Supervised Self Administration of Methadone and Buprenorphine

Guidelines for Pharmacists And Pharmacy Technicians

April 2007
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Introduction

The guidelines below outline the background to and the Standard Operational Procedures and administrative processes for the Central Lancashire PCT Supervised Self Administration Scheme for Methadone and Buprenorphine (Subutex®). This document also contains an application for those interested in joining the scheme (see page 34).

Pharmacy services for drug users qualify as locally Enhanced Services under ‘The Contractual Framework for Community Pharmacy’ and as such participation by community pharmacists in this service remains voluntary and guided by localised need. However, those who join the scheme will have a contractual obligation to adhere to these guidelines and to input as appropriate into the ‘shared care’ of substance users.

Pharmacists participating in this service will be expected to take on the number of clients that they feel appropriate for their pharmacy within the parameters of good practice advised by the local Community Drug & Alcohol Team, taking into account all their community responsibilities.

Models of Care, introduced by the National Treatment Agency in 2002 outlines a four tier system of service provision based on the principles of National Service Frameworks. The aim is to provide treatment through integrated care pathways across these four tiers. Pharmacists are regarded as a tier one service in Central Lancashire PCT, a non-substance misuse specific service, but which offers advice and support to substance users. The Models of Care pathway developed for Supervised Self Administration of Methadone and Buprenorphine is shown in Appendix 1.

One key element of drug treatment for opiate users is the prescribing of Methadone or Buprenorphine. Studies have shown that Methadone Maintenance Treatment reduces levels of injecting drug use and associated health problems, acquisitive crime and drug related death among those in treatment. Thus the Clinical Guidelines believe it to be ‘an important part of drug misuse services’ (DoH, 1999:45). Prescribing substitute medications allows time for individuals to implement personal or social changes that can reduce the impact of their illicit drug use and is a key element to increase the opportunities of individuals to achieve their goals.

Across Central Lancashire opiate substitution treatment services are managed by (a) local Substance Misuse Services (SMS) (formerly Community Drug Teams (CDT)), (b) through Shared Care, a partnership arrangement between GPs, SMS, LCT and the PCT, where patients are seen in Primary Care and (c) Addaction.
The Role of Community Pharmacy

Pharmacists play a key and unique role in the care of the substance users. ‘Key’, in that through the supervision of consumption of methadone or buprenorphine, the pharmacist is instrumental in supporting drug users in complying with their prescribing regime, therefore reducing incidents of accidental death through overdose. Also through supervision, pharmacists are able to keep to a minimum the misdirection of controlled drugs, which may help to reduce drug related deaths in the community.

The ‘unique’ role that pharmacists play in the treatment of drug users is the daily contact that they have with their patients, and their ability to monitor and offer advice on the patient’s general health and well being. By integrating the pharmacists into the ‘shared-care’ service this gateway role can be developed to maximise the positive impact treatment has for patients.

An important consideration however is that adhering to daily supervision regimes reduces opportunities for individuals to integrate back into society through employment, education, holidays etc. It is important that once the patient is stabilised and feeling confident, that the opportunity to increase their take home doses is fully considered. In line with the ‘Drug Misuse and Dependence – Guidelines on Clinical Management’ take home doses are unlikely to be provided for the first three months. At times of crisis or relapse, supervision may need to be temporarily re-instated. It should be noted that re-instatement dose may not be the same as the most recent dose. This should not be seen as a failure, as making changes to drug use and habitual behaviours can be a lengthy process with ‘lapsing’ a common feature.

It is therefore important that the patient attends the same pharmacy with each new prescription and that the pharmacist is supportive with an understanding attitude. The relationship between patient and pharmacist should ideally be friendly, but professional.

Methadone Substitution

Methadone is a long acting agonist for opioid receptors. One oral dose per day can eliminate the need for opiates but there may still be a craving for opiates and for injecting. Methadone is most frequently prescribed as methadone mixture 1mg/ml, which is unlikely to be injected. The half-life of methadone is approximately 1-2 days. This makes it particularly suitable for once daily dosing.

Methadone maintenance treatment has been shown to have a protective effect, reducing overdose among those in treatment. It is also linked to reductions in crime IV use and injecting related harm. Patients stabilised on methadone should be alert and coherent.

Methadone is a schedule 2 drug subject to full controlled drug requirements relating to prescriptions, safe custody, the need to keep registers etc.
Buprenorphine Substitution

Buprenorphine is available in 0.4mg, 2mg and 8mg sublingual tablets. The tablets are administered sublingually because it has poor oral bioavailability – inactivated by gastric acid and a high first pass metabolism.

High doses of buprenorphine produce milder, less euphoric and less sedating effects than high doses of other opioids. Clients locally have also reported that it has less sedating effects and a less euphoric high leaving them clearer headed.

Buprenorphine is a mixed agonist/antagonist. It partially activates the mu opioid receptors whilst exerting sufficient opiate effects to prevent or alleviate withdrawal. It has a high affinity for the mu receptors and binds more tightly than methadone or heroin. It also binds strongly to the kappa opioid receptors where it acts as an opioid antagonist. In doing so it reduces the effects of using opiates on top of buprenorphine.

Buprenorphine is relatively safe during pregnancy and breastfeeding with less frequent, severe and shorter neonatal withdrawal than with methadone. It may be better suited to those wishing to cease heroin use.

The RCGP (2004:2) recognises that:

There is a growing body of evidence that treatment for opioid dependence can be effective. Buprenorphine is an effective, safe medication for use in the treatment of opioid dependence and is a valuable addition to the formulary of medications for treating opioid dependence.

Buprenorphine is also reported to have lower overdose potential, although caution should still be exercised when prescribing to patients using other CNS depressants such as alcohol, benzodiazepines, barbiturates, neuroleptics and tricyclic antidepressants.

Buprenorphine is a schedule 3 drug subject to special prescription requirements and must be kept in a CD cabinet, but there is no requirement to keep registers – although invoices must be retained for 2 years.

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1 See RCGP (2004) ‘Guidance for the use of buprenorphine for the treatment of opioid dependence in Primary Care’, for further details. Copy to be found in references section of this guidance.


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4
The Need for a Supervised Methadone and Buprenorphine Self-Administration Programme

The supervised consumption of opiate substitution treatments can:

- Prevent sale on the black market.

- Provide an opportunity for the pharmacist to build a rapport with the patient, which is to the patient’s benefit and may well result in more orderly behaviour within the pharmacy.

- Provide an opportunity for the pharmacist to make a daily assessment of compliance with the programme and of the general health and well being of the patient and advise accordingly.

Whilst supervision is desirable when patients enter the programme, it should also be noted that supervision itself may create a secondary dependence. It is important that once the patient is stabilised that they are trusted to accept a degree of responsibility, by extending treatment to the introduction of ‘take home’ doses. For example, from daily to twice weekly down to once weekly.

Methadone

Although Methadone Mixture has a relatively low street value, there may be a temptation for the client to sell the daily dose to help pay for a more euphoric alternative. In most cases it is preferable that self-administration of the daily dose of methadone is supervised by a pharmacist at the initiation into treatment. Through daily observation the pharmacist can monitor that adequate blood and tissue levels of methadone are maintained, therefore reducing the need for additional opiates.

Supervising the self-administration of methadone to patients on a daily basis has emerged as a key component of methadone programmes. Supervised consumption is recommended by the Clinical Guidelines for a minimum of 3 months or until patient compliance with treatment is achieved. This has the additional benefit of reducing the overdose risk during induction into treatment and reducing the diversion of methadone which also contributes to drug related mortality among those not in treatment both nationally and locally.

Methadone has a narrow safety window and small amounts can be lethal for those not used to it, which makes diversion a particular concern. Moreover, tolerance can drop quickly such that missed doses resulting in reduced opiate tolerance increase the risk of accidental overdose.
Buprenorphine

Currently Buprenorphine is associated less with abuse although evidence suggests it is traded on the black market for oral consumption. However, in the late 1980s in Glasgow there was widespread abuse of Buprenorphine where, due to its ready solubility, it was prepared and injected. Similar health problems and injecting related complications have been found in France where monthly dispensing resulted in approximately a half of clients injecting their own buprenorphine. A study of treatment centres in France reported 52% experiencing medical complications from injecting the drug with 33% experiencing hospitalisation as a result. 4 Reports suggest buprenorphine injection is associated with acute hepatitis in patients with Hep C. 5

On the basis of the Scottish experience the clinical guidelines concluded that ‘safeguards such as daily dispensing, with supervised consumption, should be inherent to any well-delivered buprenorphine substitution programme’ (DoH, 1999:39)

There has recently been much debate regarding crushing buprenorphine tablets as part of supervised consumption programmes. Crushing buprenorphine tablets is not included in the product licence. However, doing so can significantly promote client compliance through on-premises consumption given the practical difficulties of effectively supervising consumption of whole tablets which can take 5-10 minutes to dissolve under the tongue and possibly longer depending on the dose. Ineffective supervised consumption is associated with the development of a market for partially consumed buprenorphine tablets, referred to as ‘fuzzies’ by users in some parts of the country. 6 In Australia it is mandatory in certain states, including Victoria, to crush the buprenorphine tablets unless a prescriber specifically requires otherwise. 7

This debate has culminated in:

- The Royal Pharmaceutical Society of Great Britain (RPSGB) releasing guidance to members advising that crushing can take place where the pharmacist and client agree to this course of action, the pharmacist is confident that this is in the best interests of the client, and it does not compromise the efficacy of the treatment.

- The National Pharmaceutical Association (NPA) advising members that they will indemnify members crushing buprenorphine, against the licence, as long as they comply with a defined protocol for doing so. See appendices 2 and 3 for further details. Note: this covers NPA members only.

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5 Ibid.
6 Posting to SMMGP discussion group.
7 NPA Guidance ‘Supervised Subutex Supply – Professional Indemnity’ see appendix 2.
There are some key principles of the NPA and RPSGB guidance:

- There **must be collaboration** between pharmacist, prescriber and client to ensure that everyone understands:
  - the objectives behind a supervised scheme
  - the reasons for the crushing of Subutex®
  - that crushing is without the manufacturer’s marketing authorisation
  - there is clear understanding of the clinical and logistical implications of crushing.

- Pharmacies crushing Subutex® need to be satisfied that crushing is in the patient’s best interest; crushing must be for the benefit of the patient rather than the convenience of the pharmacist. Pharmacies need to be satisfied that there is a true clinical need for crushing. They also need to consider the potential for distortion of the bioavailability profile of Subutex® as a result of crushing.

Clinicians in Central Lancashire have sought to provide a supervised consumption protocol for crushed Subutex® on the grounds that it increases the efficacy of treatment by significantly reducing opportunities for diversion and non-compliance with the treatment regime. This is especially important during induction into treatment and as an option available if there are concerns about compliance in later stages of treatment process.

With regard to bio-availability there are a number of precautions pharmacist should take to ensure maximum bioavailability of buprenorphine when crushed:

- Bio-availability is seriously reduced if taken orally – studies suggest ½ bioavailability of oral compared to sublingual administration. Therefore even crushed it should be deposited under the tongue to dissolve. The manufacturers suggest that the active ingredients should be gone by 2-3 minutes.

- Some pharmacists are also concerned about reduced availability due to wastage in crushing. Even breaking the tablet along the score line will speed up dissolution and reduce value on the black market as the saliva will have begun to dissolve the matrix. In Australia advice is not to crush to a fine powder but to granules so that less of the medication clings to the crusher. Loss due to crushing appears to be highest with low dose pills and negligible with higher dose pills.

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9 Posting to SMMGP discussion group 19/04/05
10 Posting to SMMGP discussion group 01/4/04 from Community Pharmacist.
11 Posting to SMMGP discussion group 01/4/04
12 Posting to SMMGP discussion group 02/04/04, Shared Care Substance Misuse Manager based on local London trial prior to commencement of crushing scheme.
• A trial in Australia showed that crushing to granules led to no apparent change in bioavailability.\textsuperscript{13}

**Aims and objectives of the service**

To ensure compliance with the agreed treatment plan by;

• Dispensing prescribed medication in specified instalments

• Ensuring each supervised dose is correctly administered to the patient for whom it was intended (doses may be dispensed for the patient to take away to cover days when the pharmacy is closed)

• Liaising with the prescriber, named key worker and others directly involved in the care of the patient (where the patient has given written permission)

• Monitoring the patient’s response to prescribed treatment; for example if there are signs of overdose, especially at times when doses are changed, during titration of doses, if the patient appears intoxicated or when the patient has missed doses and if necessary with holding treatment if this is in the interest of patient safety, liaising with the prescriber or named key worker as a appropriate

• Improving retention in drug treatment

• Improving drug treatment delivery and completion

To reduce the risk to local communities of:

• Overuse or underuse of medicines

• Diversion of prescribed medicines onto the illicit drugs market

• Accidental exposure to the dispensed medicines

\textsuperscript{13} Posting to SMMGP discussion group 12/3/04
Operational Procedures

Outlined below are the Operational Procedures for delivering substitution therapy with supervised consumption via pharmacies. All staff, including locums, should be aware of the following procedures. It is these procedures, along with the key principles outlined immediately above, which constitute a robust protocol. The operational procedures below make specific reference to buprenorphine, integrating all elements of the NPA model protocol.

Accepting new clients into Supervised Consumption

- The prescriber, usually the Substance Misuse Service will ask the client which pharmacy participating in the supervised self-administration programme, would be most convenient for daily visits and at what times.

- The prescriber will contact that pharmacist before issuing the first prescription to ensure the pharmacist has the capacity to accept the client at that time.

- The prescriber or keyworker will complete the Patient Identification Form with the client including signing the form and stamping it with an official clinic stamp. (see appendix 4)

- Clients will be briefed by the prescriber on the date of commencement of supervised administration. The prescriber should inform the client fully of what is expected when commencing supervised administration. In doing so the prescriber will inform the client that the pharmacy will enter into a contractual arrangement with the client which the client will be expected to adhere to.

- The client will attend the pharmacy with their prescription for supervised methadone or buprenorphine administration as agreed with the prescriber or keyworker. The Patient Identification must accompany the prescription.

- For clients in receipt of crushed Subutex® a signed agreement should be sought from both the prescriber and client as confirmation that they understand the implications associated with supervised supply of crushed Subutex® and that they agree to participation on this basis. See appendix 3 for the model supplied by the NPA.

Patient contracts

- Clients may have a written contract with the SMS, part of which covers behaviour in the pharmacy. However, it is important that pharmacists use the agreement (Appendix 5), outlining in greater detail the procedure for daily supervision.

- The aim of the agreement is to reduce the potential of misunderstandings and bad feeling to arise between client and pharmacist.
Clients should be informed in advance of what arrangements you make for when the pharmacy is closed.

In addition the client should be given a practice leaflet detailing additional professional services offered by the pharmacy. Health promotion is an important issue for this group of patients and pharmacists should take every opportunity to provide advice on diet, exercise and oral hygiene.

**Identification of clients**

- The clients’ identity must be checked to ensure the prescription is dispensed to the correct person.
- The Patient Identification Form (appendix 4) aims to assist this process.
- If there is any uncertainty with the identity of the client the prescriber must be contacted and the dose withheld until the individuals identity is ascertained.

**Controlled drugs prescriptions**

Controlled Drug prescriptions are subject to additional regulation and therefore must be checked before medication is dispensed.

- The prescription must be checked for legality
  Statutory instrument No2005/2864 has amended the Misuse of Drugs Regulations 2001 to allow all details, including the date, to be computer generated. This removes the need for doctors to apply for handwriting exemptions to computer generate prescriptions. However, the *signature must be handwritten*.

- Methadone should be prescribed on FP10 (MDA) for no more than 14 days.

- Buprenorphine may be prescribed on FP10 (MDA) or FP10HP(AD).

- If the starting date for dispensing is other than the date of writing the prescription, this must be clearly stated. Start dates should always be clear to prevent the possibility of obtaining two doses at the end of one prescription and the beginning of another.

- The prescription should provide clear dispensing instructions. The amount of the instalments and the intervals to be observed must be specified. Prescriptions ordering ‘repeats’ on the same form are not permitted.

- The prescription must specify clearly that supervision is required.

- The prescription should also state if the Subutex®/buprenorphine tablets are to be crushed.

- The prescription should not be in any way tampered with, or in a condition where the instructions are no longer clear – e.g. water damaged, torn etc.
The Home Office have recently confirmed that prescriptions can now be worded as follows ‘Instalment prescriptions covering more than one day should be collected on the specified day; if this collection is missed the remainder of the instalment (i.e., the instalment less the amount prescribed for the day(s) missed) may be supplied’,\(^\text{14}\) this provision should be used in exceptional cases only, and the prescriber must alert the pharmacist that this instruction is to be made. The pharmacist should also notify the prescriber when this occurs.

**Emergency supply** of methadone mixture and buprenorphine – The Misuse of Drugs Act does not allow for the ‘emergency supply’ of Schedule 2 or 3 Controlled Drugs (exemption – phenobarbitone or phenobarbitone sodium for epilepsy). Doses should never be given in advance of receipt of a valid prescription at the pharmacy. Phoned or faxed prescriptions for controlled drugs are also illegal.

Pharmacists must satisfy themselves of the legality of the prescription, and its clinical appropriateness. If you have any doubts about the validity of the prescription – contact the prescriber.

If a client’s prescriber changes, the clinic or service should inform the pharmacist of this change.

**Preparation of medication**

- **Methadone** - The daily amount should be measured into a container, capped and labelled. When the client arrives, ideally the measured dose may be poured into a disposable cup. Please note drinking medicines directly from the bottle can set a bad example to children in the pharmacy.

  **The RPSGB issued guidance on the extemporaneous preparation of methadone mixture in February 2006.**

  - *If a licensed product is available, methadone mixture should only be prepared extemporaneously if the quantity of methadone dispensed on regular basis is large enough to preclude storage of sufficient quantities of the licensed product.*
  - *SOPs must be in place for the extemporaneous preparation of methadone*
  - *It is essential that robust standards and systems are in place to ensure the quality of extemporaneously prepared methadone so that patient care is not compromised*

- **Buprenorphine** – The prescribed tablets should be removed from the foil and placed an appropriate container. If they are to be crushed they should be crushed into granules rather than a fine powder, in the client’s presence. This way the client can confirm their dose before the medication is crushed. An appropriate crushing device should be used that minimises any loss of dose and has the confidence of clients.

It is important that the dose is ready for the client’s arrival. The whole operation should be as discreet and efficient as possible, maintaining the patient’s dignity and saving the pharmacist’s time.

Doses that are collected to be taken on Sundays or bank holidays must be dispensed in a container with a child resistant closure. Clients must also be advised to store their medication out of the reach of children.

**Discreet and efficient supervision by pharmacist or registered pharmacy technician**

Administration should take place in a discreet area and/or at times when the pharmacy is not likely to be busy, as agreed with the pharmacist. This will be discussed with pharmacies as part of the application process.

- Methadone - The pharmacist or pharmacy technician, see additional requirements below, must be satisfied that the dose has actually been swallowed, for example, by water being swallowed after the dose or conversing with the client to ensure that the methadone is not retained in the mouth. ‘Spit Methadone’ has a street value and some clients may be under a great deal of pressure to hand over their dose to others.

- Buprenorphine – the tablet or crushed granules must be tipped directly under the tongue without handling and the client supervised by the pharmacist or pharmacy technician until the tablets have dissolved – this can take 3-7 minutes depending on the dose, the client and whether the tablets have been crushed. Providing or advising the client to bring a drink of water with them for consumption before administering their medication, will help speed up the process. Clients should be advised that increased or excessive saliva production may reduce the effectiveness of the drug and is not desirable, and that saliva should be kept in the mouth rather than swallowed during dissolution. You may also wish to inform them that the medication has a bitter taste.

**Supervision by a registered pharmacy technician**

The accredited pharmacist providing this service may delegate the role of supervising the self-administration of Methadone and/or Buprenorphine to a registered pharmacy technician, provided that clients using the service for the first time, or re-commencing treatment following relapse, are supervised by the accredited pharmacist for the first 4 weeks of treatment. Thereafter the pharmacy technician may be delegated this role. However overall responsibility and accountability will remain with the pharmacist.

Please note this service cannot be initiated or provided solely by an accredited pharmacy technician. At all times, including during supervision by the accredited pharmacy technician an accredited pharmacist must be present and accountable, except for annual leave and sick leave (see steps 7, 8 and 9 below).
Pharmacist Training & Qualifications

Pharmacists routinely involved in the provision of this service should have completed or have plans to complete within 6 months of joining the scheme:

- The distance learning package ‘Substance Use and Misuse” available from the Centre for Postgraduate Pharmaceutical Education. This is available online and takes approx 10 hours. Information is available from www.cppe.man.ac.uk

OR

- The Royal College of General Practitioners Pt 1 Certificate level Training for the Management of Drug Misuse in the Primary Care Setting’. This course has been made available to Pharmacists and includes 2 online modules which take approx 2 hours each and one locally organized face-to-face training session equivalent to 6 hours Continuing Professional Development. Information is available from www.rcgp.org.uk

The Substance Misuse in General Practice website is also a useful source of information and guidance and contains discussion groups to support those working with substance users. This can be found at www.smmgp.co.uk

The UK psychiatric pharmacists’ substance misuse e-mail group (www.ukppg.org.uk) is another forum for discussion.

If a pharmacist signs up not having completed their qualification, successful completion will be expected within 6 months of their being accepted on to the programme. The PCT must be informed once the qualification has been awarded.

Local training will also be provided by Central Lancashire PCT and the SMS at the commencement of the scheme and updates if there are significant changes to clinical practice.

Pharmacy Technician Training & Qualifications

Pharmacy Technician’s involved in the provision of this service must be registered with the RPSGB, have an up to date CPD portfolio and have completed the CPPE distance learning package “Substance Use and Misuse: fundamentals and practicalities for the pharmacy technician.” This is package is available online and takes approx 6 hours. Information is available from www.cppe.man.ac.uk

Pharmacists and pharmacy technicians participating in the service must:-

1. Ensure compliance with all legal and professional requirements.

2. Ensure they have appropriate insurance cover.

3. From Jan 1st 2005 the pharmacy must have a Standard Operating Procedure (SOP) for all personnel operating the scheme. If a pharmacy technician is to provide this service the SOP must make specific reference to their role and responsibilities, highlighting steps in the
procedure where referral to the pharmacist is necessary. SOPs are intended to support staff working in the community by setting out strategies for risk management and harm reduction that comply with clinical governance requirements. The NPA provides guidance for developing Standard Operational Procedures for dispensing schedule 2 and 3 controlled drugs (see www.npa.co.uk).

4. Supervise the daily consumption of methadone mixture (1 mg per ml) or buprenorphine 0.4mg, 2mg or 8mg sublingual tablets in accordance with the prescribers wishes;

5. Follow the procedures recommended in local guidelines.

6. Respect patient confidentiality at all times.

7. Ensure an accredited pharmacist or an accredited pharmacy technician, provided the first 4 weeks treatment is supervised by an accredited pharmacist, provides this service at all times. This excludes locums covering holidays or sick leave, however regular locums require accreditation (see point 9).

8. Inform the PCT if there is an interruption to the delivery of this service for longer than 2 weeks duration by an accredited pharmacist. See appendix 9 ‘Changes in the provision of Supervised Self Administration of Methadone or Buprenorphine by Accredited Pharmacist’.

9. Ensure new staff or locums are fully aware of the SOP and are able to enact this agreement appropriately. Regular locums should undergo accredited training.

10. Allow regular audit of service provision and patient records in line with PCT requirements and those to be developed by a Controlled Drugs Inspectorate and the Healthcare Commission.

Liaison

Pharmacists should develop and maintain close links with prescribers and drugs services.

The pharmacist may be contacted by the prescriber/keyworker:

- For feedback after the first week of treatment
- After three months to feed into the review of the care plan/treatment package
- As required, to update on treatment goals or any significant issues regarding the management of the clients treatment package.

At all other times all steps should be taken to maintain the client’s confidentiality, with all staff protecting the privileged information they are party to by not divulging anything about the clients outside of the pharmacy.
Daily contact with the client may allow the pharmacist to provide health promotion support and monitor patient compliance, suspected alcohol/drug intake, physical appearance and family support. People who are dependent on substances often have difficulty in accessing help and other social care.

As you get to know the patient you may be in a position to notice deterioration in their health.

The LPC supports the pharmacist developing a more formal role in monitoring and review.

Premises

Pharmacies, which offer the Supervised Methadone and Buprenorphine Self Administration Service, shall have the following facilities:

- a patient medical records system
- appropriate storage conditions for the increased supply of methadone/buprenorphine.
- a consultation area that is fit for purpose for administering methadone/buprenorphine to clients under supervision, as determined by the PCT. The prescriber should discuss this with the client when selecting a pharmacy. In agreement with the pharmacist the client may choose not to consume their supervised medication in the consultation area but in another area of the pharmacy that is fit for purpose. In all circumstances the pharmacy must have a fit for purpose consultation area.
- an area for display of relevant health promotion leaflets including advice on the safe and secure storage of medicines.

Disposal of waste

Labels should be removed from containers and the container rinsed and immediately discarded.

Waste should be disposed of safely and steps taken to minimise risks of infection through meticulous hygiene and vaccination of staff if required.

Recording of information

Pharmacists may delegate but ultimately are responsible for maintenance of each client’s Patient Medication Record. This should include if Subutex®/buprenorphine tablets have been crushed. You should be able to record daily attendance, missed doses and other concerns that you may need to report back to the prescribers. Thus the Patient Medication Record should note any additional services (e.g. general medical information) or advice provided to clients, referrals made on their behalf and liaison with the prescriber.
The Record of Medication Administered must also be completed—this allows you to record the total number of daily supervised consumptions conducted and is also used for remuneration purposes. See Appendix 8 for this pro forma and guidance regarding completion and submission.

These forms will be regularly audited by the PCT in line with the increased requirement for PCTs to monitor the use of controlled drugs in their areas.

Controlled Drugs Register must also be completed for methadone and invoices, requisitions, orders for Buprenorphine must be kept for 2 years. Subsequent to statutory Instrument 2005/2864 a controlled drugs register may be computerised and copies of this register may be requested by the Secretary of State or an authorised person. Requisitions and orders for buprenorphine may be preserved in original form or as a copy on computer.15

**When to contact the prescriber**

You should contact the prescriber in the following circumstances:

- **The patient does not consume the whole dose under supervision**
- **The patient appears to be ill**
- **The patient tries to avoid supervision or the process for proper administration.**
- **The patient appears to be intoxicated** - Clients stabilised on methadone or buprenorphine should be clear-headed and coherent. If the pharmacist considers the client is grossly intoxicated, the prescriber should be contacted and the dose withheld.

  Methadone taken on top of other opiates, alcohol or benzodiazepines may increase the sedative effects leading to respiratory depression and potential overdose.

  Buprenorphine is a partial opiate antagonist and, in isolation is less likely to cause overdose in opiate naive individuals, although it is still a risk. The risk with buprenorphine is also increased when taken in combination with alcohol and benzodiazepines.

- **The patient misses doses** –

  _Missed doses may result in a drop in opiate tolerance with an increased risk of accidental overdose._

  If a client comes in after having missed three consecutive doses, their dose should be withheld and they must be referred back to the prescriber.

  If clients regularly miss a single days dose, for example 3 doses in a 7-day period, the prescribing doctor must be informed.

---

15 See new regulation 24a which has been added to the 2001 regulations.
Missed doses should not be replaced or issued at a later date.

- **There are problems with the prescription** – e.g. uncertainty about dates, validity, has been tampered with etc.

- **The behaviour of the client is unacceptable** and contrary to the client/pharmacy agreement - ultimately only you can decide what behaviour is ‘unacceptable’. In circumstances where a dose is not administered, or you wish to cease future administrations, both the client and prescriber must be made aware of this decision.

Appendix 6 further outlines circumstances in which the pharmacist should contact the prescriber. The decision is a professional one that should be made after considering the risk to the patient of non-disclosure and the damage that may be done to the supportive relationship between the pharmacist and the patient. Patient confidentiality should be respected at all times.

Contact with the prescriber should be swift following any reason for concern and especially where does are missed or further administration has been withdrawn. Appendix 7 provides a proforma which can be completed and faxed, or completed and the details telephoned through to the prescribing agency. A copy of the original should be kept with the patient record for audit purposes. It is important that this information is relayed to the appropriate prescriber or keyworker for a client.

**Payments**

Payments will be made per supervision at a rate of:

- Methadone £1.50 per dose supervised
- Buprenorphine/Subutex £1.50 per dose supervised

It is recognised that there is no differential in payments to compensate for the additional time incurred in ensuring that the Buprenorphine tablet(s) has been appropriately consumed. Therefore authorised pharmacies can choose not to provide this aspect of the service provided that both the PCT and SMS have been notified of this decision.

Pharmacies will not be limited to numbers of clients that they “take on” at any one time as long as they can fulfil their obligations to providing a full and high quality service to clients.

Payments will be made monthly following the submission of the Pharmacy Record Form (Appendix 8). These forms should be sent to Customer Services at Lancashire and South Cumbria Agency (LASCA):

Claims Section
Lancashire & South Cumbria Agency
3 Caxton Road
Fulwood
Preston
PR2 9ZZ

These forms should arrive by the 7th of the following month to be paid at the end of the month. Payment against late forms will be held over until the end of the following month. Payments can only be made to pharmacies that have signed up to this scheme and have agreed to provide the service outlined above. Payments are Pharmacy not pharmacist based.
Applying to join the scheme

Pharmacies wishing to join the scheme should complete the application form on page 34 and indicate if they are prepared to provide both aspects of the service i.e. Supervision of both Buprenorphine and Methadone or just Methadone.

Leaving the scheme

If pharmacists wish to leave the scheme, or cease providing any aspect of the service at any point they should inform the PCT in writing of this intention, 28 days in advance. This will enable prescribers to make alternative arrangements allocating clients to alternative scheme providers.

Contact Details:

<table>
<thead>
<tr>
<th>Community Pharmacy Adviser:</th>
<th>Stephen Gough</th>
<th>Tel: 01772 676179</th>
</tr>
</thead>
<tbody>
<tr>
<td>Central Lancashire PCT</td>
<td>Central Lancashire PCT</td>
<td></td>
</tr>
<tr>
<td>Shared Care Manager:</td>
<td>Liz Jennings,</td>
<td>Tel: 07795 812793</td>
</tr>
<tr>
<td>Central Lancashire PCT</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Locality Manager:</td>
<td>Debra Bretherton,</td>
<td>Tel: 01772 773535</td>
</tr>
<tr>
<td>Central Lancashire PCT</td>
<td>Lancashire Care Trust (LCT)</td>
<td></td>
</tr>
<tr>
<td>Team Manager (Preston):</td>
<td>Alec Grimshaw (LCT)</td>
<td>Tel: 01772 676000</td>
</tr>
<tr>
<td>Team Manager: (Chorley and South Ribble)</td>
<td>Mags O'Neill (LCT)</td>
<td>Tel: 01772 645780 /</td>
</tr>
<tr>
<td>Team Manager: (West Lancs)</td>
<td>Dave Elsworthy (LCT)</td>
<td>Tel: 01695 50740</td>
</tr>
<tr>
<td>Shared Care Coordinator: (West Lancs)</td>
<td>Helen Jones (PCT)</td>
<td>Tel: 01695 566375 /</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Tel: 07917 658691</td>
</tr>
</tbody>
</table>
Appendices

These appendices provide further information and are for reference and illustrative use only.

Blank copies of all forms in these appendices are found in the resources section.

Acknowledgements

Teresa Rutter, Drug Related Death Researcher, Commissioning & Modernisation Blackpool PCT
Appendix 1 - Models of Care Pathway

Pathway

Pharmacy Pathway for the Observed Consumption of Methadone and Administration of Buprenorphine (Subutex®)

Aim

This is the pathway for clients who, in line with the guidelines on good clinical practice, require observed consumption of Methadone or Buprenorphine.

Who is this pathway for?

- Clients who are already receiving treatment, that includes prescribed drugs, from one of the services in Central Lancashire PCT.
- Clients who have a care plan in place

Who is the pathway not suitable for?

- Clients who have not yet been fully assessed.
Pharmacy Pathway for the Observed Consumption of Methadone and Administration of Buprenorphine (Subutex®)

Client requiring supervised consumption as part of treatment package

Telephone call by service provider to pharmacy to request supervision for new client. Name of client and details of prescription provided. Service provider to check prescription is legal & correct

Needle exchange scheme explained, as appropriate

See Needle Exchange Pathway

Code of conduct explained to client by service provider and signed by client

Client presents at pharmacy with prescription written by service provider. Identity of client confirmed

Pharmacist checks prescription details are correct and legal

FIRST VISIT

Pharmacist explains guidelines to client and introduces them to key members of staff Negotiates suitable time for collection of dose Prescription prepared

No Health Issues

Acute /other Health Issues

Information and advice provided, with reference to other health professionals e.g. Dentist Refer as appropriate

Assessment of client’s health and well-being

Regular attendance

Irregular attendance

Client fails to attend for three consecutive doses, further supply withheld. Contact service provider

Supervised consumption

Supply withheld Contact service provider

Re

g

ular attendance

Intoxicated

Client asked to come back later in day. Record action on client record sheet

Ref:
protocols on identification of clients
News release

For immediate release
Tuesday 29 March 2005

SOCIETY GUIDANCE FOR BUPRENORPHINE TABLETS

The Royal Pharmaceutical Society of Great Britain is issuing guidance to pharmacists regarding the crushing of buprenorphine sublingual tablets (Subutex) prior to administration. Crushing buprenorphine sublingual is outside of the manufacturer’s marketing authorisation and will render the product unlicensed.

Pharmacists who are considering crushing buprenorphine tablets prior to administration need to be satisfied that this is in the patient’s best interests as there is the potential for the product’s bioavailability profile to be distorted. The prescriber and the patient should agree to the tablets being crushed prior to administration – and the patient should be informed of the risks and the benefits of crushing. Any crushing of buprenorphine tablets should be for the benefit of the patient, rather than the convenience of the pharmacist.

A pharmacist may assume some liability for the supply of a product outside licensed indications and should ensure that their indemnity insurance covers such activity.

In support of this guidance, the National Pharmaceutical Association (NPA) is offering the following advice its members:

The NPA will indemnify NPA members involved in the provision of a crushed Subutex service, provided they comply with a defined protocol. Further details of this protocol can be found at the CDA channel on NPAnet, the Association’s member-only intranet.

Ends

For further information please contact Natalie Sticklen or Felicity Slayford in the Royal Pharmaceutical Society of Great Britain's Public Relations Unit
020 7572 2335/6
Background

Subutex (buprenorphine) is used as an adjunct in the treatment of opiate dependence. Subutex is a sublingual formulation and it is not uncommon for addicts, even where their administration is being supervised, to remove the tablet and then sell this on the black market or inject it.

As a result, it is now common place for addiction centres to request that the tablets are crushed prior to administration for those addicts where diversion is suspected or where a high dose means an unacceptably long waiting time for tablets to dissolve. The instances of crushing are on the increase. In Australia it is mandatory in certain states to crush the tablets unless a prescriber specifically requires otherwise.

Crushing Subutex is outwith the manufacturer’s marketing authorisation and so the manufacturer is unwilling to recommend or endorse the crushing of tablets. Their view is that no studies have been carried out on the impact of crushing the tablets. Crushing increases the surface area of the drug and will thus increase the dissolution and absorption of the drug. On the other hand, crushing increases saliva production which will enhance the possibility of swallowing unabsorbed drug therefore reducing slightly its blockade effects.

Professional Indemnity

The NPA will indemnify NPA members involved in the provision of a crushed Subutex service. However this cover is conditional upon participating members complying with the “model protocol” set out below.
Supervised Consumption of Subutex (Buprenorphine) – Model protocol

The following requirements are over and above the general legal and ethical requirements associated with the running of a pharmacy business and the specific requirements relating to the provision of controlled drugs and services to drug misusers.

- Pharmacies crushing Subutex need to be satisfied that crushing is in the patient’s best interest; crushing must be for the benefit of the patient rather than the convenience of the pharmacist. Pharmacies need to be satisfied that there is a true clinical need for crushing. They also need to consider the potential for distortion of the bioavailability profile of Subutex as a result of crushing.

- Pharmacies must have a standard operating procedure to cover all the processes involved in the scheme which is readily available to and understood by all staff (and locum pharmacists) involved with the scheme.

- There must be collaboration between pharmacist, prescriber and client to ensure that:
  - everyone understands the objectives behind a supervised scheme
  - the reasons for the crushing of Subutex,
  - that crushing is outwith the manufacturer’s marketing authorisation
  - there is clear understanding of the clinical and logistical implications of crushing.

- A signed agreement should be sought from both the prescriber and client as confirmation that they understand the implications associated with supervised supply of crushed Subutex and that they agree to participation on this basis.

A model patient information/consent form is included as an Annex.

- Prescriptions must clearly indicate that the consumption is to be supervised. Ideally the prescription should also state that the Subutex tablets are to be crushed. Alternatively a signed agreement between the prescriber and pharmacist could specify circumstances in which it is appropriate to crush tablets – for example where diversion is suspected, where prescribed doses exceed 8mg or for all clients.

- Pharmacists must satisfy themselves of the legality of the prescription, and its clinical appropriateness.

- Pharmacists should refuse to supply, and contact the prescriber if:
  - There are any queries with the prescription
  - There is any uncertainty with the identity of the client
  - The client misses the number doses prescribed in local treatment agreements
  - The client avoids, or attempts to avoid, supervision
  - The client does not consume the full dose, or attempts to avoid the process for proper administration
  - The patient appears to be ill, under the influence of alcohol or other drugs to the extent that in the pharmacist’s judgement this may impair treatment
  - The client displays threatening, violent or abusive behaviour toward staff

- Pharmacists must keep adequate records of supply preferably on the PMR clearly indicating that a crushed supply has been made.
Appendix 3 - Client leaflet – Subutex®/buprenorphine

Client Leaflet
Supervised Subutex (Buprenorphine)

Your doctor has prescribed Subutex and stated that this is to be “supervised consumption”. This means the following must happen.

- You come into the pharmacy on your own.
- You hand in your medication card
- We positively identify you
- You remove any chewing gum or sweets from your mouth and dispose of them in a waste bin.
- You will be provided with a drink of water as this speeds up the time it takes for the tablets to dissolve.
- The dispensed tablet is taken from the container with your name on and squeezed out of the foil and into a plastic medicine measure
- If the prescriber specifies “crushed” then the tablet(s) will be broken into smaller granular pieces. This will have been explained to you by your prescriber as crushing is off-licence
- You are expected to tip the tablet(s) or granules under your tongue without touching them and hand back the measure.
- **You must then sit down and allow these to dissolve - this usually takes between 3 and 5 minutes for tablets - significantly less time for granules.**
- Once the tablets have dissolved you should report to the pharmacist and will be provided with a drink of water, which you should drink.
- You will then be given back your medication card and may leave.

**Important**
- Failure to follow the points above will result in the prescription being suspended and you being referred back to your doctor.
- Missing 3 consecutive doses will also mean that you have to contact your clinic/doctor.

Name of GP/Prescriber: (please print)…………………………………………

Prescribers signature:………………………………………………………… Date:………………

Clients Name: (please print)…………………………………………………………

Clients signature:………………………………………………………… Date:………………
Appendix 4 – Patient Identification Form

Client Information

Client Name: ____________________________________________

Address: ________________________________________________

DoB: ___________________ Gender: ________________________

Signed (client): ________________________ Date: ____________

Medical Service Details

Doctor: ___________________ Keyworker: ___________________

Clinic address: __________________________________________

Telephone: ______________________________________________

Signed (Doctor/Keyworker): ________________________ Date: ____________

For the Pharmacist

The client should present a form of ID, which contains either, a photograph and name or name and address, which match that given above.

Acceptable forms of ID include:

- Photo ID
- Driving licence, passport, proof of age card e.g. prove it, photo student ID,
- Name and address ID – no older than 3 months
- bank statement, credit card statement, utility bill (not mobile phone bill), benefits correspondence, Council tax bill or payment book.

Form of ID Shown: ____________________________________________

Date: ______________
Appendix 5 - Client/Pharmacy Agreement

We are pleased to welcome you to the Central Lancashire PCT’s Supervised Consumption Scheme and wish you all the best with your treatment. We aim to offer you a discreet and efficient service that supports you in achieving your treatment goals.

This ‘agreement’ sets out the arrangements for the service and a brief explanation as to why these arrangements are necessary. The pharmacist will go through each of the points with you and explain any that you are unsure about.

When you have completed the Agreement, the pharmacist will introduce you to the staff so that they know who you are and can help you should you require it.

We hope that the scheme proves helpful to you.

<table>
<thead>
<tr>
<th>The Arrangements</th>
<th>Why they are necessary</th>
</tr>
</thead>
<tbody>
<tr>
<td>We are available to supply your medication between:</td>
<td>We want to give you your medicine as quickly as possible. You must be punctual. We prepare your medicine first thing in the morning and write up our records before the shop closes. When the pharmacy is busy, we must take all customers in turn, which may leave you standing around.</td>
</tr>
<tr>
<td>From………….To………….</td>
<td></td>
</tr>
<tr>
<td>From…………..To………….</td>
<td></td>
</tr>
<tr>
<td>You will need to collect your take home doses on………………………..………. for weekends and Bank Holidays</td>
<td>The pharmacy is closed on …………….day and …………….day and on Bank Holidays. Opening times are:</td>
</tr>
<tr>
<td>We will need some way of identifying you. Our pharmacist will explain how this is done.</td>
<td>We want to ensure that we don’t give your supply to anyone else.</td>
</tr>
<tr>
<td>If you have missed three days collections in a row, we cannot supply your medication without speaking to your prescriber.</td>
<td>Your tolerance to the drug quickly drops and to take the full dose may risk your health</td>
</tr>
<tr>
<td>We must supervise you taking your medicine because this has been stipulated on your prescription</td>
<td>This is done to support you achieving your treatment goals and to reduce the risk of overdose</td>
</tr>
<tr>
<td>We cannot let anyone else collect your medication for you.</td>
<td>Again, we want to make sure you get your medicine and not anyone else</td>
</tr>
<tr>
<td>When you collect your medication we need time to update our records. Please be patient</td>
<td>By law, we have to make detailed records on each collection. We cannot do this in advance.</td>
</tr>
<tr>
<td>If you lose your prescription, we cannot supply the medication to you no matter how well we know you</td>
<td>Again, by law, we can only supply medications with a legally written prescription. If you have lost one you will need to contact your prescriber.</td>
</tr>
<tr>
<td>We cannot give you ‘missed doses’ that you have not picked up</td>
<td>The supply of your medication has to be made on the day and date specified on the prescription.</td>
</tr>
<tr>
<td>Please bring your new prescription promptly before,</td>
<td>There is sometimes a waiting list for places. If you do not</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>
We would like you to come alone and to behave in a reasonable manner in the pharmacy and in the area outside the pharmacy. We want our pharmacy to be a welcoming place to you and all our customers and expect all our patients/customers to behave in a reasonable manner. **Failure to do so will force a withdrawal of services.**

Please feel free to ask about other health related issues that maybe worrying you. We offer information and advice on health related matters to all members of our communities. You are a customer of ours and we value your custom.

**Confidentiality:** We respect your right to keep matters relating to your health private and confidential and shall endeavour to provide a confidential service for you. However we may talk to your GP/Prescriber or drug therapist about your health care or medicines.

Name of Pharmacist: 

Pharmacy Stamp: 

Phone number of Pharmacy: 

Name and contact details of GP/Prescriber: 

Name and contact details of therapist: 

Patients signature:.......................... Date........................

Print Name....................................

Pharmacists signature:.......................... Date........................

**Complaints procedure**

If you are not satisfied with the service that you have received, please speak with your pharmacist therapist or drugs worker.

Your complaint will be investigated and you will be kept informed of the process and the outcome. A complaints procedure will be made available to you on request.

**Notes or Comments**

We value your custom and will endeavour to do all we can to meet your health needs.
Appendix 6 - When to Contact the Prescriber

CONSIDER CONTACTING THE PRESCRIBER IF:

- The patient does not consume the whole dose under supervision
- The patient tries to avoid supervision
- The patient appears to be intoxicated e.g. alcohol, other prescription and/or illicit drugs
- The patient appears to be ill
- The patient misses three doses
- The behaviour of the patient is unacceptable e.g. shoplifting verbal and/or physical abuse
- The Pharmacist is aware of other issues that may affect treatment compliance e.g. being made homeless.
- The Pharmacist believes there may be a concordance/drug interaction issue with other prescribed drugs being taken
- There are problems concerning the prescription e.g. patient moves prescription, ambiguity of dates for dispensing, identity of patient in doubt
- The Pharmacist is contacted by secondary care Re: dosage information due to hospitalisation
- The Pharmacist is contacted by secondary care
- The patient does not consume the whole dose under supervision
- The patient appears to be intoxicated e.g. alcohol, other prescription and/or illicit drugs
- The patient appears to be ill
- The patient misses three doses
- The behaviour of the patient is unacceptable e.g. shoplifting verbal and/or physical abuse
- The Pharmacist is aware of other issues that may affect treatment compliance e.g. being made homeless.
- The Pharmacist believes there may be a concordance/drug interaction issue with other prescribed drugs being taken
- There are problems concerning the prescription e.g. patient moves prescription, ambiguity of dates for dispensing, identity of patient in doubt
- The Pharmacist is contacted by secondary care

Remember:
- Missing doses may result in a drop in opiate tolerance with an increased risk of accidental overdose
- Clients stabilised on methadone or buprenorphine should be alert and coherent
- As you get to know the patient you may be in a position to notice deterioration in their health
- Only you can decide what behaviour is ‘unacceptable’.
Appendix 7 - Pharmacist - Prescriber Contact Form

Client: __________________________

Doctor: __________________________

Keyworker: __________________________

Supervised self administration of prescribed medications has been withdrawn because the client above has:

☐ Missed three doses (please append a copy of the patient record form)

☐ Exhibited unacceptable behaviour
   Including: __________________________

☐ Refused to consume the whole dose under supervision

☐ Tried to avoid supervision

☐ Appeared intoxicated when attending the pharmacy
   Please give details: __________________________

☐ Been admitted to hospital

Further information

Signature of Pharmacist: __________________________

Date: ______________

Please note this form is only for use when treatment is withdrawn – refer to the ‘when to contact the prescriber’ flowchart in appendix 6 for guidance where swift action is required.

The prescriber should deal with further issues at their own discretion and in discussion with clients.

Concordance/Drug interaction issues should similarly be dealt with at the discretion of the pharmacist and may require more urgency depending on individual circumstances.
Appendix 8 - Pharmacy Record Form

Application for payment in respect of Supervised Methadone and Buprenorphine Self Administration
Record of Medication Administered

Claim for the Month of ______________________

Payment will be based on the total number of monthly supervised doses

I declare that for the above month:-

a) The pharmacy was open 5/6/7 days each week (delete as appropriate)
b) The doses were supervised as listed below and marked (M) or (B)
c) There is a written procedure for locums on supervision arrangements
d) The service complies with the scheme Conditions and Guidance
   “Supervised self-administration of Methadone and Buprenorphine: Guidelines for Pharmacists”.

| Days of the Month | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 | 21 | 22 | 23 | 24 | 25 | 26 | 27 | 28 | 29 | 30 | 31 | Total Number of Administrations |
|-------------------|---|---|---|---|---|---|---|---|---|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|---------|

Client Code*

*Following the client code – please put ‘M’ in brackets to indicate Methadone and ‘B’ in brackets to indicate Buprenorphine.

Name of Pharmacist providing Supervised Administration Services (please print) .................................................................

Signed ..................................................... Date  ...................................

KEEP COPY IN PHARMACY FOR 2 YEARS

Please return to: - Customer Services, Lancashire and South Cumbria Agency, Caxton Rd, Fulwood, Preston PR2 4ZZ
Appendix 9 - Changes in the provision of Supervised Self Administration of Methadone or Buprenorphine by Accredited Pharmacists/Registered Pharmacy Technicians

Pharmacy name: __________________________________________________________

Pharmacy address: _________________________________________________________

Please complete the relevant section:

Section A – newly accredited pharmacist

_________________________ has now ____________ completed __________________________________________
(Pharmacist’s name) (date) (Course name and provider)

Section B – change in accredited pharmacist

The Supervised Self Administration of Methadone and Buprenorphine Scheme at: ________________

_________________________ will henceforth ____________ be administered by ________________
(Pharmacy name) (date) (name)

who has completed ____________________________________________________________
(Course name, provider and date of completion)

Section C – newly accredited registered pharmacy technician

_________________________ has now ____________ completed __________________________________________
(Technician’s name) (date) (Course name and provider)

Section D - temporary / interim arrangements longer than 2 weeks duration

This pharmacist must be aware of the Standard Operating Procedures for the scheme.

Between ____________ and ____________ the Supervised Self Administration of Methadone and
Buprenorphine Scheme will be provided by _________________________________

This pharmacist has/has not completed an accredited course. (delete as appropriate)

Complete if appropriate _______________________________________________________
(Course name, provider and date of completion)

Section E – to be completed for any other changes to the scheme.

Please explain any other changes to the implementation of the scheme by trained pharmacists.

__________________________________________________________________________

Please send to: Stephen Gough, Community Pharmacy Adviser, Central Lancashire PCT, Jubilee
House, Lancashire Business Park, Centurion Way, Leyland PR26 6TR fax: 01772 220274
Resources

This section of this guidance document contains blank copies of the forms required for the administration of the Supervised Self Administration of Methadone and Buprenorphine scheme, including:

- Application to join the scheme
- Patient Identification Form
- Client leaflet for Subutex
- Client/pharmacy agreement
- Pharmacist - Prescriber Contact Form
- Pharmacy Record Form
- Notification of changes in the delivery of the scheme form
Application to Join the Supervised Self Administration Scheme

AGREEMENT

I apply to be paid for the supervision of methadone and buprenorphine self-administration by drug misusers in the premises named below in line with the Scheme Conditions and Guidance and to submit a monthly log of activity to Central Lancashire PCT.

The pharmacy will provide supervised self-administration of (please tick):

1. Methadone  

2. *And Buprenorphine per dose supervised*  

* It is recognised that there is no differential in payments to compensate for the additional time incurred in ensuring that the Buprenorphine tablet(s) has been appropriately consumed. Therefore authorised pharmacies can choose not to provide this aspect of the service.

The pharmacy is open for (5) (6) (7) days a week. (Circle correct figure)

I will claim the fees appropriate to this number of days opening following supervision of methadone and buprenorphine self-administration.

Signed: ........................................................................................  Contractor

Pharmacy Name: ......................................................................................

Pharmacy Address: ...................................................................................

Tel No:  ...............................................................

Date:  ...............................................................

Relevant Training Courses attended by Supervising Pharmacists who work routinely in the premises and registered pharmacy technicians.

<table>
<thead>
<tr>
<th>Pharmacist</th>
<th>Date of Course</th>
<th>Organiser</th>
<th>Title</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tbody>
</table>

And Pharmacy Technician

<table>
<thead>
<tr>
<th>Pharmacist</th>
<th>Date of Course</th>
<th>Organiser</th>
<th>Title</th>
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<td></td>
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</tbody>
</table>

Pharmacies wishing to join the scheme should complete this application and return it to:

Stephen Gough, Community Pharmacy Adviser, Central Lancashire PCT, Jubilee House, Lancashire Business Park, Centurion Way, Leyland PR26 6TR fax: 01772 227025
Patient Identification Form

Client Information

Client Name: ________________________________
Address: ___________________________________
DoB: _______________ Gender: ________________
Signed (client): ____________________________ Date: ________________

Medical Service Details

Doctor: _______________ Keyworker: _______________
Clinic address: ___________________________________
Telephone: ___________________________________
Signed (Doctor/Keyworker): ____________________ Date: ____________

Clinic Stamp

Photograph of Client (Provided by CDT)

(If providing a photo of client please ensure clinic stamp partly over stamps the photo)

For the Pharmacist

The client should present a form of ID, which contains either, a photograph and name or name and address, which match that given above.

Acceptable forms of ID include:

- Photo ID
- Driving licence, passport, proof of age card e.g. prove it, photo student ID,
- Name and address ID – no older than 3 months
- bank statement, credit card statement, utility bill (not mobile phone bill), benefits correspondence, Council tax bill or payment book.

Form of ID Shown: ____________________________________________
Date: _________________
Your doctor has prescribed Subutex and stated that this is to be “supervised consumption”. This means the following must happen.

- You come into the pharmacy on your own.
- You hand in your medication card
- We positively identify you
- You remove any chewing gum or sweets from your mouth and dispose of them in a waste bin.
- You will be provided with a drink of water as this speeds up the time it takes for the tablets to dissolve.
- The dispensed tablet is taken from the container with your name on and squeezed out of the foil and into a plastic medicine measure
- If the prescriber specifies “crushed” then the tablet(s) will be broken into smaller granular pieces. This will have been explained to you by your prescriber as crushing is off-licence
- You are expected to tip the tablet(s) or granules under your tongue without touching them and hand back the measure.
- You must then sit down and allow these to dissolve - this usually takes between 3 and 5 minutes for tablets - significantly less time for granules.
- Once the tablets have dissolved you should report to the pharmacist and will be provided with a drink of water, which you should drink.
- You will then be given back your medication card and may leave.

Important

- Failure to follow the points above will result in the prescription being suspended and you being referred back to your doctor.
- Missing 3 consecutive doses will also mean that you have to contact your clinic/doctor.

Name of GP/Prescriber: (please print)………………………………………

Prescribers signature:…………………………………………………….. Date:………………

Clients Name: (please print)…………………………………………………………

Clients signature:…………………………………………………… Date:………………
We are pleased to welcome you to the Central Lancashire PCT’s Supervised Consumption Scheme and wish you all the best with your treatment. We aim to offer you a discreet and efficient service that supports you in achieving your treatment goals.

This ‘agreement’ sets out the arrangements for the service and a brief explanation as to why these arrangements are necessary. The pharmacist will go through each of the points with you and explain any that you are unsure about.

When you have completed the Agreement, the pharmacist will introduce you to the staff so that they know who you are and can help you should you require it.

We hope that the scheme proves helpful to you.

<table>
<thead>
<tr>
<th>The Arrangements</th>
<th>Why they are necessary</th>
</tr>
</thead>
<tbody>
<tr>
<td>We are available to supply your medication between: From………….To…………. From…………..To…………..</td>
<td>We want to give you your medicine as quickly as possible. We prepare your medicine first thing in the morning and write up our records before the shop closes. When the pharmacy is busy, we must take all customers in turn, which may leave you standing around.</td>
</tr>
<tr>
<td>You will need to collect your take home doses on………………………..………. for weekends and Bank Holidays</td>
<td>The pharmacy is closed on ……………day and …………day and on Bank Holidays. Opening times are:</td>
</tr>
<tr>
<td>We will need some way of identifying you. Our pharmacist will explain how this is done.</td>
<td>We want to ensure that we don’t give your supply to anyone else</td>
</tr>
<tr>
<td>If you have missed three days collections in a row, we cannot supply your medication without speaking to your prescriber.</td>
<td>Your tolerance to the drug quickly drops and to take the full dose may risk your health</td>
</tr>
<tr>
<td>We must supervise you taking your medicine because this has been stipulated on your prescription</td>
<td>This is done to support you achieving your treatment goals and to reduce the risk of overdose</td>
</tr>
<tr>
<td>We cannot let anyone else collect your medication for you.</td>
<td>Again, we want to make sure you get your medicine and not anyone else</td>
</tr>
<tr>
<td>When you collect your medication we need time to update our records. Please be patient</td>
<td>By law, we have to make detailed records on each collection. We cannot do this in advance.</td>
</tr>
<tr>
<td>If you lose your prescription, we cannot supply the medication to you no matter how well we know you</td>
<td>Again, by law, we can only supply medications with a legally written prescription. If you have lost one you will need to contact your prescriber.</td>
</tr>
<tr>
<td>We cannot give you ‘missed doses’ that you have not picked up</td>
<td>The supply of your medication has to be made on the day and date specified on the prescription.</td>
</tr>
<tr>
<td>Please bring your new prescription promptly before,</td>
<td>There is sometimes a waiting list for places. If you do not</td>
</tr>
</tbody>
</table>

Please bring your new prescription promptly before,
or just after your current one finishes show we may have to give your slot to someone else

We would like you to come alone and to behave in a reasonable manner in the pharmacy and in the area outside the pharmacy.

We want our pharmacy to be a welcoming place to you and all our customers and expect all our patients/customers to behave in a reasonable manner. **Failure to do so will force a withdrawal of services.**

Please feel free to ask about other health related issues that maybe worrying you.

We offer information and advice on health related matters to all members of our communities. You are a customer of ours and we value your custom.

**Confidentiality:** We respect your right to keep matters relating to your health private and confidential and shall endeavour to provide a confidential service for you. However we may talk to your GP/Prescriber or drug therapist about your health care or medicines.

Name of Pharmacist: 

Pharmacy Stamp: 

Phone number of Pharmacy: 

Name and contact details of GP/Prescriber: 

Name and contact details of therapist: 

Patients signature:…………………………………….. Date…………………….. 

Print Name……………………………………………

Pharmacists signature:…………………………….. Date…………………….. 

**Complaints procedure**

If you are not satisfied with the service that you have received, please speak with your pharmacist therapist or drugs worker.

Your complaint will be investigated and you will be kept informed of the process and the outcome. A complaints procedure will be made available to you on request

**Notes or Comments**

We value your custom and will endeavour to do all we can to meet your health needs.
Pharmacist - Prescriber Contact Form

Client: __________________________

Doctor: __________________________

Keyworker: __________________________

Supervised self administration of prescribed medications has been withdrawing because the client above has:

☐ Missed three doses
   (please append a copy of the patient record form)

☐ Exhibited unacceptable behaviour
   Including: __________________________

☐ Refused to consume the whole dose under supervision

☐ Tried to avoid supervision

☐ Appeared intoxicated when attending the pharmacy
   Please give details: __________________________

☐ Been admitted to hospital

Further information


Signature of Pharmacist: __________________________

Date: ______
Pharmacy Record Form

Application for payment in respect of Supervised Methadone and Buprenorphine Self Administration

Record of Medication Administered

Claim for the Month of ______________________

Payment will be based on the total number of monthly supervised doses

I declare that for the above month:-

a) The pharmacy was open 5/6/7 days each week (delete as appropriate)
b) The doses were supervised as listed below and marked (M) or (B)
c) There is a written procedure for locums on supervision arrangements
d) The service complies with the scheme Conditions and Guidance “Supervised self-administration of Methadone and Buprenorphine: Guidelines for Pharmacists”.

| Days of the Month | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 | 21 | 22 | 23 | 24 | 25 | 26 | 27 | 28 | 29 | 30 | 31 | Total Number of Administrations |
|-------------------|---|---|---|---|---|---|---|---|---|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|---|
| Client Code*      |   |   |   |   |   |   |   |   |   |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |

*Following the client code – please put ‘M’ in brackets to indicate Methadone and ‘B’ in brackets to indicate Buprenorphine.

Name of Pharmacist providing Supervised Administration Services (please print) ............................................................

Signed ..................................................... Date  ...................................

KEEP COPY IN PHARMACY FOR 2 YEARS

Please return to: - Customer Services, Lancashire and South Cumbria Agency, Caxton Rd, Fulwood, Preston PR2 4ZZ

Pharmacy stamp
Changes in the provision of Supervised Self Administration of Methadone or Buprenorphine by Accredited Pharmacists/Registered Pharmacy Technicians

Pharmacy name: ________________________________
Pharmacy address: ________________________________

Please complete the relevant section:

Section A – newly accredited pharmacist

_________ has now _________ completed ________________
(Pharmacist’s name) (date) (Course name and provider)

Section B – change in accredited pharmacist

The Supervised Self Administration of Methadone and Buprenorphine Scheme at :__________

_________ will henceforth _________ be administered by _________
(Pharmacy name) (date) (name)

who has completed _____________________________________________
(Course name, provider and date of completion)

Section C – newly accredited registered pharmacy technician

_________ has now _________ completed ________________
(Technician’s name) (date) (Course name and provider)

Section D - temporary / interim arrangements longer than 2 weeks duration
This pharmacist must be aware of the Standard Operating Procedures for the scheme.

Between _________ and _________ the Supervised Self Administration of Methadone and Buprenorphine Scheme will be provided by _____________________________

This pharmacist has/has not completed an accredited course. (delete as appropriate)

Complete if appropriate ____________________________________________
(Course name, provider and date of completion)

Section E – to be completed for any other changes to the scheme.

Please explain any other changes to the implementation of the scheme by trained pharmacists.

Please send to: Stephen Gough, Community Pharmacy Adviser, Central Lancashire PCT, Jubilee House, Lancashire Business Park, Centurion Way, Leyland PR26 6TR fax: 01772 220274
Additional Information

Clinical Guidelines

A full copy of the ‘Drug Misuse and Dependence – Guidelines on Clinical Management’ can be found at:


Guidance for the Use of Buprenorphine for the Treatment of Opioid Dependence in Primary Care

- RCGP & SMMGP (Updated Oct 2004)
These are the new guidelines that are intended to aid GPs in the use of buprenorphine as a substitute medication for opioid dependence for maintenance and detoxification. Includes main document, Patient Information Sheet, and Summary Sheet.

Medico-legal aspects

The Royal Pharmaceutical Society of Great Britain provides guidance on all legal aspects and standards for professional indemnity, both of which can be found in the latest edition of ‘Medicines, Ethics, and Practice’.
http://www.rpsgb.org.uk/