Manchester Health & Care Commissioning
A partnership between Manchester City Council and NHS Manchester CCG

MANCHESTER CITY COUNCIL

NHS Manchester Clinical Commissioning Group

Service Specification

Observed Supervised Administration (OSA) of Methadone, Buprenorphine, Opiates and Suboxone®

Service Specification No.	
Service	Observed Supervised Administration (OSA)
Authority Lead	Lindsay Laidlaw Commissioning Manager Population Health Team Manchester Health and Care Commissioning Mobile – 07903 429041 Email – lindsay.laidlaw@manchester.gov.uk
Provider Lead	
Period	1 April 2021 to 31 March 2022
Date of next Review	1 January 2022

EXECUTIVE SUMMARY

1.0 Overview

a. Manchester Health and Care Commissioning (MHCC) is commissioning and funding a community pharmacy Methadone, Buprenorphine, Opiates and Suboxone® observed supervised administration service. This service specification is for pharmacists and appropriately qualified and trained pharmacy technicians and outlines the standard operational procedures and administrative processes for the MHCC observed supervised administration for Methadone, Buprenorphine and Buprenorphine-naloxone (Suboxone®)[1].

b. Pharmacy services for citizens 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 the citizen accessing the service.

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

NATIONAL AND LOCAL CONTEXT

2.1 NATIONAL CONTEXT

2.1.1 National Strategy

A. Drugs and substance misuse impacts on the health and wellbeing of our residents and the safety of our communities. The effects of substance misuse can be far reaching and often complex in nature. The Government's updated 2017 Drug Strategy, outlines a need to do more to address the evolving challenges of drug misuse through effective partnership working between treatment providers, the criminal justice system, housing and employment support.

B. Drug treatment services are key to supporting individuals misusing substances, such as opiates. Studies have shown that methadone maintenance treatment (sometimes referred to as medically assisted treatment MAT) 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 MAT 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.

2.1.2 Overview of commissioning responsibilities

a. The Health and Social Care Act (2012) divided responsibilities for the commissioning and funding of some health protection and improvement services between local authorities, Clinical Commissioning Groups (CCGs) and NHS England. Local authorities have the lead for improving health and for coordinating efforts to protect public health.

b. Local authorities are in the main responsible for commissioning and funding local substance misuse services. This includes the commissioning of specialist integrated drug and alcohol services that deliver substance misuse support (including MAT), to help support citizens to manage their substance misuse or achieve their goal of recovery. Local authorities may also commission and fund other prevention and support programmes to reduce the harm caused by substance misuse, such as needle and syringe programmes (NSP).

2.1.3 Public Health Outcomes Framework

a. The Public Health Outcomes Framework sets out a vision for public health. The Framework includes the below indicators relating to substance misuse:

1. Indicator C19a: Successful completion of drug treatment – opiate users
2. Indicator C19b: Successful completion of drug treatment – non opiate users
3. Indicator C19c: Successful completion of alcohol treatment

4. Indicator C19d: Deaths from drugs misuse
5. Indicator C20: Adults with a substance misuse treatment need who successfully engage in community-based structured treatment following release from prison
6. Indicator C21: Admission episodes for alcohol related conditions (narrow)

2.2 Rationale

a. Community pharmacies can promote health and wellbeing among their local population which includes integrating with existing health and care pathways and other activities to encourage more people to use their services, in a holistic and non-judgemental way.

b. Community pharmacies offer accessible healthcare because:

- Appointments are unnecessary
- Opening hours are long
- Many staff are from the local community and understand local culture and social norms
- Able to offer advice on healthy behaviours and onward referral to other services, if appropriate
- Pharmacies provide services on a wider geographical footprint.

c. 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.

3.0 GREATER MANCHESTER LOCAL PHARMACEUTICAL COMMITTEE

3.1 MHCC work closely with the Greater Manchester Local Pharmaceutical Committee (GMLPC) on the development of community pharmacy service specifications and payment tariffs to support and promote standardisation of OSA services across Greater Manchester, whilst ensuring local variation to meet needs.

4.0 MANCHESTER

4.1 Overview of commissioning responsibilities

a. Manchester Health and Care Commissioning (MHCC) is a partnership between NHS Manchester Clinical Commissioning Group and Manchester City Council (MCC). MHCC is responsible for commissioning and funding health and care services in Manchester. The current contracting responsibility for this service is held by MCC.

b. MHCC commission and fund the integrated drug and alcohol service for Manchester, delivered by 'Change, Grow, Live' (CGL). CGL provide specialist substance misuse support to Manchester citizens, across the life course, to reduce the harm caused by drugs and alcohol and work together with partners in supporting individuals to access the treatment they need to reduce dependency, promote recovery, and manage high risk injecting behaviours. CGL also work together with a number of General Practice (GP) surgeries in Manchester to deliver a 'shared care' service within a primary care setting, again commissioned by MHCC.

c. MHCC currently contract with a number of community pharmacies to deliver OSA for MAT. This specification will supersede any existing OSA service and all community pharmacy OSA services contracted with MHCC from 01.03.2021 will deliver services in line with the standard operating procedure outlined in this specification.

d. MHCC currently commission a basic community pharmacy NSP service in selected community pharmacies across Manchester. From 01.03.21 any community pharmacy contracted with MHCC to deliver NSP services will be offering a Level 2 service in line with NICE Public Health Guidance 52: Needle and Syringe Programmes (National Institute for Health and Clinical Excellence, 2014).

4.2 Overview of drug misuse prevalence in Manchester[2]

a. Local prevalence estimates (National Drug Treatment Systems 2016/17) indicate there are 4150 people dependant on opiates (crack/heroin) in Manchester, with a rate of 10.7 per 1000, however we know there is significant unmet need.

b. In 2018/19, the numbers of all adults within structured treatment were 2515, with the majority of referrals into treatment systems 'self-referral', followed by the criminal justice system. Of those in structure treatment above, 71% of these male however, women in treatment services are more likely to be caring for children.

c. In 2018/19, 40% of all people in treatment were between the ages of 40-49, with 26% 50-59. The drug using population is getting older, with a greater risk of long-term health conditions.

d. Manchester has had as high as 41% of citizens engaged in treatment services prescribed supervised MAT, however these numbers change depending on need. The integrated drug and alcohol service continues to support individuals whose specific circumstances are best met by the prescribing of MAT via OSA within a community pharmacy.

e. Drug misuse is a major contributor to premature mortality. People who use drugs are up to ten times more likely to die suddenly or from chronic diseases than people who do not use drugs, with many of these deaths preventable.

[2] Manchester Data: Public Health England (PHE) Commissioning Support Pack 2020/21

AIMS & OBJECTIVES

5.0 AIMS AND OBJECTIVES

5.1 Aims

a. The aim of the provision of OSA in community pharmacy is to:

- Provide OSA opiate substitution therapy to citizens engaged in the integrated drug and alcohol service to ensure those individuals accessing prescribed specialist medication do so under professional supervision and that appropriate information is recorded.
- Offer citizens a non-judgemental client focussed, confidential service in managing their substance misuse or recovery journey
- To maximise the benefit citizens will receive by signposting to other services for advice and lifestyle support
- Prevent/reduce diversion of prescribed medicines onto the illicit drugs market
- Reduce/eliminate accidental exposure to the dispensed medicines
- Prevent the overuse or underuse of medicines
- To reduce the number of drug-related deaths caused by opioid overdose by increasing awareness of symptoms of opioid overdose, how to respond in an emergency and promoting harm minimisation.

5.2 Objectives

a. 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 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

OVERVIEW

6.0 SERVICE DESCRIPTION

6.1 The Role of Community Pharmacy

a. Pharmacists play a key and unique role in the care of Manchester residents. In relevance to this service, 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 and minimising misdirection of controlled drugs, which may help to reduce drug related deaths in the community.

b. 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.

c. It is important that once the citizen accessing MAT is stabilised and feeling confident, that the opportunity to increase their take home doses is fully considered, in consultation with the prescriber. 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 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.

6.2 Methadone Substitution

a. 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, which makes it particularly suitable for once daily dosing. Methadone is a schedule 2 drug subject to full controlled drug requirements relating to prescriptions, safe custody and therefore the need to keep registers etc.

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

c. 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, intravenous use and injecting related harm. Citizens stabilised on methadone should be alert and coherent.

6.3 Buprenorphine Substitution [3]

[3] See RCGP (2011) 'Guidance for the use of buprenorphine for the treatment of opioid dependence in Primary Care'.

a. 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.

b. 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.

c. The Royal College of General Practitioners 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 citizens locally have also reported that it has less sedating effects and a less euphoric high leaving them clearer headed.

d. Buprenorphine is relatively safe during pregnancy and breastfeeding with less frequent, severe and shorter neonatal withdrawal than with methadone[4] and therefore may be better suited to those wishing to cease heroin use.

e. 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.

f. 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.

6.4 Buprenorphine/naloxone (Suboxone®) Substitution

a. 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 buprenorphone/naloxone 2mg/0.5mg and 8mg/2mg strengths.

b. 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.

c. The RCGP note that;

[4] 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'.

"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)

6.5 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 in the aims and objectives, which constitute a robust protocol.

6.5.1 Accepting new citizens into Supervised Consumption

a. The integrated drug and alcohol service, CGL, will ask the citizen which pharmacy participating in the OSA service would be most convenient for daily visits and at what times. CGL will contact that pharmacist before issuing the first prescription to ensure the pharmacist has the capacity to accept the citizen at that time.

b. The citizen accessing the service will be briefed by CGL on the date of commencement of supervised administration. CGL should inform the citizen attending the service what is expected when commencing OSA. The citizen will attend the pharmacy with their prescription for supervised methadone, buprenorphine or Suboxone® administration as agreed with the prescriber or keyworker.

c. The citizen accessing the service must present a form of ID, which contains either, a photograph and name or name and address, which match that given by the prescriber, CGL. 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 citizen is unable to provide any of the above, the Clinical Team will provide a letter to confirm identification).

.

6.5.2 Service use and Pharmacist contracts

a. It is important that pharmacists use the agreement (Appendix 3), 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 the citizen and the pharmacist. Appendix 3 has been provided by GMLPC to support the Manchester OSA service.

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

c. In addition, citizens should be given a practice leaflet detailing additional professional services offered by the pharmacy. Health promotion is an important issue for citizens

attending OSA, and pharmacists should take every opportunity to provide advice on diet, exercise and oral hygiene in line with Health Living Pharmacy.

6.5.3 Identification

The citizens 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 presenting citizen, the prescriber must be contacted and the dose withheld until the individual's identity is ascertained.

6.5.4 Controlled drugs prescriptions

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

b. 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, and the use of stamped signatures is prohibited.

c. 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.

d. 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).

e. 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.

f. 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.

g. 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.

h. 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.

i. Emergency supply of methadone mixture and buprenorphine – The Misuse of Drugs Act does not allow for the 'emergency supply' of Schedule 2 or 3 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.

j. 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.

k. 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 Greater Manchester Police, the Greater Manchester Controlled Drugs Accountable Officer and the prescriber must be informed. A replacement prescription can be requested 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 by the prescriber.

6.5.5 Preparation of medication

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

b. Doses that are collected to be taken on Sundays or bank holidays must be dispensed in a container with a child resistant closure. Citizens must also be advised to store their medication out of the reach of children, and contact made with the prescriber to issue a safe storage box where a citizen declares they do not have one.

c. 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 citizen 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.

d. 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 citizen's arrival. The whole operation should be as discreet and efficient as possible, maintaining the patient's dignity and saving the pharmacist's time.

e. 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.

f. 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 citizen 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.

g. Buprenorphine/ Suboxone®– the tablet must be tipped directly under the tongue without handling and the citizen supervised by the pharmacist or pharmacy technician until the tablets have dissolved – this can take 3-7 minutes depending on the dose and the pharmacist should advise the citizen to bring a drink of water with them for consumption before administering their medication. This will help speed up the process. Citizens 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.

h. The responsible pharmacist providing this service may delegate the role of OSA of Methadone, Buprenorphine and/or Suboxone® to an appropriately qualified, trained and competent pharmacy technician once the citizen has stabilised on their medication. For those citizens 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.

i. All administration should be discreet and efficient supervision by pharmacist or the appropriately qualified, trained and competent pharmacy technician.

6.6 Role of the pharmacist and pharmacy technician

a. Ensure compliance with all legal and professional requirements.

b. Ensure they have appropriate insurance cover.

c. 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.

d. 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;

e. Follow the procedures recommended in local guidelines.

f. Respect patient confidentiality at all times.

g. 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.

h. Inform CGL, the integrated drug and alcohol service if there is an interruption to the delivery of this service for longer than 2 weeks duration by an accredited pharmacist (see Appendix 3 provided by the GMLPC).

i. 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.

j. Allow regular audit of service provision and patient records in line with CGL requirements and those to be developed by a Controlled Drugs Inspectorate and the Care Quality Commission (CQC).

6.7 General

a. Pharmacies will offer a user-friendly, non-judgemental and confidential service, and will ensure that all staff involved in the OSA respect the privacy of citizens accessing the service.

b. The integrated drug and alcohol service will ensure the pharmacy has appropriate harm reduction material available for the user group and will share current health promotion messages via PharmOutcomes. The Contracted Pharmacy is responsible for cascading this learning.

c. Pharmacies will provide the Commissioner and integrated drug and alcohol service with details of their opening hours and advise in a timely manner of any changes.

d. The pharmacy will promote the uptake of harm reduction materials and take on the responsibility of providing other health promotion messages as appropriate.

e. Pharmacies will be expected to act on feedback provided by citizens using the service, the Commissioner or the integrated drug and alcohol service in order to ensure a high-quality service provision.

f. Pharmacists will share relevant information with other health care professionals and agencies, in line with locally determined confidentiality arrangements and user permissions.

6.8 Inclusion and exclusion criteria

a. The OSA service will be available to all presenting adults (aged 18 and over), who have been referred to the service (and accepted by the Contracting Pharmacy) as requiring and suitable candidates for OSA.

b. Contracted pharmacies must be committed to ensuring equality of access to the service and that every person associated with this service is treated with dignity and respect. The contractor must ensure that no person is treated less favorably than another because of their age, sex, gender, colour, race, disability, faith/belief, nationality, ethnicity, citizenship, physical appearance, health status, social position, employment status, family/marital status, political belief, trade union membership, sexual orientation or non-relevant previous convictions.

6.9 Referral sources and processes

a. The Contractor is required to signpost or refer clients to other relevant services, as and when required – e.g. general practice, sexual health.

GOVERNANCE AND OPERATION

7.0 CLINICAL GOVERNANCE

7.1 General requirements

a. The Contractor is required to ensure compliance with the requirements for clinical governance set out in The National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013[5] including to:

- Ensuring the premises are maintained in accordance with the approved particulars for premises[6]

b. The Contractor is required to have a clinical governance lead for the pharmacy.

7.2 Clinical skills and competencies

[5] https://www.legislation.gov.uk/uksi/2013/349/schedule/4/made?view=plain

[6] https://www.england.nhs.uk/wp-content/uploads/2018/02/approved-particulars-premises.pdf

a. 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.

b. 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.
  And
- The CPPE assessment 'Substance Use and Misuse – delivering Pharmacy services (2015)
- CPPE safeguarding children and vulnerable adults e-learning module[7] and the associated learning

Pharmacists routinely involved in the provision of this service must complete the Declaration of Competence on PharmOutcomes.

c. 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. The UK psychiatric pharmacists' substance misuse e-mail group is another forum for discussion.

d. Local training will also be provided by CGL at the commencement of the scheme and updates if there are significant changes to clinical practice or pathways in the referring of citizens onto community pharmacy OSA services.

e. The Contractor is required to ensure that all pharmacists (including locums) have completed and signed the relevant declaration of competence statement. Copies should be kept on file and made available to the Commissioner on request.

f. The Contractor is required to ensure that each pharmacist has had a Disclosure and Barring Service (DBS) enhanced check. DBS checks should be renewed on a periodic basis in line with best practice guidance.

g. PharmOutcomes must be completed at each consultation.

h. 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. Alternatively, a supervising accredited pharmacist must sign off the DOC for the appropriately qualified, trained and competent dispensing assistant.

[7] https://www.cppe.ac.uk/programmes/l/safegrding-w-05

7.3 Clinical Incidents and reporting

7.3.1 General

a. Pharmacies have a legal obligation[8] to use an approved incident reporting system. Contractors should record, report, and respond to incidents in a manner that complies with the requirements set out in the approved particulars[9].including but not limited to:

- Maintaining a patient safety incident log
- Reporting patient safety incidents to the National Patient Safety Agency (NPSA), via the National Reporting and Learning Service (NRLS)

b. The pharmacist must contact the prescriber in the following circumstances:
- The citizen does not consume the whole dose under supervision
- The citizen appears to be ill
- The citizen tries to avoid supervision or the process for proper administration.
- The citizen appears to be intoxicated - citizens stabilised on methadone, buprenorphine or Suboxone® should be clear-headed and coherent. If the pharmacist considers the citizen is grossly intoxicated, the prescriber must be contacted and the dose withheld.

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

d. 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.

e. The Contractor is required, as part of this contract, to inform Manchester Health and Care Commissioning of any and all incidents relating to the OSA service.

7.3.2 Missed doses

a. The patient misses doses – missed doses may result in a drop in opiate tolerance with an increased risk of accidental overdose.

b. If a citizen 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 citizen 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 prescribing service must be contacted on Monday morning to inform them of the situation. It may be possible for the pharmacy to contact the service

[8] https://www.legislation.gov.uk/uksi/2013/349/schedule/4/made?view=plain

[9] https://www.gov.uk/government/publications/clinical-governance-approved-particulars

on the Friday, in anticipation of the citizen missing three consecutive days to inform them of the situation.

c. 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. Missed doses should not be replaced or issued at a later date. Missed doses:

- There are problems with the prescription – e.g. uncertainty about dates, validity, has been tampered with etc.
- The behaviour of the citizen is unacceptable and contrary to the citizen/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 citizen and prescriber must be made aware of this decision.

d. The decision under which the pharmacist chooses to contact the prescriber 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.

e. 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 the person accessing the service.

7.4 Infection control

a. The Contractor will maintain their premises to a high standard of cleanliness in order to minimise the risk of healthcare acquired infection for staff and customers.

7.5 Disposal of waste

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

b. 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.

8.0 INFORMATION GOVERNANCE

a.

8.1 General requirements

a. The Contractor must be compliant with the requirements set out in the Information Governance Toolkit. The current version can be found on the website of NHS Digital (also known as the Health and Social Care Information Centre). The associated assessment should be completed on an annual basis.

b. The Contractor is required to have an appropriate range of policies, procedures and processes, to secure and protect the personal information of clients in line with the requirements of the law.

c. The Contractor must ensure that all members of staff (including locums) are aware of their responsibilities in relation to the protection of personal information.

8.2 Confidentiality

a. The Pharmacy Contractor is required to have a confidentiality code of conduct (or similar).

b. The Pharmacy Contractor is required to ensure that citizens accessing the service are offered consultation in a private room. The room or area should allow for the conversation between the pharmacist and the client to remain confidential.

c. The Pharmacy Contractor is required to ensure that all members of staff (and locums) know and understand their responsibilities in relation to maintaining confidentiality and are able to explain the code of conduct (or similar) to citizens accessing the service.

8.3 Recording

a. Manchester Health and Care Commissioning (MHCC) requires the Contractor to use PharmOutcomes to record consultations/interventions on the agreed data recording web form.

b. The Contractor is also required to use PharmOutcomes for the purposes of audit and for generating, submitting invoices to MHCC and the purpose of remuneration.

c. Contracted Pharmacists may delegate but ultimately are responsible for maintenance of each citizens 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.

d. 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.[10]

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

9.0 SAFEGUARDING

9.1 General requirements

a. The Contractor is required to develop, adopt and implement policies and procedures for safeguarding children and vulnerable adults. These should be developed with reference to the policies and procedures of the Manchester Safeguarding Partnership.

b. The Contractor is required to ensure that all members of staff (including locums) are aware of their safeguarding duties and responsibilities. Staff should receive initial and refresher training.

c. The Contractor is required to ensure that all members of staff (including locums) know how to record concerns and refer to local safeguarding teams. Further information can be found here.

9.2 Child Sexual Exploitation

a. The OSA service is for citizens aged 18+ however in order to improve the effectiveness of safeguarding and protecting children and young people form child sexual exploitation (CSE), the Pharmacy Contractor is expected to ensure staff are fully able to recognise the signs of CSE and act according to the relevant pathways and procedures. More information on CSE and relevant training can be found on the Manchester Safeguarding Partnership website.

10.0 PREMISES

10.1 General requirements

a. Manchester Health and Care Commissioning (MHCC) notes that the Contractor has a legal requirement to develop and implement a premises standards programme. NHS England requires contractors to ensure that their programme sets out how the approved particulars[11] will be implemented.

b. Appropriate storage conditions for the increased supply of methadone/buprenorphine/ Suboxone®.

[11] https://www.england.nhs.uk/wp-content/uploads/2018/02/approved-particulars-premises.pdf

c. The Pharmacy Contractor is required to have a confidential consultation room (or area) for the purpose of supervised administration. It must:

- At a minimum meets the standards required to provide Advanced Services under the terms of the Community Pharmacy Contractual Framework.
- Ensure that there is sufficient space for customers, patients and staff members;
- Be kept clean and in good repair
- Be laid out and organised for the purpose of supervised administration, consulting or providing a healthcare service
- Be laid out and organised so that, once a consultation has commenced and is in progress, other members of staff (or customers) cannot interrupt the consultation or enter the room / area without permission.
- Not be used for storage of stock (other than stock that could be used or supplied during a consultation)
- Have an area for the display of relevant health promotion leaflets, including advice on the safe and secure storage of medicines.

d. In agreement with the pharmacist, the citizen may choose not to consume their supervised medication in the consultation area but in another area of the pharmacy that is fit for purpose. Where this is required, prescribers should notify Contracted Pharmacists in advance where known.

11.0 PARTNERSHIP WORKING AND RELATIONSHIPS

11.1 Integration

a. The Contractor should note that Manchester City Council and NHS Manchester Clinical Commissioning Group have contracted Manchester Local Care Organisation to deliver out-of-hospital health and social care services. The responsibilities for substance misuse may transfer to Manchester Local Care Organisation in due course.

11.2 Relationship with other services

a. The Contracted Pharmacy is expected to work closely with the integrated drug and alcohol service. The prescriber/substance misuse service may ask the Contracted Pharmacy for information on the care provided to the citizen. This may include:

- Feedback on progress after the first week of treatment
- An update on care provided to the citizen from the Contracted Pharmacy at the three-month juncture, 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 prescriber service; Pharmacists should be able to

appropriately void prescriptions/halt dispensing for a few days based on verbal communication from the prescriber's clinical team.
- Communication as and when required, to update on treatment goals or any significant issues regarding the management of the citizen's treatment package.

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

c. The Contractor is required to develop and maintain links with other relevant services including such as general practice and sexual health service where appropriate.

11.3 Interdependencies

a. The Contractor should note the following interdependencies:

1. Pinnacle Health Partnership is the operator of PharmOutcomes. MHCC requires our contractors to use PharmOutcomes to record consultations
2. The Centre for Pharmacy Postgraduate Education (CPPE) offers e-learning for pharmacists and technicians involved in delivering substance misuse interventions.

PERFORMANCE AND OUTCOMES

12.1 Outcomes monitoring

a. Manchester Health and Care Commissioning (MHCC) anticipates that provision of the OSA service will contribute to achieving the following outcomes, which are regularly monitored:

	Outcome	Indicators	Source
1	Support individuals to successfully complete drug treatment programmes through the supervised consumption of prescribed substitute medication	Number of successful completions	National Drug Treatment System (NDTMS)
2	Reduce the possibility of accidental overdose	Number of citizens risk assessed as requiring OSA	National Drug Treatment System (NDTMS)

12.2 Service monitoring

a. Manchester Health and Care Commissioning requires the Contractor to record all consultations using PharmOutcomes and to submit invoices.

b. Manchester Health and Care Commissioning will use the data for the purposes of monitoring provision, audit, and for post-payment verification.

	Key Indicators	Source	Frequency
1	Number of OSA interventions	PharmOutcomes	Commissioners will extract from PharmOutcomes on a quarterly basis

12.3 Contract monitoring and compliance

a. NHS England is responsible for monitoring compliance with the NHS Community Pharmacy Contractual Framework.

b. Manchester Health and Care Commissioning will monitor compliance with the terms and conditions set out in this contract. Contract officers my visit on an annual basis to monitor performance and contract compliance.

12.4 Complaints, compliments and suggestions

a. The Contractor is required to have a process for receiving, reviewing, and responding to complaints and suggestions.

b. The Contractor will inform the Commissioner in the event that a complaint is received regarding the OSA service.

RENUMERATION

13.1 Fees

a. Manchester Health and Care Commissioning has set the fees as outlined below. Payment will be made to the Pharmacy Contractor for each administration.

b. Pharmacies will not be limited to numbers of citizens that they “take on” at any one time as long as they can fulfil their obligations to providing a full and high-quality service. Citizens will choose the most appropriate and convenient service for them.

Service Provided	Fee
Methadone - per supervised dose	£1.80
Buprenorphine/Suboxone® - per supervised dose	£3.50

c. Contractors are required to submit invoices via PharmOutcomes. Invoices for the previous month's OSA activity will automatically be generated through the PharmOutcomes system (date to be agreed). It is the Pharmacy Contractor's responsibility to ensure that all activity is recorded on PharmOutcomes prior to the agreed date as failure to do so may result in non-payment. Payments will be paid to the agreed bank account details (timeframe to be agreed) for the activity outlined within this specification only.

d. All Pharmacy Contractors must record activity 'live' on PharmOutcomes during the intervention with patients. If Contractors try to complete interventions retrospectively they may not have asked all of the questions necessary at the time of the intervention to complete the web form correctly.

e. Payments can only be made to pharmacies that have signed up to this scheme and have agreed to provide the service outlined above. Payments are Pharmacy Contractor not pharmacist based**.**

f. Manchester Health and Care Commissioning reserves the right to revise fees.

13.2 Volume

a. Manchester Health and Care Commissioning is not setting a minimum or maximum number of consultations. However, the Commissioner reserves the right to limit or suspend the service on a temporary basis in the event that demand for provision exceeds the available budget.

GUIDELINES

14.0 NATIONAL GUIDELINES

14.1 National Guidelines

a. **Clinical Guidelines -** A full copy of the 'Drug Misuse and Dependence – Guidelines on Clinical Management' can be found here.

b. **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 general practitioners in the use of buprenorphine as a substitute medication for opioid dependence.

c. **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'.

d. **Supervised Consumption of Prescribed medicines** – Declaration of Competence

e. **GPhc Guidance for Registered Pharmacies preparing unlicensed medicines**

15.0 LOCAL GUIDELINES AND SERVICES

15.1 Local services

Change Grow Live (CGL) integrated drug and alcohol service

15.2 Safeguarding

Actions and policies with regards to safeguarding adults and children can be found on the Manchester Safeguarding Partnership (MSP) website. Pharmacies must ensure appropriate policies and procedures are in place to comply with MSP safeguarding requirements (please also see Safeguarding section).

15.3 Point of contact -

The operational contact for the agreement at MHCC/Manchester City Council is:

Lindsay Laidlaw
Email Lindsay.Laidlaw@manchester.gov.uk
Telephone: 07903 429041

The operational contact for CGL is:-
Lisa Collier
lisa.collier@cgl.org.uk
Telephone 07881 340869

16 AGREEMENT TERMINATION

16.1 The Commissioner and the provider may agree, in writing, to terminate the contract and, if agreement is reached, the date on which the termination should take effect, with a minimum notice period of 30 days.

16.2 The Commissioner will have the right to suspend or terminate delivery of the service if the provider fails to meet the terms of this agreement, including accredited pharmacist status.

16: AGREEMENT VARIATION

16.1 The Commissioner reserves the right to vary any part of this agreement at any time as a result of any Act of Parliament or direction of Central Government or outcome of review of audit, providing that no less than 30 days' notice to this effect is given.

Appendix 1 – Draft 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</u> and allow these to dissolve - 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 *(insert provider here)* Clinical Team.
- Missing 3 consecutive doses will also mean that you have to contact the *(insert provider here)* Clinical Team.

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

Prescriber signature:……. Date:……..

Service user name: (please print)……

Service user signature:…….. Date……..

Appendix 2 – Draft Service user/Pharmacy Agreement

We are pleased to welcome you to *(insert provider here)* 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	The supply of your medication has to be made on

you have not picked up	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 (insert provider here) .

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 3 - 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.