Cheshire West and Chester Pharmacy Supervised Consumption Procedures and Service Level Agreement

1st January 2020 to 31st March 2024

Service Level Agreement for the provision of a Supervised Consumption Service

AN AGREEMENT BETWEEN WDP, 18 Dartmouth Street, London, SW1H 9BL (hereinafter referred to as 'Company') and the person, firm or company shown in Schedule A (hereinafter referred to as 'Contractor')

WHEREAS:

(i) Company has asked Contractor to provide certain services ('the Services') as described in Schedule A to this Agreement.

(ii) Contractor has agreed to provide the Services in accordance with the terms set out below and in consideration of the payments herein agreed to be made.

IT IS AGREED AS FOLLOWS:

1. Appointment and Term

1.1. Company hereby engages Contractor to carry out the Services and Contractor hereby agrees to provide the Services on the following conditions. Any terms and conditions stipulated by or referred to by Contractor are expressly excluded from this Agreement unless specifically included in this Agreement.

1.2. Contractor's appointment shall commence from and (subject to the powers of termination hereinafter contained) continue to the respective dates set out in Schedule B to this Agreement. These dates are agreed on the basis that, normal circumstances prevailing, the Services shall have been completed to the satisfaction of the Company.

1.3. Subject to clause 1.4, Contractor will ensure the Services are delivered by Pharmacists with the relevant Centre for Pharmacy Postgraduate Education (CPPE) in place and according to the General Pharmaceutical Council (GPhC) standards.

1.4. If for any reason the Pharmacist is no longer available, the Contractor will replace him/her immediately by another person or persons of equal competence chosen by the Contractor. The Company reserves the right to terminate this Agreement without notice if Contractor is unable to provide a suitable replacement (person of equal competence).

1.5. Where Contractor considers that it is necessary to use the services of a third party including for the purposes of information or for the supply of goods or

services it shall, except in matters of a minor nature, first obtain the written consent of Company.

1.6. It is agreed that, for the purposes of carrying out the Services under this Agreement, Contractor is an independent contractor who shall not hold itself out as or purport to be an employee of Company. Nothing in this agreement shall be deemed to imply that the relationship between Company and Contractor under this agreement is that of master and servant, principal and agent or employer and employee.

1.7. If either party shall be prevented from carrying out its obligations under this Agreement due to causes beyond its reasonable control including, without prejudice to the generality of the foregoing, strikes, lock-outs, labour disputes, act of God, war, riot, civil commotion, malicious damage, compliance with any law or government order, rule, regulation or direction, accident, breakdown of plant or machinery, fire, flood, storm, then:

1.7.1. subject to 1.7.2 and 1.7.3, that party's obligations under the contract shall be suspended during the period and to the extent that that party is prevented or hindered from performing its obligations under the Agreement;

1.7.2. the party concerned shall give notice of suspension as soon as reasonably possible to the other party stating the date and extent of the suspension and its cause. The omission to give such notice shall forfeit the rights of that party to claim suspension. Any party whose obligations have been suspended as aforesaid shall resume the performance of those obligations as soon as reasonably possible after the removal of the cause and shall so notify the other party;

1.7.3. In the event that the cause continues for more than one month either party may terminate this Agreement immediately and with one month's notice.

1.8. This Agreement, including the attached schedules, contains the whole Agreement between the parties. This Agreement may not be altered, amended or modified except in writing signed by duly authorised representatives of the parties which in the case of Company is the Chief Pharmacist.

2. Scope of Appointment

2.1. During the continuance of this Agreement Contractor shall provide the Services with due care and skill and to the best of Contractor's ability and according to the General Pharmaceutical Council (GPhC) standards.

2.2. Contractor undertakes that appropriate time will be spent (if appropriate at Company) (including the preparation of any documentation) to ensure completion of the Services within any set deadlines.

2.3. The Services shall conform with the particulars (if any) set out in Schedule B, (or in any relevant correspondence – agreed between the parties). Contractor shall ensure that the Services are performed in time, and to the skilled and expert standards to be expected in the provision of such Services. Contractor should exercise and carry out such functions and observe all such directions as Company may lawfully direct, give or impose upon Contractor within the scope of the services as set in this Service Level Agreement.

2.4. Liaison relating to technical and/or operational matters in respect of the Services shall be dealt with by the parties' respective representatives.

2.5. Liaison relating to commercial and/or contractual matters shall be dealt with on behalf of Company by the company's Chief Pharmacist who is the only person empowered to amend any of the terms of this Agreement on behalf of Company with Contractor.

3. Assignment and Confidentiality

3.1. Except as provided in this Agreement, Contractor shall not delegate assign or sub-contract the performance of the Services or any duties or obligations arising under this Agreement.

3.2. Contractor shall not assign the benefit of this Agreement without the prior written approval of the Company.

3.3. Contractor shall not either during or after the termination of this Agreement without limit in point of time divulge or communicate to any person or persons except to those members of Company whose province it is to know the same any secret or confidential or other information which Contractor may receive or obtain in relation to the affairs of Company or the working of any process or invention which is carried on or used by Company or which Contractor may make or discover during this Agreement and shall not for Contractor's own purposes nor for any purposes other than those of Company use or disclose any information or knowledge of a confidential nature which Contractor may from time to time acquire in relation to Company. Contractor shall ensure that its employees or agents also observe the provisions of this clause.

4. Termination

4.1. This Agreement may be terminated by Company and the Contractor with either party giving not less than three months' written notice at any time after the commencement date. Company reserves the right to require Contractor to perform the Services during any period of notice.

4.2. This Agreement shall be subject to termination by Company by summary notice in writing in the circumstances set out in clauses 4.2.2, 4.2.3, or if contractor shall have: -

4.2.1. committed any serious breach or repeated or continued (after reasonable warnings) any material breach of its obligations hereunder including failing to supply the Services on time and failing to supply the Services to the quality or standard required; or
4.2.2. been guilty of conduct tending to bring itself or the Company into disrepute; or
4.2.3. failed to discharge its duties hereunder efficiently or diligently.

4.3. On the termination of this Agreement howsoever arising Contractor shall forthwith deliver to Company all books, documents, papers and other property of or relating to the business of Company which may then be in Contractor's possession or under its control. Due to the General Pharmaceutical Council (GPhC) regulatory requirements contractors can keep copies of any documents according to the General Data Protection Regulation (GDPR) standards but must return the originals to the company.

4.4. Termination of this Agreement shall be without prejudice to any rights which have accrued at the time of termination.

4.5. Contractor shall be responsible for all losses incurred by Company as a result of Contractor's breach of the terms of this Agreement including losses incurred by Company in replacing Contractor.

4.6. Any notice sent by first class post to the address set out in Schedule A party shall be deemed to have been received two days from the date of posting.

4.7. No forbearance or indulgence by Company in enforcing any condition of this Agreement shall prejudice or restrict Company's rights or powers under this Agreement and no waiver of any breach shall operate as a waiver of any subsequent or continuing breach.

5. Indemnity and Insurance

5.1. Contractor agrees to indemnify and keep indemnified the Company from and against any or all loss, damage or liability (whether criminal or civil) suffered and legal fees and costs incurred by the Company resulting from a breach of this agreement by Contractor (including employee's or agents of Contractor) including:
5.1.1. any act, neglect or default in the performance of the Services;
5.1.2. breaches in respect of any matter arising from the provision of the Services resulting in a successful claim from any third party.
5.1.3. any Court action against Company for infringement of any copyright or intellectual property used by Contractor, or by Company in accordance with Contractor's instructions or with Contractor's consent.

5.2. Contractor agrees to maintain at its own cost a comprehensive policy of insurance to cover:

5.2.1. public liability insurance with a limit of indemnity of not less than ten million pounds (£10,000,000) in relation to any one claim or series of claims;

5.2.2. employer's liability insurance with a limit of indemnity of not less than ten million pounds (£10,000,000) in relation to any one claim or series of claims;

5.2.3. professional indemnity insurance with a limit of indemnity of not less than five million pounds (£5,000,000) in relation to any one claim or series of claims and shall ensure that all professional consultants or Sub-Contractors involved in the provision of the Services hold and maintain appropriate cover.

6. Payment Terms

6.1. In consideration of the provision of the Services Company shall pay to Contractor such amounts, and in accordance with the procedures, as are set out under Remuneration Section on Page 24 of this document.

6.2. The amounts set out in the Remuneration Section are on a fixed price basis and no modifications or variations to those amounts will be allowed for the agreed term of the contract.

6.3. The PharmOutcomes system will generate an invoice which will be sent directly to the Company via PharmOutcomes. The Company will pay in full correct invoices within thirty (30) days of the date of receiving the invoice from Contractor.

7. Taxes

7.1. Any payment of or responsibility for any VAT, income tax or other taxes, national insurance as a self-employed person or similar impost or other such payment of a fiscal nature which may be found due in respect of the appointment and the payment of fees by the Company to Contractor hereunder (together referred to as “the Taxes”) shall be exclusively borne by Contractor.

7.2. Contractor hereby agrees to indemnify the Company against all costs, claims, actions, demands, penalties and liabilities incurred in respect or arising in connection with all or any of the Taxes.

8. Law

8.1. The construction, performance and validity of this Agreement will be governed by the laws of England, and the parties hereby agree to submit to the jurisdiction of the English Courts.

9. Confidential Information

9.1 Each of the Parties agrees that it shall keep any information designated as confidential or which is otherwise clearly confidential in nature ("**Confidential Information**") received by it from the other before or during the term of this Agreement and which relates to the business, assets, affairs, financial results, plans, customers and suppliers of the other Party or its Affiliates or of any third party strictly confidential and that it shall not use any such Confidential Information for its own benefit (save as is necessary in order to perform its obligations and/or exercise its rights under this Agreement) or disclose any such Confidential Information to any third party and that it shall ensure that no third party shall have access to it. Notwithstanding the foregoing, the Parties shall be entitled to disclose the Confidential Information to its employees, or to the employees of its Affiliates, to the extent that those employees have a genuine need to know the same to enable the Parties to perform their obligations or exercise their rights under this Agreement and who have been advised of the existence and terms of this Agreement, and who are legally obligated to protect the Confidential Information from unauthorised disclosure or use on terms at least as stringent as those contained herein. The recipient shall be liable for acts by any of its Affiliates in violation of this Agreement as if they were actions or omissions of that Party.

9.2 The restrictions in clause 9.1 shall not apply to any Confidential Information which:-

9.2.1 the recipient can prove is already known to it at the time of disclosure of the Confidential Information to it;

9.2.2 is in the public domain at the time of disclosure of the Confidential Information to the recipient or which subsequently comes into the public domain through no fault of the recipient;

9.2.3 is subsequently disclosed to the recipient (other than subject to conditions of confidentiality and without any restriction on disclosure) by a third party which is itself not subject to any restriction on disclosure imposed by the disclosing party hereunder; or

9.2.4 is required to be disclosed as a matter of law or by the rules of a recognised stock exchange provided the recipient notifies the disclosing party, if legally permissible, as soon as possible following any relevant demand or request for disclosure.

10. Data Protection

10.1. Each of the parties will comply with current Data Protection Legislation. Please refer to Appendix 1.

SCHEDULE A

Contractor Agreement Contact:

Name:	
Address of Head Office:	
Name of Main contact for Contractor	
Telephone number:	
Email address:	

Company Agreement Contact:

Name:	WDP
Address:	18 Dartmouth Street, London, SW1H 9BL
Name of individual to provide services:	Marylyn Nathan-Wilson
Telephone number:	07918 626 674
Email address:	marylyn.nathan-wilson@wdp.org.uk

Company Agreement Contact:

Name:	WDP Finance Department
Address:	18 Dartmouth Street, London, SW1H 9BL
Telephone number:	020 7421 3106
Email address:	finance@wdp.org.uk

SCHEDULE B

Services:

The contractor shall provide a range of contracted services in accordance with the General Pharmaceutical Council (GPhC) standards.

1. Introduction

1.1 Prescription of opioid substitution treatment (OST) (methadone and buprenorphine) is the main pharmacological intervention for treatment of substance misuse. Drug Misuse and Dependence – Guidelines on Clinical Management (2017) and NICE recommend that supervised consumption should be available for all patients for a length of time appropriate to their needs and risks.

1.2 This scheme wishes to recognise and enhance the day-to-day work of the pharmacist and staff with substance misuse service users.

1.3 This agreement shall serve as the formal contract between the WDP Cheshire West and Chester Service and the Contractor detailed for the provision of a Supervised Consumption Service.

1.4 The terms and conditions as set out in this agreement shall exist between the WDP Cheshire West and Chester Service and the following contractor:

PLEASE PRINT
Contractor name:
Company name:
Address:
Telephone number(s):
Fax number(s):
DATES FOR PROVISION OF SERVICES
Start date: 1st January 2020
End date: 31st March 2024

2. Aims

2.1 The Supervised Consumption Programme is an integral and complementary part of WDP Cheshire West and Chester 's strategy for substance misuse.

2.2 To provide regular contact for substance misusers with healthcare professionals and where necessary, to help them access further advice and assistance.

2.3 To improve the health of substance misusers by developing a shared care scheme, based within pharmacies, which ensures that prescribed medication for the treatment of substance misuse is consumed under professional supervision and that appropriate information is recorded.

2.4 To formalise communication and governance between community pharmacists, prescribers, their service users and other health care professionals.

***For the purposes of this document the term "medication" refers to methadone, buprenorphine, Espranor®, Subutex®, Suboxone®, diazepam and all other medicines that are permitted to be prescribed for instalment dispensing and that have been agreed to be funded under the individually locally agreed pharmacy supervised consumption (PSC) schemes.**

2.5 To ensure compliance with the agreed treatment plan by:

2.5.1 Dispensing prescribed medication in specified instalments.

2.5.2 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).

2.5.3 Liaising with the prescriber, named key worker and others directly involved in the care of the service user (where the service user has given written permission).

2.5.4 Monitoring the service user'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 service user appears intoxicated or when the service user has missed doses and if necessary withholding treatment if this is in the interest of service user safety, liaising with the prescriber or named key worker as appropriate.

2.5.5 Improving retention in drug treatment.

2.5.6 Improving drug treatment delivery and completion.

2.6 To reduce the risk to local communities of:

2.6.1 Overuse or underuse of medicines.

2.6.2 Diversion of prescribed medicines onto the illicit drugs market.

2.6.3 Accidental exposure to the dispensed medicines.

2.6.4 To help service users access treatment by offering referral to specialist drug and alcohol treatment centres and health and social care professionals where appropriate.

3. Pharmacy Supervised Consumption Service Scheme

3.1 The pharmacist is expected to operate the scheme in accordance with the Code of the Ethics and Professional Standards as laid down by the General Pharmaceutical Council (GPhC).

3.2 To introduce local community-based services that meets the needs of service users with substance misuse problems. This means the service may be accessed by any drug user who presents at a participating pharmacy after introduction by WDP.

3.3 All participating pharmacies will be expected to provide supervised consumption* of methadone/buprenorphine/Suboxone®/Espranor® and other medication as agreed locally with the borough.

3.4 To offer a professional, user-friendly, non-judgmental, service user-centred, confidential service.

3.5 To improve consistency and quality of care to the service user.

3.6 To minimise over-usage and under-usage of prescribed medicines.

3.7 To ensure the safe and consistent consumption of medication by service users and to keep to a minimum the misdirection of these medications, thus contributing to a reduction in drug-related deaths in the community.

3.8 To minimise the risk of harm to the service user and to others by avoiding accidental exposure to the supervised medications.

3.9 To monitor and offer advice to the service user on their general health and wellbeing.

3.10 To improve communication between pharmacists, prescribers (GPs and drug treatment teams), their service users and other named healthcare professionals, taking into consideration service user consent.

3.11 To support the improvement of service delivery to service users through the reporting and communication of incidences between community pharmacies, specialist drug services and primary care trusts, monitoring and audit.

3.12 To support the pharmacies involved by the provision of regular training and updates.

3.13 To promote access and signpost to other primary care agencies where appropriate.

3.14 To collect routine information that will inform service delivery and further service development.

4. Membership Conditions for Pharmacy Contractors

4.1 All pharmacies on the supervised consumption scheme are required to comply with the conditions stated below:

4.1.1 The pharmacy must be a registered pharmacy at an address in the Borough of Cheshire West and Chester Service and possess a NHS dispensing contract. The pharmacy should not be under investigation or be of concern to Cheshire West and Chester Public Health.

4.1.2 The pharmacist must be willing to dispense controlled drugs to substance misuse service users, if not already doing so.

4.1.3 The pharmacy contractor must ensure that the pharmacy environment and protocols are in such condition as to be able to facilitate a quiet, discreet/confidential area where consumption of substitute medication and other healthcare interventions can take place as well as the capacity to provide relevant information and leaflets.

4.1.4 The pharmacist must aim to provide a good quality service for substance misuse service users receiving community pharmacy services via the scheme.

4.1.5 The pharmacist involved must operate a non-discrimination and equal access policy.

4.1.6 The pharmacist must work collaboratively with the service user; drug treatment team or their GP and any named GP Liaison Worker directly involved in the service user's treatment for substance misuse.

4.1.7 The pharmacist must report all incidents for the purpose of risk management and service improvement linked to the service. This can be reported to the Service Manager and WDP Chief Pharmacist.

4.1.8 The pharmacist must adhere to the scheme guidelines and procedures provided by the Service Level Agreement.

4.1.9 The pharmacist must ensure accuracy inputting information on PharmOutcomes system when claiming payment for supervised consumption.

4.1.10 The pharmacist must be competent at managing the PharmOutcomes system.

4.1.11 The pharmacist and relevant pharmacy staff must undertake regular annual training as required by the scheme.

4.1.12 The pharmacist must agree to monitoring visits or where there is concern about the pharmacy. The visits aim to monitor practice against the

scheme guidelines and to discuss training and support needs, the implementation of good practice and address any areas of concern or difficulty.

4.1.13 The pharmacist must participate in an audit of the service and supply the necessary information as required by the scheme Coordinator/auditor, if concerns arise.

4.1.14 The pharmacist will review their standard operational procedures (SOP) and referrals pathway for the service every two years. This may be monitored by the WDP Service Manager.

4.1.15 There is a written SOP for operation of the supervised consumption scheme at their pharmacy, that is easily accessible to staff and pharmacists. These SOPs should facilitate a 'safe and efficient' service that minimises waiting times for service users.

4.1.16 Access to service user information must be restricted to authorised staff only. The pharmacy contractor must ensure compliance with the Data Protection Act and General Data Protection Regulation (GDPR) see Appendix 1.

5. Recruitment and Induction of service users into the scheme

5.1 Pharmacists may introduce the scheme to any service user who is known to be a substance misuser. This can be done by signposting the service user the WDP service or by contacting the local drug treatment service to make an appointment for the service user to attend. The pharmacist must obtain verbal consent from the service user before contacting the drug treatment centre. A record should be made on the Patient Medication Record of having received service user consent to refer to specialist services.

5.2 The pharmacist can check that the GP is on the Shared Care scheme. An updated list can be requested from the WDP Service Manager.

5.3 The service user must agree to be a part of the scheme. To register the service user on the scheme, the prescriber will sign the service user Pharmacy Introductory Letter.

5.4 Before the service user visits the pharmacy with the Pharmacy Introductory Letter, the prescriber must telephone the pharmacist to introduce the service user and communicate any relevant information.

5.5 At induction, the pharmacist should read through the Pharmacy Introductory Letter with the service user and:

5.5.1 Clarify any queries.

5.5.2 Communicate clearly to the service user the rules of behaviour that apply to the pharmacy.

5.5.3 Agree supervised consumption times with the service user.

5.6 When the agreement form has been signed, the community pharmacist must keep it on file until the service user stops receiving treatment on the scheme.

5.7 The pharmacist should ensure that the prescriber has indicated on the referral form the number of missed doses (maximum of three missed days) before the prescriber is contacted.

5.8 The induction of new service user by the WDP Recovery Worker will cover:

5.8.1 How the medication works as a substitute.

5.8.2 Time taken to act and how long it works.

5.8.3 Dosing.

5.8.4 Side effects.

5.8.5 Drug interactions especially with alcohol and benzodiazepines.

5.8.6 Overdose prevention and action to take in the event of an overdose.

5.8.7 Safe storage of medicines at home if service user has pick up doses for weekends and bank holidays.

5.8.8 Arrangements for subsequent prescriptions to be brought in advance etc.

5.8.9 In addition, for buprenorphine, Espranor®, Subutex® and Suboxone® (buprenorphine/naloxone) service users, induction will include precipitated withdrawal and administration procedure and approximate time required for dissolution of tablet i.e. waiting time.

5.9 The service user's details should be registered on the pharmacy's Patient Medical Record (PMR). It is good practice to inform the service user of the registration.

5.10 We recommend that the pharmacist considers what level of service user caseload he/she is prepared to manage on the scheme, i.e. how many buprenorphine treatment slots at any one time.

6. Accepting new service users into Supervised Consumption

6.1 The prescriber (WDP Cheshire West and Chester) will ask the service user which pharmacy participating in the supervised consumption programme, would be most convenient for daily visits and at what times.

6.2 The prescriber will contact that pharmacist before issuing the first prescription to ensure the pharmacist has the capacity to accept the service user at that time.

6.3 The prescriber or keyworker will complete the Pharmacy Introduction Letter (including the service user agreement) with the service user, including signing the form and stamping it with an official clinic stamp.

6.4 All prescriptions will have the agreed dispensing pharmacy address printed on the prescription.

6.5 The service user will attend the named pharmacy with their prescription for supervised methadone or buprenorphine consumption as agreed with the prescriber or keyworker. The Pharmacy Introduction Letter must accompany the prescription.

6.6 Service users will be briefed by the prescriber on the date of commencement of supervised consumption. The prescriber should inform the service user fully of what is expected when commencing supervised consumption. In doing so the prescriber will inform the service user that the pharmacy will enter into a contractual arrangement with the service user which the service user will be expected to adhere to.

7. Service user/pharmacy agreement (contract)

7.1 Service users must have a written contract with the WDP Cheshire West and Chester Service, part of which covers behaviour in the pharmacy. However, it is important that pharmacists use the service user agreement in the Pharmacy Introduction Letter, which outlines in greater detail the procedure for daily supervision.

7.2 The aim of the contract is to reduce the potential for misunderstandings and negative feeling to arise between service user and pharmacist.

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

8. Identification of service users

8.1 The service user's identity must be checked to ensure the prescription is dispensed to the correct person. The Pharmacy Introduction Letter aims to assist this process.

8.2 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.

9. Controlled drugs prescriptions

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

9.2 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.

9.3 Methadone should be prescribed on FP10MDA forms for no more than 14 days. On rare occasions, a FP10SS (green) form may be used if a single dose is being requested.

9.4 If more than one item is prescribed, separate forms should be used as the FP10MDA form only has space to record 14 dispensing episodes.

9.5 Buprenorphine may be prescribed on FP10MDA or FP10SS forms.

9.6 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

9.7 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.

9.8 The prescription must specify clearly that supervision is required.

9.9 The prescription should not be in any way tampered with, or in a condition where the instructions are no longer clear – e.g. water damaged, torn, etc. The pharmacist must contact the WDP Service for guidance.

9.11 Whilst the Home Office have confirmed that prescriptions can now be worded as follows 'Instalment prescriptions covering more than one day should be collected on the specified day; if this collection is missed the remainder of the instalment (i.e., the instalment less the amount prescribed for the day(s) missed) may be supplied', The pharmacist should annotate the prescription accordingly.

9.12 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.

9.13 Pharmacists must satisfy themselves of the legality of the prescription, and its clinical appropriateness. If you have any doubts about the validity of the prescription – contact the prescriber. If a service user's prescriber changes, the clinic or service should inform the pharmacist of this change.

9.14 If a service user fails to pick up their medication for three consecutive days, please do not dispense to said service user and contact the WDP Cheshire West and Chester Service immediately on one of the following telephone numbers: 0300 303 4549 (Chester), 0300 303 4550 (Ellesmere Port) or 0300 303 4548 (Northwich), or by email on cwac@wdp.org.uk.

10. Procedures specific to Methadone

10.1 The daily amount should be measured into a suitable container, capped and labelled. When the service user arrives, ideally the measured dose may be poured into a disposable cup. Please note drinking medicines directly from the bottle can set a bad example to children in the pharmacy.

10.2 The pharmacist should be satisfied that the dose has been swallowed. This can be carried out by giving the service user water to take immediately afterwards, or by conversing with the service user. The service user should always be offered a drink of water in a disposable cup. Please note that diversion can occur in the following ways:

10.2.1 Swapping of bottles – make sure you take the top off the methadone bottle when given to the service user so that this can't be swapped with an empty one.

10.2.2 "Spit-methadone" – some people may say that they prefer to wash down their methadone with a can of soft drink. However, what they might do is to discharge ('spit') the methadone into the can instead for a later sale.

10.3 Sugar free or colourless methadone mixture should only be dispensed if specifically requested on the prescription. It is important that the dose is ready for the service user's arrival.

10.4 The whole operation should be as discreet and efficient as possible, maintaining the service user's dignity and saving the pharmacist's time.

10.5 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 also be advised to store their medication out of the reach of children.

11. Procedure specific to Buprenorphine

11.1 The prescribed tablets should be removed from the foil and placed in an appropriate container.

11.2 Confirm the time of last dose or if any other illicit substances have been used in the previous 24 hours, this is to establish precipitated withdrawal.

11.3 The tablet should be placed in a clean dry dispensing container and the service user asked to tip the medication under the tongue to avoid handling.

11.4 The speed of dissolution varies from service user to service user.

11.5 Approximate dissolution times are as follows:

11.5.1 8mg = 8 to 10 minutes

11.5.2 2mg = 5 minutes

11.5.3 0.4mg = 3 minutes

11.6 Please note that Espranor® dissolution times will be less than stated above.

11.7 Service users should be advised that increased or excessive saliva production may reduce the effectiveness of the drug and is not desirable, and that saliva should be kept in the mouth rather than swallowed during dissolution. You may also wish to inform them that the medication has a bitter taste.

11.8 The pharmacist should be satisfied that the dose has not been concealed in the mouth by talking to the service user. After the estimated dissolution time, the pharmacist must check to see that only a chalky white residue remains under the service user's tongue, before allowing the service user to leave the supervision area. Please note that diversion can occur in the following ways:

11.8.1 Whole tablets can be hidden between two fingers, or they can be spat out and reclaimed later, or they can even be dropped onto the floor and picked up on the way out, especially if there is a counter obscuring the pharmacist's view.

11.8.2 Once out of the view of the pharmacist it can be transferred to somebody else via a kiss or a syringe could be used to remove the foaming powder from under the tongue. Or the service user could suddenly rush off to the toilet, explaining that they are going to be sick.

12. Disposal of waste

12.1 Labels should be removed from containers and the container rinsed and immediately discarded. Waste should be disposed of safely and steps taken to minimise risks of infection through meticulous hygiene and vaccination of staff if required.

13. Incidents

13.1 If an incident occurs at the pharmacy involving one of the WDP Cheshire West and Chester 's service users, please ensure that details are sent to the WDP Service Manager or cwac@wdp.org.uk.

13.2 The designated pharmacist must document and communicate clinical and/or medication related incidences involving service users on the scheme to the prescribing service.

14. Additional scheme requirements

14.1 The part of the pharmacy used for provision of the service needs to afford sufficient levels of privacy and safety to service users.

14.2 The pharmacy contractor entering into the service level agreement will ensure that the equipment and facilities necessary for the provision of the service are available in the pharmacy. This includes adequate stocks to meet the anticipated

demand but stored in such a way so as to be inaccessible to customers. Storage conditions must be appropriate to the storage of medical equipment.

14.3 The pharmacy contractor has its own Standard Operating Procedure (SOP) in place for this service. In addition, the contractor also has a duty to ensure that pharmacists and staff involved in the provision of the service have read and understand the SOP for that service.

14.4 The pharmacy should maintain appropriate records to ensure effective ongoing service delivery and audit.

14.5 With the exception of bank holidays, the service will normally operate Monday to Saturday inclusive. Adjustments to the service will be made to cover those pharmacies not open on Saturdays.

14.6 All transactions involving the Supervised Consumption Programme must be conducted under the supervision of a pharmacist.

14.7 All members of staff must exercise, and be contractually obliged to exercise, strict confidentiality in all matters relating to the Supervised Consumption Programme.

14.8 All pharmacists participating in the scheme must make arrangements to ensure that they have indemnity insurance covering the provision of the service.

14.9 A representative from all pharmacies participating in the scheme must attend a yearly training session held with WDP Cheshire West and Chester Service.

15. Access, referral and discharge plans

15.1 The service is accessed by self-referral. Service users are not normally discharged from the service. Should a service user be discharged, they must be provided with information on other locations where they can access the service.

15.2 The pharmacist may refuse to supply service users who become abusive and disruptive. The Supervised Consumption Champions and WDP Cheshire West and Chester Service must be kept informed of any problems with a particular service user or group. However, due to the anonymity of the service it may be difficult to implement an outright ban.

15.3 The community pharmacists are supplied with information on specialist services and referral pathways from WDP Cheshire West and Chester Service.

16. Record-keeping

16.1 All pharmacies on the Supervised Consumption Programme are required to use PharmOutcomes, a secure web-based record-keeping and audit system. System log-ins and activation details are provided to each pharmacy by WDP Cheshire West and Chester Service.

16.2 The pharmacist is required to register all service users on PharmOutcomes before details of supervisions can be entered on the system. Service users only need to be registered once.

16.3 The service user information that needs to be entered at the point of registration is:

16.3.1 Service user name

16.3.2 Service user date of birth

16.3.3 Gender

16.3.4 Medicine type (either Methadone, Buprenorphine or Espranor®)

16.4 Recording a supervision has been designed to mimic a 14-day blue prescription and data should be entered on the day the prescription is completed. When a prescription is complete, either enter on PharmOutcomes after endorsement or at the end of that day.

16.5 The information to be included when recording a supervision is:

16.5.1 The start date of the prescription (this dictates pick-up dates as these are calculated from the start date and will change in line with start date entered)

16.5.2 The service user name (after entry of the first four letters, names that are registered will appear along with date of birth). If a name does not appear then registration has not been completed and the pharmacist should return and register the service user.

16.6 Once the start date has been chosen, each day has a drop-down box that allows data to be recorded that is relevant to that day's collection, i.e. whether doses were supervised or missed. If 'Refused supply' is chosen, the pharmacist needs to select a reason for refusal from a list of options.

16.7 There is also a free text entry box at the end of the service user record to allow the inputting of any other relevant information.

16.8 Once all the information is completed accurately and reflects the script, the data entry is saved, and the claim is recorded.

16.9 Once pharmacists and pharmacy technicians have saved data on the system they do not need to return any paperwork to process claims as this is an automated process.

16.10 All claims should be recorded within 24 hours of supply. The grace period for claims is two months and any claims recorded past this point will not be honoured.

17. Training and accreditation

17.1 Training requirements for the Designated Pharmacist and Pharmacy Staff involved in provision of service are:

17.1.1 Mandatory training is provided by WDP Cheshire West and Chester Service for the pharmacy team involved in the provision of the service. This training informs on good practice, health and safety and other issues deemed appropriate.

17.1.2 It is pharmacist's responsibility to recommend and put forward relevant staff member (s) for training as it is desirable that key members of pharmacy staff are also appropriately trained.

17.1.3 All community pharmacists providing the service should complete an appropriate distance learning pack from the Centre for Pharmacy Postgraduate Education (CPPE). The pharmacy contractor must ensure that the designated pharmacist has completed the compulsory training and is a member of General Pharmaceutical Council.

17.1.4 Compulsory training that pharmacists need to complete is as follows:

Centre for Pharmacy Postgraduate Education (CPPE) open learning packs	
Opioids	https://www.cppe.ac.uk/programmes/l/opioids-e-01/
Module 1: Substances of misuse	https://www.cppe.ac.uk/programmes/l/substance1-e-01
Module 2: Harm reduction	https://www.cppe.ac.uk/programmes/l/substance2-e-01
Module 3: Communication with patients and support networks	https://www.cppe.ac.uk/programmes/l/substance3-e-01
Module 4: Provision of services	https://www.cppe.ac.uk/programmes/l/substance4-e-01

17.1.5 If a new designated pharmacist is appointed, it is their responsibility to complete the compulsory training within one month of commencing their post. A copy of the certificate must be available for monitoring and investigation visits.

17.1.6 The designated pharmacist must read and sign the relevant SOPs for the service.

17.1.7 Pharmacists providing this service will be expected to participate in appropriate Continuing Professional Development in compliance with the criteria set out by the General Pharmaceutical Council (GPhC).

17.1.8 The Designated Pharmacist must ensure that copies of CPPE certification and updated record of training undertaken by the designated pharmacists, second pharmacists, pharmacy technicians and staff are retained at the pharmacy as required by the scheme. Certificates and training records must be available for monitoring and investigation purposes.

17.1.9 The pharmacist must satisfy the requirements of CPPE "Self- declaration of Competence for Supervised Consumption of Prescribed Medicines for

Substance Misusers (Opioids)" and complete a self- assessment of core competencies and their "Personal Declaration of Qualifications and Competence to deliver a Supervised Consumption of Prescribed Medicines service". This can be completed on PharmOutcomes.

17.1.10 If agency pharmacists are used to cover pharmacist leave, the agency pharmacists must be fully briefed on this SLA and the minimum standards and requirements for dispensing.

17.1.11 Failure to complete the compulsory training may result in removal of the pharmacy from the scheme. The designated pharmacist is responsible for notifying the Service Manager in advance if these completion or attendance dates cannot be met. An extension of up to six months to facilitate the completion of training may be given at the discretion of the Service Manager.

17.1.12 All staff are aware of the requirement to respect confidentiality of service user information. Staff must be aware not to disclose any information to the service user's family, relations, careers or any other person requesting information about the service user, without first receiving written consent from the service user. The exception to this rule is any communication with the service user's GP, prescriber, key worker or on issues relating to safeguarding children and adults.

18. Terms of contract

18.1 The duration of this contract and service level agreement will be for the period beginning from **1st January 2020 to 31st March 2024.**

18.2 In the event of termination of the service the party terminating the service will ensure a minimum of 30 days' notice of termination of the scheme is provided to service users receiving the service.

18.3 The WDP Cheshire West and Chester Service may terminate this agreement by giving notice in writing to the pharmacist at any time in the event of any of the following:

18.3.1 The pharmacist ceasing to, or threatening without good reason to cease to, carry out all or part of the agreed obligations and responsibilities as constituted at the start of this contract

18.3.2 The pharmacist being in breach of contract

18.3.3 Any other unforeseeable events that deem the scheme inoperable

18.4 The contractor may terminate this agreement by giving notice in writing to the Service Manager at WDP Cheshire West and Chester Service.

18.5 Termination of this agreement by either party, whether by expiry or early determination, shall not affect any monies owed up to the date of termination provided

that the terms and conditions of the scheme have been met and that the scheme forms have been completed and returned.

19. Disputes

19.1 In the event of a dispute regarding the provision of this service, the matter will be referred to the WDP Service Manager and then to the WDP Operations Manager.

20. Remuneration

20.1 The fee payable for the provision of a community pharmacy Supervised Consumption Programme service is a fee for each dose issued:

Payments to be made (fee per visit)	Amount
Methadone (Liquid/Tablets)	£1.54 per dose
Buprenorphine	£1.85 per dose
Espranor	£1.85 per dose
Morphine supervision	£1.85 per dose
Dexamphetamine supervision	£1.54 per dose

20.2 The fees for doses issued will be paid monthly in arrears.

20.3 All sums are exclusive of VAT, which shall be applied at the appropriate rate where applicable

21. Pharmacy queries

21.1 Please direct your queries to the Service Administrator at the relevant WDP Cheshire West and Chester Service (cwac@wdp.org.uk).

22. Contract agreement

22.1 The signatures below constitute an agreement between the parties concerned for the provision of a Supervised Consumption Programme.

23. Relevant contact details

Chester
Aqua House
51 Boughton CH3 5AF
Tel: 0300 303 4549
Email: cwac@wdp.org.uk

Ellesmere Port
Unity House
4 York Road CH65 0DB
Tel: 0300 303 4550

Northwich
The Old Council House
Church Road CW9 5PD
Tel: 0300 303 4548

Appendix 1

1. Data Protection

1.1 Definitions

Agreed Purposes: the provision of certain community-based pharmacy services, including but not limited to smoking cessation pharmacotherapy and emergency hormonal contraception.

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

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

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

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

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

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

1.3 To the extent that the Provider is acting as a Data Processor on behalf of the Authority:

1.3.1 In consideration of the Provider's provision of the goods and/or services under this Agreement, the Provider warrants that it shall and shall procure that its personnel that Process the Company's Personal Data:

(a) Process the Company's Personal Data at all times in accordance with the Company's documented instructions as set out in this Agreement, and, Annex I;
(b) Only engage other Processor(s) with the prior written authorisation of the Company;
(c) Taking into account the nature of the Processing, assist the Company by appropriate technical and organisational measures, insofar as this is possible, for the fulfilment of the Company's obligations to respond to requests for exercising the Data Subject's rights under applicable Data Protection Laws;
(d) Ensure that all the Provider personnel that Process the Company's Personal Data have committed themselves to confidentiality, and receive training in data protection;
(e) Assist the Company, to the extent the Provider is legally required to do so, to ensure its compliance with its respective obligations pursuant to applicable Privacy Laws in relation to the security of processing and the notification of Personal Data Breaches;
(f) At the Company's option, delete or return the Company's Personal Data (including any copies thereof) upon expiration or termination of this Agreement, unless Union or Member State law requires storage of the Company's Personal Data;
(g) Make available to the Company all information reasonably necessary to demonstrate the Provider's compliance with the obligations laid out herein;
(h) Allow for and contribute to audits, including inspections conducted by the Company or another auditor mandated by the Company, provided that the Company shall (i) provide no less than ten (10) business days' advance written notice to the Provider of its intention to conduct such audit; and (ii) comply with the Provider's reasonable policies and procedures for conducting such audits or inspections; and
(i) Notify the Company without undue delay (and within no more than forty-eight (48) hours) after becoming aware of a personal data breach

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

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

1.4.2 **Effect of non-compliance with Data Protection Legislation.** Each party shall comply with all the obligations imposed on a controller under the Data Protection Legislation, and any material breach of the Data Protection Legislation by one party shall, if not remedied within 30 days of written notice

from the other party, give grounds to the other party to terminate this agreement with immediate effect.

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

(a) ensure that it has all necessary notices and consents in place to enable lawful transfer of the Shared Personal Data to the Permitted Recipients for the Agreed Purposes;

(b) give full information to any data subject whose personal data may be processed under this agreement of the nature such processing. This includes giving notice that, on the termination of this agreement, personal data relating to them may be retained by or, as the case may be, transferred to one or more of the Permitted Recipients, their successors and assignees;

(c) process the Shared Personal Data only for the Agreed Purposes;

(d) not disclose or allow access to the Shared Personal Data to anyone other than the Permitted Recipients;

(e) ensure that all Permitted Recipients are subject to written contractual obligations concerning the Shared Personal Data (including obligations of confidentiality) which are no less onerous than those imposed by this agreement;

(f) ensure that it has in place appropriate technical and organisational measures to protect against unauthorised or unlawful processing of personal data and against accidental loss or destruction of, or damage to, personal data.

(g) not transfer any personal data received from the Data Discloser outside the European Economic Area (EEA).

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

(h) consult with the other party about any notices given to data subjects in relation to the Shared Personal Data;

(i) promptly inform the other party about the receipt of any data subject access request;

(j) provide the other party with reasonable assistance in complying with any data subject access request;

(k) not disclose or release any Shared Personal Data in response to a data subject access request without first consulting the other party wherever possible;

(l) assist the other party, at the cost of the other party, in responding to any request from a data subject and in ensuring compliance with its obligations under the Data Protection Legislation with respect to security, breach

notifications, impact assessments and consultations with supervisory authorities or regulators;

(m) notify the other party without undue delay on becoming aware of any breach of the Data Protection Legislation;

(n) at the written direction of the Data Discloser, delete or return Shared Personal Data and copies thereof to the Data Discloser on termination of this agreement unless required by law to store the personal data;

(o) use compatible technology for the processing of Shared Personal Data to ensure that there is no lack of accuracy resulting from personal data transfers;

(p) maintain complete and accurate records and information to demonstrate its compliance with this clause 1.4 and allow for audits by the other party or the other party's designated auditor; and

(q) provide the other party with contact details of at least one employee as point of contact and responsible manager for all issues arising out of the Data Protection Legislation, including the joint training of relevant staff, the procedures to be followed in the event of a data security breach, and the regular review of the parties' compliance with the Data Protection Legislation.

ANNEX I: PROCESSING DETAILS

This Annex I includes details relating to the Processing activities of the Provider with respect to the Company's Personal Data.

Subject matter and duration of the Processing of the Personal Data

The subject matter and duration of the Processing of the Personal Data are set out in the Agreement.

The nature and purpose of the Processing of the Personal Data

The Provider shall process Personal Data in order to provide the goods or services to the Company.

The types of the Personal Data to be Processed

Personal data processed may include, but is not limited to, the name, identification number(s), location data, online identifier(s) or one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of a Data Subject. The the Provider may also Process special categories of data which includes, but is not limited to, information relating to a Data Subject's health.

The categories of Data Subject to whom the Personal Data relates

Personal Data will be processed in relation to customers and/or staff of the Company.

The obligations and rights of the Data Controller and Data Controller Affiliates

The obligations and rights of the Data Controller are set out in the Agreement

Signature Sheet

Signed for and on behalf of Company: WDP
Signature:
Print name:
Position:
Date:
Signed for and on behalf of Contractor:
Signature:
Print name:
Position:
Date:

List of stores from which the service will be provided from:

Name of pharmacy, address, email address, telephone number, fax number: