaway bottle must be labelled to show which day the dose is to be consumed. The ADS provides 100mL takeaway dose bottles with a child resistant lid free of charge from the pharmacy's designated wholesaler.

All takeaway doses must be provided to the patient in child-resistant packaging, as stated in national legislation (Therapeutic Goods Act 1989, Therapeutic Goods Order No. 80).

Labelling

Takeaway doses must be labelled in accordance with legislation and require appropriate Cautionary and Advisory labels (C&A). To comply with the legislation, the following needs to be included on the container:

- drug name and quantity;
- day and date it needs to be consumed;
- patient's name;
- prescription number (a requirement of Pharmaceutical Services Branch (PSB));
- pharmacy name, address, and telephone number;
- Cautionary and Advisory (C&A) Label I.

In addition, it is preferred that the following warnings are added to the label:

- do not inject;
- may cause death or serious injury if taken by another person; and
- to be taken by mouth by the person named on the label on the day stated on the label.

These warnings can be prepared in the pharmacy's dispensing program as a separate generic label and also placed on the bottle.

Takeaway doses have the same labelling requirements as other S8 medications. When there is a dosing program in use it will generate a takeaway dose label on request. Where the pharmacy uses a manual system for dosing, a label can be prepared using the dispensing program.

Methadone takeaway procedure

For methadone takeaway doses:

- complete the appropriate section on the dosing sheet for the day the takeaway dose is to be consumed;
- clearly mark that the dose was supplied as a takeaway dose;

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- ask the patient to sign and pay for the dose prior to dispensing;
- measure the dose (as described above) and place in an approved takeaway container;
- dilute dose with filtered or purified water (not tap water) so that the total volume is 100mL. If the doctor requests a greater dilution and larger bottles are unavailable, divide the dose between bottles and label accordingly. This means the patient will need to consume the contents of several bottles for the one dose;
- the takeaway dose cannot be left undiluted or diluted with an amount less than 100mL (unless the dose is prepared for a hospital, prison, or nursing home setting for dosing by a health professional);
- do not dilute the dose with any other fluid as there is the possibility it may interfere with the methadone;
- ensure that the child proof lid is tightly closed to prevent spilling; The lid can also be secured with tape to help prevent spillage and for security reasons;
- inform the patient that spilt doses are not replaced;
- label the takeaway dose with directions and a C&A Label I;
- hand the takeaway dose to the patient (not to a third party); and
- provide the patient with a paper bag if they do not have somewhere to put the takeaway dose. This helps to maintain the patient's confidentiality.

Buprenorphine (Subutex® & Suboxone®) takeaway dose procedure

For buprenorphine tablet takeaway doses:

- complete the appropriate section on the dosing sheet for the day that the takeaway dose is to be consumed;
- clearly mark that the dose was supplied as a takeaway;
- ask the patient to sign and pay for the dose before they receive it;
- check the tablet type and strength and crush the dose (as described above). It is recommended that the dose is crushed to diminish its "street" value. Studies show no appreciable loss of potency with crushing (Simojoki et al., 2010);
- place the crushed doses into an approved takeaway container;
- ensure that the child proof lid is tightly closed to prevent spilling. The lid can also be secured with tape to help prevent spillage and for security reasons;
- inform the patient that spilt doses are not replaced;
- label the takeaway dose with directions and a C&A Label I;
- hand the completed takeaway dose to the patient (not to a third party); and
- provide the patient with a paper bag if they do not have somewhere to put the takeaway dose.

For Suboxone® film takeaway doses:

- complete the appropriate section on the dosing sheet for the day that the takeaway dose is to be consumed;
- clearly mark that the dose was supplied as a takeaway;
- ask the patient to sign and pay for the dose before they receive it;
- check the strength and number of films required;
- place the unopened film packets in a box and seal it;
- label the takeaway dose with directions and a C&A Label I;
- hand the completed takeaway dose to the patient (not to a third party); and
- provide the patient with a paper bag if they do not have somewhere to put the takeaway dose.

For all takeaway doses

Finally, due to the risks to patient and public safety, takeaway doses should never be given to a third party to administer to the patient, such as a family member, employer or partner. The takeaway dose is the sole responsibility of the patient, and therefore needs to be handed directly to them. If there are concerns about ongoing requests for takeaway doses to be given to someone other than the patient, the pharmacist can contact the prescriber for advice.

Give the takeaway dose directly to the patient.

DO NOT give the takeaway dose to a third party.



Figure 16.1: Example of Takeaway Dose Label

16.4 Regulatory Requirements

The prescription of opioids in Tasmania is subject to regulatory requirements under the *Tasmanian Poisons Act 1971*. All opioid pharmacotherapy medications are Schedule 8 (S8) medications and dispensing of pharmacotherapy is also subject to the same legislative requirements. For more information see Section 14 Legislative Requirements.

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16.4.1 End of Month

At the end of each month, a copy of all dosing sheets need to be sent to the Pharmaceutical Services Branch (PSB). PSB collates data on dosing on behalf of the ADS.

These sheets can either be sent via facsimile or post, the details are:

Facsimile address: 03-6233 3904

Postal address: Attention: Chief Pharmacist
Pharmaceutical Services Branch
GPO Box 125
Hobart 7001

16.4.2 Dispensing of the prescription and completing the PSB narcotic return

It is important the prescription for pharmacotherapy doses is dispensed in the pharmacy's dispensing program. The prescription provides the pharmacy with the authorisation to dose the patient. In addition, it is used by PSB to assess that the patient can be dosed (i.e. there are no restrictions or other concurrent prescriptions). When the prescription is dispensed it is important to record all relevant details (i.e. dosage, frequency, takeaway doses and the date range for which the prescription is valid). It is recommended that the prescription is dispensed as soon as possible after it is received.

One option is to create a generic item for each type of drug and then dispense the scripts under this in the pharmacy dispensing program. The created "drug" needs to be specified as S8 to enable automatic transmission to PSB. For advice on how to do this, please contact the ADS pharmacy.

16.4.3 Drug Storage & Handling

Since methadone and buprenorphine are S8 medications, they must be stored in an approved narcotic safe. Registered health professionals allowed access to S8 medication can handle them (e.g. doctors, nurses, pharmacists). Within a pharmacy, S8 medications can only be handled under pharmacist supervision.

Within a pharmacy, S8 medications can only be handled under pharmacist supervision.

16.4.4 Prescriptions

Interstate prescriptions

Tasmanian legislation and regulations do not allow pharmacists to dispense interstate prescriptions for S8 and S4D medications.

Tasmanian pharmacists CANNOT dispense opioid pharmacotherapy for patients with prescriptions from interstate doctors.

Possession of prescriptions

Once a dosing site has been secured, it is the prescriber's responsibility to post (or fax, then immediately post) the prescription to the pharmacy. As per Section 6, patients should never be given a prescription for opioid pharmacotherapy. If a patient presents with a prescription the pharmacist should not dispense and should contact the prescriber as soon as possible.

Similarly, for any ancillary medications that require staged supply, they should be sent to the pharmacy as for the S8 prescriptions.

Prescribers are required to send prescriptions for opioid pharmacotherapy patients directly to the pharmacist.

DO NOT dispense a prescription for opioid pharmacotherapy if it is presented by the patient.

Patients on both S8 and S4D medications

A patient on the pharmacotherapy program cannot have S4D medications prescribed by anyone other than the pharmacotherapy prescriber. If a patient presents with a prescription for an S4D medication from another doctor, then the pharmacist has a duty of care to contact the opioid pharmacotherapy prescriber and S4D prescribing doctor. Retain the prescription and do not dispense the S4D medication.

DO NOT dispense S4D medications prescribed to the patient by a doctor other than the pharmacotherapy prescriber.

Alprazolam

Alprazolam can only be prescribed for an opioid pharmacotherapy patient with the approval of the Alcohol and Drug Services Clinical Director. If a pharmacotherapy patient presents with an alprazolam prescription, confirm the prescription with the prescriber and the ADS before dispensing.

Expired prescriptions

Patients may present for dosing after a prescription has expired for a number of reasons. Prior to prescription expiration, the patient will need to arrange an appointment with their prescriber for a prescription renewal. Pharmacists are encouraged to remind patients in the weeks leading up to their prescription expiration to make an appointment with their prescriber. The pharmacist can contact the prescriber to negotiate an

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extension on an expired prescription. This will be followed up with a posted (or faxed and then immediately posted) confirmation from the prescriber. Regardless of the reason, the pharmacist should NOT dose the patient without a current prescription.

DO NOT dose the patient if the prescription is expired, regardless of the reason for the expiration.

Changes to dosing

To prevent dosing errors or someone other than the prescriber trying to change a patient's dose, verbal communication about a prescription change for both supervised and takeaway doses must be confirmed by a faxed (and posted) prescription.

Confirm all prescription changes with the prescriber prior to dispensing.

Unexpected changes to a new prescription

Sometimes the pharmacist will observe an unexpected change to a new prescription. For example, the dose may have altered or a patient who previously had access to takeaway doses may now not have takeaways documented on the new prescription. The pharmacist can contact the prescriber to check whether the prescriber is no longer approving the provision of takeaway doses. Regardless of the reason for the change, the pharmacist cannot provide takeaway doses until prescribed. Confirmation by post (or fax and immediate post) is required before dispensing.

16.5 Dosing Errors

All dosing errors should be responded to promptly and referred to the prescribing doctor. If the pharmacist is unsure of how to respond to dosing errors, they can speak with their supervisor or contact the ADS for advice.

It is preferable for the pharmacy to have a process for recording dosing errors and the reason for the error. Pharmacists should examine and change their dosing protocols to minimise errors occurring again.

Prescribers must be notified of all dosing errors.

16.5.1 Buprenorphine

Buprenorphine is a partial agonist; hence, buprenorphine dosing errors are usually less dangerous than methadone (full agonist) dosing errors. Nevertheless, buprenorphine errors can still pose a significant risk, particularly if other drugs have also been used. Buprenorphine dosing errors should be:

- responded to promptly while the patient is either in the pharmacy or by contacting the patient if they have already left the pharmacy;
- referred to a doctor (or 000 if it's a significant error); and
- reported to the prescriber.

16.5.2 Methadone

In Australia, methadone liquid/syrup is supplied in a concentration of 5mg/mL. This can lead to errors when the pharmacist transposes the mLs for mgs. For example, if a patient is prescribed 25 mg (i.e. 5mL) and the pharmacist gives 25 mLs (i.e. 125 mg), this equates to a five-fold error. Such errors can be fatal.

In the case of a methadone dosing error, the pharmacist should cease all other tasks and focus on organising medical treatment for the patient. This is because methadone is absorbed rapidly and peaks within 20-30 minutes; therefore, methadone dosing errors require an immediate response.

If the patient is still in the pharmacy:

- explain the seriousness of the error;
- ask the patient to remain in the pharmacy until medical help arrives;
- call an ambulance to take the patient to hospital for assessment and treatment; and
- notify the prescriber of the error.

If the patient has left the pharmacy:

- try to contact the patient or look for the patient in the vicinity of the pharmacy;
- explain the seriousness of the error;
- call an ambulance to take the patient to hospital for assessment and treatment; and
- notify the prescriber of the error.

If the patient cannot be located:

- try phoning any other contact numbers that you may have for the patient;
- contact the prescriber and request next of kin contact numbers;
- phone the police and ask for their assistance to find the patient;
- ask the police to organise for an ambulance to be on standby to attend to the patient; and
- notify the prescriber of the error.

16.6 Dosing Challenges

The following section will provide information relating to dosing procedures in certain circumstances. In the situation that a pharmacist is unsure about the safety of providing a dose to a patient, support and advice can be accessed from the patient's prescriber and/or the ADS. The patient should not be dosed until the pharmacist has assessed them as safe to

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receive this. The risk of overdose or death to a patient who is not safe to be dosed outweighs the discomfort of withdrawal experienced from delaying or missing one dose.

If the private prescriber is unavailable, clinical staff at the ADS are available for advice. Contact details are available on Page XX.

A prescription is an authorisation to supply a medication by the patient's medical prescriber; and is not a mandate to provide drugs. The pharmacist makes the final decision to dose the patient. Therefore, the pharmacist should dispense opiate medication only if it is safe to dose the patient.

If you are unsure, DO NOT DOSE.

The Alcohol and Drug Service can be contacted for advice at any time.

16.6.1 Intoxication

Patients should always be assessed for signs of intoxication prior to dosing. Intoxication can be the result of:

- excessive use of a drug;
- combination of certain drugs (including alcohol); or
- the patient's dose being too high.

Signs of intoxication will vary depending on the drug. A list of signs and symptoms of opioid intoxication is included in Table 2.1 of Section 2 . A full list of signs of intoxication for a number of drugs is included in Appendix XX.

It is important to remember that dosing an intoxicated patient has the potential to result in severe harm or death.

Furthermore, the ADS specifies that patients cannot be dosed if they have a blood alcohol level (BAL) of greater than 0.00. Ideally, pharmacists should have access to a BAL machine to test patients if they suspect alcohol intoxication; however, this is not possible in most pharmacies. Therefore, pharmacists are encouraged to be alert for other signs of alcohol intoxication, such as the smell of alcohol on the patient's breath and slurred speech.

If a pharmacist believes that a patient is intoxicated, the following steps are recommended:

- Ask the patient about their presentation in a non-judgemental manner, being mindful that patients may be uncomfortable disclosing substance use or fearful of consequences;

- If there are obvious objective signs of intoxication, or if they disclose unsanctioned or risky substance use, explain your concerns about dosing;
- If a patient is intoxicated with alcohol or other CNS depressant drugs (e.g. benzodiazepines or opioids, do not dose or give the patient their takeaway doses. Dosing intoxicated patients has the potential to cause adverse outcomes such as overdose and even death;
- Inform the prescriber or ADS the patient is intoxicated and dosing was refused. (It may be possible to dose the patient in a few hours when they are no longer intoxicated. Before initiating, the pharmacist should discuss this with the prescriber);
- If you are unsure, contact their prescriber or ADS (available 24 hours) for further advice;
- Direct the patient to their prescriber if they have further questions; and
- If the patient is severely intoxicated, **contact 000**.

DO NOT dose or provide takeaway doses to intoxicated patients.

Ancillary medications when intoxicated

Many patients on opioid pharmacotherapy will also be on daily collection of ancillary medications. If it is inappropriate to dose the pharmacotherapy medication due to intoxication, then it is also unwise to be dosing or supplying CNS depressant medications. The pharmacist may ask the patient to return later in the day when they are no longer intoxicated.

Observation of patients

It is important for all pharmacy staff to observe patients as they enter the pharmacy for dosing. It is possible, for example, for an intoxicated patient to appear fine to dose while standing at the counter but may have an unsteady gait while walking to the counter. If a pharmacy staff member observes behaviour that indicates that the patient is unsafe to dose (e.g. unsteady gait, disorientation), the staff member should raise their concern with the pharmacist.

16.6.2 Behavioural Considerations

Retention in opioid pharmacotherapy is an important and is known to enhance treatment outcomes for patients. All patients are expected to follow a code of conduct whilst attending a pharmacy for dosing. Prior to entering the ADS pharmacotherapy program, patients must review and sign a code of conduct (see Section 6). This code stipulates that the following behaviours may result in withdrawal from the program:

- Violence – including physical or verbal threats of harm or acts of harm against staff or other patients;
- Property damage or theft from the service or dosing facility;

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- Diversion of prescribed medications, especially where there is an ongoing pattern of diversion; and
- Dealing of substances in and around the service or dosing facility.

It is also important for the pharmacist to set limits and make clear that certain behaviours will not be tolerated by pharmacy staff. Therefore, it is important for the pharmacist and patient to have a similar contract that outlines the pharmacy's code of conduct, acceptable behaviours, and patient rights and responsibilities. A sample contract is provided in Appendix XX.

Pharmacists are encouraged to have a contract with patients that outline the pharmacy's code of conduct and patient rights and responsibilities.

Inappropriate and unacceptable behaviour includes displays of aggression, offensive language, disruptive behaviour or intimidation. Section 12 provides some guidance on de-escalating these types of behaviours. Pharmacists should communicate with the prescriber and/or contact ADS for advice if the patient's behaviour is concerning pharmacy staff. When patient behaviours are extreme or if there is suspicion of drug diversion, dealing, or other criminal activity, then it is appropriate to inform the police.

Contact police if there is any evidence of drug diversion, dealing, or other criminal activity in or around the pharmacy.

Patients are also expected to adhere with requests made by the pharmacist regarding dosing procedures. These procedures ensure that doses are delivered safely and consumed by the patient. The pharmacist has the right to refuse dosing either temporarily or permanently if the patient's behaviour contravenes the code of conduct.

The pharmacist has the right to refuse dosing either temporarily or permanently if the patient's behaviour contravenes the code of conduct.

It is important for the pharmacist to inform the prescriber if the patient's behaviour is inappropriate. This will assist the prescriber in determining the patient's safety and stability on the program.

Maintaining professional boundaries

It is important for the pharmacist and pharmacy staff to be professional and maintain clear boundaries with patients. This includes:

- not accepting gifts or favours;
- not socialising with the patient;
- not loaning the patient money or personal items; and
- not inviting the patient to the pharmacist's home.

16.6.3 Identifying Diversion of Dose

Diversion of doses poses significant risks to the safety of both the patient and the general public. Diversion can also be an indicator of clinical instability, thus affecting the patient's suitability on the program. A more detailed discussion of the risks associated with diversion can be located in Section 12.

A diverted dose includes the inappropriate use of either a supervised or a takeaway dose. Diverted doses can be injected by the patient to increase the effects of the drug or sold to another member of the public.

The diversion itself may not be directly observed by the pharmacist or pharmacy staff; however, certain patient behaviours and body language may indicate diversion or attempted diversion of supervised doses. These can include:

- not wanting to stay for the supervision period;
- causing distractions;
- reading books or magazines close to the face and mouth;
- touching their mouth with their hand or sleeve;
- browsing the shop;
- spitting, coughing, sneezing;
- general out of character behaviour, such as being overly nice;
- nervousness;
- closely watching the pharmacist; and
- suspicious interaction with other patients or acquaintances after dosing.

Note: Adapted from Department of Health, Western Australia Government, 2006.

If the pharmacist has reason to believe that a patient is diverting a dose, it is appropriate for the pharmacist to ask the patient about this and to inform the patient of their concerns. It is also appropriate for the pharmacist to request to see the patient's hands. The patient should also be informed that the prescriber will be informed of these concerns. Diversion of takeaway doses may be more difficult for pharmacists to identify.

16.6.4 Minimising Diversion of Dose

To minimise the risk of diversion, patients should be provided with clear guidance about how their medication will be given, the risks associated with misuse of doses and how they should present at the pharmacy each day to avoid unnecessary suspicion of diversion. The pharmacist may also communicate what are considered as signs of diversion to patients.

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Diversion of supervised doses can be reduced by the following procedures:

For both methadone and buprenorphine:

- Dose one patient at a time;
- Do not allow other people (including children where possible) in the dosing area while a patient is being dosed;
- Do not allow bags, drinks, or other containers in the dosing area;
- Ensure the patient throws away (into a designated bin) or hands back any items used during dosing;
- To reduce diversion it is important the pharmacist observes the patient throughout the dosing process, especially when the dose is placed in the mouth and immediately afterwards; and
- CCTV monitoring is useful as it can record any inappropriate behaviour and it is important to tell patients about it as they tend to modify their behaviour when it is being recorded.

For buprenorphine:

- Ask patients to remove chewing gum from their mouth prior to dosing;
- If possible, ask the patient to remove dentures while still maintaining the dignity of the patient;
- The dose should be rough crumbled to large granule size;
- Dispense the dose in a clear plastic cup or disposable spoon;
- Avoid powdering the dose; and
- View and inspect the mouth cavity after the patient reports the dose has been absorbed.

For methadone:

- Use an individual disposable cup for each patient;
- Do not pour methadone into another drink container; and
- Always dilute the dose to approximately 100mL with water or cordial.

16.6.5 Missed Doses

Missed doses can be a sign of clinical instability and can impact on the effectiveness of opioid pharmacotherapy (see Section 8). Missing one or more doses affects steady state of the medication in blood levels. If a patient misses two or more doses, the pharmacist can only resume dosing on the instruction of the prescriber (or ADS case manager).

The following procedures should be followed when a dose is missed.

One missed dose:

- assess patient suitability for dosing;

- if the patient is not intoxicated, and no other risks or concerns are identified, proceed with dosing; and
- notify the prescriber (or case manager in ADS) of the missed dose using the “Did Not Dose” form (Appendix xx) or via telephone.

Two consecutive missed doses:

- do not dose the patient;
- notify the prescriber (or case manager in ADS) of the consecutive missed doses using the “Did Not Dose” form (Appendix xx) or via telephone;
- inform the patient that you cannot dose them without further approval from their prescriber (or case manager in ADS); and
- inform the patient to contact their treating service and request a review from their prescriber (or case manager in ADS).
- If the patient misses two (2) or more consecutive doses, the pharmacist can only resume dosing on the instruction of the prescriber (or Alcohol and Drug Services Case Manager).

Three or more consecutive missed doses:

- do not dose the patient;
- notify the prescriber or treating service of the consecutive missed doses using the “Did Not Dose” form (Appendix XX) or via telephone;
- inform the patient that you cannot dose them without further approval from their prescriber only;
- inform the patient to contact their treating prescriber or service and request a review from the prescriber; and
- if the patient is pregnant, refer them to the hospital as they are at risk of miscarriage.

If the patient misses three (3) or more consecutive doses, the pharmacist can only resume dosing on the instruction of the prescriber (or Alcohol and Drug Services Case Manager).

The prescriber will determine the appropriate recommencement dose for the patient after two or more missed doses.

If in doubt, the safest approach is to decline dosing and contact the prescriber for advice. The prescriber can determine whether the patient’s pattern of missed doses affects their suitability for the program.

16.6.6 Vomited Doses

Sometimes patients will report having vomited a dose and consequently request a replacement dose. The pharmacist cannot authorise a replacement dose. Replacement

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doses can only be provided following the instruction and provision of a prescription from the prescriber. If the pharmacist witnesses the patient vomiting, the pharmacist should contact the prescriber concerned (Section 8 contains guidelines for replacing doses and what to do if the pharmacist has not witnessed this event).

There are special considerations for a patient who is pregnant or reports to be pregnant (see Sections 8 and 11 for guidelines). For patients who experience genuine problems with nausea or vomiting related to dosing, it is important to discuss with the prescriber the use of an antiemetic prior to the dose.

As buprenorphine is absorbed sublingually, vomiting after the dose has been absorbed will have no effect on the blood levels of the drug. If a patient vomits whilst the dose is being absorbed (i.e. they still have pieces of the dose in their mouth) then it may affect the blood levels but unfortunately it will be extremely difficult to determine how much of the dose has been absorbed. In such cases the dose would usually not be replaced.

The pharmacist cannot authorise a replacement dose. Replacement doses can only be provided after authorisation from the prescriber.

16.6.7 Drug Interactions

Pharmacists should be aware of medications that may interact with the patient's pharmacotherapy treatment. A list of drug interactions is listed in Appendix XX.

Some over the counter (OTC) medications can also interfere with the patient's pharmacotherapy. Furthermore, they may impact on the results of patient's urine sample results. Patients should be informed of the potential impact of OTC medications on their pharmacotherapy treatment and urine testing. (A list of these OTC medications can be found in Appendix XX)

16.6.8 Side Effects and Adverse Drug Reactions

The pharmacist should contact the prescribing service if they believe the patient is experiencing an adverse reaction to pharmacotherapy. Of particular concern is the development of serotonin syndrome in patients on opioid medication and an SSRI SNRI. If the patient is significantly unwell, or the reaction occurs outside business hours, the pharmacist should seek urgent medical advice.

16.7 Financial Considerations

Pharmacists are reimbursed for their participation in the opioid pharmacotherapy program by charging the patient a daily dosing fee and by the provision of free medication and dosing ancillaries (i.e. cups and takeaway bottles).

16.7.1 Payment by Patients

Patients are required to pay a fee for the administration of their dose. This fee is set by each pharmacy and is part of the contract between the pharmacy and the patient. The ADS is not responsible for this fee: therefore, the ADS is not obligated to take back

patients who can no longer access dosing because they have accumulated a pharmacy debt.

The fee is part of the patient's responsibilities and the pharmacy has the right to refuse dosing if the patient does not pay the fee and accumulates a debt. If the patient cannot be dosed due to accumulation of debt, the patient can either:

- look for another dosing site;
- commence detoxification; or
- attend an appointment with their prescriber to be removed from the program.

To minimise restricted access to dosing due to the accumulation of debt, pharmacists are advised to request payment for dosing before the dose is dispensed. Pharmacists can also arrange for patients to pay for their weeks dosing ahead of time (e.g. on pay day) or direct debited from the patient's pay (e.g. via Centrepay).

A policy of NO PAYMENT, NO DOSE is recommended.

16.8 Documentation

16.8.1 Recording Doses

All the doses dispensed for a drug on a particular day can be recorded on a summary sheet (either by hand or electronically). This can ease the process of writing up the narcotic registers at the end of day. If a summary sheet is used, it must be signed by the pharmacist and stored in a designated folder and kept for the same number of years as the narcotic register. The ADS/PSB approved summary sheets are located in Appendix x.

16.8.2 Maintaining Patient Records

It is recommended that each opioid pharmacotherapy patient dosing at the pharmacy has a separate folder that is kept in a secure place and accessible only by the pharmacist. The folder should contain:

- an identification sheet;
- a notes sheet;
- copy of prescription(s); and
- dosing administration charts for both pharmacotherapy and ancillary medications.

Colour coding the folders with a different colour for each of the three pharmacotherapy preparations can help prevent dosing errors and improve dosing efficiency.

16.8.3 Blind Dosing

Some prescribers may request a patient to be dosed without the patient being aware of the amount that they are receiving. This dosing technique requires the patient's consent.

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Appendix XX contains a blind dosing sheet for each of the pharmacotherapy drugs with a section for the patient's witnessed consent.

16.8.4 Supplementary Doses

During the induction phase, patients may receive supplementary doses, as directed by the prescriber. To assist in dosing in this circumstance, an induction dosing sheet for each of the pharmacotherapy drugs, with ability to record several doses, can be found in Appendix XX.

While supplementary doses can be prescribed, the TOPP does not support split dosing regimes (See Section 8).

16.8.5 Communication between Pharmacists

Good internal communication systems are essential for reducing dosing errors and improving dosing efficiency. One strategy is having a diary or book in which information that pharmacists need to know about a patient can be recorded. Notes can then be attached to the dosing sheet so that they are seen and read by the pharmacist before the patient is dosed; (e.g. circumstances or agreements that have been put in place to assist dosing stability for patients.)

16.8.6 Computer dosing programs

Computer dosing programs are available to assist with the dosing process for methadone, Subutex® and Suboxone®. Such programs can be attached to an approved automated pump for methadone. These programs have many advantages over a paper system, including:

- they are an additional checking process for the pharmacist;
- they provide photo identification;
- they alert the pharmacist when the prescription is due to expire;
- they prevent the dose being marked as dispensed once the prescription is expired;
- they provide an electronic narcotic register; and
- a summary of the daily dosing for each drug can be printed at the end of day.

The ADS Pharmacy currently uses the Meth.D.A program. To see this program in use or to discuss dosing programs in general, please contact an ADS pharmacist on (03) 6230 7984 or (03) 6230 7983.

16.8.7 Pharmacy transfers

Pharmacists are required to follow procedure when transferring patients. To ensure a smooth transfer occurs, the pharmacy from which the patient is transferring should communicate to the new pharmacy and confirm when the final dose was given. This helps prevent double dosing the patient and potentially dangerous dosing errors occurring.

The original pharmacy must complete a confirmation of last dose sheet and fax or post this and a confirmation of the patient's dosing schedule to the receiving pharmacy. The

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receiving pharmacy will require a new prescription from the prescriber: it is not appropriate to continue using the old prescription. The new pharmacy will need to confirm the dosing schedule with the prescriber. For more information, Section 14 Transfers.

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