**Lot 2 Supervised Consumption of Prescribed Opiate Substitution Therapy**

**Schedule 1 Specification**

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| **Service** | **Supervised Consumption of Prescribed Opiate Substitution Therapy**  |
| **Authority Lead** | **Kate Holburn** |
|  | **1st April 2022-31st Mar 2026** |

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| **1. Population Needs** |
| This specification sets out the requirement for the provision of a Public Health service for the supervised consumption of prescribed medication within a Community Pharmacy. The principal focus of the Service is to provide supervision of the self-administration of Opiate Substitutes, such as methadone and buprenorphine, in specified instalments, according to the prescription. . **1.1 National Context/Evidence Base**The National Institute for Health and Clinical Excellence (NICE) Clinical Guidelines recommend the use of opiate substitution therapy (OST) to treat individuals with addiction to opiates[[1]](#footnote-1).Pharmacological treatments are broadly categorized as maintenance (also known as 'substitution' or 'harm-reduction' therapies), detoxification or abstinence. The aims of the maintenance approach are to provide stability by reducing craving and preventing withdrawal, eliminating the hazards of injecting and freeing the person from preoccupation with obtaining illicit opioids, and to enhance overall function. To achieve this, a substitution opioid regime (a fixed or flexible dose of methadone or buprenorphine to reduce and stop illicit use) is prescribed at a dose higher than that required merely to prevent withdrawal symptoms. The aim is for people who are dependent on illicit opioids to progress from maintenance to detoxification and then abstinence (when a person has stopped taking opioids). The introduction of supervised methadone dosing has resulted in substantial declines in deaths related to overdose of methadone[[2]](#footnote-2),[[3]](#footnote-3).Opiate Substitutes such as methadone and buprenorphine should be administered daily, under supervision, for at least the first 3 months of treatment. Supervision should be relaxed only when the person who uses the service's compliance is assured. Both drugs should be given as part of a programme of supportive care[[4]](#footnote-4).A recent PHE review of evidence[[5]](#footnote-5) found research literature suggesting that investment in drug treatment is likely to substantially reduce social costs associated with drug misuse and dependence. Current estimates suggest that the net benefit-cost ratio is approximately 2.5 to 1 Although deaths from drug misuse remain relatively low in Oxfordshire, nationally rates have increased by 80% since 2012, and therefore the need to have a whole systems approach to tackling drug misuse is a priority for Government as outlined in the government’s response to Part 2 of Dame Carole Black’s review,and a new long-term strategy with a focus on high quality drug treatment is expected by the end of 2021. In line with recommendation 11, Oxfordshire County Council will continue to commission a range of evidence-based harm reduction and treatment services to meet the needs of the local population.The Drug Misuse Service is key to this aim. The Review has also made recommendations which include a focus on better training for all professionals working in the drug treatment system.[[6]](#footnote-6)**1.2 Local Context**In Oxfordshire, a range of services are commissioned to meet the needs of substance misusers, and the provision of OST dispensed with supervised consumption is a core component of the treatment pathway. In 2019-2020 there were 1505 patients across Oxfordshire prescribed OST by either a GP (at one of the 26 GP Practices commissioned to deliver the Drug Misuse Shared Care Services on the Approved Provider List) or the Community Alcohol and Drug Service, currently provided by Turning Point[[7]](#footnote-7). Turning Point have four Service Hubs located in Banbury, Didcot, Oxford and Witney. In July 2021, there were 107 pharmacies commissioned under the Council Approved Provider List to provide supervised consumption for these patients, seeing on average 513 patients per month.* 1. **Social Value Considerations**

The delivery of OST services, including supervised consumption, addresses priorities which disproportionately affect socially disadvantaged communities in Oxfordshire. These include reduction of substance misuse and supporting individuals to make choices to reduce the harms caused to themselves, their families and the wider community. Outcomes include a reduction or complete abstinence from illicit drugs, cessation of injecting, a reduction in injecting site wounds, abscesses and blood-borne virus transmission, and a reduction in needle stick injuries in the general public resulting from discarded needles. It also reduces death from accidental overdose from illicit use. OST, alongside supervised consumption, reduces the risk to communities in a number of ways including overuse or underuse of medicines, diversion of prescribed medicines onto the illicit drugs market and accidental exposure to the dispensed medicine of people it was not intended for.Therefore, the delivery of these services improves the person’s health in the longer-term, as well as improves the economic and social well-being of Oxfordshire, by keeping people who use this service healthier for longer and reducing demand on health and social care services and criminal justice services. The Pharmacist is instrumental in supporting substance users to comply with their prescribed regime, helping to reduce incidents and accidental deaths through overdose. |
| **2. Key Service Aims, Objectives and Outcomes** |
| **2.1 Service Aims**The principle aim of the supervised consumption service is to provide a harm reduction intervention which:* Reduces drug related morbidity/mortality and potential for overdose
* Positively impacts upon anti-social behaviour and drug-related crime
* Supports sustained maintenance of a drug-free lifestyle
* Prepares people to move towards abstinence and recovery from the illicit use of opioid substances
* Supports people to remain healthy (physically and mentally)
* Reduces the number of drug related deaths;
* Reduces the complications from drug use and the prevention of transmission of blood borne viruses associated with drug use.

**2.2 Service Objectives**This Service will: * Enable people using the service to achieve stabilisation of opiate addiction;
* Enable abstinence and recovery from the use of illicit opioid substances;
* Provide people who use the service a quick and efficient access to services across the county;
* Provide an opportunity for regular contact between people using the service and mainstream healthcare services;
* Provide a key link in the delivery of an effective treatment system.
	1. **Substance Misuse Key Outcomes Framework Indicator**

The Public Health Outcomes Framework (PHOF)[[8]](#footnote-8) sets out a vision for public health and desired outcomes. The provision of Prescribed Opiate Substitution Therapy, and supervised consumption,will contribute to PHOF Key Indicators ‘Successful completion of drug treatment - opiate users’ (PHOFC19a), ‘Deaths from drug misuse (C19d) and ‘Adults with substance misuse treatment need who successfully engage in community-based structured treatment following release from prison (C20). The government’s 2017 Drug Strategy outlines the ambition for fewer people to use drugs in the first place, and for those that do, and who experience problems, to be helped to stop and live a life free from dependence[[9]](#footnote-9). The provision of Prescribed Opiate Substitution Therapywill help achieve the national ambitions as set out in the national Drug Strategy 2010 *“Reducing Demand, Restricting Supply, Building Recovery”* carried forward in the 2017 Drug Strategy. The Strategy introduced the concept of recovery from drugs and alcohol dependence into policy with clear practice outcomes, namely:* Freedom from dependence on drugs or alcohol
* Prevention of drug-related deaths and blood borne viruses
* A reduction in crime and re-offending
* Sustained employment
* The ability to access and sustain suitable accommodation
* Improvement in mental and physical health and wellbeing
* Improved relationships with family members, partners and friends
* The capacity to be a caring and effective parent.
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| **3. Service Delivery**  |
| **3.1 Service Description/Pathway**This Service will provide supervised consumption of prescribed opiate substitution therapy medications to people living in Oxfordshire, according to the directions of the prescriber. The Service Provider will offer a user-friendly, non-judgmental, person-centred and confidential service at all times.  The prescriber, will be either a Drug Misuse Shared Care GP or Turning Point clinician, who will issue a prescription for OST, and include a request for supervision, on a regular basis, either as part of a detoxification programme or maintenance treatment. People will be prescribed: * Methadone solution 1mg in 1ml; or
* Buprenorphine sub-lingual tablets.

The Service Provider shall:Professional Standards: * Engage Pharmacists registered with General Pharmaceutical Council for the provision of this service.
* Provide the service in line with NICE guidelines[[10]](#footnote-10)
* Conform to General Pharmaceutical Council Standards for registered Pharmacies[[11]](#footnote-11)and Standards of conduct, ethics and performance.
* work with a number of people who use the service that is appropriate to the capacity of the Pharmacy within the parameters of good practice, as advised by the Commissioner. Ensure compliance with safeguarding responsibilities in relation to children and vulnerable adults (see Schedule 4 for full safeguarding requirements and responsibilities);
* Promote a non-judgemental and confidential service at all points of delivery within each Pharmacy;
* Comply with all relevant Controlled Drugs guidance, Regulations and legislation during delivery of this service including

Specific Service Standards:* Ensure compliance with an agreed care plan by dispensing prescribed medication in specified instalments, according to the prescription.
* Inform people who use the service of the times of day they can access the Service
* Emphasis must be given to the safety of people who use the service and timely communication with the treatment provider, currently Turning Point, must take place.
* Ensure there is staff capacity in the pharmacy so that checks can be carried out thoroughly for each person using the service
* If the Pharmacy has to close unexpectedly, ensure the prescriber is informed as a matter of urgency so other arrangements for those people expecting to have their OST supervised that day/s can safely attend another pharmacyEnsure each supervised dose is correctly administered to the individual for whom it was intended (Doses may be dispensed for the individual to take away to cover days when the pharmacy is closed, if this is directed on the prescription).
* Liaise with the prescriber, named key worker and, where the person using the service has given written permission, others directly involved in their care.
* Monitor the person’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 person using the service appears intoxicated or when they have missed doses, if necessary withholding treatment if this is in the interest of that person’s safety, liaising with the prescriber as appropriate.
* Liaise with the prescriber or named key worker where the individual has missed three consecutive doses. The Pharmacist should consider liaising after two consecutive doses have been missed (dependant on the risk).

Dispensing and supply can be refused in certain circumstances, according to the Pharmacist’s professional judgement, including but not limited to:* If the Pharmacist believes the prescription is not genuine or for the person named on the prescription form.
* If the Pharmacist believes the prescriber has made a clinical error or that the prescription is clinically inappropriate.
* If the person who uses the service, or anyone with them, behaves or threatens to behave violently, or commits or threatens to commit any criminal offence in the pharmacy.

In any of these situations, the prescriber should be contacted urgently and if possible, before the person using the service has left the pharmacy.People receiving prescribed medication for opioid substitution will not be refused access to SWOP packs if Needle Exchange services are also delivered by the Pharmacy; the Service Provider will encourage the individual to discuss this with their prescriber.The Service Provider shall:* Identify a lead Pharmacist who has successfully completed the relevant training (see 3.2 below) to take responsibility for the Service at each site;
* Comply with the Public Health Shared Care Pathway Guidance (Guidance for Primary Care Drug Misuse)[[12]](#footnote-12);
* Abide by all legal constraints when dealing with controlled drugs. The Pharmacist cannot dispense the prescription if it does not fully comply with legal requirements;
* Ensure that the supervision of self-administration of OST is undertaken in a designated area of the pharmacy, which provides a sufficient level of privacy and safety;
* Maintain appropriate standard operating procedures (SOPs) for the safer management of controlled drugs;
* Provide advice on safe storage of methadone and buprenorphine at home and signpost to Turning Point for safe home storage boxes
* Provide advice and display health promotion leaflets relating to harm reduction;
* Maintain sufficient Staff in place to provide and/or support the Service in relation to the patient numbers;
* Provide a continuous Service on all days of opening;
* Ensure that sensitive documents and confidential waste, no longer required, are ethically and securely disposed of in line with the General Data Protection Regulations (GDPR);
* Ensure that contemporaneous documentation is maintained for every contact with each person who uses the service;
* Notify the Council if the lead Pharmacist changes and provide a copy of the new lead Pharmacist qualifications as required for delivery of this service (see 3.2 below);
* Ensure that Standard Operating Procedures are in place for supervised consumption. Service Providers may develop their own operational procedures/SOP to enhance the implementation of the operational guidelines within the community pharmacy, have clearly stated objectives and stipulate whose responsibility it is to implement them. The process for monitoring, review and development must also be clearly defined. The SOP should include the following areas:
	+ Methadone/buprenorphine dispensing and supervision
	+ Confidentiality and data protection
	+ Incident monitoring
	+ Risk assessment and risk management.

Health and wellbeing of people using the Service:* Provide people who use the service with details of local healthcare professionals
* Provide referral or signposting to other related services such as sexual health, smoking cessation or other public health services.
* Use the Health Education England information on Making Every Contact Count via: <http://www.makingeverycontactcount.co.uk/>
* Work in partnership with drug treatment providers and General Practitioners
* Promote harm reduction to the people who use the service, carers and families
* Make referral to drug services as relevant.
* Take part in health and wellbeing campaigns as required

**3.2 Training**In addition to demonstrating evidence of commitment to continuing professional development, Pharmacists and registered technicians providing this service shall:* Identify Lead Pharmacist with responsibility for delivering this service;
* The Lead Pharmacist should have successfully complete either the distance learning pack, *Substance use and misuse* CPPE 2014[[13]](#footnote-13) or RCGP Part One Certificate in the Management of Drug Misuse[[14]](#footnote-14) prior to delivery of the Service.
* Ensure that competence against this training is reconfirmed **at least every 3 years and notify the Council on each occasion;**
* Notify the Council where the Lead Pharmacist changes and send a copy of the new Lead Pharmacist qualifications for delivery of this service (i.e. RCGP Part 1 or CPPE);
* Attend a local training session (Oxfordshire Pharmacy Training) on the care and management of opiate-dependent drug misusers arranged by the Community Alcohol and Drug Service (currently provided by Turning Point);
* Ensure that all Pharmacy staff (including Locum & support staff) involved in the delivery of supervised consumption, have successfully completed Training/CPD relevant to the provision of this Service;
* Ensure all staff coming into contact with people who use the service are trained on the delivery of a user-friendly, non-judgmental, person-centred and confidential service at all times.

If a Pharmacist is new to the Pharmacy, then they are recognised as qualified to deliver the service, provided that, the distance learning pack, *Substance use and misuse* CPPE 2014, or RCGP Part One Certificate in the Management of Drug Misuse, has been completed, and that they attend the next available Community Alcohol and Drug Service training session.**3.3 Audit/Review**The Service Provider shall:* Participate in service audit as per the quality schedule.
* Co-operate with any locally agreed assessment of Service User experience.
* Demonstrate that key Staff have undertaken continuous Professional Development relevant to this service. Pharmacists should ensure that at least one staff member at any one time has attended the Oxfordshire Pharmacy Training, currently provided by the Community Alcohol and Drug Service, Turning Point.
* Participate in any review of the Dynamic APL by the Council.
* Respond to the Council’s annual Monitoring Self-Assessment of the service standards

The Council will contract monitor the service on a regular basis as well as responding to issues which may require a more urgent review;**3.4 Transfer of Ownership**If the Service Provider or Legal Entity of the Provider for any site on the Dynamic APL changes during the Call-off contract period, the Provider is required to give at least 3-months written notice to the Council to enable the relevant procurement and contractual processes to be undertaken prior to the change.**3.5 Population covered**The target group of people for the Service are Oxfordshire residents aged 18 years or older, who are prescribed OST for the treatment of opioid addiction, by the Drug Misuse Shared Care Service, or the Community Alcohol and Drug Service in Oxfordshire. However, the Service may be required to dispense and supervise the consumption of methadone or buprenorphine to individuals aged under 18 years. This must always be in close collaboration with the prescriber and children and young people’s treatment service, currently provided by Aquarius Action Projects. |
| **4. Applicable Service Standards**  |
| **4.1 Applicable National and Local Standards** The Service Provider shall comply with all relevant current clinical guidelines and quality standards including, but not limited to, the following: * Opioid detoxification regimes in accordance with NICE clinical guideline CG52: <http://publications.nice.org.uk/drug-misuse-opioid-detoxification-cg52/guidance>
* Methadone and buprenorphine prescribing in accordance with NICE clinical Guideline: TA114 <http://publications.nice.org.uk/methadone-and-buprenorphine-for-the-management-of-opioid-dependence-ta114>
* Naltrexone programmes in accordance with NICE clinical guideline TA115: <http://www.nice.org.uk/guidance/TA115>
* Drug Misuse and dependence is conducted in accordance with the DoH guidelines: Drug misuse and dependence: UK guidelines on clinical management (the ‘Orange Book’): <https://www.gov.uk/government/publications/drug-misuse-and-dependence-uk-guidelines-on-clinical-management>
* QS23 – Relevant Quality Standards for drug use disorders. <https://www.nice.org.uk/guidance/qs23>
* NICE Guidance on Controlled Drugs NG46: <https://www.nice.org.uk/guidance/ng46>
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| **5. Location of Service Provider Premises** |
| Community Pharmacies in Oxfordshire commissioned to deliver this Service. |
| **6. Data Requirements**  |
| **6.1** **DATA Entry**The Service Provider shall:* Ensure completion of the Council minimum data set for each person who uses the service , which will be completed per person per month.
* Input data onto the web-based system provided by the Commissioners (currently PharmOutcomes) within 7 days of the end of the month in which the activity took place.

Payments will be made according to the number of Service Users entered onto the system as having been supervised each month, and as such the data entered onto this system will determine the level of payment to each Service Provider. Data will be collected 28 days after the quarter end for calculation of payments. Therefore, all data for the quarter must be entered onto this system by this date. There will be no late payment made for data entered after this date.The information required for each person who uses the service may be developed to reflect the Council’s contract monitoring requirements. |

**SCHEDULE 2 - FINANCE**

Payment for delivery of services under this contract shall be £32.03 per Service User supervised, per month, paid in aggregate at the end of each quarter.

* Payments will be made quarterly in arrears, on receipt of data collected on the Council’s data system, currently PharmOutcomes.
* Data will be collected from the system 28 days after the quarter ends. Payments will be calculated and processed for people receiving supervision each month within that period. All data for the quarter must be entered onto this system by this date. There will be no late payment made for data entered after this date.
* Any queries regarding payments should be referred to the Council’s Public Health team.

Please note the Service does not include payment for dispensing a methadone or Buprenophine prescription where there is no supervision requirement.

In addition to the payment per person per quarter, the Council may at its discretion offer Service Providers the opportunity to periodically access: (i) training grants of £500 for attending Council agreed sessions, up to a maximum of once a year; or (ii) training grants of £1,500 where the Service Provider completes the RCGP Part 2 Certificate in the Management of Drug Misuse, a maximum of once per Service Provider per three-year period.

Payments will be made following confirmation of attendance at the prior agreed training session.

1. *TA114 - Methadone and buprenorphine for the management of opioid dependence, NICE, January 2007* [↑](#footnote-ref-1)
2. *BMJ2010;341:c4851* [↑](#footnote-ref-2)
3. *Drug Misuse and Dependence: UK Guidelines on Clinical Management; DoH July 2017;* [↑](#footnote-ref-3)
4. *TA114 - Methadone and buprenorphine for the management of opioid dependence, NICE, January 2007* [↑](#footnote-ref-4)
5. *An evidence review of the outcomes that can be expected of drug misuse treatment in England. Published: January 2017 PHE publications gateway number: 2016489* [↑](#footnote-ref-5)
6. [Review of drugs: phase two report - GOV.UK (www.gov.uk)](https://www.gov.uk/government/publications/review-of-drugs-phase-two-report) [↑](#footnote-ref-6)
7. PHE. Recovery Diagnostic Tool Q4 2019-2020 [↑](#footnote-ref-7)
8. Public Health Outcomes Framework 2016 to 2019. Available at: www.gov.uk/government/collections/public-health-outcomes-framework [↑](#footnote-ref-8)
9. www.gov.uk/government/publications/drug-strategy-2017 [↑](#footnote-ref-9)
10. <https://www.nice.org.uk/guidance/ta114> [↑](#footnote-ref-10)
11. [Standards | General Pharmaceutical Council (pharmacyregulation.org)](https://www.pharmacyregulation.org/standards) [↑](#footnote-ref-11)
12. Drug Misuse Shared Care Pathway & Protocol Guidance for Substance Misuse. Public Health 2021 [↑](#footnote-ref-12)
13. Available here: www.cppe.ac.uk/gateway/substance [↑](#footnote-ref-13)
14. Available here: www.elearning.rcgp.org.uk/course/info.php?id=130 [↑](#footnote-ref-14)