Introduction

Prescription of substitute opiate medication (methadone and buprenorphine) is the main pharmacological intervention for treatment of substance misuse. *Drug Misuse and Dependence – Guidelines on Clinical Management* (2007) recommend that supervised consumption should be available for all patients for a length of time appropriate to their needs and risks.

This service specification outlines the requirements of the enhanced service for pharmacy-based supervised consumption of substitute opiate medication for treatment of substance misuse to be provided to substance misusers in the London Borough of Hackney and the City of London. The specification of this service is designed to cover the enhanced aspects of clinical care of individual patients from this group of patients, all of which are beyond the scope of essential services. No part of the specification by commission, omission or implication defines or redefines essential or additional services.

This service is jointly commissioned by NHS City and Hackney, Hackney Drug and Alcohol Action Team (DAAT) and City of London Drug Action Team (DAT).

1. Agreement

This agreement is made on the date shown on page 10 between NHS City and Hackney (the Commissioner, hereinafter referred to as ‘the tPCT’) and the pharmacy named on page 10 (hereinafter referred to as ‘the Service Provider’).

2. Background

Drug misuse and its complications pervade every part of society and social classes and are a problem found across the whole country.

Studies consistently show that the UK (Scotland and England in particular) has among the highest rates of recorded illegal drug misuse in the western world. In particular, the UK has comparatively high rates of heroin and crack cocaine misusers. However, over the past ten years there has been a rapid expansion in the provision of drug treatment in the UK and in the number of drug misusers in treatment.

In 2004/5, 1180 of the known problem drug users in Hackney were in treatment (69.2%); in the fourth quarter of 2005/6 this had fallen to 64.5%. Two thirds of discharged patients had been retained in treatment for more than twelve weeks. In 2004/5 there were 20 problem drug users in treatment in the City; in 2005/6 this had risen by 50% to 30. The drug treatment rate per 100,000 population
Substance Misuse Supervised Consumption Enhanced Service April 2010

Aged 15-44 in 2004/5 was 425 in the City, 1077 in Hackney, compared with 784 in London and 768 in England. Approximately 24% of the estimated problem drug user population in Hackney are in treatment, compared with a London average of 52%. We, therefore, need to use this enhanced service to increase the number of patients in treatment and to capture data about all those in treatment.

The Department of Health’s drug misuse clinical guidelines identify a range of goals of drug treatment:

- Reducing health, social, crime and other problems directly related to drug misuse.
- Reducing health, social or other problems not directly attributable to drug misuse.
- Reducing harmful or risky behaviors associated with the misuse of drugs (for example sharing injecting equipment).
- Attaining controlled, non-dependent or non problematic drug use.
- Abstinence from main problem drugs.
- Abstinence from all drugs.

Supervision of consumption by an appropriate professional provides the best guarantee that a medicine is being taken as directed. Since the advent of supervised consumption, the number of drug-related deaths involving methadone has reduced, during a period when more methadone is being prescribed, providing indirect evidence that supervising the consumption of medication may reduce diversion.

Current national guidelines recommend that, in most cases, new patients being prescribed methadone or buprenorphine should be required to take their daily doses under the direct supervision of a professional for a period of time that may be around three months, subject to assessment of an individual patient’s compliance and individual circumstances. The clinical need for supervised consumption should be reviewed regularly and the decision on when to relax the requirement for supervised consumption is one for the individual clinician based on advice or input from the patient’s keyworker and community pharmacist.

3. Aims and objectives

This service requires pharmacists to supervise the consumption of prescribed opioid replacement therapy at the point of dispensing in the pharmacy to ensure that the prescribed and dispensed dose has been administered to the patient.

The overall objectives of this service are to:
Ensure compliance with the agreed treatment plan and thereby to stabilise service users on substitute medication to alleviate withdrawal and to reduce craving by:

- dispensing in specified instalments and when appropriate
  - NB: doses may be dispensed for the patient to take away to cover days when the pharmacy is closed if stated by the prescriber,
- ensuring each supervised dose is correctly consumed on site by the patient for whom it was intended.

Ensure the involvement of pharmacists in the multidisciplinary team to make sure that the patient receives optimal care.

Reduce the risk to local communities of:

- over usage or under usage of medicines;
- diversion of prescribed medicines on to the illicit drugs market; and
- accidental exposure of others to substitute opioids.

Assist service users to remain healthy by providing them with regular contact with healthcare professionals and to help them access further advice or assistance. The service user will be referred to specialist treatment centres or other health and social care professionals where appropriate.

Promote safer drug-using practices and healthier lifestyles through the provision of information, resources and advice on harm reduction strategies, health issues and the range of services available.

Reduce dangers associated with substance misuse, including risks of HIV, hepatitis B and C and other blood-borne infections and risks of drug-related death.

Complement existing drug and alcohol services within the Models of Care framework by facilitating referral of clients to other agencies where specialist treatments can be obtained.

Determine the level of need in the area and adequacy of provision through systematic monitoring, review and evaluation.

4. Service provider

The service may only be provided by an accredited pharmacist who meets the following criteria:

- The pharmacist must have successfully completed the Centre for Pharmacy Postgraduate Education (CPPE) open learning course ‘Opiate Treatment – Supporting Pharmacists for Improved Patient Care’ or the RCGP part 1
course: the pharmacist must provide the tPCT with a copy of the certificate confirming completion of the course.

- The pharmacist must attend in full an initial local training event prior to commencement and at least one annual update training event in full thereafter when these are held. Training from other PCT areas may be transferable but must be proven and approved by the Shared Care Substance Misuse Manager.

- It is the responsibility of the accredited pharmacist to train pharmacy staff on the operation of the scheme.

- Each service provider must develop and implement a comprehensive Standard Operating Procedure (SOP) for provision of the service which must be up-to-date and will be open to inspection by the tPCT. The SOP must, as a minimum, cover instalment dispensing to substance misuse patients and include supervised consumption.

- It is the responsibility of the pharmacy contractor and the accredited pharmacist to ensure that all locums employed to work in the pharmacy are made familiar with all aspects of the service and the requirements of this SLA by appropriate means, e.g. a signed and dated declaration that the locum has read and will work according to the SOP.

- The pharmacist must maintain clinical knowledge appropriate to their practise by attending relevant study days, courses and to make themselves aware of and familiar with appropriate literature.

- If a change of a named pharmacist occurs, the Shared Care Substance Misuse Manager must be notified at the earliest opportunity. The replacement pharmacist will be permitted to take over provided they meet all the required criteria for this enhanced service. However, payments will be withheld until the CPPE/RCGP part 1 course has been completed and attendance at or a commitment to attending the earliest tPCT provided training session must be made depending on individual circumstances and based on a risk assessment by the tPCT.

5. Premises

The service can only be provided in an approved pharmacy which is registered in City & Hackney. NB On occasions, out of area pharmacies may provide the service for patients receiving treatment from City & Hackney substance misuse services. In such circumstances, the pharmacist must meet the service provider criteria detailed in 4 above and this must be agreed with the Shared Care Substance Misuse Manager.

The pharmacy premises are required to have a suitable consultation room/area. This may be a quiet area within the pharmacy where privacy can be maintained for the patient or a separate room.
Premises will be visited by the Shared Care Substance Misuse Manager prior to acceptance of the pharmacy contractor to the service with periodic visits thereafter is required.

6. Service outline

Pharmacists are expected to operate the scheme in accordance with the Code of Ethics and Professional Standards laid down by the Royal Pharmaceutical Society of Great Britain and within the boundaries of the Misuse of Drugs Act.

The service provider should offer a user friendly, non-judgemental, client-centred and confidential service.

The accredited pharmacist is responsible for ensuring that the service is delivered as set out in this service specification.

- Prescriptions must state ‘For supervised consumption’.

- The majority of prescriptions for methadone will be for Methadone 1mg/ml mixture. Prescriptions ordering higher strengths must be confirmed with the prescriber prior to dispensing.

- When buprenorphine is prescribed with supervised consumption, the tablets should be crushed – this is unlicensed, but accepted practice (see Appendix 1 for a suitable form of indemnity to be used for the crushing of buprenorphine for supervised consumption). It is more convenient for patients and easier for pharmacists to manage. In addition, it prevents patients leaving the premises with buprenorphine tablets which can be spat out and passed on (referred to as ‘leakage’). The implications of crushing must be explained to the patient, i.e. that it renders the product unlicensed. If the patient does not agree to crushing, the pharmacist should consider whether they are willing to watch the patient for the full 8 minutes: if not, the pharmacist should discuss with the prescriber whether to supply without full supervision or whether the patient should be changed to methadone.

- The pharmacist will present the dispensed medication in a suitable receptacle and will provide the patient with water to facilitate administration and/or reduce the risk of doses being held in the mouth.

- Methadone or buprenorphine must not be dispensed to any patient who has missed 3 or more consecutive doses. Such patients must be referred back to the prescriber for re-assessment, since their tolerance to opiates may have fallen: the prescriber should be contacted.

- Terms of agreement must be set up and agreed between the pharmacist and the patient to agree how the service will operate, what constitutes acceptable behaviour by the patient and what action will be taken if the patient does not comply.
Patients should be provided with the following information:

- harm minimisation advice;
- information leaflets, such as health literature and harm reduction interventions for drug and alcohol misuse;
- information about drug treatment and services available in the boroughs.

Whilst no maximum or minimum numbers of patients are specified in the contract, it is suggested that pharmacists do not refuse to take patients, without good reason, if their numbers are less than five (5), but can reasonably refuse to take on more once they exceed twenty (20). In addition, if a pharmacist wishes to take more than 25 patients, then they may wish to undertake further studies e.g. the Royal College of General Practitioners certificate Part 2 or additional annual training approved by the tPCT and agreed via the Shared Care Substance Misuse Manager and ensure that the facilities in the pharmacy are adapted to meet the needs of larger numbers and approved by the tPCT.

**Information sharing**

It is good practice that pharmacists share relevant information with prescribers and other healthcare professionals and agencies in line with locally determined confidentiality agreements:

- when the pharmacist is aware that patients are failing to comply with their treatment - for example when patients have missed scheduled pick-ups;
- when there are concerns about a patient’s health, wellbeing or the;
  pharmacist is aware of other serious concerns
- when the patient attends the pharmacy in a state of intoxication.

It should be noted that pharmacists who are also operating a needle exchange scheme will not usually share information with the prescriber that a patient receiving prescribed medication is also obtaining supplies of injecting equipment from the pharmacy except where the pharmacist has the permission of the patient to do so.

7. Data recording

All data is recorded electronically through the community pharmacy website http://www.caht.firstpct.org/

**New patients**

When a new patient attends the pharmacy for acceptance into the service, the pharmacist is required to complete the New Patient Acceptance Form (Appendix 2). Completed forms should be faxed immediately to Aisha Achha, Prescribing Technician on 020 7683 4464.
**Supervised consumption**
The pharmacist is required to complete the relevant monthly self-administration record form (Appendix 2) in full for each patient receiving the supervised consumption service. Record the following information:

- whether the supervision took place on the relevant date;
- the dose of methadone/buprenorphine; and
- all relevant comments.

Where a patient fails to attend for three (3) or more consecutive doses and is referred back to the prescriber and they subsequently re-attend for their next dose following agreement with their prescriber that they can be accepted, then a full comment **must** be recorded on the form.

**8. Critical incidents**

Adverse incidents, such as aggressive or threatening behaviour or theft, occasionally occur. The following points should be considered when managing adverse incidents:

- Under no circumstances is the pharmacist to put themselves or their staff at any risk of any type of harm or injury.

- It is not expected that pharmacy staff will accept threatening, violent or otherwise abusive behaviour from substance misuse clients to any more or less extent than they would from anyone else.

- The client should be asked to leave the premises with a verbal warning if there are signs of a risk situation escalating.

If the client returns subsequently and does not modify their behaviour the pharmacist has the right to withhold services. The Shared Care Substance Misuse Manager must be advised of such incidents so that the DAAT/DAT is kept informed and risk to others minimised. If appropriate, information on other local service providers can be given. If the client does not leave voluntarily when requested, the pharmacist is advised to call the police to escort the person from the premises.

**9. Quality indicators**

The following quality indicators will be used to monitor delivery of the service:

- The pharmacy contractor must have standard operating procedures in place for instalment dispensing and supervised consumption.

- The pharmacy contractor must be able to demonstrate relevant training has been undertaken by all staff involved in the service and that this is up-to-date.
The pharmacy contractor must participate in an annual tPCT audit of service provision and claims.

The pharmacy contractor must co-operate with any tPCT-led assessment of patient experience feedback.

The pharmacy contractor informs the Shared Care Substance Misuse Manager of any incidents, errors or complaints relating to the service and:

- is aware of, understands and operates in accordance with local policy; and
- works in an appropriate multidisciplinary manner.

10. Payments

Supervision fee
Participating Pharmacy Contractors will be paid £2.50 per supervised dose of methadone, or buprenorphine.

All records must be maintained on the tPCT’s Pharmacy Website and submitted to the tPCT monthly. http://www.caht.firstpct.org/

In exceptional circumstances, the pharmacist may keep clear records of each contact on the paper sheets: monthly self-administration record form in order to be eligible for payments (See Appendix 3). These record sheets must be returned to Aisha Achha, Prescribing Technician at the tPCT on a monthly basis, together with the summary sheet (see 11. Data returns).

11. Data returns

Data should be returned to the tPCT on a monthly basis, by the fifteenth (15th) day of the following month.

The pharmacist is required to complete all records electronically at http://www.caht.firstpct.org/

In exceptional circumstances where the electronic versions cannot be submitted, the pharmacist is required to complete and return the paper summary sheets for methadone and/or buprenorphine for each month (Appendix 4).

Summary sheets and individual patient record sheets must be sent to Aisha Achha, Prescribing Technician, City and Hackney Teaching PCT, Louis Freedman Centre, St Leonard’s Hospital, Nuttall Street, London N1 5LZ.

12. Indemnity

The service provider will operate in accordance with all Acts of Parliament, statutory regulations or other such laws, recommendations, guidance or
practices as may affect the provision of services specified under the Agreement.

Any litigation resulting from an accident or negligence on behalf of the Service Provider is the responsibility of the Service Provider who will meet the costs and any claims for compensation, at no cost to the tPCT. The pharmacist must ensure that their professional indemnity insurance provider has confirmed that this activity is included in their current policy.

13. Transfer and subcontracting

The service provider will not assign the whole or any part of this Agreement or sub-contract the supply of services without the previous consent in writing of the tPCT, the Commissioner, unless special conditions are included elsewhere in the Agreement or are negotiated purely for contingency purposes.
Contract Agreement

The signatures below constitute the agreement between the parties concerned for the provision of supervised consumption of opioid replacement therapy services. The agreement will be reviewed annually by the Scheme Coordinator via the Shared Care Management Group and the DAAT/DAT.

The lead tPCT commissioning officer for this agreement is:

Name: Jonathan Mason
Position: Head of Prescribing and Pharmacy

City and Hackney tPCT
Louis Freedman Centre
St Leonards
Nuttall Street
London
N1 5LZ

Telephone: 020 7683 4454
Email: jonathan.mason@chpct.nhs.uk

The lead service provider officer for this agreement is:

Name: 
Position: 
Pharmacy: 

Address:

Telephone: 
Email: 

SIGNING OF THE AGREEMENT

This document and the attached notes comprise the Agreement concluded between NHS City and Hackney and the pharmacy named above.

SIGNED: ___________________________ Date: ________________

SIGNED: ___________________________ Date: ________________
APPENDIX 1

Supervised buprenorphine (Subutex) supply

Professional Indemnity

Background

Subutex (buprenorphine) is used as an adjunct in the treatment of opiate dependence. Buprenorphine 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 to 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 buprenorphine tablets 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.

Supervised consumption of buprenorphine (Subutex) – 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.

- Pharmacists crushing buprenorphine tablets 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. Pharmacists 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 buprenorphine as a result of crushing.

- Pharmacists 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 buprenorphine tablets;
  - That crushing is outwith the manufacturer’s marketing authorisation;
There is a 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 buprenorphine tablets 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 buprenorphine 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 a number of doses prescribed in local treatment agreements (usually consecutive 3 doses);
  - 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, or under the influence of alcohol or other drugs to the extent that in the pharmacist’s judgment 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.
ANNEX

Client leaflet - supervised buprenorphine (Subutex)

Your doctor has prescribed buprenorphine 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.
- Having a drink of water at this stage 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. A newspaper is provided for your entertainment!
- 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 three (3) consecutive doses will also mean you have to contact your clinic/doctor.
APPENDIX 2

New Patient Acceptance Form

Name of pharmacist:

Pharmacy:

Address of pharmacy:

Patient identifier:

<table>
<thead>
<tr>
<th>Initials</th>
<th>Date of Birth</th>
<th>Male (M) or Female (F)</th>
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The above should now be used on all returns as the patient identifier

Prescriber name: .................................................................

Name of GP Practice or specialist Service: ...........................................

Key worker full name: ...........................................................................

Supervision of: METHADONE or BUPRENORPHINE (please circle which)

Date on which supervision commenced:

Starting dose: ..................................................................................

Date on which supervision terminated ..................................................

Please fax this form to Aisha Achha on 020 7683 4464

Aisha Achha, Prescribing Technician
City & Hackney TPCT
Primary Care Commissioning
Louis Freedman Centre
St Leonard’s
Nuttall Street
London N1 5LZ
### APPENDIX 3

**Supervised Self Administration of Methadone Record**

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<th>Month &amp; Year</th>
<th>Pharmacy Name &amp; Invoice Number</th>
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NB State any reasons for non-supervision  

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NB State any reasons for non-supervision  
Total
APPENDIX 4

Supervised Consumption of Methadone

Pharmacist Claim Form

Month ________________    Invoice Number ______________

I claim for a total number of _____________ supervisions at £2.50 each and attach the daily supervision record sheets for the month.

Total Claim  £___________    Date ___________________

I declare that the information I have provided on this form is true and correct. I understand that if I provide false or misleading information this may result in criminal prosecution and civil recovery proceedings. I consent to this information being used for enquiries in relation to the prevention, detection and investigation of fraud.

Signed ___________________    Print Name _________________________

Please note payment will only be authorised if supervision record sheet is completed and attached. Please return claim form and record sheet to:

Aisha Achha, Prescribing Technician
City & Hackney TPCT
Primary Care Commissioning
Louis Freedman Centre
St Leonard’s
Nuttall Street
London N1 5LZ

Tel 020 7683 4483
Fax: 020 7683 4464
E-mail: aisha.achha@chpct.nhs.uk

PCT Use Only

Total Payment Authorised  £___________________    Date ____________

Shared Care Substance Misuse Manager Signature _______________________

Code: CC3N-E80331-6950-09808
Supervised Consumption of Buprenorphine

Pharmacist Claim Form

Month ________________  Invoice Number ________________

NAME AND ADDRESS OF PHARMACY  
(Please use pharmacy stamp)

I claim for a total number of _____________ supervisions at £2.50 each and attach the daily supervision record sheets for the month.

Total Claim  £_____________  Date ____________________

I declare that the information I have provided on this form is true and correct. I understand that if I provide false or misleading information this may result in criminal prosecution and civil recovery proceedings. I consent to this information being used for enquiries in relation to the prevention, detection and investigation of fraud.

Signed ___________________  Print Name _________________________

Please note payment will only be authorised if supervision record sheet is completed and attached. Please return claim form and record sheet to:

Aisha Achha, Prescribing Technician  
City & Hackney TPCT  
Primary Care Commissioning  
Louis Freedman Centre  
St Leonard’s  
Nuttall Street  
London N1 5LZ  

Tel 020 7683 4483  
Fax: 020 7683 4464  
E-mail: aisha.achha@chpct.nhs.uk

PCT Use Only

Total Payment Authorised  £___________________  Date ________________

Shared Care Substance Misuse Manager Signature  _________________________

Code: CC3N-E80331-6950-09808