

**Service Specification for the Provision of
Supervised Self administration oral Opioid Substitution Therapy (OST)**

Staffordshire Treatment and Recovery Service (STaRS)

1st April 2024-31st March 2027

Including guidelines for pharmacists and accredited pharmacy technicians

SERVICE SPECIFICATION

Service	Provision of Supervised Self administration oral Opioid Substitution Therapy (OST)
Trust	Inclusion - Midlands Partnership University NHS Foundation Trust (MPFT)
Provider	Staffordshire Treatment and Recovery Service (STaRS)
Period	3 years
Date of Review	December 2026

Service Summary
<p>Midlands Partnership University NHS Foundation Trust is working in partnership with Staffordshire County Council to provide Substance Misuse Services and does this via their Inclusion directorate. This Specification and guidelines outline the requirements, background and the administrative process for the supervised self-administration scheme for methadone, buprenorphine and espranor. Opiate substitute treatment medication is administered daily, under supervision, normally for the first 3 months of treatment.</p> <p>Provision of Pharmacy services for service users qualify as locally Commissioned ‘enhanced’ 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.</p> <p>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 Inclusion Services, considering all their community responsibilities.</p> <p>The service aligns with the Drug Misuse and Dependence: UK Guidelines on Clinical Management, 2017. These Clinical Guidelines are intended for clinicians (doctors, nurses, psychologists, pharmacists, key workers) providing drug treatment for people who misuse or are dependent on drugs. The community pharmacy plays an integral role in the delivery of evidence-based treatment for drug misuse by supporting interventions for different types of drug problems in different treatment settings. This impacts positively on levels of drug use, offending, overdose risk and the spread of blood-borne viruses.</p>

1. Purpose

<p>1.1 Aims</p> <p>To provide pharmacist supervision of consumption of prescribed medications ensuring service users compliance with their agreed treatment plan by:</p> <ul style="list-style-type: none"> • Offering a safe, non-judgemental, safe, service user centred and confidential service. • Dispensing prescribed medication in specified instalments. • Ensuring each supervised dose is correctly administered to the service user for whom it was intended. (Doses may be dispensed for the service user to take away to cover days when the pharmacy is closed). • To provide service users with regular contact with healthcare professionals and to help them access further advice or assistance (It is good practice to record this intervention on the patients PMR). • The pharmacy will provide a consultation area that is fit for purpose for administering oral Opioid Substitution Therapy (OST) to clients under supervision and meets the following,
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- General Pharmaceutical Council (GPhC) Standards for Registered Premises.
- Clearly designated for confidential consultations.
- Separate from General Public areas of the Premises.
- It must be a room where both the service user receiving services and the pharmacist providing those services are able to sit down together and talk at normal speaking volumes without being overheard by any other person.
- 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.

1.2 Evidence Base

Opioid Substitution Therapy (OST) is defined as the administration of a prescribed (daily) dosage of opioid medicines to patients with opioid dependence problems. Treatment will include the following agents:

Methadone/Physeptone Substitution

Methadone is a long-acting synthetic opioid analgesic and acts as a full opiate agonist. Methadone is most frequently prescribed as Physeptone oral solution 1mg/ml sugar free, 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 is a schedule 2 controlled drug subject to full controlled drug requirements relating to prescriptions, safe custody, the need to keep registers etc.

Buprenorphine Substitution

Buprenorphine is an opioid-receptor partial antagonist.

Buprenorphine is available as a sublingual tablet in strengths of 200 microgram, 400microgram, 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 schedule 3 drug, subject to the requirements relating to prescriptions and safe custody but records in registers do not need to be kept.

Espranor Substitution

Espranor is an oral lyophilisate, indicated for substitution treatment of opioid dependency and has been designed to deliver Buprenorphine with rapid dispersal as an alternative to conventional sublingual Buprenorphine. It is a schedule 3 drug, subject to the requirements relating to prescriptions and safe custody but records in registers do not need to be kept.

It is available as 2mg, 8mg strengths. The maximum dose is 18mg daily.

NB Espranor is not interchangeable with other Buprenorphine sublingual tablets.

1.3 General Overview

Inclusion Services offer a range of interventions to help reduce the harmful consequences of drug dependency. They will assess the risk, progress, safeguarding and health and wellbeing of service users including the need for supervised consumption.

At times of crisis or relapse or where risk has been identified, supervision may need to be temporarily reinstated. This will

provide the service user with additional support during times of need and ensure closer monitoring of health and well-being.

Pharmacists play a key role in the care of people who use substances, helping to maximise the benefits of pharmacological treatment by supervising consumption. They have a unique role in that they have regular and sometimes daily contact with service users and can monitor and offer advice on a patient’s health and wellbeing.

Supervised consumption of opiate substitute medication helps to reduce and prevent early mortality for those who use substances. It also helps to reduce the diversion and illicit supply of a controlled medication which help keep our communities safer. Supervised consumption helps build a more robust ‘care team’ around the person using substances and helps to ensure safety, provide regular reduction and motivation for those people on a treatment journey.

The aims of a community pharmacy based supervised consumption service include:

- ensuring the patient receives the prescribed dose
- reducing diversion of prescribed doses
- providing an opportunity for the pharmacist to make a regular assessment of patient compliance with treatment and of their general health and wellbeing
- providing an opportunity for the pharmacist to build a therapeutic relationship with the patient that is beneficial to promote health and harm reduction.
- reducing the risks of drug related overdose and deaths
- minimising the risk of accidental consumption by children

Pharmacists and pharmacy staff play a key part also in reducing the stigma associated with substance use. It is important that the service user attends the same pharmacy with each new prescription and that the pharmacist is supportive and professional.

1.4 Objectives

To reduce the risk to local communities

- Of diversion of prescribed medicines onto the illicit drugs market
- Of accidental exposure to prescribed medicines
- Overuse or underuse of medicines

1.5 Expected Outcomes

Domain 1	Preventing people from dying prematurely	x
Domain 2	Enhancing quality of life for people with long-term conditions	
Domain 3	Helping people to recover from episodes of ill-health or following injury	
Domain 4	Ensuring people have a positive experience of care	x
Domain 5	Treating and caring for people in safe environment and protecting them from avoidable harm	x

2. Service Scope

○ Service Description

The supervised administration of prescribed Opioid Substitution Therapy (OST) will be available to service users 18 years and over who have been assessed by STaRS as suitable for this treatment.

This service specification requires that an accredited pharmacist or accredited technician is available to oversee the scheme for a minimum 60% of the working week. The supervision of medication should be undertaken by a registered pharmacist or

registered pharmacy technician whose personal competence allows them to do so.

There should always be adequate and suitably trained pharmacy support staff in the pharmacy to support the pharmacist in the operational elements of the service and help ensure the safe and smooth running of the service. This includes ensuring that support staff are familiar with, have access to and operate within the standard operating procedure.

All staff, including locums, should be aware of their roles and responsibilities and the service provision. It is the responsibility of the superintendent pharmacist to ensure locum staff and other pharmacists are aware of the requirements and have the appropriate level of training to deliver this service. Where an accredited pharmacist or accredited technician leaves the pharmacy, a three-month period will be given to ensure new accreditation can be undertaken.

The pharmacy contractor must ensure that standard operating procedures aligned to this service specification are in place, reviewed as appropriate, read and signed by relevant staff members and pharmacists.

- **Accessibility/acceptability**

Service users 18 years and over who have been assessed as suitable for this treatment will be acceptable for this service. Pharmacies should ensure they have the capability and capacity to support prior to accepting service users.

- **Whole System Relationships**

UK Health Security Agency
Office for Health Improvement and Disparities (OHID)
General Pharmaceutical Council (GPhC)
NHS England
Local CDLIN

- **Interdependencies**

Reporting

PharmOutcomes
LPC – Community Pharmacy Staffordshire and Stoke-On-Trent.

- **Governance**

The Service delivered must be to the standard specified and comply with the legal and ethical boundaries of the profession. Should an issue be identified an action plan will be produced following the process below:

- Parties will identify any issues and will agree with the named pharmacist an action plan.
- Inclusion Services will issue written report to the named pharmacist within two weeks of the visit summarising what action needs to be taken and by when.
- Inclusion Services will contact the pharmacy again once the agreed timescales have elapsed to confirm that the action plans have been completed.
- If any further action needs to be taken, this will be documented, and new timescales agreed.
- If the issues remain unresolved after this, the option to withdraw the service from the pharmacy may be exercised.

The pace with which the process progresses will be determined by the level of risk. In addition, any serious professional matters identified may be escalated to the Inclusion governance team and the GPhC as appropriate.

- **Training & Education**

Substance misuse providers (SMS) have adopted the Declaration of Competence (DoC) framework as the local process for accreditation; they wish to access the evidence that pharmacy professionals have taken the appropriate steps to reflect on their

competence to deliver this service, therefore a DoC and a signed self-declaration of competence certificate will be required as proof of accreditation. This DoC will ensure that pharmacy professionals have a knowledge and understanding of the legal and professional issues, clinical management and common practice relating to substance misuse and misuse in pharmacies. This should be evidenced on PharmOutcomes. A new DoC must be provided at least once every two years.

Pharmacists, pharmacy technicians and locums involved in the provision of this service must have completed or plan to complete within 3 months of joining the scheme:

- The CPPE assessment for substance use and misuse- delivering pharmacy services (2021)
This includes CPPE Substance use and misuse modules 1-4
The declaration of competence (DoC) “Supervised consumption of prescribed medicines”.
Permission to share CPPE data with PharmOutcomes MUST be given by the individual practitioner (specific tick box on the DoC)
- The CPPE assessment for safeguarding children and vulnerable adults’ level 2
- Additional training will be provided through Inclusion’s Training Lead and includes but not limited to:
 - Overdose Awareness and use of Naloxone
 - Drug and Alcohol Awareness
 - Harm Reduction advice and information
 - Relapse Prevention
- Health and safety training must be provided to staff and remains the responsibility of the pharmacy contractor to do so. In addition, the pharmacy contractor must advise the service user regarding on-going health concerns and refer or signpost into primary care or specialist services.
- The pharmacy contractor will provide advice and display health promotion leaflets relating to harm reduction. They will advise the service user regarding reducing the harms associated with substance use as appropriate. Harm reduction leaflets can be obtained from STaRS. Where local or national drug intelligence highlights a change in risk regarding illicit substances Drugs Bulletins will be issued by STaRS.

3. Service Delivery

3.1 Service Model

a) Service Responsibilities

The STaRS Service 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 Service will contact that pharmacy 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 Service on the date of commencement of supervised administration. The Service 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 a contractual arrangement with them, which they will be expected to adhere to.

The service user will complete a pharmacy contract form with the Service. The Service will retain a copy and the original given to the service user.

The service user will attend the pharmacy with their prescription for supervised Opioid Substitution Therapy (OST) administration as agreed with the prescriber or keyworker.

b) Service User

The service user must provide identification to the pharmacy on the date of commencement of treatment, which contains either, a photograph and name or name and address; where this is not possible or appropriate an agreed password and person description is permissible.

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.

The service user must sign a written contract, which outlines the service arrangements in the pharmacy and behaviour policy (Appendix 3).

c) Pharmacy Contractor

The client's identity must be checked using the identification detailed in b) to ensure the prescription is dispensed to the correct person. If there is any uncertainty, then the prescriber must be contacted and the dose withheld until the individual's identity is ascertained.

All medications must be administered in a private consulting room that provides a sufficient level of privacy and safety. Supervised consumption must be as discreet and as efficient as possible, with consideration of the dignity of the service user. Under no circumstances can doses be issued to a service user outside the pharmacy building.

The Pharmacy Contractor will dispense the dose according to the pharmacy's own standard operating procedure and prescription. It is the responsibility of the contractor to make sure all staff, including locums, are familiar with these documents and work in line with the terms of the contract; this includes any certification and accreditation.

All Pharmacy staff delivering supervised consumption must conform to General Pharmaceutical Council Standards for registered Pharmacies and Standards of conduct, ethics and performance.

The pharmacist will provide health related advice such as risk of overdose, safe keeping of medication or contradictions with other medications taken. Any concerns should be referred to the prescribing service.

The pharmacist will continue to provide health related advice and support to service users who are moving from supervised consumption to other instalments such as daily pick-ups, three times weekly or otherwise.

The Pharmacy Contractor will prepare the medication to the service user:

- Methadone (Physeptone) - The daily amount to be measured into a suitable container, capped and labelled. On arrival of the service user the dose is poured into a single-use cup. The pharmacist/pharmacy technician must be satisfied that the dose is swallowed, for example, by water being swallowed after the dose or conversing with the service user to ensure that the medicine is not retained in the mouth. **The service user will be provided with water to facilitate administration.**
- Buprenorphine sublingual (Subutex) - The medication must be tipped directly under the tongue without handling and the service user supervised until the tablets have dissolved. This can take between 5-10 minutes, depending on dose. **Do not offer any water after taking.**
- Buprenorphine oral lyophilisate (Espranor) - The medication is placed on the tongue (not under it) and allowed to disintegrate. This can take 15 seconds- 2 minutes. Swallowing should be avoided for 2 minutes and no food or liquids should be consumed for 5 minutes after dissolution. **Do not offer any water after taking.**
- Doses that are collected to be taken on Sundays or Bank holidays must be dispensed in a container with a child resistant closure. Service users must be advised to keep out of reach of children.

Storage and disposal of waste

The Pharmacy Contractor will provide safe storage conditions for the supply of Opioid Substitution Therapy (OST) and maintain appropriate standard operating procedures for the safer management of controlled drugs.

The return of any unwanted or unused Opioid Substitution Therapy (OST) must be denatured before placing into waste containers and a record kept of returned schedule 2 drugs (Methadone/Physeptone) as recommended by RPS guidelines.

For dispensed medication, labels should be removed or redacted from containers and immediately discarded. Waste should be disposed of safely.

If the medication is dispensed for non-supervised consumption (e.g. Sundays, bank holidays) the service user must be provided with information regarding the safe storage of the medication and reminded of the danger this medication presents to others.

All disposable items should be recyclable and sourced sustainably.

Missed doses and concerns regarding service user

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

- The community pharmacy contractor must contact the service immediately if a service user misses any dose, i.e. on the first day missed. This enables the recovery worker to contact the service user. If three consecutive pick-ups are missed the pharmacist must STOP dispensing and the service user be referred to the prescriber to be clinically reassessed. This can be done on Pharmoutcomes and is the easiest and most direct way to communicate with STaRS.
- Similarly, the pharmacist must STOP dispensing and refer the service user back to the prescriber if they miss an increased/titrating dose where the previous dose was lower and the following dose would be greater.
- If a service user regularly misses a single days dose, for example 3 doses in a 7-day period or makes attempts to avoid supervision/divert medication, the pharmacist must inform STaRS so that this can be addressed with the service user.
- If a service user is in police custody and is unable to collect, a representative can collect on behalf of the service user, e.g., known person with ID and/or police officer. The service user should supply a letter of authorisation for the representative to collect on their behalf. (This includes those detained in police custody who should supply a letter of authorisation to a police custody officer to present to the pharmacist).

NB. If the directions on the prescription state that the dose must be supervised, it would not be necessary to contact the prescriber if the person has been detained in police custody and the representative collecting the dose is a police custody officer or a custody healthcare professional. This is because the administration of any Schedule 2 or 3 CD in custody will be supervised by a healthcare professional.

- If there is a problem with the prescription e.g., validity has been tampered with or uncertainty about dates, the service should be contacted immediately.
- If there is concern about the behaviour of the service user and this is contrary to the service user and pharmacy agreement, then the pharmacy (using their NHS.net email) must contact the service immediately by email or telephone call.
- In circumstances where a dose is not administered or the pharmacy contractor wishes to cease the administration of further consumptions, the key worker and prescriber must be contacted immediately via email and telephone call (see appendix 3)
- If an incident occurs in the pharmacy relating to a service user the Service should be contacted immediately using email and phone call
- The prescriber/key worker must be contacted as soon as possible in the following circumstances (see appendix 3). If the service user:
 - Does not consume the whole dose under supervision.
 - Appears to be ill or injured.
 - Misses a dose
 - Tries to avoid supervision for the process for proper supervised consumption.
 - Appears to be intoxicated or under the influence of alcohol.

Supervision by a registered pharmacy technician

The accredited pharmacist providing this service may delegate the role of supervising the self-administration of Opioid Substitution Therapy (OST) to a registered pharmacy technician, if clients using the service for the first time, or re-commencing treatment following relapse, are supervised by the accredited pharmacist initially. Thereafter the

pharmacy technician may be delegated this role. However overall responsibility and accountability will remain with the pharmacist, due consideration should be given to the risks associated during the first 4 weeks where there is an increased risk of adverse events such as overdose and death.

Please note this service cannot be initiated or provided solely by an accredited pharmacy technician. At all times, including during supervision by the accredited pharmacy technician an accredited pharmacist must be present and accountable.

3.2 Pathways

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

- The prescription must be checked for legality. On most occasions, prescriptions will be computer generated, except for the signature.
- Opioid Substitution Therapy (OST) should be prescribed on FD10 (MDA) for no more than 14 days.
- If more than one item is prescribed, separate forms should be used as FP10 (MDA) only has space to record 14 dispensing episodes.
- Where the total daily dose of Buprenorphine prescribed requires the dispensing of two tablets i.e., 8mg and 2mg for a total 10mg daily dose, only one enhanced supervision fee may be claimed as this is not classed as two supervisions. The intention of the supervised fee is to cover supervision of one dose regardless of the number of tablets required to make up that dose.
- 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.
- The prescription must specify clearly that supervision is required.
- The prescription should not be tampered with in any way, or in a condition where the instructions are no longer clear e.g., water damage or torn. The prescriber must be notified immediately.
- Where indicated, the following wording will apply, “instalment prescriptions covering more than one day should be collected on the specified day; if collection is missed the remainder of the instalment (i.e. the instalment less the amount prescribed for the day(s) missed may be supplied)”. This provision should only be used in exceptional circumstances and the prescriber should alert the pharmacist that this instruction is to be made.
- The pharmacist should notify the prescriber in the event of any missed doses of medication.

4. Service Standards and Requirements

Guidance as per the following links:

- <https://www.nice.org.uk/Guidance/TA114>
- <https://www.pharmacyregulation.org/standards/standards-registered-pharmacies>
- <https://www.pharmacyregulation.org/standards-for-pharmacy-professionals>
- <https://psnc.org.uk/dispensing-supply/dispensing-controlled-drugs/methadone-dispensing/>
- <https://www.england.nhs.uk/wp-content/uploads/2013/11/som-cont-drugs.pdf>
- https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/214915/15-02-2013-controlled-drugs-regulation-information.pdf
- <https://www.cdreporting.co.uk/>
- <https://www.cppe.ac.uk/gateway/substance>
- <https://www.cppe.ac.uk/programmes/l/?Substance-A-12>

5. Referral, Access and Acceptance Criteria

5.1 Geographic coverage/boundaries

Patients known to the Buckinghamshire Substance Misuse Service

5.2 Location(s) of Service Delivery

Pharmacy address

5.3 Days/Hours of operation

Pharmacy hours

5.4 Referral process

Telephone referral to community pharmacy and agree 3-way contract (Pharmacy, STaRS and service user)
FP10 or FP10(MDA)

5.5 Exclusion Criteria

Patients not registered to receive the Service provision.

5.6 Response time and prioritisation

Within 24 hours of referral

6. Discharge Criteria Planning & Service exit considerations

Patient discharge – relapse, end of 3 months, risk assessment review

7. Patient and Carer Information

- The Pharmacy Contractor should maintain appropriate records using PharmOutcomes to ensure effective ongoing service delivery and audit.
- The Pharmacy is required to record daily attendance of each service user. Any missed doses are required to be entered on the PharmOutcomes system regularly, including any days when the client fails to attend to receive supervised medication, or they are refused due to being under the influence of alcohol or drugs.
- The Pharmacy Contractor will be responsible for ensuring that access to the system is maintained for current pharmacy staff only to ensure the security of service user information.
- Pharmacists are responsible for maintenance of each client's patient medication record.

8. Continuity arrangements

8.1 Where a service is delivered from the Pharmacy Premises;

8.2 Continuity arrangements:

- 8.2.1 **Minor disruption (1 day)** - The Sub-Contractor will assess the severity of the incident and its possible consequences. If the incident is unlikely to escalate, then control of the incident will be undertaken locally.
- 8.2.2 **Medium/short term (2-7days) disruption** - Where the incident is deemed to result in minor disruption to the service, and the incident is unlikely to escalate, the Sub-Contractor will then inform the Head Provider and of the decision to manage the incident locally.
- 8.2.3 **Major/long term (>7 days) disruption** - Where the incident is deemed to result in a major/long term disruption to the service, the Sub-Contractor must inform the Head Provider immediately and convene a meeting to discuss the continuity of the service.

8.2.4 Pharmacy Business Continuity Requirements

- The Pharmacy contractor is responsible for ensuring adequate arrangements are in place for continuity of the service in the event of staffing shortages, facilities and system failures appropriate to the service and to notify the Service if such arrangements are put into place.
- In the event of a pharmacy being unable to dispense medication for any reason the Service must be notified immediately. All reasonable measures must be taken to ensure continuity of dispensing.
- The pharmacy contractor should be aware of:
 - The medicines and health care products regulatory reporting systems for adverse reactions to medication (yellow card scheme)
 - The legal obligation to report certain incidents to the Health and Safety executive under the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (RIDDOR)
 - If there is a temporary suspension of pharmaceutical services for unplanned reasons NHS England to be notified as soon as possible
 - Any controlled drugs issues should be reported to the Accountable Officer team NHS England AOCD via the web-based CD reporting tool www.cdreporting.co.uk

9. Quality and Performance Standards

9.1 Monitoring Requirements

The Provider shall participate in audits of compliance as required by the Service and agree to action plans to address areas of non-conformance as appropriate.

The Service reserves the right to carry out an audit of supervised consumption and audit against the service user supervision record on PharmOutcomes, Pharmacists will:

- Participate in organised audit of Service.
- Participate in audit of prescribing.
- Co-operates with any locally agreed assessment of Service User experience.
- Demonstrate that key staff have undertaken continuous Professional Development relevant to this Service.
- The Service will review the service provision, on a regular basis as well as responding to issues which may require a more urgent review.
- Health and safety training must be provided to staff and remains the responsibility of the pharmacy contractor to do so. In addition, the pharmacy contractor must advise the service user regarding on-going health concerns and refer or signpost into primary care or specialist services.
- The pharmacy contractor will provide advice and display health promotion leaflets relating to harm reduction. They will advise the service user regarding reducing the harms associated with substance use as appropriate.

Incidents

Reportable incidents (including dispensing errors and suspected breaches of the Controlled Drugs Regulations 2013) will be reported in line with local and national guidelines. The Pharmacist will provide full details of the incident to the Service/ Prescriber.

All incidents will be investigated by the Service who may require further details to help with the investigation. Incidents will be recorded by the Service on their local reporting system. The Pharmacy should still report incidents via their own reporting system. Learning outcomes from all incidents will be shared between the Service and Pharmacy, in line with national guidance.

9.2 KPIs				
Performance Indicator	Indicator	Threshold	Method of Measurement	Consequence of breach
Data Reporting	Receiving data report as required from PharmOutcomes	100%	Monthly Report	Service review
Incident Reporting	Any incidents raised to the Service within 24 hours	100%	Ad hoc	Service review
Controlled Drug Incident Reporting	Any incidents raised to the Service within 24 hours	100%	Ad hoc	Service review
Communication	Trust to Pharmacy, and vice versa, communication between valid email addresses to address incidents, patient on boarding or other queries: Urgent – 3 hours High – 1 working day Low – 3 working days	100%	Email time stamps	Service review

10. Activity

10.1 Indicative Activity Plan
Activity entered onto PharmOutcomes will allow for robust monitoring and auditing of provision, ensuring compliance with the terms of this specification.

10.2 Capacity/Workforce
Appropriately qualified individuals as defined within this specification.

Trust Contact Details:

Service Lead
Jim Barnard (Deputy Head of Operations)
Inclusion, Mellor House
St Georges Hospital,
Corporation Street
Stafford. ST16 3AG
Email: Jim.Barnard@mpft.nhs.uk

Procurement Lead
Liz Salter. Trust Head Quarters
St Georges Hospital,
Corporation Street
Stafford. ST16 3AG
Email: liz.salter@mpft.nhs.uk

Pharmacy Lead
Denis Kanu (Inclusion Lead Pharmacist)
Inclusion, Mellor House
St Georges Hospital,
Corporation Street
Stafford. ST16 3AG
Email: Denis.kanu@mpft.nhs.uk

11. Prices & Costs

11.1 Price

- £2.00 for methadone (physeptone), buprenorphine sublingual and buprenorphine oral lyophilisate (Espranor)

To claim the pharmacy contractor will need to input on PharmOutcomes, entries to be made at end of each completed script (ie every fortnight) payment will be processed at end of month.

Payment for service provision is generated via activity entered onto the internet-based software system, PharmOutcomes. All activity must be recorded on PharmOutcomes at the earliest opportunity as invoices are generated monthly, allowing a two-week period for retrospective data to be entered. If data is entered outside of this period, it will be paid at the discretion of the Service.

This information will be used to calculate payment for services, determine stock replenishment, and identify waste collection requirements.

12. Exit Arrangements

12.1 Exit arrangements.

- This enhanced service agreement is awarded on the basis that there has been an identified and on-going need in the area for this service provision.
- This service agreement may be terminated by either party by the giving of three months’ notice in writing.
- Failure to comply with the terms of this contract may result in the withholding of payment for the service.
- Changes in accredited pharmacist providing the service to be communicated to STaRS by email

Signed and Agreed on behalf of the Head Provider by:

Signature

Designation

Date

Signed and Agreed on behalf of the Provider by:

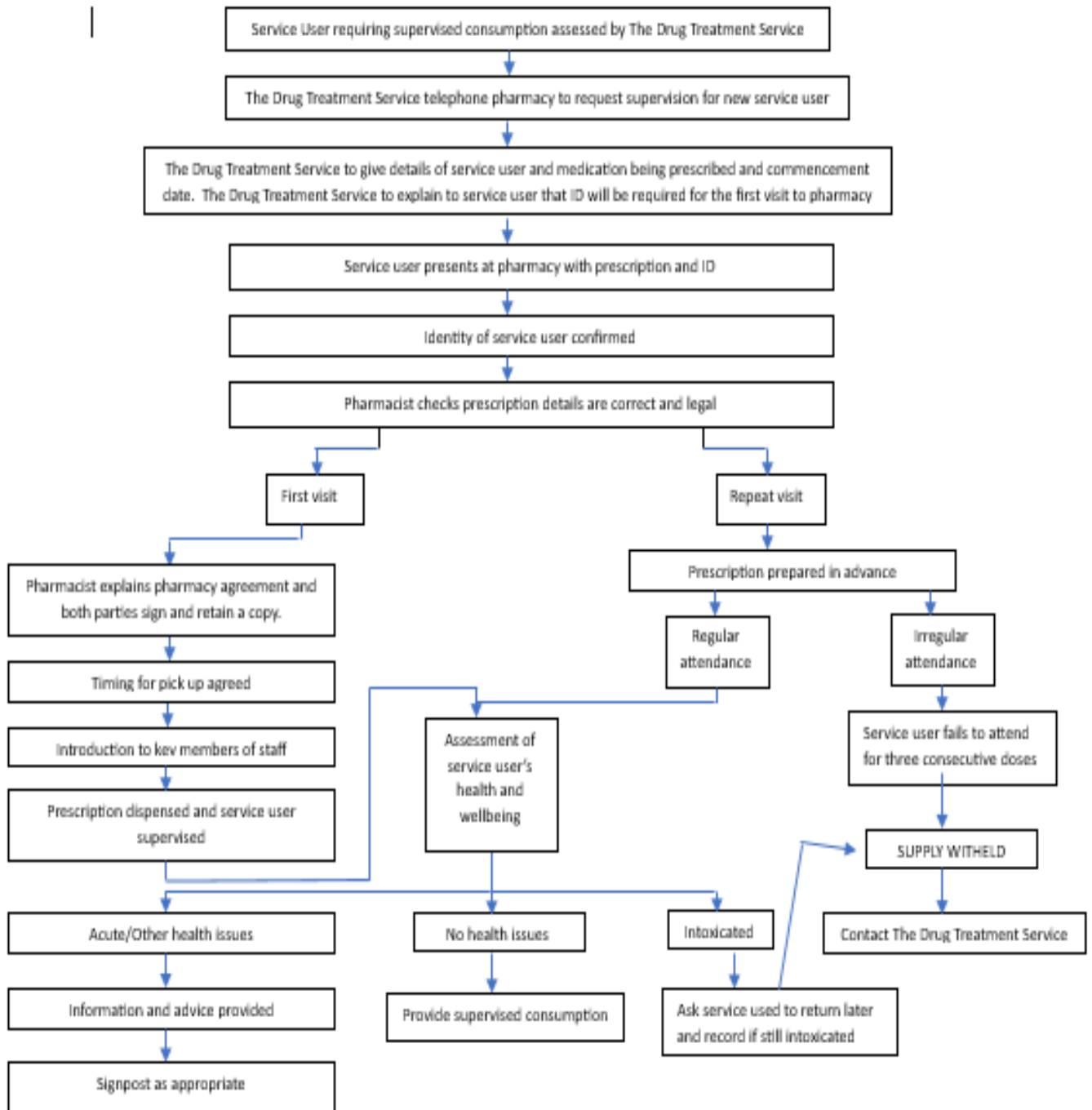
Signature

Designation

Date



Appendix 1 - Pharmacy Pathway for the observed consumption of Self-administered oral Opioid Substitution Therapy (OST)



Appendix 2

When to contact the Prescriber immediately.

1. Drug related death on pharmacy premises
2. Overdose.
3. Incorrect correct dispensing of any controlled substance.
4. The behaviour of the service user is unacceptable e.g., verbal/physical abuse, shoplifting
5. The pharmacy contractor decides to withdraw treatment from the service user due to unacceptable behaviour.
6. The service user does not consume the whole dose under supervision or refuses to consume their dose as prescribed.
7. The service user tries to avoid supervision.
8. The pharmacist is contacted by secondary care re dosage information due to hospitalisation.
9. The service user appears to be intoxicated.
10. There are concerns re the prescription e.g., ambiguity of dates for dispensing, identity of service user in doubt.
11. The service user is seen to be diverting prescribed medications.

When to contact the key worker/prescriber at the Service

1. The service user appears ill or shows a deterioration of physical/mental health.
2. The service user repeatedly misses odd days or has an erratic collection pattern.
3. The Service user has missed 3 consecutive days.
4. The pharmacist is aware of other issues that may affect treatment e.g. being made homeless.
5. The pharmacist believes there may be a concordance/drug interaction with other prescribed drugs being taken.
6. The decision to withdraw treatment from the service user.
7. Any other occasion when the pharmacist is concerned about the service user's well-being
8. When a single dose is missed during the titration phase

The decision is a professional one that should be made after considering the risk to the service user of non-disclosure and the damage that may be done to the supportive relationship between the pharmacist and the service user. Service user confidentiality should always be respected.

Appendix 3 - Service user agreement

This ‘agreement’ sets out the arrangements for the supervised consumption 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.

Name of Service User _____

Name of Pharmacy _____

We are available to supply your medication between: 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, which may leave you standing around.
You will need to collect your take home doses on..... for weekends and Bank Holidays	The pharmacy is closed on 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 supply 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 achieving your treatment goals and to reduce the risk of overdose
We cannot let anyone else collect your medication for you.	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 must 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	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 must be made on the day and date specified on the prescription
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 will not tolerate verbal or physical abuse	We want our pharmacy to be a welcoming place to you and all our customers and expect all our service users/customers to behave in a reasonable manner. Failure to do so will force a withdrawal of services immediately.
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 customers

I understand the above agreements and that a failure to comply with any of the arrangements may result in the withdrawal of the service by the pharmacy.

Signature of service user: _____ Date: _____

Signature of pharmacist: _____ Date: _____