Greater Manchester Mental Health NHS Foundation Trust

Service Level Agreement

between

Greater Manchester Mental Health NHS Foundation Trust

AND

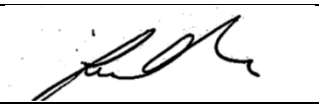
[name of pharmacy]

for the provision of

Supervised Self Administration of Methadone, Buprenorphine, Opiates and Suboxone®

As part of the Achieve Bolton, Salford and Trafford Substance Misuse Service

(i) The term of this Service Level Agreement is **1 April 2021** to **08 January 2023.**
(ii) The Pharmacy named below agrees to undertake the duties and responsibilities associated with the role of the Community Pharmacy that are described in the service specification for the provision of Supervised consumption services set out in Annex A below.
(iii) GMMH agree to make payment to the Pharmacy provider named below in line with the process set out in the payment section of the service specification set out in Annex A below.
(iv) The Pharmacy named below agrees to comply with the data protection requirements set out in Appendix 5.

Signed by:	**Jonathan Miller**
for and on behalf of Greater Manchester Mental Health NHS Foundation Trust	
Signature:	
Title:	**Service Manager – Achieve BBST**
Date:	**28th September 2021**

Community Pharmacy Provider

Signed by:	
for and on behalf of [name of pharmacy]	
Signature:	
Title:	
Date:	

Annex A

Supervised Self Administration of Methadone, Buprenorphine, Opiates and Suboxone®

Service Specification for Pharmacists and Appropriately Qualified and Trained Pharmacy Technicians

April 2021

Contents

1. Introduction

The guidelines below outline the Standard Operational Procedures and administrative processes for the Achieve Bolton, Salford and Trafford Supervised Self Administration Scheme for Methadone, Buprenorphine and Buprenorphine-naloxone (Suboxone®)[1].

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

Pharmacists participating in this service will be expected to take on the number of clients that they feel appropriate for their pharmacy within the parameters of good practice advised by Achieve Bolton, Salford and Trafford, taking into account all their community responsibilities.

Models of Care, introduced by the National Treatment Agency in 2002 outlined a four-tier system of service provision based on the principles of National Service Frameworks. The aim is to provide treatment through integrated care pathways across these four tiers. Pharmacists are regarded as a tier one service, a non-substance misuse specific service, but one, which offers advice and support to substance users.

One key element of drug treatment for opiate users is the prescribing of opiate substitute subscribing. Studies have shown that Methadone Maintenance Treatment reduces levels of injecting drug use and associated health problems, acquisitive crime and drug related death among those in treatment. Thus the Clinical Guidelines believe it to be 'an important part of drug misuse services' (DoH, 2007:45). Prescribing substitute medications allows time for individuals to implement personal or social changes that can reduce the impact of their illicit drug use and is a key element to increase the opportunities of individuals to achieve their goals.

Opiate substitution treatment services are managed by, Achieve Bolton, Salford and Trafford who are part of the Specialist Services Network within Greater Manchester Mental Health NHS Foundation Trust (GMMH).

2. The Role of Community Pharmacy

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

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

An important consideration however is that adhering to daily supervision regimes reduces opportunities for individuals to integrate back into society through employment, education, holidays etc. It is important that once the patient is stabilised and feeling confident, that the opportunity to increase their take home doses is fully considered. In line with the 'Drug Misuse and Dependence – Guidelines on Clinical Management' take home doses are unlikely to be provided for the first three months with the exception of weekend or bank holiday doses. At times of crisis or relapse, supervision may need to be temporarily re-instated. It should be noted that re-instatement dose may not be the same as the most recent dose.

[1] Drug misuse and dependence UK guidelines on clinical management, DoH (2007

This should not be seen as a failure, as making changes to drug use and habitual behaviours can be a lengthy process with 'lapsing' a common feature.

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

3. Methadone Substitution

Methadone is a long acting synthetic opioid analgesic and acts as a full opiate agonist. Methadone is most frequently prescribed as methadone mixture 1mg/ml, which is unlikely to be injected. The half-life of methadone is approximately 24 – 36 hours with repeated doses. This makes it particularly suitable for once daily dosing.

Methadone alleviates opioid withdrawal symptoms at adequate doses and blocks the effects of additional opioids, while at the same time alleviating craving

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

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

4. Buprenorphine Substitution[2]

Buprenorphine was licensed in 1999 for the treatment of opioid dependence in the UK. There are tablets of 0.4mg, 2mg and 8mg. The tablets are administered sublingually because it has poor oral bioavailability – inactivated by gastric acid and a high first pass metabolism.

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

The RCGP (2011) states;

"*Buprenorphine is a useful choice for substitute opioid prescribing because its clinical effectiveness is supported by research and alleviates opioid withdrawal symptoms*."

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

Buprenorphine is relatively safe during pregnancy and breastfeeding with less frequent, severe and shorter neonatal withdrawal than with methadone.[3] It may be better suited to those wishing to cease heroin use.

[2] See RCGP (2011) 'Guidance for the use of buprenorphine for the treatment of opioid dependence in Primary Care', for further details. Copy to be found in references section of this guidance.
[3] de Wet et al (2005) 'The rise of buprenorphine prescribing in England: analysis of NHS regional data, 2001-03', in *Addiction,* 100:495-499, and, RCGP (2004) 'Guidance for the use of buprenorphine for the treatment of opioid dependence in primary care'.

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

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

5. Buprenorphine/naloxone (Suboxone®) Substitution

Buprenorphine/naloxone was licensed in 2007 for the treatment of opioid dependence. It includes the opioid antagonist naloxone (Buprenorphine:Naloxone 4:1) in a combined sublingual tablet.

Suboxone is available as sublingual tablets in buprenorphine/naloxone 2mg/0.5mg and 8mg/2mg strengths.

The naloxone element of this medication has the potential to reduce its misuse. When buprenorphine/naloxone is taken sublingually, the absorption of naloxone is negligible and the full opiate effect of buprenorphine is experienced. However, if the tablet is injected, then the user will experience the opiate antagonist effect of naloxone, which would precipitate withdrawal from opiates.

The RCGP note that;

"International research has demonstrated the good safety profile of Suboxone when prescribed in community drug treatment settings and that patients can easily switched from Subutex to Suboxone without destabilising their treatment"

(RCGP 2011- p7)

6. The Need for a Supervised Methadone, Buprenorphine and Suboxone® Self-Administration Programme

6.1 *Stabilisation*

The supervised consumption of opiate substitution treatments is used as a therapeutic tool at the beginning of opiate dependence treatment. The RCGP (2011) recommend it should continue for 3 months and until the prescriber is satisfied the service user has been stabilised at the correct dose and maintaining a reasonable level of compliance. Factors such as distance to travel, work commitments and childcare may be considered as a reason to shorten this period of supervision.

The supervised consumption of opiate treatment can;

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

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

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

6.2 Reducing diversion

Supervising the self-administration of opiate medication can also prevent sale on the 'black market' and reduce the risk of diversion and its associated harm; the diversion of Methadone has long been implicated as a contributing factor on fatal and non-fatal opiate poisoning.

7. Aims and objectives of the service

Aim
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

Objectives
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, Achieve Bolton, Salford and Trafford Clinical team (see contacts page 15) and others directly involved in the care of the patient (where the patient has given written permission)
- Monitoring the patient's response to prescribed treatment; for example if there are signs of overdose, especially at times when doses are changed, during titration of doses, if the patient appears intoxicated or when the patient has missed doses and if necessary withholding treatment if this is in the interest of patient safety, liaising with the prescriber or named key worker as appropriate
- Improving retention in drug treatment
- Improving drug treatment delivery and completion

8. Operational Procedures

Outlined below are the Operational Procedures for delivering substitution therapy with supervised consumption via pharmacies. All staff, including locums, should be aware of the following procedures. It is these procedures, along with the key principles outlined immediately above, which constitute a robust protocol.

9. Accepting new service users into Supervised Consumption

- The Clinical Team will ask the service user which pharmacy participating in the supervised self-administration programme would be most convenient for daily visits and at what times.
- The Clinical Team will contact that pharmacist before issuing the first prescription to ensure the pharmacist has the capacity to accept the service user at that time.
- The service user will be briefed by the Clinical Team on the date of commencement of supervised administration. The Clinical Team should inform the service user fully of what is expected when commencing supervised administration. In doing so the team will inform the service user that the pharmacy will enter into a contractual arrangement with them, which they will be expected to adhere to.
- The service user will attend the pharmacy with their prescription for supervised methadone, buprenorphine or Suboxone® administration as agreed with the prescriber or keyworker.
- The service user must present a form of ID, which contains either, a photograph and name or name and address, which match that given by the SMS.

Acceptable forms of ID include:

- Photo ID driving licence, passport, proof of age card e.g. prove it, photo student ID,
- Name and address ID – no older than 3 months
- Bank statement, credit card statement, utility bill (not mobile phone bill), benefits correspondence and Council tax bill or payment book (If the service user is unable to provide any of the above, the Clinical Team will provide a letter to confirm identification).

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10. Service use and Pharmacist contracts

- It is important that pharmacists use the agreement (Appendix 4), outlining in detail the procedure for daily supervision.
- The aim of the agreement is to reduce the potential of misunderstandings and bad feeling to arise between service user and pharmacist.

Service users should be informed in advance of what arrangements are to be put into place to support them when the pharmacy is closed.

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

11. Identification of service user

- The service user's identity must be checked to ensure the prescription is dispensed to the correct person (see previous).
- If there is any uncertainty with the identity of the service user the prescriber must be contacted and the dose withheld until the individual's identity is ascertained.

12. Controlled drugs prescriptions

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

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

- Methadone and buprenorphine to be dispensed in instalments should be prescribed on a FP10MDA-SS and each script may have a maximum of 14 days' worth of treatment prescribed.

- Methadone and buprenorphine to be dispensed in a single transaction should be prescribed on a FP10-SS, which can have up to 30 days' worth of treatment (unless special arrangements are made).

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

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

- The prescription must specify clearly that supervision is required.

- The prescription should not be in any way tampered with, or in a condition where the instructions are no longer clear – e.g. water damaged, torn etc.

The Home Office have confirmed that prescriptions can be worded as follows **'If an instalment's collection day has been missed, please still dispense the amount due for any remaining day (s) of that instalment'.**

Emergency supply of methadone mixture and Buprenorphine – The Misuse of Drugs Act does not allow for the 'emergency supply' of schedule two or three controlled drugs (exemption – Phenobarbitone or Phenobarbitone sodium for epilepsy). Doses should never be given in advance of receipt of a valid prescription at the pharmacy. Phoned or faxed prescriptions for controlled drugs are also illegal.

Pharmacists must satisfy themselves of the clinical appropriateness of the prescription and its clinical appropriateness based on the limited information typically available to a community Pharmacist. If there is any doubt about the validity of the prescription or clinical concerns – the prescriber should be contacted.

- Pharmacist must have arrangements in place for receipt and safe storage of controlled drug prescriptions
- If a prescription is lost by the community pharmacy this must be reported to the Police, the Greater Manchester Controlled Drugs Accountable Officer and the Clinical Team must be informed. A replacement prescription will be issued to cover the days remaining on the lost prescription, after the matter has been reported to the police and a crime number obtained. Requests for backdated prescriptions will be reviewed on a case-by-case basis.

13. Preparation of medication

- **Methadone** - The daily amount should be measured into a container, capped and labelled. When the service user arrives, the measured dose must be poured into a disposable cup.

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

- **Guidance for Registered Pharmacies preparing unlicensed medicines** -the GPhc (2014) has published guidance on the preparation of unlicensed medicines, which sets out the key areas that need to be considered by the pharmacy owner and superintendent pharmacist in any registered pharmacy where unlicensed medicines are prepared by a pharmacist or under supervision of a pharmacist. Every patient has every right to expect that when an unlicensed medication is prepared by, or under supervision of a registered pharmacist in a registered pharmacy it's of equivalent quality to a licensed medicine. This guidance also applies when unlicensed methadone is extemporaneously prepared. The guidance explains that pharmacies preparing unlicensed medicines including extemporaneous preparations of methadone, must mitigate risks to patients and meet the GPhC's standards for registered pharmacies.
  - https://www.pharmacyregulation.org/sites/default/files/guidance_for_registered_pharmacies_preparing_unlicensed_medicines_may_2014.pdf

- **Buprenorphine/Suboxone** – The prescribed tablets should be removed from the foil and placed in an appropriate container. It is important that the dose is ready for the service user's arrival. The whole operation should be as discreet and efficient as possible, maintaining the patient's dignity and saving the pharmacist's time.

14. Discreet and efficient supervision by pharmacist or the appropriately qualified, trained and competent pharmacy technician.

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

- **Methadone** - The appropriately qualified, trained and competent pharmacy technician see additional requirements below, must be satisfied that the dose has actually been swallowed, for example, by water being swallowed after the dose or conversing with the service user to ensure

that the methadone is not retained in the mouth. 'Spit Methadone' has a street value and some clients may be under a great deal of pressure to hand over their dose to others.

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

15. Supervision by the appropriately qualified, trained and competent pharmacy technician

The responsible pharmacist providing this service may delegate the role of supervising the self-administration of Methadone, Buprenorphine and/or Suboxone® to the appropriately qualified, trained and competent pharmacy technician once the service user has stabilised on their medication. For those service users using the service for the first time or re-commencing treatment following relapse, this process of stabilisation may take up to four weeks and would require supervision by the responsible pharmacist. Thereafter the pharmacy technician may be delegated this role. However, overall responsibility and accountability will remain with the responsible pharmacist.

16. Pharmacist Training & Qualifications

This service will only be commissioned through pharmacy contractors that have a competent by Declaration of Competence (DoC) pharmacist on duty 75% of the pharmacy opening hours.
To gain accreditation, pharmacists routinely involved in the provision of this service must have made the CPPE 'Supervised consumption of prescribed medicines' Declaration of Competence. Before making this declaration of competence the following must be completed:

- The distance learning package 'Substance Use and Misuse" (2nd Edition May 2012) available from the Centre for Postgraduate Pharmaceutical Education (CPPE). This is available online and takes approximately 10 hours.
  Information is available from https://www.cppe.ac.uk/mycppe/login#doc
  And
- The CPPE assessment 'Substance Use and Misuse – delivering Pharmacy services (2015**)**

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

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

If in exceptional circumstance Achieve Bolton, Salford and Trafford choose to commission this service from a pharmacy who employs a pharmacist that have not completed their qualification, commencement of the required training will be expected within four weeks of their being accepted on to the programme and successful completion within 12 weeks. Achieve Bolton, Salford and Trafford must be informed once the qualification has been awarded with copies of certificates of completion submitted to Achieve Bolton, Salford and Trafford Senior Clinical Nurse.

Local training will also be provided by Achieve Bolton, Salford and Trafford at the commencement of the scheme and updates if there are significant changes to clinical practice.

17. Pharmacy Technician Training & Qualifications

Pharmacy Technicians involved in the provision of this service must be registered with the GPhC and have completed the same learning modules, assessment and declaration of competence as described above. Information is available from www.cppe.man.ac.uk. Alternatively, a supervising accredited pharmacist must sign off the DOC for the appropriately qualified, trained and competent dispensing assistant.

18. Pharmacists and Pharmacy Technicians participating in the service must:-

1. Ensure compliance with all legal and professional requirements.
2. Ensure they have appropriate insurance cover.
3. The pharmacy must have a Standard Operating Procedure (SOP) for all personnel operating the scheme. If a Pharmacy Technician is to provide this service the SOP must make specific reference to their role and responsibilities, highlighting steps in the procedure where referral to the pharmacist is necessary. SOPs are intended to support staff working in the community by setting out strategies for risk management and harm reduction that comply with clinical governance requirements.
4. Supervise the daily consumption of methadone mixture (1 mg per ml) or buprenorphine or morphine or Suboxone® 0.4mg, 2mg or 8mg sublingual tablets in accordance with the prescribers wishes;
5. Follow the procedures recommended in local guidelines.
6. Respect patient confidentiality at all times.
7. Ensure an accredited pharmacist or an appropriately qualified and trained dispensing assistant, provides this service at all times. This excludes locums covering holidays or sick leave, however regular locums would need to be able to complete the Declaration of Competence for Pharmacy Services of Prescribed Medicines Services.
8. Inform Achieve Bolton, Salford and Trafford if there is an interruption to the delivery of this service for longer than 2 weeks duration by an accredited pharmacist. See Appendix 6 'Changes in the provision of Supervised Self Administration of Methadone, Buprenorphine or Suboxone® by Accredited Pharmacist'.
9. Ensure new staff or locums are fully aware of the SOP and are able to enact this agreement appropriately. Regular locums should be able to make a Declaration of Competence.
10. Allow regular audit of service provision and patient records in line with Achieve Bolton, Salford and Trafford requirements and those to be developed by a Controlled Drugs Inspectorate and the Care Quality Commission (CQC).

19. Liaison

Pharmacists should develop and maintain close links with The Achieve Bolton, Salford and Trafford Clinical Team and the Recovery Coordinators

The pharmacist may be contacted by the Clinical Team/Recovery Coordinator:

- For feedback after the first week of treatment
- After three months to feed into the review of the recovery plan/treatment package
- When prescriptions need halting/cancelling to encourage patients to attend review appointments with the Achieve Bolton, Salford and Trafford prescriber or Recovery coordinator, Pharmacists should be able to appropriately void prescriptions/halt dispensing for a few days based on verbal communication from the Achieve Bolton, Salford and Trafford clinical team.
- As required, to update on any significant issues regarding the management of the service users prescribing regime.

At all other times all steps should be taken to maintain the service user's confidentiality, with all staff protecting the privileged information they are party to by not divulging anything about the service user outside of the pharmacy.

Daily contact with the service user may allow the pharmacist to provide health promotion support and monitor patient compliance, suspected alcohol/drug intake, physical appearance and family support. People who are dependent on substances often have difficulty in accessing help and other social care.

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

20. When to contact the Clinical Team

The pharmacist must contact the prescriber in the following circumstances:

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

  Methadone taken in combination with other opiates, alcohol or benzodiazepines may increase the sedative effects leading to respiratory depression and potential overdose.

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

- **The patient misses doses –**

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

  If a service user comes in after having missed three consecutive doses, their dose must be withheld and they must be referred back to the prescriber. For example, if a service user misses doses on Wednesday, Thursday and Friday and presents to the pharmacy on Saturday, the dispensing should NOT be made, as they have missed three consecutive days. The service must be contacted on Monday morning to inform them of the situation. It may be possible for the pharmacy to contact the service on the Friday, in anticipation of the service user missing three consecutive days to inform them of the situation.

  If clients regularly miss a single day's dose, for example 3 doses in a 7-day period, or are a frequent irregular attender, the prescribing doctor must be informed.

  If a service user has missed a dose on a Thursday and Friday the service should be contacted by the pharmacist to advise of this. The likelihood is that that service user will not attend on the Saturday for the third dose. Contacting the service will allow the opportunity to contact the service user so that they do not miss the third dose.

- **<u>Missed doses should not be replaced or issued at a later date.</u>**

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

- **The behaviour of the service user is unacceptable** and contrary to the service user/pharmacy agreement - ultimately the pharmacist is the one to decide what behaviour is 'unacceptable'. In circumstances where a dose is not administered, or the pharmacist wishes to cease future administrations, both the service user and prescriber must be made aware of this decision.

Appendix 4 further outlines circumstances in which the pharmacist should contact the prescriber. The decision is a professional one that should be made after considering the risk to the patient of non-

disclosure and the damage that may be done to the supportive relationship between the pharmacist and the patient. Patient confidentiality should be respected at all times.

Contact with the prescriber should be swift following any reason for concern and especially where doses are missed or further administration has been withdrawn. The details must be telephoned through to the prescribing agency. It is important that this information is relayed to the appropriate prescriber or keyworker for a service user.

21. Premises

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

- A patient records system (PharmOutcomes)
- Appropriate storage conditions for the increased supply of methadone/buprenorphine/ Suboxone®.
- A consultation area that is fit for purpose for administering methadone/buprenorphine/ Suboxone® to clients under supervision, as determined by Achieve Bolton, Salford and Trafford. The prescriber should discuss this with the service user when selecting a pharmacy. In agreement with the pharmacist the service user may choose not to consume their supervised medication in the consultation area but in another area of the pharmacy that is fit for purpose. In all circumstances the pharmacy must have a fit for purpose consultation area that at a minimum meets the standards required to provide Advanced Services under the terms of the Community Pharmacy Contractual Framework.
- An area for display of relevant health promotion leaflets including advice on the safe and secure storage of medicines.

22. Recording of information

Pharmacists may delegate but ultimately are responsible for maintenance of each service user's Patient Medication Record. There should a record of daily attendance, missed doses and other concerns that may need to be reported back to the prescribers.

Dispensing records for each supervised dose are to be recorded on PharmOutcomes. This system will also be used for monitoring and audit purposes and for the purpose of remuneration.

Controlled Drugs registers must be used to record details of all schedule 2 controlled drugs received or supplied by a pharmacy. Electronic Controlled Drug registers are permitted so long as they are compliant with required standards for Controlled Drugs registers. Subsequent to statutory Instrument 2005/2864 a controlled drugs register may be computerised and copies of this register may be requested by the Secretary of State or an authorised person. Requisitions and orders for buprenorphine may be preserved in original form or as a copy on computer.[4]

23. Disposal of waste

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

Standards of appropriate disposal of Controlled Drugs bottles that contain irretrievable amounts of liquid drugs must always be adhered to. Any excess liquid in Controlled Drug used containers should be denatured. The container should then be rinsed out and the rinsing added to the denaturing kit. Excess Controlled Drug liquid and rinsing liquid should not be disposed of down the sink. Any patient identifying information should be obliterated from the rinsed container. The cleaned and unlabelled container can then be placed in the recycling or general waste.

[4] See new regulation 24a which has been added to the 2001 regulations.

24. Payments

Payments will be made per supervision at a rate of:

Methadone	£1.50 per supervised dose (VAT zero-rated)
Buprenorphine/Suboxone®	£2.34 per supervised dose (VAT zero-rated)

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

- Invoices for the previous month's exchange activity will automatically be generated through the PharmOutcomes system on the 5th day of each month. It is the pharmacy contractor's responsibility to ensure that all activity is recorded on PharmOutcomes prior to this date.

- Pharmacies are to ensure the data for each observed dose is entered onto PharmOutcomes in a timely way.

- There is a grace period of two months, which will allow data to be entered and claimed for retrospectively for one month, any claims made after this grace period will not be processed.

- Payment will be made via BACS to the bank account details provided.

- GMMH will undertake to make a payment to CHL within 2 weeks of receiving the invoice.

- CHL undertake to make payments to contractors within 2 weeks of receiving payment from GMMH.

- Achieve will not make payment for the following reasons:
    - Failure to enter data into the PharmOutcomes for observed consumption within the agreed time frame

25. Leaving the scheme

If a pharmacy contractor wishes to leave the scheme, or cease providing any aspect of the service at any point, they should inform Achieve Bolton, Salford and Trafford in writing of this intention, 56 days in advance. This will enable prescribers to make alternative arrangements allocating clients to alternative scheme providers.

Similarly, Achieve Bolton, Salford and Trafford will give 56 days' notice in writing to contractors if the decision is taken to decommission the service. This period of notice will be waivered if patient care is compromised or if fraud is suspected.

26. Contact Details:

Achieve Service contacts are listed below:
Achieve BST Interim Service Manager: Jonathan Miller
jonathan.miller@gmmh.nhs.uk
07827899058

Salford and Trafford Clinical Team: Lisa Sloan
lisa.sloan@gmmh.nhs.uk
01613580750

Bolton Clinical Team: Ann McKernan
ann.mckernan@gmmh.nhs.uk
01204557977

27. Appendices

Appendix 1 - Service user leaflet – Buprenorphine / Suboxone®

Service user Leaflet
Supervised Buprenorphine / Suboxone®

Your doctor has prescribed Buprenorphine or Suboxone® and stated that this is to be "supervised consumption". This means the following **must** happen.

- You attend the pharmacy on the days indicated on your prescription
- We positively identify you
- You remove any chewing gum or sweets from your mouth and dispose of them in a waste bin
- You will be provided with a drink of water as this speeds up the time it takes for the tablets to dissolve
- The dispensed tablet is taken from the container with your name on and squeezed out of the foil and into a plastic medicine measure
- You are expected to tip the tablet(s) or granules under your tongue **without touching them** and hand back the measure
- **<u>You must then sit down and allow these to dissolve</u> - this usually takes between 3 and 5 minutes** for tablets - significantly less time for granules.
- Once the tablets have dissolved you should report to the pharmacist and will be provided with a drink of water, which you should drink
- You may then leave

Important
- Failure to follow the points above will result in the prescription being suspended and you being referred back to the Achieve Bolton, Salford and Trafford Clinical Team.
- Missing three consecutive doses will also mean that you have to contact the Achieve Bolton, Salford and Trafford Clinical Team.

Name of Prescriber: (please print)……..

Prescribers signature: ……. Date: ……..

Service Users Name: (please print)……

Service Users signature: …….. Date: ……..

Appendix 2 – Information Leaflets

Patient Information Leaflets for Buprenorphine and Methadone

Bup PiL.pdf

MethPiL.pdf

Drug Driving Leaflet in association with THINK and FRANK

drugdrive-leaflet.pdf

Safe Storage of Medication Leaflet

safestorage.pdf

Service contact details

BST Pharmoutcomes con

Appendix 3 - Service user/Pharmacy Agreement

We are pleased to welcome you to Achieve Bolton, Salford and Trafford Supervised Consumption Scheme and wish you all the best with your treatment. We aim to offer you a discreet and efficient service that supports you in achieving your treatment goals.

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

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

We hope that the scheme proves helpful to you

The Arrangements	**Why they are necessary**
We are available to supply your medication between: From…….To…….. From……..To……..	We want to give you your medicine as quickly as possible. We prepare your medicine first thing in the morning and write up our records before the shop closes. When the pharmacy is busy, we must take all customers in turn, so at periods you may have to wait in a queue for your medication
You will need to collect your take home doses on……..……. for weekends and Bank Holidays	The pharmacy is closed on ……..day and ……..day and on Bank Holidays. Opening times are:
We will need some way of identifying you. Our pharmacist will explain how this is done.	We want to ensure that we don't give your medication to anyone else
If you have missed three days collections in a row, we cannot supply your medication without speaking to your prescriber.	Your tolerance to the drug quickly drops and to take the full dose may risk your health
We must supervise you taking your medicine because this has been stipulated on your prescription	This is done to support you in achieving your treatment goals and to take your medication safely
We cannot let anyone else collect your medication for you.	Again, we want to make sure you get your medicine and not anyone else
When you collect your medication we need time to update our records. Please be patient	By law, we have to make detailed records on each collection. We cannot do this in advance.
If you lose your prescription, we cannot supply the medication to you no matter how well we know you	Again, by law, we can only supply medications with a legally written prescription. If you have lost one you will need to contact your prescriber.
We cannot give you 'missed doses' that you have not picked up	The supply of your medication has to be made on the day and date specified on the prescription.
Please bring your new prescription promptly before, or just after your current one finishes	There is sometimes a waiting list for places. If you do not show we may have to give your slot to someone else
We would like you to come alone and to behave in a reasonable manner in the pharmacy and in the area outside the pharmacy.	We want our pharmacy to be a welcoming place to you and all our customers and expect all our patients/customers to behave in a reasonable manner. **Failure to do so will force a withdrawal of services.**
Please feel free to ask about other health related issues that maybe worrying you.	We offer information and advice on health related matters to all members of our communities. You are a customer of ours and we value your custom.

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

Name of Pharmacist: Pharmacy Stamp:

Phone number of Pharmacy:

Name and contact details of Prescriber:

Name and contact details of therapist:

Service Users signature:…….. Date……..

Print Name……

Pharmacists signature:…… Date……..

Complaints procedure

If you are not satisfied with the service that you have received, please speak with your pharmacist therapist or Recovery Coordinator at Achieve Bolton, Salford and Trafford.

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

Notes or Comments

We value your custom and will endeavour to do all we can to meet your health needs.

Appendix 4 - Changes in the provision of Supervised Self Administration of Methadone, Buprenorphine or Suboxone by Accredited Pharmacists/The appropriately qualified, trained and competent dispensing technicians

Pharmacy name: _____

Pharmacy address: _____

_____

Please complete the relevant section:

Section A – newly accredited pharmacist

_____ has now _____ completed _____
(Pharmacist's name) (date) (Course name and provider)

Section B – change in accredited pharmacist

The Supervised Self Administration of Methadone, Buprenorphine and Suboxone® Scheme at:_ _____

_____will henceforth _____ be administered by _____
(Pharmacy name) (date) (name)

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

Section C – newly accredited the appropriately qualified, trained and competent dispensing technician

_____ has now _____ completed _____
(Technician's name) (date) (Course name and provider)

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

Between _____ and _____the Supervised Self Administration of Methadone and

Buprenorphine Scheme will be provided by _____

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

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

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

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

Please send to the relevant team: Bolton: achievebolton@gmmh.nhs.uk
Salford: achieve@gmmh.nhs.uk
Trafford: achievetrafford@gmmh.nhs.uk

APPENDIX 5 – DATA PROTECTION AGREEMENT

1.1 Definitions

Agreed Purposes: the provision of certain community-based pharmacy services

Controller, data controller, processor, data processor, data subject, personal data, processing and appropriate technical and organisational measures: as set out in the Data Protection Legislation in force at the time.

Data Protection Legislation: all legislation and regulatory requirements in force from time to time relating to the use of personal data and the privacy of electronic communications, including, without limitation (i) any data protection legislation from time to time in force in the UK including the Data Protection Act 2018 or any successor legislation, as well as (ii) the General Data Protection Regulation ((EU) 2016/679) and any other directly applicable European Union regulation relating to data protection and privacy (for so long as and to the extent that the law of the European Union has legal effect in the UK).

Permitted Recipients: The parties to this agreement, the employees of each party, any third parties engaged to perform obligations in connection with this agreement.

Shared Personal Data: the personal data to be shared between the parties under this clause. Shared Personal Data shall be confined to the following categories of information relevant to the following categories of data subject:

a) personal data including but not limited to name, identification number(s), location data, online identifier(s) or one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of a data subject;

b) special category data including but not limited to information relating to a data subject's health.

1.2 Each party shall comply with its respective obligations pursuant to the Data Protection Laws.

1.3 To the extent that the Provider is acting as a Controller in Common/Independent Controller:

1.3.1 Shared Personal Data. This clause sets out the framework for the sharing of personal data between the parties as data controllers. Each party acknowledges that one party (the Data Discloser) may choose to disclose to the other party (the Data Recipient) Shared Personal Data collected by the Data Discloser for the Agreed Purposes.

1.3.2 Effect of non-compliance with Data Protection Legislation. Each party shall comply with all the obligations imposed on a controller under the Data Protection Legislation, and any material breach of the Data Protection Legislation by one party shall, if not remedied within 30 days of written notice from the other party, give grounds to the other party to terminate this agreement with immediate effect.

1.3.3 Particular obligations relating to data sharing. Each party shall:

(a) ensure that it has all necessary notices and consents in place to enable lawful transfer of the Shared Personal Data to the Permitted Recipients for the Agreed Purposes;
(b) give full information to any data subject whose personal data may be processed under this agreement of the nature such processing. This includes giving notice that, on the termination of this agreement, personal data relating to them may be retained by or, as the case may be, transferred to one or more of the Permitted Recipients, their successors and assignees;
(c) process the Shared Personal Data only for the Agreed Purposes;
(d) not disclose or allow access to the Shared Personal Data to anyone other than the Permitted Recipients;
(e) ensure that all Permitted Recipients are subject to written contractual obligations concerning the Shared Personal Data (including obligations of confidentiality) which are no less onerous than those imposed by this agreement;
(f) ensure that it has in place appropriate technical and organisational measures to protect against unauthorised or unlawful processing of personal data and against accidental loss or destruction of, or damage to, personal data.
(g) not transfer any personal data received from the Data Discloser outside the EEA.

1.3.4 Mutual assistance. Each party shall assist the other in complying with all applicable requirements of the Data Protection Legislation. In particular, each party shall:

(h) consult with the other party about any notices given to data subjects in relation to the Shared Personal Data;
(i) promptly inform the other party about the receipt of any data subject access request;
(j) provide the other party with reasonable assistance in complying with any data subject access request;
(k) not disclose or release any Shared Personal Data in response to a data subject access request without first consulting the other party wherever possible;
(l) assist the other party, at the cost of the other party, in responding to any request from a data subject and in ensuring compliance with its obligations under the Data Protection Legislation with respect to security, breach notifications, impact assessments and consultations with supervisory authorities or regulators;
(m) notify the other party without undue delay on becoming aware of any breach of the Data Protection Legislation;
(n) at the written direction of the Data Discloser, delete or return Shared Personal Data and copies thereof to the Data Discloser on termination of this agreement unless required by law to store the personal data;
(o) use compatible technology for the processing of Shared Personal Data to ensure that there is no lack of accuracy resulting from personal data transfers;
(p) maintain complete and accurate records and information to demonstrate its compliance with this clause 1.3 and allow for audits by the other party or the other party's designated auditor; and
(q) provide the other party with contact details of at least one employee as point of contact and responsible manager for all issues arising out of the Data Protection Legislation, including the joint training of relevant staff, the procedures to be followed in the event of a data security breach, and the regular review of the arties' compliance with the Data Protection Legislation.

1. Additional Information

Clinical Guidelines

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

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/673978/clinical_guidelines_2017.pdf

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

- RCGP & SMMGP (Updated Oct 2011)
These are the new guidelines that are intended to aid GPs in the use of buprenorphine as a substitute medication for opioid dependence for maintenance and detoxification.
Includes main document, Patient Information Sheet, and Summary Sheet.

https://www.drugsandalcohol.ie/13633/1/RCGP_buprenorphine.pdf

Medico-legal aspects

The Royal Pharmaceutical Society of Great Britain provides guidance on all legal aspects and standards for professional indemnity, both of which can be found in the latest edition of 'Medicines, Ethics, and Practice'.

http://www.rpsgb.org.uk/

Supervised Consumption of Prescribed medicines – Declaration of Competence

https://www.cppe.ac.uk/services/declaration-of-competence2?srv=9#doc

GPhc Guidance for Registered Pharmacies preparing unlicensed medicines

https://www.pharmacyregulation.org/sites/default/files/guidance_for_registered_pharmacies_preparing_unlicensed_medicines_may_2014.pdf