Administering Authority:	East Riding of Yorkshire Council
Provider Name:	
Contract Title	ERYC Public Health
Contract Number:	PH/003/2019
Service Area:	Supervised Consumption Service
Service Type:	Public Health
Contract Type:	Fixed Term, Variable Volume
Start Date:	1 April 2019
End Date:	31 March 2022
Extension Options:	Option to extend for up to two years at the ERYC discretion
Authority Lead Officer:	Tony Margetts

APPENDIX A1 - SERVICE SPECIFICATIONS – SUPERVISED CONSUMPTION SERVICE

A1.1 POPULATION NEEDS

A1.1.1 National/Local Context and Evidence Base

Drug Misuse and Dependence; UK guidelines on clinical management, DoH 2007

Guidance on pharmaceutical services for drug misusers in England has been published by the National Treatment Agency for Substance Misuse (NTA), the Royal Pharmaceutical Society and the Pharmaceutical Services Negotiating Committee. The guidance entitled "Best practice guidance for commissioners and providers of pharmaceutical services to drug users" is available to download from:

http://www.nta.nhs.uk/uploads/nta_best_practice_pharma_services_for_drug_users_pharmguide06.pdf

A1.1.2 Key Service Outcomes

Local Outcomes:

- To provide safe, supervised and accessible alternatives to those people participating in a drug rehabilitation programme with an opiate dependency in line with relevant guidance;
- To reduce the number of opiate dependent residents within the ERYC boundary;
- To contribute to the reduction of harm caused by drug misuse;
- To reduce the instances of drug related offending and drug related crimes;
- Contribute to the reduction of transmitted blood born viruses, including hepatitis and HIV.

A1.3 SCOPE

A1.3.1 Aims and Objectives of Service

- To ensure compliance with the agreed treatment plan (prescription) by:
    - Ensure access and administration of prescribed methadone or buprenorphine based drugs to dependent users as part of an opiate dependency rehabilitation programme
- Dispensing in specified instalments (doses may be dispensed for the patient to take away to cover days when the Pharmacy is closed),
    - Ensuring each supervised dose is consumed by the patient for whom it was intended.

- To reduce the risk to local communities of diversion of methadone and buprenorphine onto the illicit drugs market and accidental exposure to methadone and buprenorphine.

- 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.

A1.3.2 Service Description/Pathway

This service is only provided by Pharmacies contracted by the ERYC Public Health Team to procure, store administer and record details of Methadone or buprenorphine drug based products prescribed by drug treatment services or GPs contracted by the ERYC and working within the shared care services for residents of the East Riding of Yorkshire, commissioned by the ERYC.

A1.3.3 Population Covered

This service will only be funded by the ERYC for:

- Those service users who are normally residents within the boundary of the East Riding of Yorkshire: and
- Participating in a recognised drug rehabilitation programme.

Pharmacies who provide the service to non-eligible Service Users must record this on the "NR" templates on PharmOutcomes.

A1.3.4 Acceptance and Exclusion Criteria

Only those cost relating to residents of the East Riding who are:

- participating in a ERYC recognised drug rehabilitation programme; and

- prescribed Methadone or Buprenorphine based drugs by an appropriately qualified medical practitioner as part of that rehabilitation programme,

will be eligible for payment by the East Riding of Yorkshire Council.

A1.3.5 Interdependencies

Individuals participating in a recognised opiate rehabilitation/abstinence programme will be signposted to Pharmacies participating in this service.

Pharmacies participating in this service will provide information as agreed with ERYC PH Team and signpost individuals to other relevant services and record it via the PharmOutcomes Software.

A1.3.6 Activity Planning Assumptions

This service will be included and reviewed within the ERYC Local Pharmacy Needs Assessment undertaken by ERYC PH Team and may be offered as part of a package of services dependent on need, capacity and access for service users.

It is expected that subject to qualifications and available facilities the majority of Pharmacies delivering this service will also deliver the other drug misuse services which currently consist of Supervised Buprenorphine, Supervised Methadone, Needle Exchange and Hepatitis Testing.

A1.4 APPLICABLE SERVICE STANDARDS

National
This service will be delivered in accordance with relevant NICE guidance, in particular the Technology Appraisal Guidance 114 (DoH 2007) "Methadone and Buprenorphine for the management of opioid dependence" (NHS Jan 2007 reviewed March 2010).

Local
Applicable local standards please see Annex B1, B2, B3 and B4 to this Specification (Appendix A1 – Supervised Methadone Consumption).

A1.5 SUMMARY OF SCHEME

- this service is commissioned by East Riding of Yorkshire Council (ERYC) Public Health Team.
- this service requires a pharmacist or trained member of staff under the supervision of a pharmacist to supervise the consumption of methadone or buprenorphine at the point of dispensing to ensure that the correct dose has been administered to the patient.
- the Pharmacy will provide the service according to a locally written Standard Operating Procedure.
- Pharmacies will provide a user-friendly, non-judgmental, client-centred and confidential service.
- the Pharmacy will provide support and advice to the patient, and liaise with primary care or specialist centres where appropriate.
- the service will be monitored by the ERYC PH Team.
- the ERYC PH Team will manage the budget for the scheme and authorise the payments to Providers for residents of the East Riding of Yorkshire.
- the Pharmacy must be contracted with the ERYC Public Health Team to provide this service to enable payments to be claimed.

A1.6 SERVICE OUTLINE

- this service must be provided throughout the Pharmacy's contracted hours although it is recognised that some restriction at the beginning or end of the day may be necessary.
- the part of the Pharmacy used for provision of the service will (must) provide a sufficient level of privacy and safety. It must allow for the client to be seated.
- Prior to commencing supervised treatment, all clients must be issued with an information/consent form (for an example see appendix 2). This must be agreed and signed by the client and pharmacist and retained for the duration of supervision.

The client must be observed at all times by a member of Pharmacy staff during the points below:

- the Pharmacy will present the medicine to the service user in a labelled dispensing container which could be used as a suitable single use receptacle and will provide the service user with water to facilitate administration and/or reduce the risk of doses being diverted.
- The Pharmacy must closely observe the client placing the tablet(s) or liquid under the tongue until the client informs them that the tablet has dissolved or the liquid has been swallowed. A drink of water must then be provided and consumed before the client leaves the Pharmacy.
- If the client avoids or attempts to avoid supervision or the process of proper administration the prescriber must be informed by the Pharmacy

A1.7 STAFFING/TRAINING

The Pharmacy contractor will ensure that pharmacists, locums and staff involved in the provision of the service have relevant knowledge and are appropriately trained in the operation of the service.

All pharmacists providing this service will complete the CPPE Open Learning programme entitled "Substance Use and Misuse" A copy of their certificate of completion will be held in the Pharmacy and available to the Commissioner on request.

All pharmacists providing this service will ensure staff involved in the delivery of the service undertake relevant training agreed with the ERYC PH Team.

The Pharmacy contractor will ensure that pharmacists and staff involved in the provision of the service are aware of and operate within any agreed local protocols.

The ERYC PH Team will provide details of relevant referral points, which Pharmacy staff can use, to signpost service users who require further assistance. This will be provided via PharmOutcomes.

The ERYC PH Team in conjunction with other agencies will obtain or produce health promotion material relevant to the service users and make this available to Pharmacies for display.

The Pharmacy contractor should ensure that all staff responsible for completing claim forms are fully conversant with the use of PharmOutcomes and aware of the necessity to follow the correct procedures with regards to patient data protection.

A1.8 REQUIRED INSURANCES

In addition to Clauses B27.1, B27.2, B27.3 and B27.4 of the Contract Terms and Conditions, Providers are required to have insurances at the minimum levels detailed below:

Insurance type	Minimum level	Preferred level
Employer's liability	£10m	£10m
Public liability	£5m	£10m
Medical negligence	£2m	£10m
Products liability	£5m	£5m
Professional indemnity	£2m	£5m

Providers will be required to evidence the above by submitting copies of their policy documents and proof of payment prior to being awarded a contract.

Regarding cover, the successful parties will need to evidence that the cover will operate in respect of Public Health contracts issued by the local authority for which they will receive a fee.

A1.9 RECORDS / AUDIT

The Pharmacy will maintain appropriate records to ensure effective ongoing service delivery and audit. A record of each client will be maintained on a patient medication record (PMR) at the Pharmacy.

Pharmacists will share relevant information with other health care professionals and agencies, in line with confidentiality arrangements. They will input into the prescriber/client reviews of supervised consumption as requested.

The ERYC PH Team will where necessary provide a license for PharmOutcomes as the system for the recording of relevant service information and the purposes of audit and the claiming of payments. Where data is missing or unclear then claims for payment will be returned to the Pharmacy for clarification and resubmission.

Claims for payment will be submitted automatically by the PharmOutcomes software within five days of the month end.

Pharmacists will record relevant service information for the purposes of audit using the framework provided (Annex B1) and submit to the ERYC PH Contract Manager annually on request or via the PharmOutcomes annual service assessment.

ANNEX B1 to Appendix A1, Supervised Consumption Service Specification

Audit of Service

Please complete and return on request or at least annually to the nominated ERYC PH Contract Manager or via PharmOutcomes

Service Standard		**Rating**			**How can my service be improved? (Action plan for improvement)**
		Always	**Mostly**	**Never**	
1	Where a new service user presents without prior notification by the prescriber, contact is made with the prescriber to confirm the client's identity and prescription details before issuing the first dose.				
2	An agreement on the "conduct of behaviour" should be explained and two copies signed by each new service user (one for them to keep and one to be kept in the Pharmacy). ***See Annex B4 of Appendix A1 for example.***				
3	A signed copy of any agreement is held securely in the Pharmacy for 11 Years.				
4	Service users are given a practice leaflet and information about appropriate times to collect doses.				
5	Information is given to service users relating to weekend and Bank Holiday doses.				
6	Service users are introduced to staff so that they can be identified and dealt with promptly each day.				
7	The Pharmacy must have a method to confirm identification if the service user cannot be identified by staff e.g. PMR ID card or check signature against agreement				
8	The service user's PMR should be complete and include name and address, date of birth, GP/prescriber details, key worker name and contact details (if applicable) and "supervised consumption" or similar note.				
9	The service user's PMR should also include all other prescription items dispensed by the Pharmacy, and where appropriate, other over-the counter medication supplied.				
10	All patient identifiable information is kept in a secure place and is not passed on to anyone other than those authorised to see it.				
11	Prescriptions must be legally correct.				

12	The methadone mixture or buprenorphine tablet used is a licensed product or is extemporaneously prepared according to an SOP in line with RPSGB guidance.				
13	Any equipment used in the manufacture or dispensing of methadone mixture or buprenorphine tablet should be cleaned, calibrated and serviced regularly according to the manufacturer's instructions				
14	Sugar and/or colour free preparations should only be dispensed if they are specifically prescribed as they have a greater potential for abuse				
15	If doses are prepared in advance (recommended if space in the CD cabinet permits) they should be suitably labelled and stored in the CD cabinet.				
16	Individual instalments are fully dispensed and labelled **prior** to supervision.				
17	Doses are measured and checked before being dispensed into a suitable container.				
18	The dispensing label should be attached to the container detailing name, directions, quantity and date of dispensing.				
19	Take home doses are provided in an appropriate leak proof container and fitted with child resistant closures.				

20	Advice is given on safe storage of take home doses as necessary a. "Keep out of reach of children" b. Pharmacists have a professional responsibility to ensure that patients are provided with sufficient information and advice to enable the safe and effective use of their medicine. Therefore, where a bottle of medicine contains more than one dose, the pharmacist should ensure that the patient is able to correctly measure out their required doses themselves. (see the Royal Pharmaceutical Society Guidance Fact Sheet 1				
21	The right hand side of the prescription is marked with the date and quantity dispensed and initialled when the service user has consumed the dose or when any "take home" doses have been supplied.				
22	If the service user does not collect a dose the prescription is marked "Not Collected" and the PMR record reflects this				
23	If the service user fails to collect three consecutive doses the prescription is suspended (NOT CANCELLED) until the prescriber has been contacted				

	and an assessment has been made as their tolerance may have fallen				
24	If a service user is intoxicated the dose is not dispensed until the service user has “sobered up” and the clinic informed. Professional discretion should be used on Saturday for take home doses				
25	If a dose is to be collected by a third party this should be stated on the prescription or a verbal authorisation from the prescriber and written authorisation from the client (retained for 1 year) is required on each occasion.				

26	Supervision takes place in a quiet area with sufficient privacy to allow both service user and Pharmacy staff member to feel comfortable (Supervision does not take place in the dispensary)				
27	Doses should be presented to the patient in a **single use disposable** receptacle (the cost of 2 disposable plastic cups is included in the costing of supervision)				
28	A drink of water is provided to the service user in a single use disposable receptacle				
29	The staff member supervising the dose should be satisfied that the dose has actually been swallowed by observing water being swallowed after the dose, or by conversing with the service user				
30	Any receptacles, which the service user has been in contact with should not be reused and should be disposed of in the normal waste. Pharmacy staff should avoid handling the used containers.				
31	Harm minimisation information has been reviewed and steps taken to minimise any risks to Pharmacy staff. *See Annex B1 to AppendixA1*				
32	Confidentiality is protected by removing identifiable labels from containers prior to disposal or by obliterating names using permanent marker				
33	Entries are made in the CD register in chronological order on the day the dose was collected (recommended) or the day following				
34	The CD entry is marked clearly to indicate a supervised dose ('S' in the margin) or unsupervised dose ('X' in the margin) to provide an audit trail. *(to be reviewed in-line with availability of electronic CD registers)*				
35	Claim form is fully completed and submitted by the 5th of each month *(See Appendix E)*				
36	The Pharmacy makes use of health promotion materials relevant to the service users e.g. harm reduction information.				
37	The Pharmacy makes use of signposting information provided by the ERYC PH Team.				
38	The Pharmacy reviews its standard operating procedures and the referral pathways for the service where necessary or at least on an annual basis				
39	The Pharmacy completes this audit at least annually and submits copies as requested for collation and review to the ERYC Contract Manager				
40	The Pharmacy Contractor ensures the quality of the service is maintained by all pharmacists, locums and staff involved in its provision.				

41	The pharmacists and staff involved in the provision of the service have undertaken CPD relevant to the service and are able to demonstrate this if requested by the ERYC PH Team.				

Pharmacy Name:

Pharmacy Address:

Pharmacist Name (please print)……..Signature:……Date:…….

ANNEX B2 to Appendix A1, Supervised Consumption Service Specification

GUIDELINES FOR SUPERVISED CONSUMPTION

Revised 2009

1. INTRODUCTION

1.1 The purpose of these guidelines is to provide local supervised consumption guidelines for the East Riding. These guidelines replace those agreed in 2005 and should be read in conjunction with the following national guidance:

- Drug Misuse and dependence: UK guidelines on clinical management. Department of Health 2007 (the “orange book” or “new orange book”).
- Best practice guidance for commissioners and providers of pharmaceutical services for drug users. National Treatment Agency February 2006.

1.2 These guidelines have been prepared by the Primary Care Substance Misuse Development Group and are primarily intended for General Practitioners, Shared Care Workers and Pharmacists participating in supervised consumption. If you have queries or concerns regarding these guidelines please raise them with Tony Margetts, Joint Commissioning Manager, East Riding Safe Communities (tony.margetts@eastriding.gov.uk) 01482 391423

2. THE PLACE OF SUPERVISED CONSUMPTION IN DRUG TREATMENT.

2.1 The best practice guidance cited above gives the role of the pharmacist in dispensing, supervised consumption and shared care as follows (section 2.2.2 p14)

2.2 Dispensing, supervised consumption and shared care – aims and objectives

2.3 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 keyworker and others directly involved in the care of the patient (where the patient has given their 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, withholding treatment if this is in the interest of patient safety, liaising with the prescriber or named keyworker as appropriate;
- improving retention in drug treatment;
- improving drug treatment delivery and completion.

2.4 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.

2.5 Below is an Extract from the relevant guidance on supervised consumption in drug misuse and dependence: UK guidelines on clinical management (pp50 – 53) are as follows:

SUPERVISED CONSUMPTION

When and how to use supervised consumption.

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.

Other guidance, such as the ACMD report on drug-related deaths (ACMD, 2000), the NICE technology appraisal on methadone and buprenorphine (NICE, 2007a) and the 1999 Clinical Guidelines (UK health departments, 1999) have described recommended practice for supervised consumption in slightly different ways. For the 2007 Clinical Guidelines the working group agreed the following recommendations.

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 patients' compliance and individual circumstances. There may be variation in practice across the UK and a range of durations of supervised consumption is likely to be seen for different patients, ranging from just a couple of weeks in highly compliant patients to much longer in patients who fail to respond to conventional treatment. 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.

Long-term, daily supervised consumption would probably not be appropriate for a patient in regular, full-time work where supervision would be a clear barrier to engagement in treatment. When a patient restarts methadone or buprenorphine after a break, or receives a significant increase in the methadone dose, daily dispensing – ideally with supervised consumption – should be reinstated for a period of time agreed in local guidelines and protocols.

In patients whose treatment is failing, a period in supervised consumption can improve observation of progress and increase interventions to improve outcomes. A good example is to enable daily breathalyser readings or monitoring of other indicators of alcohol intoxication in patients who are drinking heavily while taking methadone.

Supervised consumption may have a role in contingency management. Relaxation of supervision can be regarded as an incentive if progress, such as drug-free urine samples, can be demonstrated.

Supervised consumption is often a situation where therapeutic relationships can be built with patients and efforts should be made to stop it being viewed as a punishment.

In the majority of cases the person supervising will be a community pharmacist, although some specialist services and dispensing doctors may employ their own Pharmacy or nursing staff to provide on-site supervised consumption. There should be multi-agency protocols in place to ensure a consistent high standard of service is provided. As part of the service, there should be systems in place to ensure information about patients can be fed to and from the prescriber and keyworker, as well as agreement from the patient that confidential information can be shared between the pharmacist and named members of the multidisciplinary team. Much of this is described in Best Practice Guidance for Commissioners and Providers of Pharmaceutical Services for Drug Users (NTA, 2006).

Stopping Supervision

Relaxation of requirements for supervised consumption and for instalment dispensing should be a stepped process in which a patient first stops taking doses observed by a professional but remains on daily dispensing. Later, after further progress, the frequency of dispensing may be gradually reduced. The relaxation of supervision can be seen as an important component of rehabilitation.

Supervised consumption should only be relaxed if the prescriber has good reason to believe that compliance will be maintained. The assessment of compliance and clinical progress is covered in section 5.5. In general the prescriber needs to assess the following: changes in drug-taking

behaviours (such as injecting), compliance with prescribed drug treatment, abstinence from or significant change in drug misuse and compliance with other elements of a care plan, for example attendance at appointments.

Arrangements for daily consumption through instalment prescribing and, where appropriate, supervised consumption of other medicines should also be made.

Take-home doses should not normally be prescribed where:

- a patient has not reached a stable dose
- the patient shows a continued and unstable pattern of drug misuse, including a significant increase in alcohol intake, the use of illicit drugs, benzodiazepines or other tranquillisers
- the patient has a significant, unstable psychiatric illness or is threatening self-harm
- there is continuing concern that the prescribed medicine is being, or may be, diverted or used inappropriately
- There are concerns about the safety of medicines stored in the home and possible risk to children.

In some of these cases, especially the latter, take-home doses might be permitted but the dose taken home limited by frequent dispensing.

Passing information between pharmacist and prescriber

It is of paramount importance that communication channels between pharmacists Prescriber, and/or key worker are made and maintained.

Patient confidentiality should be respected; however it should be made known to the patient that the pharmacist is an integral part of the Treatment plan and therefore would be expected to participate in care planning. All patients should have a written and structured care plan resulting from assessment, prior to prescribing. Care plans are developed with the active participation of patients and take into account their wishes and needs. Care plans are tailored to patients' needs and circumstances and respond flexibly to the patient's problems. Prescribers, key workers and care coordinators should ensure the name of the patients chosen Pharmacy is included in the patients care plan. The Departments of Health's Drug misuse and dependence – guidelines on clinical management recommends the inclusion of the pharmacist in shared care as a model of good practice and the pharmacist should liaise with the multidisciplinary team on a regular basis.

One way of participating in the care plan process is by the keyworker/prescriber contacting pharmacists for regular verbal or written reports on issues that may be of concern; it may also help demonstrate the improvement in the person's health

The communication process between prescriber/keyworker and pharmacist allows information to pass freely between all parties.

The prescriber or keyworker should contact the pharmacist to discuss acceptance of each new patient on to the programme, if this does not happen the pharmacist should contact the prescriber/keyworker to confirm the arrangements i.e.

- Confirm the Pharmacy is willing and able to accept the client;
- Discuss dispensing arrangements e.g. opening days and hours;
- Provide client details (identifier, key worker);
- Offer details regarding identification of the client;
- Provide details of the first prescription i.e. dose and dates.

The prescriber/keyworker should also inform the client that, as part of the shared care team, the pharmacist can withhold methadone, should the client miss three consecutive doses, break the terms of either contract or present with signs or symptoms suggesting intoxication by alcohol or Psychotropic substances. By doing so at the beginning of the treatment plan it should allow for an open working relationship and prevent confrontation for all parties.

It is also important to encourage the individual in treatment to remain with the same Pharmacy thus providing a valuable, constant and regular link with the same healthcare professional. It also builds up a level of trust.

A pharmacist sees the patient on a daily basis and therefore is able to refer individuals experiencing difficulties back to the prescriber or keyworker for reassessment. This should be done at the earliest possibility usually via telephone, but with the knowledge of the patient, following the locally agreed confidentiality arrangements

Should there be any indication to withhold a dose of methadone in the interest of patients safety e.g. if the patient has missed doses or is intoxicated it is important to liaise and agree with the prescriber or keyworker the appropriate on going treatment with future doses.

Timely and effective communication between health professionals is crucial to ensuring the scheme runs smoothly, including advising the prescriber/keyworker of clients recurrently missing doses as well as any concerns they may have about their general well-being.

3. MOVING AWAY FROM SUPERVISED CONSUMPTION

3.1 Given that patients may well press for a move away from supervised consumption it is important that doctors give patients a clear message about when this is appropriate.

Compliance and Stability

3.2 In order to be considered for a move away from supervised consumption the following criteria should be met:

- The patient has been on supervised consumption for “around three months”. For most patients three months may be regarded as a minimum period and there should be a good and recorded reason for moving from supervised consumption before three months and for many drug users a period of supervised consumption longer than this will be appropriate;
- The patient is happy to be moved away from supervised consumption;
- The patient is committed to, and is stable in their treatment. Commitment and stability are relative terms and doctors and shared care workers will need to assess this on a case-by-case basis. A definition of stability, intended for guidance is attached to this guidance – see **Annex B3 of Appendix A1 – Supervised Methadone Consumption;**
- The patient can safely transport and store methadone (e.g. they will keep it away from children, are not in position where the medicine may be stolen or misused by partners, housemates etc.);
- The patient will not be vulnerable to having the doses taken from them by theft or intimidation;
- The patient is clear about the new and more complicated arrangements for the collecting and dispensing of their prescription (which may involve picking up a prescription 2-3 times a week initially, combined with prescribing daily doses if required);
- Positive changes in lifestyle (e.g. employment or training, increased contact with family) will allow consideration for movement away from supervised consumption;
- Pharmacists have a professional responsibility to ensure that patients are provided with sufficient information and advice to enable the safe and effective use of their medicine. Therefore, where a bottle of medicine contains more than one dose, the pharmacist should ensure that the patient is able to correctly measure out their required doses themselves. (See the Royal Pharmaceutical Society Guidance Fact Sheet 1 on controlled drugs, NPSA Patient Safety Alert 19 Promoting the safer measurement and administration of liquid medicines via oral and other enteral routes March 2007 and NPA updated Standard Operating Procedure (SOP) on Promoting Safer Measuring and Administration of Liquid Medicines).

Patient Responsibilities

3.3 It should be made clear to patients that take-away doses place responsibilities on them and they should be made aware of these responsibilities in any discussion about supervised consumption. These include:

- The safe transportation and storage of methadone. Methadone will be dispensed in glass bottles and transportation should be discussed with them. Methadone is dispensed in bottles with childproof caps, but this in itself is not sufficient security. In storing methadone the patient should consider safety and security – particularly if they still associate with other drug users;
- The doses will be measured accurately and taken as prescribed. Considerations should be given to dispensing in daily doses to ensure patients take the correct amount;
- Methadone will not be sold, traded or given to anyone else;
- Prescribing GPs will be under no obligation to replace lost or stolen prescriptions of methadone. Normally a prescription will only be replaced if the reason can be verified and if a replacement prescription is issued it should normally be for supervised consumption at least until the patient can see a drug worker;
- Patients should make the prescriber aware of which Pharmacy they are currently using.

4. MONITORING PATIENTS NOT SUBJECT TO SUPERVISED CONSUMPTION

4.1 Even patients where the guidelines above have been scrupulously followed may be liable to relapse or to changes in their circumstances that would suggest that is sensible to move back to supervised consumption. It is important that patients are monitored for changes in their ability to comply as part of ongoing assessment using the criteria above and taken back on to supervised consumption where this is appropriate. You may find it helpful to assess for contraindications to the definition of stability given at **Annex B3 to Appendix A1 – Supervised Methadone Consumption**.

4.2 Where possible a move back to supervised consumption should be by agreement with the patient and should not be regarded as a sign of failure or punishment. Patients may be moved off supervised consumption again when stable – it is not necessary for them to wait three months before returning to unsupervised consumption.

5. ROLE OF PHARMACIST

5.1 If doctor and patient agree to move away from supervised consumption GPs should pay attention to the orange book guidance on the role of the community pharmacist (section 5.4.1).The total dose to be taken home should not normally exceed 500 ml. This is based on the practical considerations of carrying and storing the methadone. If patients are on larger doses then twice or thrice weekly collections should be considered.

5.2 Consideration can also be given to prescribing methadone in daily doses, particularly where the quantities involved are large, or when patients first move away from supervised consumption.

5.3 Where patients will be travelling abroad doctors may, at their discretion prescribe additional methadone to cover a holiday abroad. Guidance provided by the “Substance Misuse Management in General Practice” website is attached to this guidance as **Annex B4 to Appendix A1 – Supervised Methadone Consumption.** Please note that Home Office permission to take methadone out of the country does not mean that the country visited will necessarily allow the medication in. See also Drug misuse and dependence UK guidelines on clinical management Annex B4 page 108.

5.4 Pharmacists should ensure that a suitable method of measuring the daily dose from a bulk supply of methadone is provided – this can be a tarred [marked] bottle, a plastic measuring cup or a 5ml spoon, depending on the size of dose.

5.5 Prescribers should note that they need to clearly state the intervals and quantities to be dispensed on each prescription for “take home” doses and consider bank holidays.

5.6 If pharmacists have concerns about a patient – for example they are missing collections, or their health or social functioning are deteriorating they should communicate these to the prescriber and/or key worker.

ANNEX A2 to Appendix A1- Supervised Buprenorphine:

EXAMPLE AGREEMENT FOR SUPERVISED ADMINISTRATION OF BUPRENORPHINE

Your doctor has prescribed buprenorphine (Subutex or Suboxone) and stated that this is to be "supervised consumption". In order to ensure the smooth operation of this process the following information needs to be observed:

As the Pharmacist/Pharmacy Support Staff I/we agree to:

- Discusses terms of this agreement with a client
- Check the legality of the prescription and correctness of detail
- Register the patient onto the computer Patient Medication Record (PMR)
- Keep records of attendance
- Arrange and agree a mutually convenient time with the client for administration
- Dispense the medicine in accordance with the prescription and in advance of the agreed time of administration
- Provide a quiet area for the supervised administration
- Explain that medication cannot be dispensed if the client is intoxicated and that missed doses cannot be collected the next day
- Supervise consumption according to local arrangements
- Supply weekend/bank holiday doses for self-administration as required
- Complete necessary paperwork
- Ensure that staff and locums are aware of the procedures to allow the service to run smoothly.
- Liaise with the prescriber or liaison worker with regard to the treatment
- Contact the prescriber to discuss & refer the client back to the surgery/ clinic as necessary if:
    - non-attendance of three consecutive days
    - client's health raises concerns
    - client's behaviour causes problems

As the client:

- Please come in to the Pharmacy on your own
- Positively identify yourself to a member of Pharmacy staff
- Please remove any chewing gum or sweets from your mouth and place them in a waste bin
- Have a drink of water at this stage to speed up the time it takes for the tablets to dissolve
- Remove the tablet(s) from the container and squeeze them out of the foil into a plastic "medicine measure"
- Then tip the tablet(s) under your tongue without touching them and hand back the measure
- You will be asked to sit down in a designated area to allow the tablets to dissolve – this usually takes 3-10 minutes
- A member of the Pharmacy staff will observe you to ensure the local supervised administration process is followed
- Once the tablets have dissolved please report this to the Pharmacy staff who will provide you with a drink of water. After this you may leave.

Please Note:

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

This Pharmacy operates under the NHS Zero Tolerance Policy

Patient signature:	
Pharmacist signature:	
Pharmacy address:	

Copies to: 1. Client 2. Pharmacy

ANNEX B3 to APPENDIX A1, of Supervised Consumption Service Specification

1. DEFINITION OF STABILITY

1.1 Assessing a patient's stability requires a holistic assessment of their drug use, their attitude and motivation to treatment and their social and personal circumstances. Consideration of the following factors may be helpful in assessing stability:

- Is the patient attending for appointments regularly? If they miss appointments, is it with good reason?
- Do they ring in advance to notify the practice?
- Are they collecting their prescription as required?
- Occasional missed appointments or pick-ups may not preclude moving away from supervised consumption if there appear to be good reasons for them (some drug users are able to cope with an occasional missed dose and may have a good reason for missing a pick-up or appointment);
- Do they have a positive attitude to treatment and some commitment to controlling or abstaining from drug use?
- Have there been improvements in the general health and well-being of the patient?
- Has there been an improvement in their social functioning – this can be measured by looking at their family and social contacts, changes in lifestyle, appearance and self-respect, stability of accommodation, attitude to activities not related to drug taking including employment, training or education;
- Is the patient continuing to take drugs? While continued drug use might be regarded as a contraindication to moving away from supervised consumption, it should not rule it out in all cases it should be assessed. Drug use may be assessed by self report or by testing – which should be conducted regularly while a person is being prescribed substitute medication;
- If they are "using on top" what is the reason for this? Is it because they are prescribed sub-optimal doses? Is it controlled? What are the risks of overdosing if they continue to use?
- Is the patient abstaining from or controlling their alcohol use? Patients drinking at levels regarded by the government as harmful (over 50 units per week for men or 35 for women) place themselves at increased risk of overdose and may not be suitable for moving away from supervised consumption.

ANNEX B4 TO APPENDIX A1 - SUPERVISED CONSUMPTION SERVICE SPECIFICATION

If patients prescribed methadone wish to travel abroad they should discuss this with their prescriber and keyworker. They will need a licence from the Home Office to take medication out of the country and will need to check the regulations in the country they wish to visit. These regulations are subject to change and this appendix is intended to give some useful links, rather than provide definitive guidance.

Advice on travelling abroad is given on the Substance Misuse Management in General Practice website in the Dr Fixit section below:

http://www.smmgp.org.uk/html/newsletters/net006.php#Fixit2

People taking methadone abroad are likely to need a licence; information on this is given in the link below:

http://customs.hmrc.gov.uk/channelsPortalWebApp/channelsPortalWebApp.portal?_nfpb=true&_pageLabel=pageTravel_InfoGuides&id=HMCE_CL_001589&propertyType=document#P45_2905

As well as having a licence to take controlled drugs abroad, travellers need to check whether the country they intend to visit will allow the drugs into the country. Definitive advice will be given on the relevant embassy websites, but the link below gives and overview of the regulation of most destinations.

http://www.indro-online.de/travel.htm

See also Drug misuse and dependence UK guidelines on clinical management Annex B4 page 108.

REFERENCES IN SUPERVISED CONSUMPTION GUIDELINES
List of publications:

Best practice guidance for commissioners and providers of pharmaceutical services for drug users February 2006
To download a copy: 50 pages
http://www.nta.nhs.uk/publications/documents/nta_best_practice_pharma_services_for_drug_users_pharmguide06.pdf

Drug misuse - methadone and buprenorphine
Methadone and buprenorphine for managing opioid dependence
TA114 - Technology appraisal January 2007
To download a copy: 50 pages
https://www.nice.org.uk/guidance/ta114/resources/methadone-and-buprenorphine-for-the-management-of-opioid-dependence-pdf-82598072878789

Drug misuse and dependence UK guidelines on clinical management 2007
(Orange Book)
To download a copy: 128 pages
http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_104819

Royal Pharmaceutical Society of Great Britain Fact Sheet One - Controlled Drugs and community Pharmacy (September 2007)
To download a copy: 54 pages
http://www.dhsspsni.gov.uk/pas-rpsgb-fs-controlled-drugs-community-Pharmacy-feb08.pdf

National Patient Safety Agency (NPSA)
Promoting safer measurement and administration of liquid medicines via oral and other enteral routes – Alert 19
http://www.npsa.nhs.uk/nrls/alerts-and-directives/alerts/liquid-medicines/

National Pharmaceutical Association (NPA)

The NPA has updated the **Standard Operating Procedure (SOP) on Promoting Safer Measuring and Administration of Liquid Medicines** to reflect the NPSA Alert 19, which can be accessed from the document store on http://www.npa.co.uk/members

Annex B5 of Appendix A1 – Supervised Consumption

Provider Checklist
On behalf of the Provider, I can confirm the following actions have been undertaken:

Action Completed	Y/N
The Provider has an up to date written Standard Operating Procedure (SOP) for this enhanced service signed off by all relevant staff	
All members of the Pharmacy provider staff are trained in the operation of this service according to the SOP	
The audit of service (Annex A2 to Appendix A1) has been undertaken by the Provider and a copy of the most recent review is available in the Pharmacy	
The Provider has adequate contingency planning in place to cover for key staff involved in the delivery of this service should they be unexpectedly absent from work	
The Provider is registered with NHS Connecting for Health (CfH) and has attained at least a Level 2 rating against the Pharmacy information governance requirements	
The Provider has available for the public copies of the PCT Comments Cards issued by PALs or similar successor systems	
The Provider has on file a copy of the certificate of completions of the CPPE Open Learning Programme entitled “Substance Use and Misuse for every pharmacist involved in the provision of this service.	

I understand that all information given on any claim form submitted in relation to this service must be true and correct to the best of my knowledge. I understand that action may be taken against me if I make an incorrect claim. I consent to the disclosure of relevant information on this form for the purposes of fraud prevention, detection and investigation.

SIGNED:

NAME:
(Authorised Manager)

Date: