Service Specification for Supervised Administration of Methadone and Buprenorphine

1 Service description
1.1 This service requires an appropriately trained member of staff to supervise the consumption of either methadone or buprenorphine in the management of opiate dependence at the point of dispensing, if requested to do so by the prescriber.

1.2 Pharmacies will offer a user-friendly, non-judgmental, client-centred and confidential service.

1.3 The pharmacy will provide support and advice to the client, including referral to primary care or specialist centres where appropriate.

2 Aims and intended service outcomes
2.1 To ensure compliance with the agreed treatment plan by:
   - dispensing in specified instalments (doses may be dispensed for the client to take away to cover days when the pharmacy is closed in line with the instructions of the prescriber),
   - ensuring each supervised dose is correctly consumed by the client for whom it was intended.

2.2 To reduce the risk to local communities of:
   - over usage or under usage of medicines;
   - diversion of prescribed medicines onto the illicit drugs market; and
   - accidental exposure to the supervised medicines.

2.3 To increase feedback to the prescriber to improve monitoring of service user non-compliance, in line with the terms of agreement (see 3.3 & 3.4 below).

2.4 To provide service users with regular contact with health care 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.

2.5 To contribute to minimising the number of methadone related deaths.

3 Service outline
3.1 The area of the pharmacy used for provision of the service provides a sufficient level of privacy and safety. This should not be in the dispensary.

3.2 The pharmacy will present the medicine to the service user in a suitable receptacle and will offer the service user water (in a disposable cup) to facilitate administration.

3.3 The pharmacy will ensure the dose has been taken appropriately.

3.4 It is good practice to establish terms of agreement. This is likely to take the form of a contract between the pharmacist and client (a two-way agreement) to agree how
the service will operate. This may contain information about collection times, what constitutes acceptable behaviour by the client, and what action will be taken by the prescriber and pharmacist if the user does not comply with the agreement (see appendix 1 and 2).

3.5 The pharmacy contractor has a duty to ensure that pharmacists and staff involved in the provision of the service have relevant knowledge and are appropriately trained in the operation of the service.

3.6 The pharmacy will have Standard Operating Procedures in place for the supervision of methadone and buprenorphine which includes preparation, accuracy checking, relevant entries into the CD register, supervision and confirmation of client details.

3.7 The pharmacy contractor has a duty to ensure that pharmacists and staff involved in the provision of the service are aware of and operate within local protocols and guidelines.

3.8 The pharmacy will maintain appropriate records to ensure effective ongoing service delivery and audit, in addition to legally required records. This includes

- Dates prescription covers
- Initials of patients
- Prescriber details
- Medication being supervised
- Total number of doses prescribed
- Number of doses to be supervised
- Actual number supervised
- Number of doses not collected

3.9 Pharmacists will share relevant information, where appropriate, with other health care professionals and agencies, in line with locally determined confidentiality arrangements.

3.10 The pharmacy will have completed the distance learning package ‘Substance Use and Misuse’ from the CPPE within 6 months of starting to provide a Supervised Consumption Service and a record of completion of this programme must be kept and a copy sent to the accrediting PCT for full accreditation. CPPE also has a Pharmacy Technician Substance Use and Misuse open learning programme available, which would support the development of such services and assist the pharmacy in complying with 3.5.

3.11 The pharmacist will attend an evening contractor meeting when required to do so by the PCT this will be no more frequent than annually.

3.12 From 1 July 2011, payment will be at the rate of £1.30 per methadone supervision and £2.85 per buprenorphine supervision. From 1 April 2012, payment will be at the rate of £1.40 per methadone supervision and £2.85 per buprenorphine supervision. For non-supervised, daily pick-up clients only, a fee (equivalent to the fee for methadone supervision as above) may be claimed if the client fails to collect either three consecutive days’ doses or any four doses on one prescription AND the
pharmacist notifies the prescriber of this. This claim may only be made once per prescription.

3.13 The pharmacy will feedback relevant information to the prescriber, in line with the terms of agreement,(see appendix 3) for example if:
   - The client does not consume the whole dose under supervision.
   - The client regularly tries to avoid supervision.
   - The client appears to be intoxicated e.g. alcohol, other prescription and/or illicit drugs (clients stabilised on methadone should be alert and coherent). In the case of chronic alcoholism the client should not be excessively intoxicated.
   - The client appears ill.
   - There are problems concerning the prescription e.g. ambiguity of dates for dispensing, identity of client in doubt, alterations to the prescription.
   - The behaviour of the client is unacceptable e.g. shoplifting, verbal and/or physical abuse.
   - The client misses more than three doses consecutively (missing doses may result in a drop in opiate tolerance with an increased risk of accidental overdose).
   - At the request of the client for an acknowledged clinically important matter

3.14 The pharmacist providing these services must be able to demonstrate the following core competencies. (These have been linked, where appropriate, to the general pharmacist competences of the Royal Pharmaceutical Society of Great Britain)
   - Understands the terminology and definitions of substance misuse, the theories of drug dependence, concept and practice of harm reduction [G1].
   - Is aware of commonly misused substances [G1].
   - Understands the treatment of substance misuse, including multidisciplinary team working, assessment and care planning, pharmacotherapeutic and non-pharmacotherapeutic options [G1, G5].
   - Communicates with substance misusers appropriately and sensitively. [G2, G3]
   - Is able to counsel and advise individuals about their substance misuse and enable them to take their medication as prescribed whilst respecting their privacy and treating them with dignity [G2].
   - Knows how and when to refer / signpost clients and when to ask for support and advice [G7].
   - Understands the legislation, ethics, duty of care and professional judgement for this client group [G1, G10].
   - Is aware of the management, planning, and delivery of pharmacy services for substance misusers, including conflict resolution. [G4, G5].
This will be determined through self-certification by the pharmacy plus submission of appropriate copies of certificates as outlined in 3.10

3.15 The pharmacist will be required to supply a self-certification form for re-accreditation every 2 years.

4 PCT Responsibilities

4.1 The PCT will provide a framework for the recording of relevant service information for the purposes of audit and the claiming of payment.

4.2. The PCT will provide details of relevant referral points which pharmacy staff can use to signpost service users who require further assistance.

4.3. The PCT will provide health promotion material to pharmacies which is relevant to the service users, where appropriate.

4.4. The PCT will arrange contractor meetings as necessary to promote service development and update the knowledge of pharmacy staff

5 Suggested Quality Indicators

5.1 The pharmacy reviews its standard operating procedures and the referral pathways for the service on an annual basis.

5.2 The pharmacy can demonstrate that pharmacists and staff involved in the provision of the service have undertaken CPD relevant to this service.

5.3 The pharmacy participates in an audit of service provision when requested by the PCT. This will be no more frequent than annually.

5.4 In addition to compliance with the Essential Services requirements of the Community Pharmacy Contractual Framework, it is desirable that the pharmacy also complies with local incident reporting policies.

5.5 The pharmacy co-operates with any locally agreed PCT-led assessment of service user experience. This will be no more frequent than annually

5.6 The pharmacy has appropriate PCT provided health promotion material available for the user group and promotes its uptake.
Methadone and Buprenorphine Supervision Guidelines

This document outlines the procedures to carry out the service and responsibilities of the pharmacist and of the clinic/prescriber.

1.0 Clinic/Prescriber Responsibilities

1.1 These guidelines relate to the supervised consumption of daily doses of methadone and buprenorphine. All prescriptions requiring supervision should be clearly marked ‘Supervised Consumption’.

1.2 The prescriber must reach an understanding with the client that methadone/buprenorphine will be dispensed at an agreed community pharmacy, where administration and consumption of the methadone will be supervised by the pharmacist or appropriately qualified member of staff under the supervision of a pharmacist. The prescriber must also explain to the client that the pharmacist will be required to inform the prescriber of breaches of the agreed procedure, such as failure to collect, refusal to accept supervision, bad behaviour. As part of the prescriber’s contract with the client, the prescriber must obtain the client’s informed, written consent to the fact that such information may from time to time be passed back.

1.3 The prescriber should discuss with the client the most suitable/convenient pharmacy and should seek the agreement of the pharmacist to accept this client.

1.4 It is good practice, though not always practicable, for the pharmacy to be contacted in advance by the GP or representative of the clinic to discuss the dispensing arrangements for the client.

1.5 If the pharmacy accepts the client, the prescriber should inform the pharmacy of the name and address of the client, methadone/buprenorphine dose, start and expiry date of the prescription, and the name of the key worker.

1.6 Clients should be prescribed methadone/buprenorphine in daily (or twice daily) instalments, with supervised dose on day of collection with a take home doses for remainder of instalment and chemist closed days.

2.0 Pharmacist Responsibilities

2.1 When the client arrives the pharmacist should check the details of the introductory letter and should register the client on the Patient Medication Record (PMR) system. The clients details should be checked eg DOB and address prior to collection or supervision of methadone/buprenorphine.

2.2 It is good practice for the pharmacist to go through a client contract with the client, agree and sign it. The main issues to be covered are:

2.2.1 Times between which supervision is convenient for both parties.

2.2.2 Minimum interval between supervised doses.
2.2.3 Missed doses cannot be dispensed at a later date.

2.2.4 The prescriber will be notified of failures to collect, refusal to co-operate with supervision, anti-social behaviour, general appearance etc.

2.2.5 The prescriber will be contacted, and methadone/buprenorphine may not be dispensed, if the client has missed three consecutive days’ doses.

2.2.6 Methadone/buprenorphine will not be dispensed if the pharmacist suspects there is evidence of excessive drug and/or alcohol intoxication (client to be referred back to the clinic for assessment).

2.2.7 The client should come alone or with his or her abstinence carer, e.g. parent or spouse, or where two clients co-habit and attend together by agreement.

2.3 If appropriate, the pharmacist should introduce the client to key members of staff.

2.4 When a prescription is presented it should be checked to see if it is legal, and if the quantities and details are correct for that client.

2.5 Methadone/buprenorphine should not be dispensed to clients who are excessively intoxicated with drugs and/or alcohol. If the pharmacist suspects the client is intoxicated, he/she should telephone the clinic to inform them, and to ask whether the client is to be sent back to the clinic for assessment, if appropriate.

2.6 If a client has failed to collect three or more consecutive days’ doses, no further methadone or buprenorphine should be dispensed without the agreement of the prescriber.

2.7 Where a daily dose of methadone/buprenorphine has not been dispensed by the pharmacist, or the dispensing service has been terminated for a client for whatever reason, the pharmacist should indicate this on the prescription as 'not dispensed' for any remaining days on the current prescription. The clinic should be notified of any prescriptions which have not been started. The pharmacy should document this as an intervention and shred the prescription with a witness.

2.8 Supervision must never take place in the dispensary. Where possible, a designated area offering suitable privacy should be selected in each pharmacy, and should be used for this purpose.

2.9 Doses of methadone/buprenorphine should be made up in advance each day (assuming that the pharmacist is in possession of a current prescription). All doses must be labelled in accordance with requirements of the Medicines Act. The correct date of dispensing, ie the date of supply to the client, should be shown on the label. Methadone should be dispensed into an appropriate child resistant container

2.10 When the client arrives, the pharmacist or appropriately trained staff must ensure that the client is correctly identified, and receives his/her dose of methadone or buprenorphine.

2.11 The methadone should be consumed directly from the bottle or may be poured into a disposable cup, as agreed by the pharmacist and client.

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Review date: June 2013
2.12 The pharmacist or appropriately trained staff should observe the consumption of the methadone/buprenorphine by the client. After methadone supervision clients should be offered a drink of water in a disposable cup and spoken to, to ensure the dose has been swallowed. Buprenorphine can take several minutes to dissolve especially if the mouth is dry, water should be offered to dampen the mouth before the tablet is put into the mouth, no water should be consumed until the tablet has dissolved and has had a chance to be absorbed sublingually. Care should be taken that the client does not swallow the tablet.

2.13 Methadone/ buprenorphine must not be given to the client’s representative unless previously authorised by the client him/her-self or by a member of the clinic staff, GP or police surgeon, preferably in writing.

2.14 After each dispensing/supervision the pharmacist or appropriately trained staff should then make the appropriate entries in the CD register and on the prescription. Any notable incidents/events should be recorded on the Incident Report Form and returned to the clinic - if there is a need to contact the clinic urgently this should be done by telephone. A report form can then be sent soon afterwards.

2.15 Locum pharmacists should be made aware of this service and the procedures, in advance of them providing locum cover. It is essential that the service runs smoothly and all records are kept up to date.

2.16 Pharmacists may wish to ensure that they have adequate insurance cover prior to commencing the service.

2.17 Pharmacists should discuss with their staff the desirability of Hepatitis B vaccinations.
Appendix 1
Supervised Administration of Methadone/ Buprenorphine In The Community Pharmacy

Client / Pharmacist Agreement Form

As the Pharmacist I agree to:

- Provide a quiet area for your treatment supervision.
- Keep records of your attendance.
- Dispense your treatment in accordance with the prescription.
- Liaise, when necessary, with the clinic or your GP with regard to your treatment.
- Refer you back to the clinic or your GP and discontinue dispensing your prescription if you do not collect your dose from the pharmacy for three days or more. If you attend intoxicated, your methadone/buprenorphine may not be dispensed for that day. If your behaviour causes any problems, you will also be referred back to the clinic or GP.
- Provide health promotion and education.

Date ....................................................

Pharmacist ............................................ Signature ........................................

As the client I agree to:

- Treat the pharmacy, its customers and its staff with respect.
- Attend the pharmacy daily within agreed times, and with an agreed time limit between visits if my prescription is for twice daily supervised doses.
- Not attend whilst intoxicated with alcohol and/or drugs.
- Attend alone and leave pets outside, unless agreed otherwise.
- In exceptional circumstances, wait or return later if the pharmacy is busy.
- Return to my doctor or the clinic for a re-assessment if I have not collected doses from the pharmacy for three days or more.
- Not allow any other person to attend the pharmacy on my behalf unless arranged previously.
- Raise any queries or problems in a calm and reasonable manner with pharmacist.

Date ....................................................

Client Name ............................................ Signature ........................................
Appendix 2
Bradford and Airedale tPCT Supervised Methadone and Buprenorphine Scheme
Contract

Date................................................................................................................................................

Client Name ........................................................................................................................................

GP........................................................................................................................................................

Key Worker ...........................................................................................................................................

Pharmacy Address ................................................................................................................................

Once this form has been completed you have been accepted onto the Supervised Methadone and Buprenorphine Scheme which operates in Bradford and Airedale. You will be able to receive a regular prescription, as part of a reduction programme, from the prescriber named above. Please be completely truthful about your drug use, to help the GP to prescribe the right dose of for you.

• Your prescription will be dispensed in daily/twice daily instalments at the chosen pharmacy. (delete as applicable)

• The pharmacist or member of staff will watch you consume your daily dose.

• Please note - the needle exchange scheme will remain as a confidential service. It is quite separate from the methadone and buprenorphine scheme.

Please read the rules shown below carefully.

If you do not keep to the rules your prescription may be stopped.

Please ask for more information if there is something that you do not understand.

Appointments, Prescription, and Medication

1. I agree to attend only the clinic / GPs mentioned on this form.

2. I accept responsibility for turning up for my appointments on time.

3. I agree to give urine specimens when required by the clinic or GP.

4. I understand that my prescription is a private matter between the GP, pharmacist, drug worker and myself. I will not discuss it with others.

5. I understand that the GP, the pharmacist and the drug worker are free to confer and exchange information about when I collect and when I fail to collect, and about my behaviour, apparent state of health and other factors related to my treatment.

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6. I also understand that all parties will continue to treat any usage of the needle exchange scheme as confidential and that information about this will not be exchanged.

7. I agree to be responsible for my prescription and medicines. I recognise that these cannot be replaced. I understand that no alterations can be made to the prescription except by my GP and then only on the original prescription form, prior to the amended supply.

8. It is my responsibility alone to ensure that I have a current prescription, and to visit the clinic / doctor when necessary.

9. I agree to collect my methadone/buprenorphine from the named pharmacy each day. Doses will be supplied in advance to cover pharmacy closed days. I understand that Sunday’s dose and any Bank Holiday doses will be dispensed on the last pharmacy opening day, if authorised on the prescription, and that I must look after any such doses and take them on the days for which they were supplied. If I lose any of these doses, they cannot be replaced.

10. I agree to attend the pharmacy at the arranged time daily.

11. I will attend unaccompanied, and will not loiter on or around the premises.

12. I understand that I will be required to consume my medication under the supervision of the pharmacist or member of staff in the pharmacy.

13. I understand that only exceptionally and by prior arrangement, will my daily dose be issued to any other person. No alteration can be made to the prescription by the pharmacist.

14. If I fail to collect my daily dose of methadone/buprenorphine I understand that the pharmacy will inform the prescriber. I also understand that the prescriber can cancel my prescription.

15. Any dose not collected and consumed will be subtracted from the prescription by the pharmacist; I cannot collect it later. I also understand that all doses up to the next due day (if not daily pick up) will also be forfeit unless the prescription states “If an instalment covers more than one day and it is not collected on the specified day, the total amount prescribed less the amount prescribed for the day(s) missed may be supplied.”

16. I understand that, if I miss three consecutive days, the pharmacist will not dispense any further medication instalments before referring to the prescriber. I may have to return to the clinic for an assessment.

17. I agree not to take painkillers (except aspirin, paracetamol or ibuprofen) unless they have been prescribed by a health care professional.

18. I understand that methadone/buprenorphine are powerful drugs. They can cause serious harm or death in overdose. I understand that they are addictive. I understand that they can cause drowsiness. I know that I must not drive or operate machinery if I am affected by drowsiness. I know that they are more dangerous when taken with alcohol.
Behaviour

19. I understand that it is in my best interests to be truthful about my drug use. This means telling my doctor the amount of any drug I have been taking, including alcohol.

20. I will not come to the pharmacy under the influence of alcohol or other drugs, and I understand that smoking and the consumption of alcohol on these premises is forbidden.

21. I agree not to upset the staff or patients in the pharmacy.

Agreement

Client

I have read the terms of this contract, been given a copy, and I understand what they mean. I agree to abide by them and I understand that if I do not, my doctor will be informed and drug treatment services may be withdrawn.

Signature .................................................. Date ................................

Pharmacist

I agree to supervise the self administration of methadone or buprenorphine by this client in this pharmacy, in accordance with prescriptions issued by the prescriber named in this contract. I have provided information on suitable times to collect the daily doses.

Signature ............................................................... Date .................................
### Bradford Supervised Self Administration of Methadone and Buprenorphine

#### Incident / Referral Report Form

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Please forward to the clinic or prescriber

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