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6.5 Time in treatment and allowable takeaway doses

Access to takeaway doses should be granted conditionally and gradually increased if and when the patient demonstrates continuing stability and negative urine screens for opioids.

There is a difference in the rates at which takeaway doses are allowed for buprenorphine and methadone patients. This is in recognition of the significantly greater toxicity and pharmacological availability of methadone following oral ingestion. Diverted doses of methadone or unsafely stored takeaway doses of methadone have a far greater potential to lead to fatal consequences than buprenorphine, which is poorly absorbed if swallowed and which is less likely to produce fatal respiratory depression. By requiring a longer period of demonstrated stability on methadone it is believed that fewer adverse consequences will be experienced.

Time in treatment in another opioid treatment program (including the Justice Health system) should only be counted if the prescribing doctor has full information about the patient's treatment and progress in that program. Time in treatment within the Justice Health system does not necessarily provide evidence of stability within a community setting.

Suggested approaches to allowing takeaway doses for methadone and buprenorphine

Takeaway doses are only provided when the patient has demonstrated stability in treatment and there are no contraindications to takeaway dosing. See section 6.4 (page 48).

Stage of treatment	Methadone (and occasionally buprenorphine)	Buprenorphine–naloxone
0–3 months	No access to takeaway doses other than in the most exceptional circumstances.	No takeaway doses.
3–4 months	Observe the patient no less frequently than every second day and provide a maximum of two takeaway doses per week (not consecutive) if stability has been demonstrated and contraindications are absent.	Observe the patient no less frequently than every second day and provide a maximum of two takeaway doses per week (not consecutive) if stability has been demonstrated and contraindications are absent.
4–5 months	As above.	Observe the patient no less frequently than every third day and provide a maximum of four takeaway doses per week if stability has been demonstrated and contraindications are absent.
6–8 months	Observe the patient no less frequently than every third day and provide a maximum of three takeaway doses per week if stability has been demonstrated and contraindications are absent. Patients are to receive a maximum of two consecutive takeaway doses.	Observe the patient weekly and provide a prescription for one week of dispensed buprenorphine–naloxone if stability has been demonstrated and contraindications are absent.
8–12 months	Observe the patient no less frequently than every third day and provide a maximum of four takeaway doses per week if stability has been demonstrated and contraindications are absent. Patients are to receive a maximum of two consecutive takeaway doses.	Observe the patient fortnightly and provide a prescription for two weeks of dispensed buprenorphine–naloxone if stability has been demonstrated and contraindications are absent.
12–24 months	Patients should continue to be seen no less frequently than every fourth day and the maximum number of takeaway doses should remain at four per week. There may be some flexibility in how the takeaway doses are dispensed if stability has been demonstrated and contraindications are absent.	Patients may progress at 12 months to a 28-day prescription of dispensed buprenorphine–naloxone should they have been able to demonstrate stability on the fortnightly prescription and contraindications are absent.

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6.6 Monitoring patients on takeaway doses

It is recommended that when the prescriber reviews a patient who has been receiving takeaway doses, the following issues should be dealt with by discussion and examination:

- acceptability of the dosing schedule, dose adequacy, side effects and other drug use
- sleep, mood and social functioning
- satisfaction with treatment
- mental state examination
- inspection of (at least) upper limbs for evidence of injection (groin and lower limb/neck sites should be inspected where suspicions or a history of injecting in these sites exist)
- observation for evidence of intoxication with other drugs
- urine drug screen.

> The *Suitability for takeaway doses assessment form* (see Appendix L, page 148) should be used at each review.

6.7 When to stop providing takeaway doses

This is a difficult issue for a prescriber to deal with, as a patient receiving takeaway doses usually becomes distressed at any suggestion that this is to be curtailed. Often prescribers are unwilling to cause distress and conflict, so there is a powerful pressure to overlook signs of instability and continue prescribing takeaway doses. This is not good practice. It is common for drug-dependent patients to do well for a time, then relapse into periods of destructive drug use. For people in an opioid treatment program, this does not necessarily mean return to heroin use, but may involve developing an alcohol problem, or bingeing on stimulants or benzodiazepines. It is possible to intervene to reduce the risk of such destructive drug use. Supervised dosing is an important measure to reduce risk. Patients manifesting instability are not suitable for regular takeaway doses, and if a person on takeaway dosing develops an alcohol problem or other indicator of instability they need to be returned to supervised dosing.

A return to supervised dosing may be temporary, providing the patient with the opportunity to demonstrate that they have regained control — or, if a person relapses severely or repeatedly, it may be concluded that they are not able to deal with unsupervised treatment and need long-term supervised dosing.

Issues which dictate that a person should return to supervised dosing include:

- self report of relapse to heroin use, or to other dependent drug use
- credible evidence of diversion
- recent injection marks
- deterioration in psychological, physical or social wellbeing
- child-at-risk concerns, or DOCS involvement.

Takeaway doses should only be reintroduced gradually after at least four weeks of demonstrated stability.

6.8 Takeaway dosing and the dosing schedule

Takeaway doses should be the same as those consumed under supervision at the clinic or pharmacy.

Many patients change the timing of their dose when they receive takeaway doses. Patients on methadone may split their daily dose. Patients who were taking buprenorphine once every second day will often return to daily dosing, and some patients will prefer to split their dose into smaller doses twice or thrice daily rather than having a single morning dose. This is acceptable. However, patients should be advised to take the same total dose daily and not to vary their daily dose.

6.9 Takeaway doses and transfer to another prescribing doctor

Takeaway dose arrangements are not to be automatically transferred when patients are changing prescribing doctors. The new prescribing doctor is responsible for reassessing the patient's suitability for takeaway doses and the appropriateness of the previous takeaway dose regimen. The new prescriber should communicate with the previous prescriber to obtain information that will assist in the assessment of the patient's suitability for takeaway doses.

To adequately assess the patient's stability and reliability, the number of takeaway doses provided by the new prescribing doctor during the first month should not exceed the number provided by the previous prescriber.

6.10 Authorisation, preparation, and supply of takeaway doses

Under current legislation, takeaway doses may be prepared only by a doctor or pharmacist, or under a pharmacist's direct personal supervision.

The prescribing doctor is to provide the clinic or pharmacy with written authorisation (which should be in the prescriber's own handwriting and signed) for takeaway doses. This must be attached to, or incorporated in, the current prescription and must specify the date or (when regular take-

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away doses are provided) the days of the week on which the patient is to receive takeaway doses.

Each dose is to be supplied in a clean new container fitted with a child-resistant closure.

Individual takeaway doses should be labelled with:

- the name, strength and quantity of drug
- the patient's name in full
- original prescription (or identifying number)
- the date on which the takeaway dose was dispensed
- the date the takeaway dose is to be taken
- the required warning labels:
  - — **'KEEP OUT OF REACH OF CHILDREN'** in red on a white background
  - — the driving hazard warning, preceded by an equilateral triangle coloured red: **'THIS MEDICATION MAY CAUSE DROWSINESS AND MAY INCREASE THE EFFECTS OF ALCOHOL. IF AFFECTED DO NOT DRIVE A MOTOR VEHICLE OR OPERATE MACHINERY.'**
- the name, address and phone number of the administration point.
- buprenorphine doses should remain in blister packaging and each dose should be individually labelled.

Takeaway doses are to be given to patients on the day before the scheduled absence from the dosing point. At that time the patient is to be told that methadone is for oral consumption only (or that buprenorphine–naloxone is for sublingual consumption only). The patient must be advised of the dangers of misusing the dose, the hazards of using it in combination with other drugs, and its toxic potential if taken by a child or anyone not tolerant of opioids.

6.11 Lost or stolen doses

Once in the possession of the patient, takeaway doses are the patient's responsibility. If a patient reports that takeaway doses have been lost, stolen or damaged, a replacement (either on-site or as a takeaway) should not be dispensed unless there is a medical indication to do so (such as to prevent withdrawal symptoms in pregnant patients).

If medically indicated, replacement doses should be carefully titrated against the observed clinical condition of the patient. Replacement doses are not usually full doses. Careful assessment and monitoring are required to ensure that the patient is not overdosed.

Regular loss of takeaway doses (for any reason) suggests that a return to on-site dosing is indicated.

6.11.1 Reporting lost doses

There is no legal requirement for any stolen/lost-dispensed methadone (or other substance listed in Schedule 8 of the Poisons List) to be reported to the police. There may of course be reasons why a report to the police is desirable.

Any loss or theft of a Schedule 8 substance, up to the point when it is dispensed (ie, from a clinic, pharmacy or hospital) must be reported to the Pharmaceutical Services Branch (PSB) of NSW Health (Ref Cl122 — Poisons and Therapeutic Goods Regulation 2002).

The PSB does not have to be notified of methadone being lost or stolen after it has been dispensed, but if it is notified, a note is made on the patient file.

(Attachment F ends)

Attachment G

Government of South Australia, SA Health, *Policy for non-supervised dosing of methadone and buprenorphine in drug treatment programs*, January 2012.

Government of South Australia
SA Health

Drugs of Dependence Unit
Telephone 1300 652 584
Facsimile 1300 658 447

January 2012

POLICY FOR NON-SUPERVISED DOSING OF METHADONE AND BUPRENORPHINE IN DRUG TREATMENT PROGRAMS

Within South Australia there are two opioid drug treatment programs. The Suboxone® Opioid Substitution Program [SOSP] which allows for the provision of buprenorphine with naloxone only to a person and the Opioid Dependence Substitution Program [ODSP] which allows for the provision of buprenorphine with naloxone, buprenorphine without naloxone and methadone to a person. Both programs are supervised drug administration programs. Supervision allows assessment of the client before dosing. The aim is to minimize drug overdose, abuse and diversion. The gradual introduction of non-supervised doses for clients who respond to treatment may reward treatment progress as well as improve their quality of life. The non-supervised administration of doses remains a sensitive issue and is subject to scrutiny by those persons critical of drug treatment programs. The diversion and subsequent consumption of methadone or buprenorphine preparations by an opioid-naïve person is potentially lethal.

Buprenorphine may only be provided in accordance with this Unit's Suboxone® Opioid Substitution Program [SOSP] guidelines – an information handout for medical practitioners [SA] and the policy relating to the use of Suboxone® [buprenorphine with naloxone] and Subutex® [buprenorphine without naloxone] in the Opioid Dependence Substitution Program [ODSP]. The provision of unsupervised doses is uniform across both programs.

1. All new admission clients should complete their first month at a seven-day pharmacy wherever possible.
2. Unstable clients should continue at a seven-day pharmacy to prevent access to take-away doses.
3. Take-away doses must be handed directly to the client unless prior approval has been granted by the Drugs of Dependence Unit for an agent to collect the drug. SAPOL may act as an agent while the client is remanded in the Adelaide City Watchhouse or Holding Cells within the scope of SAPOL approved policies. Adelaide City Watchhouse nurses may act as an agent while the client is remanded in the Watchhouse within the scope of approved DASSA policies.
4. i) No take-away doses may be supplied during the **first two months of treatment**. Non-supervised doses are allowed on Sundays & public holidays at six-day pharmacies.
   ii) For the **first nine months of treatment**, the take-away allowance must not exceed six doses per month at seven-day pharmacies or two doses per month plus Sundays & public holidays at six-day pharmacies.
   iii) For the period **nine to eighteen months**, the take-away allowance must not exceed twelve doses per month (three per week) at a seven-day pharmacy or eight doses per month plus Sundays & public holidays at six-day pharmacies.
   iv) **After eighteen months**, and with evidence of lifestyle improvement and abstinence from unsanctioned drug use, take-away doses may be increased gradually. There must be a minimum of **three supervised doses per week** for **methadone** or two **supervised doses per week** for **buprenorphine**.
5. The maximum number of take-away doses to be given at one time should not exceed four consecutive days' doses for methadone or five consecutive days' doses for buprenorphine. Regardless of daily dosing, second or third day dosing (buprenorphine) or missed doses there must be a minimum of three supervised doses per week for methadone or two supervised doses per week for

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buprenorphine, unless prior approval has been given by the Drugs of Dependence Unit. A missed dose should equate to a missed take-away dose.

6. All take-away doses for methadone must be diluted. (methadone liquid dispensed for non-supervised dosing should be diluted to a volume of: 100mls for doses above 25mg of methadone and 50mls for doses of 25mg methadone or less).
7. Clients must be advised to provide adequate security to prevent theft, loss or damage of take-away doses. Requests for replacements should be refused and access to future take-away doses reviewed.
8. Pharmacists should report missed doses [more than three days in a row (including second or third daily dose clients), or more than ten days per month] and intoxicated presentation to the medical practitioner or where the pharmacist holds any concerns over the client's treatment.

When calculating the period of treatment it is reasonable to consider previous treatment programs if the client has been stable. A short break in treatment or a short period where the client was incarcerated should also not adversely affect the client's status. If there are exceptional circumstances, such as employment obligations or personal hardship that may justify additional take-away doses, **application must be made in writing to the Drugs of Dependence Unit for the authority to be amended**.

Clients with work commitments may need to be transferred to pharmacies in other towns or suburbs or even transferred to an interstate program on a temporary basis.
These rules are designed to ensure a consistent application of this privilege for the joint benefit of clients, prescribers and dispensers. They replace those listed in the Private Prescriber's Manual and are required to be followed under a condition of each authority issued by the Minister for the treatment of an individual client.

It is an offence not to comply with a condition of an authority and non-compliance may result in legal prosecution, cancellation of the authority or other administrative action.

Non-supervised doses are only available for stable clients where the client responds to treatment with active lifestyle changes and a reduction or cessation of unsanctioned drug use, subject to the following:

1. There must be no suspicion of diversion of prescribed medication or illicit dealing in drugs.
2. Containers must be labelled '**Keep out of Reach of Children**' and '**Do Not Inject**' and '**May Cause Death or Serious Injury if Injected or Taken by another Person**'.
3. In the case of methadone, unless specifically exempted, all doses to be provided must be:
    a. in liquid form;
    b. in a separate container for each day's dose and containers must have a child resistant enclosure; and
    c. for doses of 25 mg of methadone and above, diluted to at least 100 mL; or
    d. for doses of less than 25 mg of methadone, diluted to at least 50 mL.

A chart describing this policy is set out on the following page. The chart also explains non-supervised dosing for alternate day dosing of buprenorphine.

Colin M. Brown
Manager
DRUGS OF DEPENDENCE UNIT

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INTRODUCTION OF NON-SUPERVISED DOSING

	DOSING AT A **SIX-DAY** PHARMACY		DOSING AT A **SEVEN-DAY** PHARMACY	
MONTH	*daily dosing*	*alternate day dosing of buprenorphine*	*daily dosing*	*alternate day dosing of buprenorphine*
1	**ZERO** take-away doses (except Sundays & public holidays) **Seven-day pharmacy** if possible	**ZERO** take-away doses (except Sundays & public holidays) **Seven-day pharmacy** if possible	**ZERO** take-away doses	**ZERO** take-away doses
1 to 2	**ZERO** take-away doses (except Sundays & public holidays)	**ZERO** take-away doses (except Sundays & public holidays)	**ZERO** take-away doses	**ZERO** take-away doses
3 to 9	**SIX** take-away doses/month	**THREE** take-away doses/month	**SIX** take-away doses/month	**THREE** take-away doses/month
10 to 18	**TWELVE** take-away doses/month	**FIVE** take-away doses/month	**TWELVE** take-away doses/month	**FIVE** take-away doses/month
>18	**METHADONE** **EIGHTEEN** take-away doses/month **BUPRENORPHINE** **TWENTY-TWO** take-away doses/month	**SEVEN** take-away doses/month	**METHADONE** **EIGHTEEN** take-away doses/month **BUPRENORPHINE** **TWENTY-TWO** take-away doses/month	**SEVEN** take-away doses/month

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Attachment H

ACT Health, *The ACT opioid maintenance treatment guidelines*, 2009, pp.13-17.

6 MAINTENANCE ON TREATMENT

6.1 Unsupervised (take-away) dosing

This Section details issues related to the assessment for and provision of unsupervised (take-away) dosing. Unsupervised (take-away) doses may be authorised for clients who have demonstrated clinically assessed stability in treatment. All clients should commence opioid maintenance treatment under conditions of supervised administration. Those clients who demonstrate stability may progress to receiving unsupervised (take-away) doses. The benefits of unsupervised (take-away) doses include:

- enhanced integration into the community;
- promotion of patient responsibility for treatment;
- enhanced capacity to obtain and maintain employment;
- convenience of treatment; and
- reduced client costs associated with daily dosing at community pharmacies (e.g. Higher travel costs of accessing centralised clinic compared with accessing local pharmacy.)

6.1.1 Assessing client stability for unsupervised (take-away) dosing

To receive unsupervised (take-away) doses, clients need to be assessed by their medical practitioner as meeting stability criteria. A tool to guide the assessment of client stability is provided at Appendix 3. Use of this tool is recommended to ascertain client stability.

The prescriber is required to specify on the prescription the authorisation of unsupervised (take-away) doses and details should be recorded in the client record.

Most new clients on opioid maintenance treatment require daily supervised doses for at least three months before qualifying for an unsupervised (take-away) dose. Clients may have demonstrated stability in another state or territory in Australia, or in another country. This information may be used to determine the level of supervised dosing after transferring to the ACT. Table 1 provides guidance on the provision of regular (weekly) unsupervised (take away) doses for opioid maintenance treatment. Doses should only be increased incrementally (e.g. after two months on each increment). It may take more than two months to attain stability following each additional unsupervised (take-away) dose provided. The prescriber is to ensure client stability is maintained with the provision, or increase, of unsupervised (take-away) dosing.

Doses not used in a time period, may not be transferred to another time period.

Table 1: Guide for the provision of regular (weekly) unsupervised (take-away) doses

Length of time in treatment (months)	Methadone	Buprenorphine/ naloxone	Comments
0-3	0	0	Exceptional circumstances may allow one dose
3-5	2	2 per week	Not consecutively
5-7	2	4 per week	Maximum 2 consecutive
7-9	3	6 per week	Methadone – maximum 2 consecutive
9-12	4	13 per fortnight	2 weeks unsupervised dosing
12-24	4	27 per 28 days	4 weeks unsupervised dosing

NB: this table is to be used as a guide and is not intended to be prescriptive for the provision of unsupervised (take away) doses.

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If a prescriber assesses a client as being sufficiently stable to receive more than four regular unsupervised (take-away) doses per week, then the prescriber must provide the Chief Health Officer (or delegate) with the details of their assessment and obtain written authority from the Chief Health Officer (or delegate) for such prescribing.

Buprenorphine should not be approved for unsupervised (take-away) dosing unless the client has a confirmed allergy to naloxone, or is pregnant and has completed a *Patient consent form for buprenorphine treatment during pregnancy/breast feeding*. Pregnancy must be confirmed to the satisfaction of the prescribing medical practitioner. The relevant consent form may be found in the Appendices of the following document.

National clinical guidelines and procedures for the use of buprenorphine in the treatment of heroin dependence
http://www.nationaldrugstrategy.gov.au/internet/drugstrategy/Publishing.nsf/content/buprenorphine-guide

The pharmacist should clearly record details of take-away doses in the client record and the administration records. Clients should be advised to store their take-away doses in a secure place out of the reach of children and other potential users, and not in a refrigerator. Take-away doses that are claimed to have been lost or stolen must not be replaced without the prescriber's written authorisation. Clients should report lost take-away doses to their pharmacist and prescriber immediately.

Where a client exhibits signs of decreasing stability the pharmacist should notify the prescriber so the prescriber can review the client and their treatment, including the indications for continuation of take-away doses.

6.1.2 Unsupervised (take-away) doses – special cases

Unsupervised dosing may be permitted in special cases due to the unavailability of supervised dosing (e.g. at Easter, Christmas, or New Year), or where the client has urgent interstate travel requirements.

Pharmacists unable to dispense on a public holiday may provide one additional special case take-away dose to a stable client to cover for a public holiday closure after obtaining authorisation from the prescriber, providing the client is already receiving regular unsupervised (take away) doses. This should not reduce the entitlement of the client to their regular (weekly) unsupervised (take-away) dose entitlements.

For circumstances not covered in this section, or for contact with other prescribers, contact ADP.

ACT Health – Alcohol and Drug Program (ADP)
Phone (02) 6244 2591 Fax: (02) 6244 4622

6.1.3 Urine screening

In the ACT, the use of urine screening is not mandatory, and will be determined on an individual basis by the prescriber. For more information, see the *National pharmacotherapy policy for people dependant on opioids*. Clients should be provided with written information regarding the locations that urine testing is conducted, and the legal status of screening in the ACT.

Treatment Options for Heroin and Other Opioid Dependence – A Guide for Users
http://www.nationaldrugstrategy.gov.au/internet/drugstrategy/Publishing.nsf/content/opioid-users
National pharmacotherapy policy for people dependant on opioids
http://www.nationaldrugstrategy.gov.au/internet/drugstrategy/Publishing.nsf/content/pharmacotherapy

6.1.4 Volume expansion

The decision to volume expand an unsupervised (take-away) dose is made by the medical practitioner in consultation with the client. Advice on this matter may also be sought from other members of the treatment team (e.g. pharmacist). Any requirement for volume expansion should be clearly marked on the prescription, with the total volume of the treatment to be dispensed noted on the prescription.

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If an unsupervised (take-away) dose is volume expanded, an appropriate diluent should be used to protect the integrity of the methadone dose from potential microbial growth up to the use-by date. If doses are volume expanded in the ACT, it is recommended that they be diluted to a maximum total volume of 100 mLs and labelled accordingly.

For circumstances not covered in this Section or for contact with other prescribers, contact ADP.

ACT Health – Alcohol and Drug Program (ADP)
Phone (02) 6244 2591 Fax: (02) 6244 4622

6.1.5 Ceasing or reducing unsupervised (take-away) doses

Ceasing or reducing unsupervised (take-away) doses can be one of the most difficult issues for a prescriber to deal with, as once a client is receiving take-aways, the suggestion of reducing access to take-aways may not be welcomed.

A client may do well for a time, and then relapse into periods of problematic drug use. Good communication between the client, prescriber and community pharmacist can help reduce the frequency, duration and intensity of relapses and allow an increase in client support to counter unstable periods.

Where relapses are severe or repetitive, unsupervised (take-away) doses are not part of optimum treatment and supervised dosing is necessary.

Indications that a return to supervised daily dosing (long-term or short-term) may be necessary include:

- self report of relapse to heroin use, or to other dependent drug use;
- credible evidence of diversion;
- recent injection marks; and
- deterioration in psychological, physical or social well-being; or
- irregular attendance.

When a return to supervised daily dosing is being considered, it may be appropriate to give a client both verbal and written indication of the concerns.

Re-introduction of unsupervised (take-away) doses should only occur after a period of at least two weeks of stability, and should proceed incrementally (see Table 1).

6.1.6 Split dosing

Split dosing may be considered for clients who rapidly metabolise methadone (e.g. in the case of acute pain or during pregnancy). Prior to authorising split dosing, the prescriber should consult with another endorsed opioid maintenance prescriber (with patient consent) to confirm the need for split dosing. If considered appropriate this may involve one half dose being administered under usual supervision and the remaining half dose dispensed for unsupervised (take-away) administration. The use of unsupervised (take away) doses in split dosing, should not reduce the total regular unsupervised (take away) doses for clients.

6.2 Vomited dose

For clients receiving methadone, if vomiting occurs within 20 minutes of ingesting the dose, the pharmacist is to contact the prescriber so that, a supplementary opioid maintenance treatment dose may be authorised. Extra care should be exercised with pregnant clients as severe withdrawal symptoms may cause foetal distress, especially in the first and third trimesters.

If vomiting occurs more than twenty minutes after ingestion, the dose is likely to have been absorbed.

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As Buprenorphine is absorbed sublingually within minutes, vomiting after a dose will not reduce the clinical effect, and no extra dose should be administered.

6.3 Missed doses

If a client receiving opioid maintenance treatment misses scheduled dosing days, the regime in the relevant National Clinical Guidelines should be consulted. Refer to page 26 and page 20 respectively in the following National Clinical Guidelines.

National clinical guidelines and procedures for the use of buprenorphine in the treatment of heroin dependence
http://www.nationaldrugstrategy.gov.au/internet/drugstrategy/Publishing.nsf/content/buprenorphine-guide

National Clinical guidelines and procedures for the use of methadone in the maintenance treatment of opioid dependence
http://www.health.vic.gov.au/dpu/downloads/guidelines-methadone.pdf

6.4 Stopping treatment

6.4.1 Voluntary

A client may withdraw from treatment at any time without affecting access to medical care. Clients should, wherever possible, be reduced appropriately from their current dose using the recommended schedule in the National Clinical Guidelines.

National clinical guidelines and procedures for the use of buprenorphine in the treatment of heroin dependence
http://www.nationaldrugstrategy.gov.au/internet/drugstrategy/Publishing.nsf/content/buprenorphine-guide

National Clinical guidelines and procedures for the use of methadone in the maintenance treatment of opioid dependence
http://www.health.vic.gov.au/dpu/downloads/guidelines-methadone.pdf

Early information should be provided to the client regarding the importance of remaining in treatment, and the best manner to cease treatment safely with minimal clinical consequences. This information should be included in care planning at the earliest opportunity.

6.4.2 Other circumstances

There may be instances of problematic behaviour from clients receiving opioid maintenance treatment. Episodes of problematic behaviour should trigger a discussion between the client and members of the treating team aimed at resolving the dispute (depending on nature and severity) with documented outcomes provided to the client and included in the client record.

More detail on involuntary cessation of treatment can be found in the National Pharmacotherapy Policy.

National pharmacotherapy policy for people dependant on opioids
http://www.nationaldrugstrategy.gov.au/internet/drugstrategy/Publishing.nsf/content/pharmacotherapy

Clients should not have access to treatment removed by ACT Health employees because of problematic behaviour, except with the approval of the Chief Executive. For those in community settings, Section 7 outlines Support Services. ACT Health has clear policy on the management of violence or aggression in the workplace. The process to be followed by ACT Health employees in these situations may be found in the following ACT Health policy document.

Preventing and managing aggression and violence in ACT Health
For users outside of ACT Health Intranet, please contact ADP
http://health.act.gov.au/c/health?a=dldivpoldoc&document=970

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Treatment should not be withheld or terminated for non-payment of financial accounts alone. The pharmacy should have discussions with the client regarding accounts, so there is clear understanding of the rights and responsibilities of the client and pharmacist. ACT Health requires that community pharmacists embed a process for the collection of fees and a process for resolution of accumulated debt if required. Clients are expected to be provided with written advice detailing the timelines and process for bringing an account into balance. (e.g. two to four weeks from the time the consumer is given the advice in writing.)

If the issues relating to accumulated debt are unable to be resolved, the client is to be referred to another dosing pharmacy or the public clinic. The Rapid Referral Mechanism (see Support Services) may be used to refer clients to ADP.

If clients are dissatisfied with decisions made regarding their care, see Complaints for information and the process to be followed to seek review.

Automatic payment deductions for pharmacy costs are recommended to reduce the incidence of accounts becoming unmanageable.

Readmission to treatment is subject to the Rights and Responsibilities detailed in Entry into Treatment.

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Attachment I

Queensland Health, Queensland Opioid Treatment Program: Clinical Guidelines, 2012, pp.51-57.

6.5.5 Triple-dosing

Some clients may tolerate triple-dosing with buprenorphine, reducing the inconvenience of further treatment. This regime should not be attempted until a two-week trial on double-dosing has been successful.

The recommended regime for triple-dosing is:

- 3-day dose = 3 times the normal 24-hour dose if the 24-hour buprenorphine dose is less than 12 mg
- 3-day dose = 32 mg when the 24-hour buprenorphine dose is greater than 12 mg.

The client should be reviewed in the week following the first 72-hour dose, and the dose titrated accordingly. If a client cannot be stabilised on a triple-dosing regime, they can return to a double-dosing regime.

Table 11: Double- and triple-dosing with buprenorphine

Daily dose (24 hours)	Two-day dose (48 hours)	Three-day dose (72 hours)
4 mg	8 mg	12 mg
6 mg	12 mg	18 mg
8 mg	16 mg	24 mg
10 mg	20 mg	30 mg
12 mg	24 mg	32 mg
14 mg	28 mg	Not advised
16 mg	32 mg	Not advised
18 mg and over	32 mg	Not advised

Some clients attempting double-dosing may benefit from doses greater than 32 mg. However, there is limited evidence regarding the safety of higher doses, and buprenorphine is registered in Australia with a maximum recommended dose of 32 mg. Practitioners should be aware of the medico-legal implications of off-label prescribing before they prescribe doses greater than 32 mg. In these cases, frequent clinical and hepatic monitoring should be undertaken because of the increased potential for adverse consequences.

6.5.6 Take-away doses

Supervised dosing is an essential component of methadone and buprenorphine treatment and, in general, doses should be consumed under direct supervision[97]. Research shows supervision significantly improves retention and outcomes with buprenorphine[98]. However, there are circumstances where the prescriber may appropriately authorise either a one-off dose or regular take-away doses. Because of the safety risks associated with providing take-away doses, restriction and monitoring are necessary. Risks include:

- accidental overdose or death of the client or another person (the risk of an accidental overdose is much greater for children or opioid-naive adults)
- dose diversion
- self-administration by injection, resulting in toxicity, bacterial infection or the spread of blood-borne viruses. It is estimated that at least 0.1 per cent of methadone and buprenorphine/naloxone doses in Queensland are injected. This rises to more than 1 per cent for buprenorphine mono[99].

97 Lintzeris et al 2006
98 Auriacombe, Franque, Daulouède, Brisseau-Gimenez, Tignol 2002
99 Smirnov and Kemp 2012

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Despite the dangers of their inappropriate use, giving select clients controlled access to take-away doses can provide benefits. Take-away doses can reinforce adherence to program goals and objectives. Take-away doses can also encourage and empower clients to take responsibility for their drug use and to play an active role in their treatment. Providing take-away doses can promote a trusting relationship between staff and clients, and free the client from the need to attend the pharmacy or clinic daily. The increased normalisation of the client's education, training, employment and home duties improves the chances of recovery.

6.5.7 Authorising take-away doses

The decision to provide a client with take-away doses requires clinicians to consider each case individually, taking into account the client's stability, reliability and progress, as well as the quantity of methadone or buprenorphine to be dispensed.

Factors demonstrating stability include:

- evidence the client is not engaging in continuing hazardous or unsanctioned concurrent substance use. (Evidence of hazardous use should be based on history, self-report, examination of injection sites for evidence of recent drug injection, urine testing, observation for signs of intoxication or withdrawal, and feedback from others involved in the client's care)
- regular presentation for dosing as prescribed
- no evidence of diversion of administered doses or take-away doses
- adherence to any care plan in place
- living in stable and secure accommodation
- regular and reliable contact with the prescriber or case manager
- history of responsible use of take-away doses.

Instability or unreliability in a client who is receiving take-away doses should prompt a review of take-away dosing arrangements. The prescriber must be satisfied that reduced dosing supervision will not encourage unsanctioned opioid use.

Clients should be able to provide adequate and safe storage arrangements for their take-away doses and should understand the potential risks of accidental ingestion by children before they are considered sufficiently reliable to receive take-away doses. Clients should also show they understand the dangers that ingestion of take-away doses poses to non-tolerant adults.

Providing take-away doses is a clinical decision and it is paramount that reasons for providing take-away doses be clearly documented in the client's clinical file. The factors that demonstrate stability should be recorded. Comprehensive and accurate documentation is critical to delivering safe and effective treatment to clients on the opioid treatment program. Documentation informs other clinicians involved in the clientcare, satisfies medico-legal proof requirements and allows monitoring through audits.

6.5.8 Clients receiving buprenorphine

All clients on buprenorphine mono suitable for take-away privileges should receive their take-away dose in the form of buprenorphine/naloxone. Using the combination product for take-away doses reduces non-conformity in taking the mono product and the harms that may follow.

- Stable clients may receive buprenorphine mono if they are not receiving any take-away doses.
- Clients on buprenorphine mono, who are assessed as suitable for regular take-away doses, can receive similar numbers of combination product take-away doses. The number of take-away doses can be increased over time if stability continues. If the client remains on the mono product, the prescriber should clearly document on the written instruction whether take-away doses are to be buprenorphine mono (for pregnant clients or people who are allergic to naloxone) or the combination.

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6.5.9 Contraindications to providing take-away doses

The following should be considered absolute contraindications to providing take-away doses:

- repeated intoxication on presentation for dosing or treatment reviews
- being intoxicated on presentation to collect take-away doses.

Other contraindications to providing take-away doses are:

- diversion of methadone or buprenorphine within the past two months
- habitual injection of methadone or buprenorphine
- chaotic and unpredictable behaviour at present
- current hazardous use of drugs (including alcohol)
- risk to child safety. That is, the client cannot demonstrate or guarantee that their storage and handling of take-away doses meets safety standards.

In assessing whether the use of alcohol or other drugs is hazardous, consider whether the client's alcohol or drug use presents a danger of overdose. If take-away doses are to be provided, the prescriber must be satisfied the combination of drugs consumed does not represent a hazard to the client. The prescriber must also be satisfied the ongoing consumption of drugs other than methadone or buprenorphine does not reflect client instability.

6.5.10 When to stop providing take-away doses

Once a client is receiving take-away doses, they may become very distressed at any suggestion that their continued access to take-away doses will be curtailed. This is one of the most difficult issues for the prescriber or clinician to manage. Clinicians usually have good relationships with their clients and may be unwilling to cause distress and conflict. There is often considerable pressure on clinicians to overlook a client's instability and continue to authorise take-away doses. This is not good clinical practice.

It is common for drug-dependent clients to do well in treatment for a time, and then, due to changes in life circumstances or unknown reasons, relapse to periods of drug use. This does not necessarily mean a return to opioid use, but may involve other drugs such as stimulants, benzodiazepines or alcohol. While it is not possible to control the behaviour of others, it is possible to intervene to reduce the risks associated with destructive drug use, and supervised daily dosing is an important measure to reduce risk. Clients exhibiting instability are not suitable for regular take-away doses, and if a person receiving take-away doses develops, for example, an alcohol problem or another indicator of instability, they may need to return to supervised dosing.

Issues showing a client may need to return to supervised dosing include:

- self-report or clinical evidence of relapse to opioid or other dependent drug use
- evidence of diversion
- recent injection marks
- deterioration in psychological, physical or social wellbeing.

Re-introduction of take-away doses should only occur after at least 12 weeks of evident stability and any re-introduction should be gradual.

6.5.11 A stepped approach to providing take-away dose

The majority of opioid treatment programs in Queensland use community pharmacies to dispense methadone and buprenorphine doses. Apart from seven-day trading pharmacies, most pharmacies are closed on Sundays and public holidays. It is, therefore, necessary for clients to receive a take-away dose for these days, providing the client is considered to be sufficiently stable and likely to adhere to the prescribed treatment. New clients undergoing induction onto opioid treatment who do not meet criteria for take-away doses and clients who require supervised dosing should either be placed with a seven-day pharmacy or required to attend an opioid treatment clinic (when available) for dosing on Sundays and public holidays.

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As an alternative to take-away doses, clients on buprenorphine may be double-dosed on Saturdays. If a client is using other substances, such as cannabis or benzodiazepines, even at doses and in a manner that suggests they are not at obvious risk of overdose, double-dosing remains the preferred treatment approach. In circumstances where double-dosing is not possible – for example, when the daily dose exceeds 16 mg or when the dose is too low for double-dosing to be effective – a Sunday take-away dose of the combination product may be allowed when there is no accessible Sunday dosing option.

If a pharmacy is closed on both Saturday and Sunday, alternative arrangements must be made. For example, double- or triple-dosing should be considered for clients on buprenorphine.

In the following areas, stability should be judged according the criteria laid down in 6.5.7.

6.5.12 Methadone take-away doses

New clients – of the clinic or prescriber – during the first 3 months

There should be no access to additional take-away doses, except in the most exceptional circumstances. Prescribers will need to consider when each newly admitted client is stable enough to receive take-away doses for Sundays or public holidays. The 3 month limit below does not apply to Sunday or public holiday doses.

After a minimum period of 3 months in treatment: 2 take-away doses

After a minimum of 3 months' continuous stability in treatment, the client may receive 2 take-away doses per week as long as they continue to meet the criteria for stability.

After a minimum period of 6 months in treatment: 3 take-away doses

If the client remains stable while receiving 2 take-away doses per week and they have been in treatment for more than 6 months, they can be considered for 3 take-away doses per week. Again, this can continue for as long as the client meets stability criteria.

After a minimum period of 9 months in treatment: 4 take-away doses

If the client remains stable while receiving 3 take-away doses per week and they have been in treatment for more than 9 months, they can be considered for 4 take-away doses each week. This can continue for as long as the client meets stability criteria.

6.5.13 Buprenorphine/naloxone take-away doses

Reflecting the greater safety offered by the combination product, an accelerated stepped approach applies to buprenorphine/naloxone take-away doses.

New clients – of the clinic or prescriber – during the first 2 months

There should be no access to additional take-away doses, except in the most exceptional circumstances, during the first 2 months. Prescribers will need to consider when each newly admitted client is stable enough to receive take-away doses for Sundays or public holidays. The 2 month limit does not apply to Sunday or public holiday doses.

After a minimum period of 2 months in treatment: 2 take-away doses

After a minimum of 2 months' continuous stability in treatment, the client may receive 2 take-away doses each week as long as they continue to meet the criteria for stability.

After a minimum period of 3 months in treatment: 3 take-away doses

If the client remains stable while receiving 2 take-away doses per week and they have been in treatment for more than 3 months, their take-away doses can be extended to three per week. Again, this can continue for as long as the client meets stability criteria.

After a minimum period of 4 months in treatment: 4 take-away doses

If the client remains stable while receiving 3 take-away doses per week and they have been in treatment for more than 4 months, they can be considered for 4 take-away doses each week. This can continue for as long as the client meets stability criteria.

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