ONERECOVERY STAFFORDSHIRE

Service Level Agreement:

For the provision of Observed Consumption of Methadone (Physeptone) & Buprenorphine (Subutex).

ADS Addiction Dependency Solutions

Specification for a Pharmacy Observed Consumption Scheme

1. SERVICE OUTLINE

1.1. This specification sets out a model for a service specification for a community pharmacy (the contractor) observed consumption service (The Service). The Service will be provided by the 'Contractor' to drug users ("Service Users") in Staffordshire who are subject to the requirement of self administering their methadone or Buprenorphine under observed conditions. The commissioning body that is responsible for the Service is Addiction Dependency Solutions (The Purchaser).

1.2. Any contractual agreement undertaken between the Purchaser and the Contractor assume the Contractors understanding of and compliance with Best practice guidance for commissioners and providers of pharmaceutical services for drug users (NTA, 2006), Compliance with the GPhC Code of Ethics and any locally set clinical governance and quality standards as agreed between the Contractor and the Purchaser.

1.3. For the purposes of this Service Specification, "The Service" includes the provision of Observation of self administration of Methadone and Buprenorphine. Supervised consumption provides the best guarantee that diversional opioids are being taken as directed and is recommended for at least three months.

1.4. This service specification will, as required, be subject to continued review and amendment in consultation between the Purchaser and North/South Staffordshire Local Pharmaceutical Committee representing the interests of Contractors. The Contractor will be expected to co-operate fully with this review.

1.5. One Recovery Staffordshire will ensure that the contractor is aware and can have access to relevant policies if requested

2. Background

2.1. Supervised consumption provides the best guarantee that diversional opioids are being taken as directed and is recommended for at least three months subject to compliance.

2.2. Supervised consumption is principally defined as the self-administration of prescribed methadone or Buprenorphine, which is supervised and monitored daily in community pharmacies by means of a 4-way agreement between the prescriber, patient, Recovery co-ordinator and pharmacy.

2.3. Methadone/Buprenorphine prescribing and supervised consumption reduces the risks associated with illicit opioid use which impact on the health and wellbeing of the individual drug user, those close to them and wider society.

3. Training and Professional Responsibility

3.1. Accreditation of pharmacies

3.1.1. All pharmacies participating in the Staffordshire supervised consumption scheme must be accredited. Accreditation will be awarded by the Clinical Governance Board for

One Recovery Staffordshire and the pharmacy informed via PharmOutcomes Pharmacy Authorisation.

3.1.2. Accreditation Criteria

3.1.2.1. Each pharmacy must nominate a lead pharmacist for the observed consumption scheme. This pharmacist must work at least three days at the pharmacy.

3.1.2.2. Where locums or part time pharmacists predominantly operate a pharmacy, the lead pharmacist for the group of pharmacies must nominate a lead technician or named staff member to act as a contact for the scheme. Where there is no technician this must be made clear to One Recovery Staffordshire (via the PharmOutcomes Pharmacy Sign-Up Module and the locum pharmacist operating the pharmacy will retain professional responsibility and liability for the scheme.

3.1.2.3. Pharmacies are not restricted to the number of patients they can accommodate in the scheme but they should consider capacity when offering the service and are encouraged to communicate with the One Recovery Staffordshire Clinical Governance Board on issues relating to capacity.

3.1.2.4. Pharmacies must meet the premises criteria outlined in section 7.

3.1.2.5. Pharmacies looking to join the scheme are advised to contact the One Recovery Staffordshire Clinical Governance Board for further information. You can do this by e-mailing Chris Judge, Service Delivery Director at chris.judge@adsolutions.org.uk.

3.2. Accreditation of Pharmacists

3.2.1. All lead Pharmacists must complete the CPPE distance learning course "Substance Use and Misuse" OR have previously completed "Opiate treatment: Supporting pharmacists for improved patient care" before accreditation is granted. Evidence of suitable training will be recorded by the pharmacist using the CPPE Declaration of Competence (DoC) and the information provided to OneRecovery via the PharmOutcomes system (Pharmacy Sign-Up module).

We would also encourage pharmacists to attend the local supervised consumption training event.

3.2.2. Where the pharmacy is part of a group and the pharmacy is operated by part-time pharmacists or locums then a pharmacist who is district / area manager or equivalent must meet these criteria and be responsible for the operation and monitoring of the scheme in those pharmacies. They will be required to complete the CPPE Declaration of Competence (DoC) as in 3.2.1 and they will then be defined as the lead pharmacist and be responsible for the organisation of the SLA in their group of pharmacies.

3.2.3. This role can be delegated to a cluster pharmacist if the area / district manager is responsible for more than six pharmacies. The area / district manager will inform the One Recovery Staffordshire Clinical Governance Board via the PharmOutcomes module if they wish to apply for this with the name of the nominated cluster pharmacist who will act as the lead pharmacist

3.2.4. A list of the lead pharmacists will be stored by PharmOutcomes.

3.3. Locum / Deputy Pharmacists.

3.3.1. The lead pharmacist must ensure that any deputy or locum pharmacist is fully aware of the Supervised Consumption Scheme and is supportive of the scheme in advance of them providing cover. The details of the scheme must be made available to locums and other members of staff in a defined location within each pharmacy.

3.3.2. Locum pharmacists may not assume the role of a lead pharmacist and act as a signatory for the scheme unless they are nominated to do so (using the PharmOutcomes Pharmacy Sign-Up Module). If they assume the role of lead pharmacist they are required to complete the Pharmacy Sign-Up module on PharmOutcomes and complete a CPPE Declaration of Competence (DoC).

3.3.3. Regular locum and deputy pharmacists should be encouraged to attend local harm reduction training and complete CPPE or other equivalent professional training even if they are not taking on the role of lead pharmacist.

3.4. Responsibility for Scheme

3.4.1. The lead pharmacist must ensure that Standard Operating Procedures (SOPs) in respect of supervised consumption are in place and that all counter staff who will be involved on observing consumption of methadone or Buprenorphine have a comprehensive understanding of these.

3.4.2. Only one lead pharmacist can be appointed per pharmacy. However pharmacies participating in the Supervised Consumption Scheme may nominate an additional pharmacist(s) to be responsible for the running of the scheme on a daily basis and for ensuring data is added to PharmOutcomes as each prescription is completed. Nominated pharmacists should be included in the Pharmacy Sign-Up module on PharmOutcomes and must also complete a CPPE Declaration of Competence (DoC) stating that they have completed CPPE or other equivalent professional training. They are also encouraged to attend local harm reduction training.

3.4.3. The lead pharmacist will inform the One Recovery Staffordshire Clinical Governance Board via the PharmOutcomes Pharmacy Sign-Up Module of any nominated additional pharmacists. If the lead pharmacist leaves, he / she must provide the One Recovery Staffordshire Clinical Governance Board with six weeks' notice. If this is not possible One Recovery Staffordshire will accept less than six week's notice but notice must be given at the earliest opportunity and no less than four weeks. The new pharmacist will be allowed up to three months to become accredited as the replacement lead pharmacist.

3.4.4. In instances of a lead pharmacist being away from work due to unprecedented circumstances (e.g. maternity, long-term sickness), advice must be sought from the One Recovery Staffordshire Clinical Governance Board.

3.4.5. Pharmacists who have already been accredited to deliver harm reduction services within another area may apply via the PharmOutcomes Pharmacy Sign-Up Module to be

accredited as responsible pharmacists for supervised consumption. They will need to complete a DoC (if not already done so) and confirm they have done this via the PharmOutcomes module. There is, however, an expectation that the lead pharmacist will continue to attend at least one local harm reduction training event on an annual basis and adhere to the conditions and principles laid out within the SLA and the Policy Guidelines.

3.4.6. While the lead pharmacist takes overall accountability for the scheme the role of the lead technician is of paramount importance. Therefore, if they leave, the One Recovery Staffordshire Clinical Governance Board must be informed as soon as possible via PharmOutcomes. The pharmacy should also provide the name of a new lead technician at this point or on appointment to the post by completing the new details on the PharmOutcomes Pharmacy Accreditation module.

3.5. Pharmacy Staff

3.5.1. Pharmacists may delegate the responsibility for supervision of methadone and Buprenorphine, to appropriately trained staff. However, the pharmacist will remain accountable for supervised consumption and must always be in a position to intervene immediately where necessary. Staff undertaking supervision should be trained pharmacy technicians, pre-registration pharmacists or healthcare assistants who have also undergone local training in pharmaceutical harm reduction. As a minimum requirement, any staff member involved in supervised consumption must be over 16 years of age and have completed medicine counter assistant training.

3.5.2. All pharmacy staff involved in the delivery of the harm reduction services to drug users should be encouraged to attend harm reduction training; to be updated on an annual basis as arranged by One Recovery Staffordshire. It is also advised that all new pharmacy staff attend forthcoming annual harm reduction training events.

3.5.3. If pharmacy staff have any concerns that a patient is intoxicated due to drug or alcohol use, they must not dispense medication to the patient and must always refer the matter to the pharmacist who will be responsible for making a judgement as to the patient's suitability for their medication. Further guidance on this is found in section 15 Intoxication.

3.5.4. Pharmacists who delegate the supervision of methadone and Buprenorphine, to appropriately trained staff will be required to maintain a list of their names which should be stored safely within the pharmacy. (Appendix 1). All previous versions of this list should be retained by the pharmacy to provide an audit trail (may be checked by One Recovery Staffordshire Clinical Governance Board if required). The lead pharmacist must make a declaration (via PharmOutcomes) that adequate written protocols and procedures are in place, confirm the list is up to date, stored in the pharmacy (along with previous versions of the list) and that the staff members are fully trained and competent to provide this service

3.6. Insurance

3.6.1. The lead pharmacist will ensure that adequate indemnity insurance to cover against all actions, claims, costs etc. in relation to carrying out the activity of this scheme is in place. This should also extend to all staff members who are involved in the scheme.

4. Service Provision: Roles and Responsibilities

4.1. Treatment Provider

4.1.1. The treatment provider will ensure that all patients undergo a comprehensive assessment as to their suitability for drug treatment via daily-supervised consumption.

4.1.2. Comprehensive assessment will include a risk assessment to establish whether the patient poses a significant identifiable risk to pharmacy staff or other customers. Any identified concerns must be discussed with the lead pharmacist or technician in advance of dispensing being started. Likewise, any emerging concerns relating to a patient already in treatment will also be referred to the lead pharmacist or technician for discussion.

4.1.3. Aspects of the care plan such as treatment goals should also be discussed with the pharmacist if appropriate and consent is given by the patient.

4.1.4. Where appropriate and in line with confidentiality agreements, the care plan may be shared with the pharmacist. The lead pharmacist is accountable for keeping this document confidential within the pharmacy.

4.1.5. National guidelines indicate supervised consumption for at least the first three months of treatment. The treatment provider will ensure that regular clinical reviews of every patient receiving a supervised consumption service will occur at regular intervals in line with published guidelines. These reviews will assist in ascertaining when a patient is able to take responsibility for managing their own medication thus avoiding inappropriate usage of the limited resources for supervised consumption and ensuring pharmacies have the capacity to offer supervised consumption to new patients starting treatment.

4.1.6. The treatment provider will ensure that every patient receiving treatment under supervised consumption is assigned a Recovery Coordinator who may be either the prescriber or another clinical professional. The treatment provider will inform the pharmacist who this is.

4.1.7. If a clinical or untoward incident occurs involving a patient, the pharmacy should contact the key worker, who will respond within the same working day or at an interval no later than 4 hours after the initial request. If the key worker is unavailable the pharmacy may contact a nominated deputy i.e. Recovery Practitioner (first) or Service Manager (second) to discuss the incident. A list of key workers and team managers is attached in appendix 2 and is also available on the PharmOutcomes module.

4.1.8. The treatment provider will ensure that all prescriptions issued are compliant with legal requirements, stating that consumption will be under supervision and specify of any weekend or Bank Holiday ‘take home’ doses.

4.1.9. All prescriptions will be delivered to the pharmacy in sufficient time for the pharmacist to dispense. Only unforeseen scenarios and exceptional circumstances, such as unprecedented changes to medication, should result in a prescription being presented to the pharmacy on the same day that it is to be dispensed.

4.1.10. The treatment provider will ensure that all new patients (including patients

transferring from another pharmacy) are discussed with the pharmacy prior to treatment being commenced and that the pharmacist receives advance warning of new patient prescriptions (ideally 3 working days notice, but no less than one working day). This is to ensure that the pharmacy has sufficient capacity to supervise an additional substitute prescription and is adequately prepared. Information which the treatment provider must include in advance warnings are:

- A Pharmacy & Patient agreement signed by the treatment provider.
- Medication details (dosage and names of all medications to be dispensed).
- Start date of prescription.
- Identified concerns, which the pharmacy must be made aware of following the risk assessment.

4.1.11. The treatment provider will ensure that the patient has signed the Pharmacy & Patient agreement and understands the responsibilities and conditions, before commencing treatment under supervision.

4.1.12. The treatment provider will be mindful of a pharmacy's available capacity for supervised consumption when referring new patients and will aim to avoid over-burdening individual pharmacies when discussing treatment under supervision with new patients. This can be ascertained by the treatment provider contacting the client's preferred pharmacy to confirm whether they have capacity to take the new patient.

4.1.13. The treatment provider will ensure that pharmacy staff or other customers are not unnecessarily placed at risk by making reductions or other changes to prescriptions, or by stopping a patient's medication without having made reasonable attempts to discuss such changes with the patient. In instances where the treatment provider has been unable to discuss impending changes to medication with the patient, the lead pharmacist or lead technician will be informed of this in order that any necessary risk management strategies can be put into place.

4.2. Pharmacy

4.2.1. The lead pharmacist will ensure that the criteria in section 3.5 (Pharmacy staff), regarding training, responsibility, and accountability are met and sustained.

4.2.2. The lead pharmacist will ensure that all methadone and Buprenorphine, dispensing is in accordance with all legal requirements and practice guidance for pharmacists providing instalment dispensing services to drug misusers, as well as the Supervised Consumption Scheme Operational Guidelines contained within appendix 3 (also available on the PharmOutcomes module).

4.2.3. The lead pharmacist may use the SOP contained in appendix 3 (also available on PharmOutcomes) or they may develop their own operational procedures / SOP to enhance the implementation of the above-mentioned operational guidelines within the pharmacy. Any operational procedures / guidelines, which are developed, must not be contrary to this document or its appendices.

4.2.4. The lead pharmacist will make reasonable efforts to accommodate all new supervised consumption patients who are referred by the treatment provider. Lead

pharmacists will not decline new referrals for supervised consumption unless they have reached their capacity for this work or there is a valid professional clinical reason for refusal (i.e. the patient is already banned from the premises or there is an identifiable reason why it would be inappropriate for the patient to be supervised at the pharmacy).

4.2.5. The lead pharmacist will provide an appropriate quiet area within the pharmacy so that supervision protects the privacy and dignity of all patients. Supervision will never take place in the dispensary.

4.2.6. The lead pharmacist will ensure that all staff adhere to patient confidentiality as laid out within section 6.3 (Confidentiality).

4.2.7. The lead pharmacist or an appropriately nominated staff member will respond to requests from the prescribing agency to discuss any clinical issues or queries within the same working day and at an interval of no later than 4 hours after the initial request.

4.2.8. The lead pharmacist or appropriately nominated staff member will relay to the key worker / prescriber any appropriate concerns or comments they may have regarding a patient's progress or conduct. Pharmacy staff will aim to do so in a manner, which maintains a good patient / pharmacy relationship and does not breach confidentiality. A list of useful contact numbers can be found on PharmOutcomes (and also in Appendix 2) for use in the pharmacy.

4.2.9. All incidents will be reported as per incident monitoring form (see appendix 4 and also available on the PharmOutcomes module). This is in addition to any in-house incident monitoring procedures within the pharmacy.

4.2.10. The lead pharmacist will ensure that all records are adequately maintained.

4.2.11. The lead pharmacist will ensure that all details are entered onto PharmOutcomes in an accurate and timely manner. The PharmOutcomes Observed Consumption Module is in two (linked) parts: Part 1 - Patient Registration and Part 2- Supply. The data for each prescription form should only be entered onto PharmOutcomes after the final instalments has been dealt with. The module will record supplies made, missed, refused or incomplete doses. If a prescription is cancelled before all doses have been given the details should be added to PharmOutcomes at that time.

4.2.12. The pharmacist is required to provide a supervised consumption service on Saturdays unless a prior agreement is in place. Pharmacies who put in an application to One Recovery Staffordshire to close on a Saturday must inform the One Recovery Staffordshire Service Manager who will assess their suitability for providing supervised consumption.

4.2.13. The pharmacy will take part in audit activity including visits and agree to share information regarding substance misuse data to allow discussion and improvement of services across the community.

4.3. The Patient

4.3.1. The Patients role is summarised in the Pharmacy/Patient Agreement (Appendix 5 and also available on the PharmOutcomes module) agreement, which the patient is required to sign at the start of treatment. It is advised that the pharmacist engages with

the patient at the start of treatment to clarify what is expected of the patient in the pharmacy.

4.4. One Recovery Staffordshire

4.4.1. One Recovery Staffordshire will undertake incident monitoring and reporting and respond to any patient complaints in line with existing policy.

4.4.2. One Recovery Staffordshire will undertake regular audits and site visits to ensure compliance with this Service Level Agreement.

5. Service Duration and Restrictions

5.1. The Staffordshire Supervised Consumption Scheme is open to all community pharmacies in Staffordshire who gain accreditation. The signed agreement will last for the duration of the contract which is up to 31st March 2017 with potential annual extensions up to 31st March 2019.

5.2. The One Recovery Staffordshire Clinical Governance Board reserve the right to give pharmacies 3 months' notice of termination of their participation in the scheme if they do not meet the conditions outlined in this service level agreement.

5.3. The contract can also be terminated by community pharmacies giving a minimum of six weeks notice.

5.4. The Staffordshire Supervised Consumption Scheme is restricted to patients who are prescribed methadone or Buprenorphine, for drug treatment via One Recovery Staffordshire.

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6. Clinical Governance

6.1 Clinical Governance is the system through which treatment organisations are accountable for continuously improving the quality of their services and safeguarding high standards of care by creating an environment in which clinical excellence will flourish. Service governance relates to quality assurance at a local level, and includes education and training, support services, managing risk and maintaining standards

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6.2. Operating Procedures

6.2.1 As stated in 4.2.3 and in line with essential service requirements of the pharmacy contract all pharmacies should develop standard operating procedures (SOP's). These should reflect the GPhC advice and the Staffordshire Supervised Consumption Scheme Service Level Agreement.

6.2.2 Supervised consumption operating procedures should include as a minimum the following areas:

- Supervision and dispensing arrangements for methadone and Buprenorphine.
- "Missed doses" procedure.
- Details of who to contact under certain situations.
- Incident monitoring procedure.
- Patient confidentiality and data protection.

6.2.3 SOP's should have clearly stated objectives and stipulate whose responsibility it is to implement them. The process for monitoring, review and development must also be defined.

6.3 Incident Monitoring

6.3.1 The prompt reporting of incidents, both positive and negative, is essential to enable effective monitoring of the service and improvements for the future. Sharing of incidents and how they were dealt with can also help pharmacies improve their practice. Reporting should be in line with the pharmacy SOP for supervised consumption. All incidents of a serious or potentially serious nature should be reported to One Recovery Staffordshire by means of the standard incident report form (appendix 4 and also available on the PharmOutcomes module). These will then be discussed at the One Recovery Staffordshire Clinical Governance Board meeting and action points agreed within a supportive framework.

6.3.2 The vast majority of patients in supervised consumption will be perfectly well behaved. However, acts of unacceptable anti-social behaviour by patients may sometimes occur and should be responded to. Pharmacies should follow guidelines outlined in their SOP to resolve such incidences. For repeated incidents or incidents of a severe nature pharmacies should involve the multi-disciplinary team in discussions. Actions to be taken include verbal or written warnings, banning orders or referral to the police where a criminal offence has taken place.

6.4 Confidentiality

6.4.1 The lead pharmacist will ensure that the supervised consumption scheme is a confidential service that protects the privacy and dignity of the patients.

6.4.2 All supervised consumption records containing personal information and sensitive data will be kept confidential and stored appropriately.

6.4.3 Any supervised consumption documentation containing sensitive data that is no longer required will be disposed of appropriately and not within the pharmacies general waste unless shredded.

6.4.4 All labels must be removed from the dispensing container and appropriately destroyed.

6.4.5 If a patient utilises the Needle and Syringe Programme (NSP) but is part of the supervised consumption scheme they should not be refused but the prescribing service should only be informed with patient consent. One Recovery Staffordshire supports a firm harm reduction philosophy, which supports the provision of NSPs within a confidential framework. Pharmacists are encouraged to discuss the request, where appropriate, with the patient and provide general advice about "on-top" use. Pharmacists may also contact the relevant agency or prescriber to discuss general concerns regarding the progress of the patient in treatment, which do not compromise patient confidentiality.

6.5 Complaints

6.5.1 Any complaints received by patients should be addressed through the normal complaints procedure outlined for the community pharmacy, which should be available on request.

6.6 Service Monitoring and Audit

6.6.1 Monitoring and audit are an essential component of providing an efficient and improving supervised consumption scheme.

6.6.2 Monitoring and audit may take the form of self-reported written reports and / or pharmacy visits. The One Recovery Staffordshire Clinical Governance Board will determine the nature of each audit in conjunction with local priorities and needs. Advanced notice of any audit will be provided in writing 5 working days before the visit.

6.6.3 There will be a maximum of one audit per year for each pharmacy involved in the supervised consumption scheme. This audit will be undertaken by One Recovery Co-ordinators. Where there are no issues it may be recommended that the pharmacy is not audited again for a period of two years.

6.6.4 The lead pharmacist will facilitate the audit process by allowing access to and inspection of the relevant documentation and services within the premises and enable discussions with relevant staff involved in the supervised consumption and NSP.

6.7 Data Collection

6.7.1 Pharmacies must record all methadone and Buprenorphine supervision activity on PharmOutcomes and claims for remuneration will be generated by the PharmOutcomes system.

6.8 Training and Development

6.8.1 Formalised harm reduction training events will be organised by One Recovery Staffordshire on an annual basis for pharmacists and pharmacy staff.

6.8.2 All new pharmacy staff involved in supervised consumption should attend the initial supervised consumption training event Lead pharmacists should ensure continued staff attendance at harm reduction training on an annual basis and demonstrate continued professional development through attendance at annual training events, CPD records or other relevant CPD activities.

6.8.3 Pharmacists who have a special interest in this field are encouraged to communicate with The One Recovery Staffordshire Service Manager to discuss additional professional training opportunities and resources.

7 Premises

7.1. Pharmacies providing supervised consumption must offer the following essential requirements:

- Adequate visual / communication systems for pharmacist to monitor and control supervised consumptions either directly or by delegated staff in a defined area within the pharmacy.
- Appropriate storage conditions for the increased supply of controlled drugs.
- Adequate privacy for patients.
- A patient medication record system.
- Separate consulting room / area for patient engagement and supervision.

8. Payment

8.1. All payments for supervised consumption for methadone and Buprenorphine doses will be made payable by Addiction Dependency Solutions monthly in arrears. A payment of £1.50 will be made per methadone supervised consumption and a fee of £3.00 per Buprenorphine supervised consumption.. A supervised dose is classed as the observed self-administration of methadone or Buprenorphine which is in accordance with the terms and guidance laid out within the SLA and policy guidance.

8.2. Pharmacy Contractors are required to complete a PharmOutcomes entry for every prescription for observed consumption. Entries on PharmOutcomes for each individual prescription should only be made when the prescription is completed i.e. all instalments given to patient / missed / cancelled by prescriber. Entry onto PharmOutcomes should be done as soon as possible after the last supply on the prescription and this will generate a claim for that prescription. Payments will be processed with the next monthly payment run

8.3. Only claims made via PharmOutcomes will be processed.

9. Dispensing

9.2. Methadone and Buprenorphine will only be dispensed if the pharmacist is in possession of a valid prescription, which is written in accordance with legal requirements.

9.3. Instalment doses should, wherever practicable, be prepared in advance to prevent delay when patients arrive in the pharmacy. These must be packed and labelled in accordance with the Medicines Act in a standard dispensing receptacle and stored in the controlled drugs cabinet (methadone & Buprenorphine). Pharmacies are encouraged to share good practice and operational procedures in this area.

9.4. Methadone should always be dispensed in a child resistant container.

9.5. Pharmacists should ensure that all measurements are double checked before issue in accordance with the Standard Operating Procedure.

9.6. Methadone dispensed should be in accordance with the valid prescription and there should be no deviation from this. Sugar free and colour free methadone 1mg/1ml

mixture have a greater potential for abuse and must not be dispensed unless specifically requested by the prescriber.

9.7. “Take home” doses for Sundays and bank holidays must be labelled and dispensed in the appropriate dispensing receptacle. If more than one dose of methadone is dispensed, the doses should be dispensed in separate containers. Pharmacy staff should offer guidance on safe storage of take home medication.

9.8. Collection of controlled drugs by a representative is an issue which is often raised and is therefore covered here. Pharmacists must be aware of the guidance from the Department of Health and the Royal Pharmaceutical Society (RPS) and the legal position when representatives present to collect prescriptions for substance misuse patients. The law allows for a representative to collect a CD prescription on behalf of the patient for whom it was prescribed, however, the clinical management guidelines7 recommend that a letter is obtained on each occasion from the patient stating that a named person is allowed to collect the medication on their behalf. The RPS recommend that a letter of authority is obtained for each supply to an agent and this is retained for a period so a comparison of signatures can be made. Pharmacists must be satisfied that the supply is reaching the patient named on the prescription and must be able to justify their actions if they supply to a representative. Pharmacists should also ask for confirmation of identity of the representative in line with the new controlled drug guidelines. Supervised consumption doses must be consumed on the premises. However, if a patient cannot present **and** the pharmacist has permission **by the prescriber** to supply the dose to a third party as a take home dose then the pharmacist may supply this. The permission can be sought by the pharmacist contacting the local office and speaking to a key worker. Records must be made of this and, ideally, a written confirmation obtained from the prescriber.

9.9. Records of all supervisions, for each patient, need to be recorded on PharmOutcomes

10. Supervision

10.1. General Supervision Advice

10.1.1. All supervised consumption should take place in a consulting room or an appropriate dedicated “quiet area” within the pharmacy. The patient should be involved in the decision as to where supervised consumption will take place and they should always be treated with dignity and respect.

10.1.1 Before initiating supervised consumption the identity of the patient should be confirmed.

10.1.2 Ensure the patient has not missed three consecutive doses (Excluding Bank Holidays). If they have, refer to **section 16**.

10.1.3 Ensure the patient is not intoxicated before giving the dose and confirm if there is any reason why they are unable to consume the prescribed dose.
See section three below for further guidance.

10.1.4 Before issuing the medication, verbally confirm the dose and medication with the patient.

10.2 Methadone Supervision

10.2.1 The patient may drink their dose straight from the labelled bottle or from a disposable cup, which should be mutually agreed by the patient and the pharmacy. All cups used in the pharmacy for supervision should be disposable and used once only. This is for infection control purposes.

10.2.2 Observe the patient drinking the methadone.

10.2.3 Once the dose has been swallowed offer the patient a drink of water or engage in conversation to ensure the dose has been swallowed (this reduces the chance of diversion).

10.3 Buprenorphine Supervision

10.3.1 If this is the patient's first dose of buprenorphine explain they must have waited at least 8 hours since last heroin use or at least 24 hours since the last methadone dose. Ideally patients should be in the early stages of withdrawal before taking their first dose. This is to minimise the risk of precipitated withdrawal (see section 14).

10.3.2 Explain that the tablet(s) must be dissolved under the tongue to absorb the active ingredient and that the patient should avoid swallowing (both the tablet and the saliva whilst the tablets are being dissolved).

10.3.3 The patient should take a drink of water **prior** to dosing. This assists in absorption of the medication.

10.3.4 Pierce the foil and pop the tablet into the patient's hand or a suitable receptacle.

10.3.5 Instruct the patient to place the tablet(s) under the tongue.

10.3.6 Carefully observe the patient's hand to mouth movement to ensure the tablets are not diverted into pockets etc ("palmed"). Check under the patients tongue after the tablets have been placed in the mouth.

10.3.7 Observe the patient for a minimum of three minutes in the designated quiet area.

10.3.8 Before the patient leaves ask to check underneath the tongue again to ensure that a chalky residue remains and the patient has not palmed or swallowed the dose.

11. Crushing of Buprenorphine

11.1 The routine crushing of Buprenorphine prior to administration is not supported due to the following reasons:

- Crushing Buprenorphine tablets places the product outside the product licence and cannot be recommended by the manufacturers.
- There are no studies in the UK examining how crushing tablets affects the product's bioavailability, although the manufacturers believe that crushing would have little impact on absorption, but may result in excess saliva

production.
- It would be more difficult to assess whether the tablet has been kept in place and absorbed sublingually as no residue would be observed after three minutes.

However, the National Pharmaceutical Association (NPA) will provide cover for pharmacies who provide a crushing service providing a model protocol is in place in the pharmacy and there must be agreement between the pharmacy, prescriber and patient before the service is commenced.

12. Time for Sublingual Absorption

12.1 Information from the manufacturer indicates that it takes 5-10 minutes for sublingual tablets to dissolve but this time will depend on a number of variables including the amount of moisture in the mouth and the dose given. Supervision is most important in the first three minutes, during which time the tablets have begun to dissolve and the risk of diversion diminishes. Once the tablets have dissolved and the chalky residue remains, the active ingredients have been fully absorbed and the patient may leave. It should be noted that generic buprenorphine dissolve a lot quicker than Subutex® and will often be dissolved within this three minute window.

12.2 After the dose is taken
- Allow the patient to leave the pharmacy.
- Complete appropriate paperwork.
- Dispose of waste to ensure all cups are used once only.
- All labels containing patient information must be disposed of in a confidential manner.
- Inform the care co-ordinator or prescriber if the patient does not consume their medication (including only partial consumption of a dose) or if the patient has not adhered to any of the contractual obligations laid out within the 4-way agreement.
- If this is the last supply on the prescription the information must be entered onto PharmOutcomes.

13. Partial Consumption of Methadone or Buprenorphine

13.1 Occasionally a patient may refuse to take their complete dose of medication. It should be recognised that a patient cannot be forced to consume their full dose but should be encouraged to do so. If this occurs, the Recovery co-ordinator or prescriber should be informed and the refusal should be recorded in an appropriate manner (e.g. on the patients PMR). When the prescription data is input onto PharmOutcomes any refusal to take the full dose should be noted against the appropriate dates and an indication of the volume actually taken by the client should be entered on the module.

13.2 When making the controlled drugs register entry for partially consumed methadone the full quantity dispensed should be entered into the register, while the unconsumed quantity should be classified as a “patient return” and should be destroyed in accordance with current guidelines and best practice.

14. Identifying Signs of Opioid Withdrawal

14.1 Buprenorphine may cause opioid withdrawal through the process of precipitated withdrawal if taken too soon after the last dose of heroin or methadone.

14.2 Patients should be experiencing mild withdrawal symptoms before taking their first dose of Buprenorphine.

14.3 It is the patient's responsibility to assess their withdrawal state and readiness for taking their first dose. This can be assessed using an Opiate Withdrawal Scale which pharmacists should be aware of as this could be of help in discussions with the patient prior to administering the first dose. A scale such as the Clinical Opiate Withdrawal Scale (COWS) could be used (can be downloaded via PharmOutcomes.

14.4 Whilst very unpleasant, withdrawal does not come with medically serious risks (except in pregnancy).

15. Intoxication

15.1 Methadone & Buprenorphine should not be dispensed in instances when the pharmacist considers the patient to be significantly intoxicated due to drug or alcohol use. When a patient presents in this manner the pharmacist should establish if this is a result of alcohol or drug use.

15.2 If significant intoxication due to alcohol or drugs is suspected, the pharmacist should telephone the prescribing service to seek advice from the care coordinator or prescriber before medication is dispensed.

15.3 In instances when the patient presents as significantly intoxicated and the Recovery Co-ordinator or prescriber cannot be contacted then the following courses of action will be taken:

- If the patient presents as significantly intoxicated at the end of a working day after the prescribing agency is closed, the pharmacist must withhold the patient's daily dose and ensure that the matter is discussed with the care co-ordinator or prescriber the following working morning. (Pharmacists handing over to locums / other pharmacists must ensure that the matter is communicated and that the pharmacist is able to deal with the matter on their behalf). The patient should be given an explanation as to why their dose is being withheld and if possible, advice given regarding the risks of overdose.
- If the patient presents as significantly intoxicated on a Saturday or a long bank holiday period when the prescribing agency is closed, the pharmacist should decline to dispense the patient's medication and ask them to return for their medication later in the day when the patient's suitability to have their medication can be re-assessed. The pharmacist should explain to the patient that if they are still intoxicated when they return, both their daily dose, and any take home/Sunday dose will be withheld and if possible, give advice regarding the risks of overdose. Regardless of the outcome, the pharmacist must ensure that the prescribing agency is contacted and informed at the beginning of the next working day.

15.4. It is appreciated that patients who are still being stabilised on their medication are likely to use additional drugs, however “significant intoxication” is demonstrated by the patient’s inability to function (e.g. has slurred or incoherent speech, they may appear sleepy or over-agitated, smell excessively of alcohol, their walking or standing is affected and their eyes show evidence of intoxication). Pharmacy staff should be aware that as many of the above symptoms could be attributed to other health problems, assumptions cannot always be made. In any doubt, the matter should always be referred to the pharmacist.

15.5. In all instances where medication is withheld due to the patient being significantly intoxicated, the pharmacist must ensure that an incident report form is completed and the Recovery Co-ordinator or prescriber informed at the earliest opportunity.

16. Missed Doses

16.1 If a patient fails to attend for their methadone or Buprenorphine, the pharmacist must write “not dispensed” next to the relevant date on the prescription and missed doses should be recorded on PharmOutcomes when the prescription data is added to the system.

16.2 If the patient misses a dose they should return the next day as usual for their next dose.

16.3 If a dose is missed for three consecutive days the treatment should be suspended and the Recovery Co-ordinator or prescriber contacted. The prescription should not be re-initiate until specific instructions to do so have been given by the Recovery Co-ordinator, Service Manager or prescriber. A note of this decision should be made on the patients PMR.

16.4 If a patient misses three or more observed doses in a 14-day prescription then the Recovery Co-ordinator or prescriber should also be contacted.

16.5 The risk of death during methadone induction has been calculated at nearly seven-fold greater than the patient’s risk of death prior to entering methadone maintenance treatment. Deaths usually occur during the first three to ten days of treatment. Therefore, extra caution should be exercised during the first two weeks of treatment and any doses missed should be reported to the Recovery Co-ordinator, Service Manager or prescriber.

Missed Dose during titration phase.

16.6 If a patient misses a dose during the titration phase of treatment (i.e. increase in dose during the first few days of induction onto a prescription), the Recovery Co-ordinator or prescriber must be contacted before the next dose is given. Titration phases should not fall upon a weekend due to observation arrangements with Clinical staff.

16.7 All emerging patterns of regular failures to attend the pharmacy should be brought to the attention of the Recovery Co-ordinator or prescriber for further investigation.

17. Incident Reporting

17.1 All incidents, that occur, including those with positive events, must be reported by using the Addiction Dependency Solutions “Significant Event Reporting Form”.

Recording should occur as soon as practicable after the event. Forms should be returned to the local One Recovery Staffordshire treatment premises.

17.2 All incidents should also be reported to the patient's Recovery Co-ordinator or prescriber as soon as possible.

17.3 The possible incidents which should be recorded are included in the following list which is not exhaustive:

- Accidents and injuries.
- Shoplifting/attempted shoplifting.
- Acts of violence towards staff or other customers.
- Verbal abuse that is threatening or intimidating by nature.
- Overdoses/incidences of significant intoxication.
- Attempts to fraudulently alter prescriptions. (Should be reported to the police and NHSBSA NHS Business Service Authority formerly the PPD)

18. General Guidance on Working With Individuals Who Misuse Substances.

18.1 Like any member of public substance misusing individuals can be challenging and rewarding people to work with, and it should not be presumed that all substance misusers are by their nature problematic to interact with. Patients are likely to sense any fear or hostility from pharmacy staff and in the vast majority of cases will treat staff in the manner similar to that with which they have been treated by staff. Similarly, many patients are likely to respond kindly to a courteous and genuinely empathetic approach.

18.2 Pharmacy staff may often be the only members of the treatment system who see patients that are in treatment on a daily basis. Staff can play a valuable role in both supporting individual patients and monitoring their day-to-day progress. For many patients, appropriately chosen words of encouragement can be a valuable source of support. However, it is also wise that staff are mindful of when to refer patient to discuss complex or ongoing matters with their Recovery Co-ordinators and not to get over-involved.

18.3 Patients who are stabilising on their medication may still be chaotic in their drug use. At times patients may present for supervision whilst they are experiencing opiate withdrawal symptoms and may be feeling physically unwell. What may seem like a reasonable wait to pharmacy staff may feel unbearable to the patient and may explain hostility or discourteousness.

18.4 It is important that patients have clear and consistent boundaries and are treated equally by all staff members within the pharmacy, regardless of whether they are a long-term customer or new to the Supervised Consumption Scheme. Patients often socialise with others who are also in treatment and will quickly hear if someone else receives what may be perceived to be "preferential treatment".

18.5 Drug use can result in unforeseen behaviour changes and a patient who normally presents as stable and amenable may unexpectedly present in a challenging manner. Therefore, pharmacy staff are advised to develop a working rapport with all patients which carefully tempers a friendly professional approach with a degree of caution that never assumes a patient will not have a bad day or present in an unforeseen manner.

SIGNED AGREEMENT

On behalf of (Pharmacy Name and Address)

……

Tel ……

Fax No ……..

E-mail ……..

I have read and understood the terms in the service specification and agree to provide the standard of service specified.

Signature ……..

Print Name ……..

Position ……..

Date ……..…..

Pharmacy stamp

On behalf of One Recovery Staffordshire, I commission the above pharmacy to provide the service detailed in the service specification for the Pharmacy Observed Consumption of Methadone and Buprenorphine.

One Recovery Staffordshire agrees to provide 3 months written notice if we wish to withdraw from this contract.

Signature (on behalf of One Recovery Staffordshire)

..... **Date**.....

Print Name: ……

Position: ……..

APPENDIX 1

Staff Authorisation Sheet

Name of Lead Pharmacist:

Name of Lead Technician (if applicable):

Full Address of Pharmacy:

Contact Telephone Number:

The following members of staff have been assessed by the Lead Pharmacists as meeting the criteria defined in the One Recovery Staffordshire Service Level Agreement for Supervised Consumption of Methadone and Buprenorphine.

Name	Signature	Date

Please Retain in Pharmacy
Previous versions should also be retained in the pharmacy to provide an audit trail

Appendix 2

ONERECOVERY STAFFORDSHIRE

Key Contacts.

Service Manager

North Staffordshire (Newcastle & Moorlands), Debbie Moores, 01782 637 545

West Staffordshire (Cannock, Stafford, Seisdon), Wayne Exton, 01785 270080

East Staffordshire (Burton, Tamworth & Surrounds), Lynn Arnold, 01283 741 053

Clinical Service Manager

North Staffordshire (Newcastle & Moorlands), Tina Mottram, 01782 637 545.

West Staffordshire (Cannock, Stafford, Seisdon), Sue Parkes, 01785 270080

East Staffordshire (Burton, Tamworth & Surrounds), Andrew Willshaw, 01283 741 053

Appendix 3

Standard Operating Procedure (sample) for supervised consumption of diversional opioids (methadone & Buprenorphine) One Recovery Staffordshire Supervised Consumption Scheme.

Name of Pharmacy	

Purpose:	Scope:
To support the self-administration of diversional opioids (Methadone & Buprenorphine) and according to the Supervised Consumption Service Level Agreement.	**All patients who are presented by the drug & alcohol services (including GpwSIs) or GPs accredited to the One Recovery Staffordshire substance misuse treatment system.**

Procedure/Process

Confirm patient's identity. Use photograph if patient is unknown to pharmacy staff. Patient confidentiality must be maintained at all times and photographs must not be made visible to non-pharmacy staff.

FOR METHADONE

• Ensure that patient has arrived alone and is complying with standards of behaviour in 4-way agreement.
• Examine rear of prescription form and ensure that patient declaration has been fully completed and NHS levy paid or evidence of exemption has been produced.
• Check that the front of the prescription form is legally valid and is marked for supervised consumption.
• Note whether the patient has recently missed a dose(s). In the case of the patient having missed three consecutive doses, do not dispense and contact the patients Recovery Co-ordinator, Service Manager or prescriber. If they cannot be contacted the patient must be referred back to them.
• Enter the dose to be dispensed into the pharmacy Patient Medication Record (PMR) system and generate the appropriate label(s).
• Dispense the required dose into an approved container and check accuracy according to the "Accuracy Checking" SOP procedure.
• Label the dispensed dose.
NB: Doses may be prepared in advance but must be packed and labelled in accordance with the Medicines Act in a standard dispensing bottle and stored in a controlled drugs cupboard.
• Take the dispensed dose to the approved quiet/private area.
• Bring the patient into the quiet/private area.
• Ask the patient if there is any reason why they are unable to consume the prescribed dose.
• Judge the patient's manner taking particular care to observe for signs of intoxication.
• If satisfied that patient is not intoxicated and has not declared anything that might cause concern, continue with procedure.
• If patient appears intoxicated or has declared that they have consumed other drugs, inform them that you are prevented from supplying the medication stating the reason why. Explain that you are withholding the dose for their own safety and protection. Inform the patient's Recovery Coordinator or the nominated deputy as soon as is possible. Final judgement of intoxication rests with the supervising pharmacist. On Saturdays or Bank Holidays, if the patient is intoxicated, instruct them to return later in the day and make a judgement at that time whether to supply the "take home" doses.
NB: An incident monitoring from must be completed in all cases of intoxication.

FOR BUPRENORPHINE/SUBUTEX®**:**

• **If this is the patient's first dose of buprenorphine, explain they must have waited at least 8 hours since last using heroin or at least 24 hours since the last methadone dose. This is because of drug interaction which may precipitate opiate withdrawal (see guidance notes on withdrawal symptoms for details). Also explain why the tablet(s) must be dissolved sublingually to dissolve and absorb the active ingredient and that they should avoid swallowing. Offer patient a cup of water from a disposable cup to moisten mouth prior to dosing (to increase speed of absorption).**

• **Pierce foil and pop the tablet(s) out of the blister pack, preferably into a small disposable pot such as a tablet bottle top. Do not let the patient pop the tablet out of the blister in case it is dropped.**

• **Instruct patient to place tablet(s) under the tongue, carefully observing their hand to mouth movement.**

• **Observe patient for THREE minutes, or until only a chalky residue remains in the mouth.**

• **Request to look under the tongue to confirm compliance.**

SELF-ADMINISTRATION PROCEDURE:

• **Before issuing any medication, verbally confirm the dose and medication with the patient.**

• **Ensure that no drinks, other than water provided in the pharmacy are being consumed by the patient during supervision.**

FOR METHADONE:

• **Observe patient drink the dose either direct from the dispensed container or a disposable cup.**

• **Once dose is consumed offer patient water to drink. If patient declines water, speak to patient to ensure dose has been swallowed and is not retained in mouth.**

Responsibility:

• **Responsible pharmacist**

• **Nominated pharmacists.**

• **Locum pharmacists.**

• **Appropriately trained pharmacy dispensing technicians and pharmacy staff.**

Review of procedure:

Annually. Or sooner in light of any significant incidents or any change in the Service Level Agreement between the One Recovery Staffordshire and pharmacy.

Known risks:

• **Patient risks (intoxicated patients, non-compliant patients, angry/abusive patients).**

• **Missing/lost prescriptions.**

• **Unfamiliar patients or staff.**

I have signed to say that I have read the procedure and understand its implications:

Name	Signature	Date

Appendix 4

ONE RECOVERY STAFFORDSHIRE

SIGNIFICANT EVENT REPORTING FORM

This form should be completed and returned to the Manager OR Clinical Governance Lead in your Practice or Pharmacy, with a copy of the completed signed form to the One Recovery Staffordshire Clinical Governance Board

Reporter's Name (optional): …….. Profession/Role: ……..

PRACTICE / PHARMACY NAME: …….
Address/Contact details: …….
Please Circle

General Practice Pharmacy Other Organisation

For Practice Internal Use Only – optional
Patient Identifier: (Computer Number or other internal code)
Date and Time of Event: ……..
Location of Event: ……..

What happened? (Include description of event, what went well and why, what went less well and why, immediate and underlying causes)
……...
.....
.....
.....
.....
.....

What impact or potential impact did the event have? (harm/distress/benefit to patient, staff, organisation or others, financial impact etc.)
……....
.....
.....
.....
.....
.....
.....
Please categorise significance/potential significance (circle A for actual harm and P for potential harm) *Insignificant, minor or moderate incidents need to be discussed in house or at Practice Manager meetings – no need to submit to One Recovery Staffordshire*

Insignificant	P	A	No obvious harm
Minor	P	A	Non-permanent harm – increased level of care 1-7 days
Moderate	P	A	Semi-permanent harm (up to 1 year). Increased level of care >8-15 days. Hospital admission?
Major	P	A	Major permanent harm.Increased level of care >15 days. Hospital admission + stay >15 days
Catastrophic	P	A	Death

As a result of your significant event review, what actions are proposed?

.....
.....
.....
.....
.....

How and when will you review these?

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.....
.....
.....
.....

What lessons might be learned and shared with others?

.....
.....
.....
.....
.....

Have you identified any factors you are not in a position to change?

.....
.....
.....
.....
.....

NOW YOU HAVE REVIEWED THE EVENT - Please attempt to assess the likelihood of a similar event happening again

A	Almost certain
B	Likely
C	Don't know
D	Unlikely
E	Rare

Copy to: Chris Judge, Service Delivery Director, One Recovery Staffordshire, 2 Hargreaves Court, Staffordshire Technology Park, Beaconside, Stafford, ST18 0WN.

Date form completed: ……/……./……

Appendix 5

Pharmacy & Patient Agreement.

(Name of chemist…….

What the patient will do:

- Treat pharmacy staff with respect and behave appropriately.
- Attend the pharmacy daily or as indicated on the prescription within agreed times if established.
- If you “miss” your pick up day you “miss” your dose(s) until your next pick up day.
- Not attend intoxicated with alcohol and/or drugs. If you do your prescription for that day will be withheld and your doctor and/or key worker informed.
- Attend alone and leave pets outside.
- Not allow any other person to attend the pharmacy on your behalf unless previously arranged by your doctor or key worker and the appropriate letter received.
- Be aware that the pharmacy may have to pass on necessary information about your case to the doctor or key worker on a “need to know” basis.
- Be aware that the pharmacy will need to inform your doctor or key worker if you miss three consecutive doses. This may result in a reassessment of your treatment.
- Provide a photo for identification purposes or allow the pharmacy to take a photo.
- Drink the methadone, or dissolve the buprenorphine under the tongue swallow in front of the pharmacist when required to do so.

What the pharmacy will do:

- Treat you with respect and maintain confidentiality
- Have responsibility for your care.
- Liaise with the doctor or Recovery worker with regard to your treatment.
- NOT dispense your prescription to a representative unless previously authorised by the doctor or key worker.
- Refer you back to your doctor or key worker if you miss three consecutive doses if we are unable to resolve the situation before your attendance.
- Dispense the medication only in accordance with the prescription.
- Provide health promotion and education.
- Provide you with the opening hours of the pharmacy and hours during which you are able to collect your dose.
- Keep records of your attendance.
- Agree an appropriate time and area of the store for supervision of your script, which respects your rights.

Date:

Patient name: Pharmacist:

Signature: Signature: