TURNING POINT
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Turning Point Supervised Consumption of Opioid Substitution Treatments and other medication Pharmacy Specification

Slough

Community Pharmacy Agreement (Part B)

V1.0 April 2025

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Turning Point Supervised Consumption of Opioid Substitution Treatments and other medication Pharmacy Specification

1. Introduction

This document sets out a Service Specification for a Contractor 'supervised consumption' service to be provided by the Contractor[1] to service users who are prescribed Opioid Substitution Treatments (OST) and other medication where defined in the specification[2] and will encompass supervised support and advice to service users in a safe environment. The practice is designed to support service users to stop or stabilise their opiate use thus enabling them to develop their personal goals.

Community pharmacies play a key role in supporting people who use drugs in complying with their prescribed regime, therefore reducing the incidents of accidental deaths through overdose.

For the purpose of the Agreement 'supervised consumption' is defined as the observed consumption, by pharmacy staff, of prescribed OST and/or other medication where defined in the specification where supervision has been requested by the prescriber.

The Service is available and limited to service users prescribed OST for the treatment of opioid dependence and other medication where defined in the specification from Turning Point

This Service is for service users of 18 years and above.

2. Aims

It is expected that dispensing and supervised consumption of OST will ensure compliance with the agreed treatment plan by:

- Dispensing prescribed medication in specified instalments.
- Ensuring each supervised dose is correctly **administered** for the service user for whom it was intended (doses may be dispensed for the service user to take away to cover the days the Contractor is closed) in accordance with the prescription and Royal Pharmaceutical Society/Home Office guidance
- Ensure each supervised dose is correctly **consumed** by the service user for whom it was intended
- Providing service users with regular access to a healthcare professional (pharmacist)
- Monitoring the service user's response to prescribed treatment for example if there are signs of overdose, especially at times when doses are changed.

[1] The term "Contractor" is used throughout this Agreement to represent Community Pharmacies

[2] Predominantly methadone oral solution 1mg/1ml (SF and standard) prescribed as a generic or brand and buprenorphine (all strengths) prescribed as a generic or brand. Other OST medications may be agreed locally in addition to other medication e.g. naltrexone, diazepam.

- Liaising with the prescriber or named Company[3] Recovery Worker as appropriate, if the service user appears intoxicated or when the service user has missed doses[4], and, if necessary withholding treatment if this is in the interest of service user safety.
- Improving retention in drug treatment and opportunities for recovery.
- Improving drug treatment delivery and successful exit from treatment.
- Help service users' access treatment by offering referral to specialist drug and alcohol treatment centres and health and social care professionals where appropriate.
- Reduce the risk to local communities of diversion of prescribed medicines onto the illicit drugs market and contribute to a reduction in drug related deaths in the community through accidental exposure to prescribed OST medication.

3. Service Outline

There is a multidisciplinary approach to prescribing (including GP shared care prescribing) which is carried out in line with recommendations of *Drug misuse and dependence guidelines on clinical management* (DH 2017[5]) and *Oral methadone and buprenorphine: recommendations* (DHSC 2024) and other central guidance and includes the service user's pharmacist. Pharmacist's activities should be governed by the relevant legislation and professional guidance e.g. the latest edition of the *Medicines, Ethics and Practice* guidelines from the Royal Pharmaceutical Society including the delegation of tasks to other members of the pharmacy team.

a) For the purposes of this specification, medicines for the management of opioid dependence which may have consumption supervised include:
   - Methadone 1mg/1ml oral solution SF and standard (trade name Physeptone®)
   - Buprenorphine 2mg and 8mg Oral Lyophilisates (trade name Espranor®)
   - Buprenorphine 400microgram, 2mg and 8mg sublingual tablets (trade name Subutex®)
   - Buprenorphine/Naloxone 2mg/0.5mg and 8mg/2mg tablets (trade name Suboxone®)

   Other medication **may** be included within a local specification but the Opioid Substitution Treatment (OST) medications outlined above will form the core of most supervised consumption services.

b) The suitably trained member of the pharmacy team of the Contractor are required to supervise the consumption (when prescribed or required) of the prescribed oral OST medication at the point of dispensing in the pharmacy, ensuring that the dose has been consumed by the service user.
   - For methadone: It is expected that the service user should be asked to drink some water and speak after the dose to demonstrate the dose has been swallowed.

   - For buprenorphine oral lyophilisates: The oral lyophilisate should be observed being place on the tongue. Each oral lyophilisate should dissolve within 15 seconds and the service user should not swallow for 2 minutes after taking the dose.

[3] The term "Company" is used throughout this Agreement to represent Turning Point
[4] Please see missed dose section (4e) and appendix 2 for further details
[5] https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/673978/clinical_guidelines_2017.pdf

- For buprenorphine sublingual tablets: A minimum of 3 minutes should be spent supervising the service user as dissolution of the sublingual tablets may take several minutes. Buprenorphine may also be crushed to aid absorption. However, the Company does not encourage this off-licence process and, if used, the service user should be aware this is off-licence use and a Contractor Standard Operating Procedure (SOP) should be in place. Contractor owners are also advised to check this is covered within their Professional Indemnity Insurance.

c) Contractor staff providing supervised consumption Services will provide a user friendly, non-judgmental, service user-centred and confidential service.

d) The Contractor staff ensures that supervised consumption takes place in a private or quiet area of the pharmacy identified as safe to staff and agreeable to the service user.

e) Contractor staff should make available to service users information about their medicines and appropriate health promotion materials.

f) The Contractor staff will promote safer practice to the service user. As deemed appropriate this can include advice on sexual health and STIs, BBV transmission, Hepatitis B immunisation. Harm reduction advice to reduce the risk of Drug Related Deaths (DRDs) will also be provided and service users and their friends, families and carers will be encouraged to liaise with drug services for supply of naloxone and further training and support in how to reduce the risk of overdose and DRDs.

g) Contractor staff providing dispensing supervised consumption services for drug users will have SOPs in place for their individual premises. An example SOP is included within this document for illustration only but pharmacies are free to adapt for use within their premises.

h) Records should be made in the CD register in line with the appropriate legislation for CD schedule 2 drugs i.e. methadone

i) Contractor staff should abide by local arrangements for clinical governance. Any incident involving Controlled Drugs (CDs) within the scope of this agreement should be reported to a Company prescriber and the Local Controlled Drugs Accountable Officer (CDAO) for NHS England.

j) Contractors will receive prompt payment for the Services provided. Please refer to Part A of this Specification for payment details.

k) Contractors will **not** be paid by the Company for supervised consumption from outside the commissioned area. Contractors are advised to contact the service issuing the prescription to confirm payment arrangements.

l) Safeguarding (adult and children): Contractors are already required to provide assurances concerning safeguarding vulnerable groups as part of their essential services clinical

governance requirements for community Contractor[6]. The requirement is that they have "(vii) appropriate child protection procedures (and) (viia) appropriate vulnerable adult (as construed in accordance with section 59 of the Safeguarding Vulnerable Groups Act 2006(..) (vulnerable adults)) Protection procedures". Relevant staff that provide pharmaceutical services to children and vulnerable adults should be aware of safeguarding guidance and the local safeguarding arrangements. The College of Contractor Postgraduate Education (CPPE) also provide a range of Level 1 and Level 2 training materials to support registered pharmacists and pharmacy technicians to deliver this requirement[7].

With the current requirements the Company will not be offering specific safeguarding training for this service (unless agreed locally between the local commissioner and the Company) but will be monitoring Contractor compliance against the essential service and quality payment standards.

4. Service Description - summary[8]

Please refer to Appendix 1 - Roles and Responsibilities for full details of the Roles and Responsibilities of the Contractor and other individuals and organisations providing this service.

a) The part of the pharmacy used for provision of the Service provides a sufficient level of privacy and safety and meets other locally agreed criteria.

b) The Contractor will present the medicine to the service user in a suitable receptacle and will provide the service user with water to facilitate administration and/or reduce the risk of doses being held in the mouth.

c) Terms of agreement i.e. 4-way agreements **may** be set up between the prescriber, pharmacy, service user and specialist service to agree how the Service will operate, what constitutes acceptable behaviour by the service user, and what action will be taken by the GP and pharmacy if the user does not comply with the agreement. This will be agreed locally prior to the Service being commissioned. Pharmacies can use their own agreement but this must be approved through the local clinical governance arrangements or, as a minimum, between the Contractor and the local Clinical Lead prior to their use. A Company 4-Way Agreement is available in Appendix 4 which can be used or adapted for local use. On certain occasions it may be decided that certain service users need a 4-Way Agreement in place due to previous behaviour concerns. Individualised 4-Way Agreements can be implemented in these circumstances in areas where 4-Way Agreements are not used if agreed between the Contractor and prescriber/Recovery Worker.

d) Service users are prepared for the provision of OST medications by the specialist drug services and this should be reinforced by the Contractor staff. This includes (but is not exclusive to)

[6] PSNC & NHS Employers (2012) Clinical governance requirements for community pharmacy. Available at Clinical_Governance_guidance_updated_final.pdf (cpe.org.uk) (Accessed 08/12/2023)
[7] CPPE Safeguarding. Available at https://www.cppe.ac.uk/services/safeguarding (accessed 08/12/2023)
[8] Refer to appendix 1: Roles and Responsibilities for full details

providing advice and written information about:

i. Methadone, buprenorphine or other pharmacotherapies and safe storage of medication to reduce harms to others especially children
ii. Alcohol use and its impact on health and risks when combined with other medication
iii. Risk of overdose especially linked to poly-drug use and IV drug use (this includes the supply of naloxone to service users starting an OST prescription)
iv. Loss of tolerance following missed or uncollected doses
v. Drug interactions
vi. An explanation of supervised consumption and where and how this will occur and
vii. Opening and closing times of the Contractor.

e) Pharmacies must offer the Service throughout their opening times. Contractor staff can discuss the best times for service users to attend but at no times should a dose be refused to a service user if they attend during the opening times of the Contractor

f) **Missed doses:**
Contractors should contact the Company's Treatment Service when a service user has:

- **Missed a single dose during titration and/or in the first two weeks of treatment:** Please **do not dispense** the service user's next dose until you have contacted the Company's Treatment Service and sought the advice of a prescriber. At the start of treatment the risk of overdose is high and increases of greater than 10mg of methadone are not recommended. For this reason even a single day missed (of either methadone or buprenorphine) should be reported.
- **Missed 3 consecutive days:** Please **do not dispense** the service user's next dose until you have contacted the Company's treatment service. The Company's Treatment Service will then advise you of the appropriate action which **may** include continuing the prescription or stopping the prescription. The requirement to contact the drug services after 3 consecutive days have been missed is highlighted in the Royal Pharmaceutical Society's Medicines, Ethics and Practice[9] and should be adhered to. If a Company's Treatment Service prescriber confirms the prescription can continue then the current prescription where the 3 consecutive days has been missed **can** be used. The Company has confirmed this with both the RPS[10] and the Home Office[11].
- **Missed 4 doses or more on any instalment prescription** or
- **Has a certain pattern of missed doses e.g. every Monday.**
  Please see Appendix 2 - Missed Dose Reporting Flowchart for further details and rationale for the missed dose procedures.

g) Information sharing – screening, risk assessment and referral. Contractor staff should:

- Feedback appropriate information to the Company's Treatment Service with the agreement of the service user, in accordance with their professional code of practise and local shared care agreements. This includes any concerns around the welfare of a child or adult.

[9] RPS (2021) Medicines, Ethics and Practice. The professional guide for pharmacists. Edition 44.
[10] Verbal confirmation by Turning Point Lead Pharmacist
[11] Email confirmation by Turning Point Lead Pharmacist

- Make a clinical judgement as to when it may be appropriate to withhold a dose, e.g. during dose titration, if the service user is intoxicated with drugs and alcohol, if there are signs of overdose or if the pharmacy staff have concerns about the service users' safety.
- Signpost and/or refer to appropriate services in accordance with the essential service standard 5 (signposting)[12] for community pharmacies and any local agreements.

h) Contractor legal and professional responsibilities. Pharmacies should:
- Ensure the legality of the prescription prior to dispensing and in a timely manner to ensure service users are not inconvenienced if the prescription is not written correctly or there are missing details
- Register the service user onto the standard Patient Medication Record (PMR) system.
- Dispense the medicine in accordance with the prescription system.
- Explain that missed doses cannot be collected the next day.
- Follow local agreed arrangements allowing the dispensing and supervised consumption of doses not collected on specified days – in accordance with Home Office guidance on instalment prescribing.
- Informing the local Company Treatment Service if a service user misses three consecutive days; a single day during titration; four non-consecutive daily doses over a 14-day period or missing in a regular pattern (see appendix 2 for further details)
- Co-operate with local Police Controlled Drug (CD) liaison officers, the General Pharmaceutical Council (GPhC), local Public Health Directorate, NHS England CD Accountable Officer (CDAO) and any other statutory or regulatory body (local or national) that are involved with any aspect of the delivery or monitoring of this specification.
- Comply with current legislation, including the Medicines Act 1968, Misuse of Drugs Act 1971, Misuse of Drugs Regulations 2001 as amended, Misuse of Drugs (safe custody) regulations 1973, National Health Services (pharmaceutical services) regulations 2005.

5. Accreditation

a. The service should be provided by suitably trained and competent pharmacy staff.

b. For the rest of this document, the term "pharmacy staff" will be used to denote pharmacists, pharmacy technicians and other non-registered members of the pharmacy team.

c. The responsible pharmacist must ensure that delegated tasks are being undertaken safely by competent pharmacy staff. The pharmacy contractor must ensure all pharmacy staff providing the service are appropriately trained.

d. Pharmacy staff providing the service must:
   - have relevant knowledge and be appropriately trained in the operation of the service

[12] CPE: Services and Commissioning: Signposting. Available at Signposting - Community Pharmacy England (cpe.org.uk) (accessed 08/12/2023)

to a standard agreed with the Company. Training in the operation of the Service is provided by the Company in the form of guidance, protocols and local workshops (at least annually). Delivery of these support services and training will be determined locally between the Company, Local Pharmaceutical Committee (LPC), local commissioners and any other organisation or group that are considered to be a valid stakeholder in the service delivery e.g. service user group.

- Be aware of and operate within local protocols agreed with the Company's Treatment Service. The Pharmacy SOP must be based on the local protocols of this service and must be regularly reviewed (see section 7b for further details)

e. Registered pharmacy professionals at the accredited pharmacy should be encouraged to complete a Declaration of Competence (DoC) for "Supervised Consumption of Prescribed Medicines Service" and complete the CPPE Substance use and misuse e-learning programme.

f. Contractors will be invited to attend at least one (1) meeting per year with the local Company's Treatment Service to promote Service development and update the knowledge of Contractor staff. This includes an awareness raising session about the drug and alcohol treatment and support services available locally and an opportunity to raise questions and/or concerns about practice. Although attendance is not mandatory, the Company would encourage engagement from Contractors to support both service development and as a CPD update for Contractor employees.

6. Support

To ensure the effective management and development of supervised consumption (including appropriate support for Contractor staff) the following Company staffing structure will be in place:

- Company Pharmacy Lead to oversee the Agreement sign up and performance monitoring and quality assurance
- Service administrator to validate claims and support process of payments
- Locally based Harm Reduction Leads and (Senior) Recovery Workers to ensure training, support and develop provision to meet the needs of the local pharmacies and to act as a single point of contact for Contractor referrals and guidance

Any queries can also be directed to the Service Pharmacy Lead at our local Turning Point service. The lead will be communicated to pharmacies through the LPC.

Support will also be provided through our Contractor IT partner (NEO360). Contact details will be provided to services to access this support.

7. Performance and Quality Monitoring

a) The Contractor must maintain appropriate records on NEO360 to ensure effective on-going Service delivery, audit and payment.

b) The Contractor must review its SOPs and the referral pathways for the service on a two-year

cycle ***or*** when a significant change to services ***or*** significant incident dictates a need to review the SOP earlier.

c) The Company reserves the right to request evidence or information that the Contractor is providing the Service in a way that is safe, convenient and in accord with the requirements of this specification. The Contractor is required to comply with all reasonable requests for evidence or information. This includes a closer review of data, ordering process, storage, safe storage and service user feedback.

d) The Contractor participates in an organised audit of service provision and co-operates with any locally agreed Company or Public Health led assessment of service user experience.

e) Service user feedback will be used to understand the quality of advice and inform training needs and service development. Feedback will be presented to individual pharmacies, LPCs and local Substance Use/Public Health Clinical Governance forums when appropriate.

f) The Company will undertake an annual audit to review quality of provision which will include the following performance and quality measures:

- **Service activity:** Volume of Service provision (supervised consumption) as measured by data in the local Contractor recording system and a review against a local needs assessment and financial viability for the Service.
- **Quality and governance:** Training attendance and compliance with local procedures. This will include
    a. Missed dose reporting compliance
    b. Vantage review of significant incidents (Vantage is the incident reporting system used by the Company)
    c. Review of SOPs and referral pathways on an annual basis
    d. Maintaining a list of staff attending local training events and pharmacist and pharmacy technician CPD relevant to the delivery of the supervised consumption service e.g. CPPE Substance Use and Misuse completions
    e. Review of safeguarding training for staff under the essential service arrangements and quality payments – safeguarding standards.
    f. A review of the health promotion material available for the user group and how the Contractor has promoted health promotion relevant to the service group
- **Service User experience:** Service user views on their experiences and satisfaction levels measured through Company service user involvement mechanisms.

Services will be reviewed against these quality indicators and assessed on financial viability and effective service delivery. This will link to quarterly monitoring and annual review. Any Contractor not meeting the quality standards will be asked to work with the Company on an improvement programme and monitored accordingly. If the Contractor continues not to meet the quality indicators and standards **or** is not financially viable they **may** be given notice of termination (see Schedule A Part 4: Termination).

Schedule 1

Payments

Payment process

NEO360 has been commissioned by the Company to act as an agent for processing supervised consumption claims. Under this Agreement

- NEO360 is funded to provide access to Contractors commissioned to provide the supervision consumption services and process service payments on behalf of the Company
- Monthly claims are completed via NEO360

Claims will be paid in line with the "Payment Terms" outlined in the Company "Services Agreement" document (Part A)

Paper-based claims will not be processed for payment.

For queries relating to the use of NEO360 please contact NEO360 directly

Payment rates

Supervision eligible for payments will be made to the Contractor at the following rates:

- £36.99 per client supervised, per month

Schedule 2

Guidelines for the registered pharmacy professional

National guidelines

- *Drug Misuse and Dependence: UK Guidelines on Clinical Management 2017:* https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/673978/clinical_guidelines_2017.pdf
- *Oral methadone and buprenorphine: recommendations 2024:* Oral methadone and buprenorphine: recommendations - GOV.UK
- *NICE Drug Misuse guidance & guidelines page:* https://www.nice.org.uk/guidance/health-protection/drug-misuse
- *NICE Drug misuse in over 16s: opioid detoxification*: https://www.nice.org.uk/guidance/cg52/chapter/1-guidance
- *NICE (2007) Drug Misuse – Opioid detoxification clinical guidance:* https://www.nice.org.uk/guidance/cg52
- *NICE (2010) Pregnancy and complex social factors: a model for service provision for pregnant women with complex social factors:* https://www.nice.org.uk/guidance/cg110
- For Contractor Teams: CPPE Substance Use learning resources: https://www.cppe.ac.uk/gateway/substance

Local Guidelines and contacts

Company Treatment Services local contact

A list of relevant local contacts for will be sent to Contractors through the LPC

For the purposes of this specification for further details please refer to:

- Appendix 1 (Roles & Responsibilities)
- Appendix 2 (Missed Dose Reporting Flowchart & Contact Numbers)
- Appendix 3 (Example Pharmacy SOP)
- Appendix 4 (Pharmacy 4-Way Agreements)
- Appendix 5 (Pharmacy Introduction Letter)

Your local Company Pharmacy Lead will also be able to provide you with on-going access to updated best practice guidance, training and support as service provision is developed. All up to date guidance documents will be available on the LPC website.

Appendix 1 – Roles and Responsibilities

Roles and Responsibilities (temp

Appendix 2 – Missed Dose Reporting Flowcharts & Contact Numbers

Missed dose appendix.docx

Appendix 3 – Example Pharmacy SOP

Pharmacy SC SOP (template).docx

Appendix 4 – Pharmacy 4-Way Agreement

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Appendix 5 – Pharmacy Introduction Letter

Pharmacy Client Introduction Letter (t