Dated XXXXX

Central and North West London NHS Foundation Trust and XXXXXX

Agreement relating to the provision of Supervised Consumption in Pharmacies in xxxxxxxxxx

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1 DEFINITION AND INTERPRETATIONS

"Agreement"	means this Agreement together with the schedules and any appendices attached hereto or referred to herein;
"Contracts (Rights of Third Parties) Act 1999"	An act in UK law which makes provision for the enforcement of contractual terms by third parties;
Confidential Information	as defined in clause 15.1;
"Data Controller"	means the entity which alone or jointly with others determines the purposes and the means of the Processing of Personal Data;
"Data Subject"	means a natural person whose Personal Data is processed in the context of this Agreement;
"Data Protection Laws"	means all applicable laws and regulations relating to data protection, privacy and the processing of Personal Data. In the UK, the key pieces of legislation governing data protection are the UK General Data Protection Regulation (Regulation (EU) (2016/679) ('UK GDPR') and the Data Protection Act 2018 ('the Act'). The current version of the legislative framework (as amended, following the withdrawal of the UK from the European Union on 31 January 2020) has applied in the UK since 1 January 2021. In respect of electronic communications (in particular marketing activities), the Privacy and Electronic Communications (EC Directive) Regulations 2003 ('PECR') sit alongside the UK GDPR and the Act, providing a further set of specialised rules;
"Force Majeure Event"	means any event beyond the reasonable control of the Party in question to include, without limitation: (a) war including civil war (whether declared or undeclared), riot, civil commotion or armed conflict materially affecting either Party's ability to perform its obligations under this Contract; (b) acts of terrorism; (c) flood, storm or other natural disasters; (d) fire; (e) unavailability of public utilities and/or access to transport networks to the extent no diligent supplier could reasonably have planned for such unavailability as part of its business continuity planning; (f) government requisition or impoundment to the extent such requisition or impoundment does not result from any failure by the Supplier to comply with any relevant regulations, laws or procedures (including such laws or regulations relating to the payment of any duties or taxes) and subject to the Supplier having used all reasonable legal means to resist such requisition or impoundment;

	(g) compliance with any local law or governmental order, rule, regulation or direction applicable outside of England and Wales that could not have been reasonably foreseen; (h) industrial action which affects the ability of the Supplier to provide the Services, but which is not confined to the workforce of the Supplier or the workforce of any Sub-contractor of the Supplier; and a failure in the Supplier's and/or Authority's supply chain to the extent that such failure is due to any event suffered by a member of such supply chain, which would also qualify as a Force Majeure Event in accordance with this definition had it been suffered by one of the Parties.
"Freedom of Information Act"	means an Act in UK law that provides public access to information held by public authorities;
"GDPR"	means the UK GDPR the General Data Protection Regulation (Regulation (EU) 2016/679) as incorporated into UK legislation by way of the European Union (Withdrawal Agreement) Act 2020 and as amended by the Data Protection, Privacy and Electronic Communications (Amendments etc.) (EU Exit) Regulations 2019;
"Guidance"	means any applicable guidance, supplier code of conduct, direction or determination and any policies, advice or industry alerts which apply to the Services or which have been notified to the Supplier by the Purchaser or a Regulatory body;
"Intellectual Property or IPR"	as defined in clause 16.1;
"Law"	means; (i) any applicable statute or proclamation or any delegated or subordinate legislation or regulation; (ii) any enforceable EU right within the meaning of section 2(1) European Communities Act 1972; (iii) any applicable judgment of a relevant court of law which is a binding precedent in England and Wales; (iv) Guidance; and (v) any applicable code, in each case in force in England and Wales;
"NHS England"	means the body responsible for overseeing the National Health Service's foundation Trusts and NHS Trusts, as well as independent providers that provide NHS- funded care. This includes any successor organizations;
Patient Safety Incidents	means any unintended or unexpected incident which could have or did lead to harm for one or more patients receiving healthcare;
"Permitted Recipients"	means the Parties to this Agreement, the directors, officers, staff and employees of each Party, any third parties engaged to perform obligations in connection with this Agreement;

"Personal Data"	means any information relating to an identified or identifiable natural person including 'special' categories of personal data set out in Article 9(1) of the GDPR. An identifiable natural person is one who can be identified, directly or indirectly, in particular by such as a name, an identification online identifier or to one or physical, physiological, generic, or social identity of that natural person;
"Processing of Personal Data" (or "Processing/Process")	means any operation or set of operations which is performed on Personal Data or on sets of Personal Data, whether or not by automated means, such as collection, recording, organization, structuring, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, restriction, erasure or destruction;
"Records Management NHS Code of Practice "	means a set of standards for the management of records for organisations who work within, or under contract to the NHS in England;
"Regulatory Body"	means a body set up to exercise a regulatory function. This involves imposing requirements, conditions or restrictions, setting the standard for activities, and obtaining compliance;
"Services"	means a supervised consumption service as set out in Schedule 1 Specification;
"Service User"	a patient or service user for whom the Purchaser has a responsibility for and who receives Services under this Agreement;
"TUPE"	means the Transfer of Undertakings (Protection of Employment) Regulations 2006 (2006/246) and/or any other regulations enacted for the purpose of implementing the Acquired Rights Directive (77/187/EEC, as amended by Directive 98/50 EC and consolidated in 2001/23/EC) into English law;
Working Days	means any day other than a Saturday, Sunday or bank or other public holiday in England;

THIS AGREEMENT is made on the day of 2025

BETWEEN

a. **Central & North West London NHS Foundation Trust,** of 350 Euston Rd, Regents Place, London, NW1 3AX (the "**Purchaser" or "CNWL"**)

And

b. Xxxxxxxxx (the "**Provider**").

Each a "Party" and together the "Parties".

BACKGROUND

(A) The Provider is a provider of health care services.

(B) The Purchaser wishes to engage the Provider to provide a supervised consumption service to Service Users in xxxxxxxx who are prescribed Opioid Substitution Treatments (OST) and other medication where defined in the specification and will encompass supervised support and advice to Service Users in a safe environment.

(C) The Provider and the Purchaser have agreed to enter into this Agreement for the provision of these Services.

2. CONTRACT PERIOD

2.1 This Agreement shall commence on the xxxxx (the "Commencement Date") and shall (subject to the other provisions of this Agreement) continue until 31st March 2027 (the "Expiry Date") unless terminated in writing by either Party in accordance with clause 25 or extended in accordance with clause 2.2

2.2 The Purchaser, with written Agreement from the Provider, may also agree to extend this Agreement by twelve (12) months up to three (3) times (e.g. maximum expiry date of 31st March 2030) on terms and conditions agreed at the time.

3. SERVICES

3.1 Subject to the terms of this Agreement, the Purchaser agrees to purchase, and the Provider agrees to provide the Services in accordance with:

3.1.1 the terms of this Agreement, including the specification in Schedule 1 Specification.

3.2 The Provider shall comply with the Purchasers policies; current copies of which shall be provided to the Provider, on receipt of a written request, if relevant and appropriate to the Services, before the Commencement Date.

3.3 The Provider will inform the Purchaser as soon as possible of any actual or potential problems concerning the Services' provision and any instances that may preclude the Provider from meeting its contractual obligations under this Agreement.

4. CHARGES AND PAYMENT

4.1 The Purchaser shall pay the Provider for the provision of the Services to XXXXXX residents in accordance with the prices detailed in Schedule 2 Charges and Payment.

4.2 The fees set out in Schedule 2 Charges and Payment are exclusive of any applicable Value Added Tax. Value Added Tax will be charged at the prevailing rate and is payable by the Purchaser following the receipt of a VAT invoice.

5. STAFF

5.1 The Provider shall assign to the Services at all times sufficient staff as are required to carry out the Services in accordance with this Agreement, who are sufficiently and adequately qualified and trained to provide the Services and who have the skills, competence and expertise necessary and appropriate for the proper performance of the Services.

5.2 The Provider shall ensure that all staff involved in the provision of the Services:

5.2.1 receive proper and sufficient training and instruction in accordance with standards of their relevant professional body, if any, in the execution of their duties; and

5.2.2 the Provider shall provide evidence of compliance with this clause to the Purchaser upon reasonable request.

5.3 The Provider shall ensure that the staff engaged in the provision of the Services are appropriately managed to perform their required duties in accordance with the specification in Schedule 1 Specification.

5.4 The Provider shall ensure its staff have a means of identification which shall be worn and kept visible at all times whilst providing the Services.

5.5 Before the Provider engages or employs any person in the provision of the Services, or in any activity related to, or connected with, the provision of Services, the Provider, at its own cost, shall without limitation, comply with the following guidance as amended from time to time:

5.5.1 the Disclosure and Barring Service (DBS).

6. EQUIPMENT

6.1 Not Used.

7. PREMISES AND FACILITIES

7.1. Not Used.

8. NON-SOLICITATION

8.1 During the term of the Agreement and for six (6) months following its expiry or termination, neither Party shall solicit any staff employed or engaged by the other Party without the other Party's prior written consent or where the employee is hired as a result of a general recruitment campaign for a particular role.

9. THE PURCHASER'S AUTHORISED OFFICER

9.1 The Purchaser will nominate an employee to be the Purchaser's Authorised Officer. Any notice, information or communication given or made by or to the Purchaser's Authorised Officer or their nominated deputy shall be deemed to have been given or made by or to the Purchaser.

The Purchasers Authorised Officer will be:
Name:
Position:
Contact details:

10. THE PROVIDER'S AUTHORISED OFFICER

10.1 The Provider will nominate an employee to be the Provider's Authorised Officer, and the Provider's Authorised Officer will be empowered to deal with the day-to-day issues associated with this Agreement.

The Providers Authorised Officer will be:
Name:
Position:
Contact details:

10.2 Any notice must be agreed in accordance with clause 29, any information or communication given or made by or to the Provider's Authorised Officer or nominated deputy shall be deemed to have been given or made by or to the Provider.

11. RECORDS

11.1 The Provider shall keep the following records in relation to the Services:

11.1.1 details of any complaints and action taken in relation to them of whatever nature regarding the provision of the Services; and

11.1.2 details of any Patient Safety Incidents as set out in clause 14 arising out of or in the course of the provision of the Services.

11.2 Copies of all records specified in Clause 11.1 shall be:

11.2.1 provided to the Purchaser's Authorised Officer, and shall form the basis of the contract meetings to be held in accordance with Clause 12;

11.2.2 kept by the Provider in accordance with the Records Management NHS Code of Practice.

11.3 Information Governance requirement;

11.3.1 where the Provider is supplying the Information Technology (IT) equipment and IT support the Provider shall achieve a minimum level 2 performance against all requirements in the NHS Data Security and Protection toolkit. Where the Provider has not achieved level 2 performance by the Commencement Date, the Purchaser may, in its sole discretion, agree a plan with the Provider to enable the Provider to achieve level 2 performance within a reasonable time.

11.3.2 where the Purchaser is supplying the IT equipment and IT Support the Provider

shall achieve a minimum level 2 performance against all requirements in the NHS Data Security and Protection Toolkit. Where the Provider has not achieved level 2 performance by the Commencement Date, the Purchaser may, in its sole discretion, agree a plan with the Provider to enable the Provider to achieve level 2 performance within a reasonable time.

12. MEETINGS

12.1 The Provider's Authorised Officer and the Purchaser's Authorised Officer shall hold meetings at times and places to be agreed between the Parties when required (**"Contract Meetings"**).

12.2 The Contract Meetings shall be held at least once every six (6) months with further meetings to be held as deemed necessary by the Agreement of the Parties.

12.3 In the event that urgent issues arise between the scheduled Contract Meetings, exceptional Contract Meetings may be convened by either Party upon written request to the other Party.

12.4 At each Contract Meeting, the attendees shall discuss the performance of the Parties' respective duties and obligations under this Agreement, the standard of the Services, the monitoring of the Services, any suggested improvements, variations, exclusions or reductions to the Services and the performance of this Agreement generally.

13. MONITORING

13.1 In order to ensure that the quantity and quality of the Services are adequately monitored, the Parties shall comply with any monitoring provisions set out in Schedule 1 Specification.

13.2 If at any time, the Purchaser is unhappy with the Services and/or the information and data provided by the Provider, it shall be entitled to call a Contract Meeting in accordance with Clause 12.3.

14. PATIENT SAFETY INCIDENTS

14.1 The Provider shall, in accordance with the patient safety and incident response policy and procedure in Schedule 4 Policies, make the Purchaser immediately aware of any Patient Safety Incident that directly concerns a Service User and send the Purchaser upon request a summary of any notification it gives to a relevant Regulatory Body, subject to any data protection requirements.

14.2 The Purchaser shall have complete discretion to use the information provided by the Provider in any report which they make to a relevant Regulatory Body in connection with such Patient Safety Incidents, or in relation to the prevention of Patient Safety Incidents.

14.3 The Provider in each case shall be notified of the information disclosed, and the body to which the Purchaser has disclosed it.

14.4 The Provider shall comply in all respects with:

14.4.1 the procedures relating to Patient Safety Incidents; and

14.4.2 the procedures for implementing and sharing lessons learned in relation to Patient Safety Incidents, that are agreed between the Provider and the Purchaser.

14.5 The Provider has a duty of candour to inform a Service User or their family/carer of a suspected or

actual Patient Safety Incident that has occurred within at most four (4) Working Days of the incident being reported to local systems and shall incorporate this into any procedures agreed between the Parties.

15. CONFIDENTIALITY

15.1 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.

15.2 The restrictions in clause 15.1 shall not apply to any Confidential Information which:

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

15.2.2 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;

15.2.3 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

15.2.4 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.

15.3 Each Party shall, if so requested by the other Party following termination of this Agreement, deliver up to the other Party or destroy all documents and (save to the extent that the same shall have been incorporated into the formal records of that Party) other material in its possession or control which include or incorporate any Confidential Information of the other Party save that one copy of the Confidential Information may be kept by the legal department of each Party for audit purposes. All such incorporated or retained Confidential Information shall remain subject to the obligations set out in the preceding provisions of this clause 15.

16. INTELLECTUAL PROPERTY

16.1 For the purpose of this clause **("Intellectual Property")** includes any copyright, design rights, patents, inventions, logos, business names, service marks and trademarks, internet domain names, moral rights, rights in databases, data, source codes, reports, drawings, specifications, know how, business methods, trade secrets, semi-conductor rights, topography rights, whether registered or unregistered, rights in the nature of unfair competition and the right to sue for passing off, applications for registration, and the right to apply for registration, for any of these rights, and

all other intellectual property rights and equivalent or similar forms of protection existing anywhere in the world.

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16.2 Except as set out expressly in this Agreement no Party shall acquire the Intellectual Property Rights ("**IPR**") of any other Party.

16.3 The Provider and the Purchaser now grant the other Party a fully paid up non-exclusive license to use respective IPR for the duration of this Agreement for the purposes of the exercise of their functions and obtaining the full benefit of the Services which shall include the dissemination of best practice within the NHS.

16.4 The Provider shall disclose all documents and information concerning the development of best practice IPR, in relation to the Services, to the Purchaser and shall grant the Purchaser a fully paid up non-exclusive perpetual licence to use this best practice IPR solely for the purpose of teaching, training and research within their own organisations.

17. DATA PROTECTION AND FREEDOM OF INFORMATION

17.1 The Parties agree that in relation to:

17.1.1 Personal Data processed by the Provider in providing Services under this Agreement (for example, patient details, medical history and treatment details), the Provider shall be the sole Data Controller; and

17.1.2 Personal Data, the processing of which is required by the Purchaser for the purposes of quality assurance, performance management and contract management, the Purchaser and the Provider will be independent Data Controllers;

together the "**Agreed Purpose**".

17.2 Schedule 4 sets out the categories of Data Subjects, types of Personal Data, Processing operations (including scope, nature and purpose of processing) and the duration of processing.

17.3 Each Party shall comply with all the obligations imposed on a Data Controller under the Data Protection Laws in relation to all Personal Data that is processed by it in the course of performing its obligations under this Agreement.

17.4 Any material breach of the Data Protection Laws by one Party shall, if not remedied within fourteen (14) days of written notice from the other Party, gives grounds to the other Party to terminate this Agreement with immediate effect.

17.5 In relation to the Processing of any Personal Data, each Party shall:

17.5.1 ensure that it has all necessary notices and consents in place to enable lawful sharing of Personal Data to the Permitted Recipients for the Agreed Purpose;

17.5.2 give full information to any Data Subject whose Personal Data may be processed under this Agreement of the nature of such processing;

17.5.3 process the Personal Data only for the Agreed Purpose;

17.5.4 not disclose or allow access to the Personal Data to anyone other than the Permitted Recipients;

17.5.5 ensure that all Permitted Recipients are reliable and have had sufficient training pertinent to

the care and handling of Personal Data;

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

17.5.7 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 in accordance with Article 32 of the GDPR;

17.5.8 not transfer any Personal Data outside the European Economic Area unless the transferor ensures that (i) the transfer is to a country approved by the European Commission as providing adequate protection pursuant to Article 45 of the GDPR; (ii) there are appropriate safeguards in place pursuant to Article 46 of the GDPR; or (iii) one of the derogations for specific situations in Article 49 of the GDPR applies to the transfer; and

17.5.9 assist the other Party (at its own cost) in responding to any request from a Data Subject and in ensuring its compliance with all applicable requirements and obligations under the Data Protection Laws with respect to security, breach notifications, impact assessments and consultations with supervisory authorities or the UK's Information Commisioner's Office.

17.7 Each Party shall notify the other Party without undue delay on becoming aware of any Personal Data breach under this Agreement.

17.8 The Parties acknowledge their respective duties under the Data Protection Laws and the Freedom of Information Act and shall give all reasonable assistance to each other where appropriate or necessary to comply with such duties.

18. COUNTER FRAUD AND SECURITY

18.1 The Parties shall comply with NHS Counter Fraud Authority Standards and NHS Security Management Standards

19. VARIATIONS

19.1 No amendment or variation to the terms of the Agreement shall be valid unless agreed in writing between the Parties.

20. DISPUTE RESOLUTION PROCEDURE

20.1 In the event of a dispute between the Parties arising out of this Agreement, either Party may serve on the other written notice of the dispute, setting out full details of the dispute.

20.2 The Provider's Authorised Officer and the Purchaser's Authorised Officer shall meet in good faith as soon as possible and in any event within seven (7) Working Days of the notice of the dispute being served, at an ad-hoc Contract Meeting convened for the purpose of resolving the dispute.

20.3 If the dispute remains unresolved after the meeting has taken place, the Provider's Authorised Officer and the Purchaser's Authorised Officer shall, as soon as is practical in the circumstances, arrange a meeting between the relevant executives or directors in relation to the Services in an attempt to resolve the dispute.

20.4 If the dispute still remains unresolved after the executives or directors have met then the Parties will attempt to settle such dispute by mediation in accordance with the Centre for Effective Dispute Resolution (CEDR) model mediation procedure or any other model

mediation procedure as agreed by the Parties. To initiate a mediation, the Parties may give notice in writing (a **"Mediation Notice"**) to the other requesting mediation of the dispute.

21. **MITIGATION**

21.1 Each Party shall at all times take reasonable steps to minimise and mitigate any loss for which the relevant Party is entitled to bring a claim against any other pursuant to this Agreement.

22. **COMPLAINTS**

22.1 The Provider shall maintain a complaints procedure compliant with all Laws applicable to it and shall appoint a person responsible for the day to day operation of the complaint's procedure, and shall provide the Purchaser with such details relating to that complaints procedure immediately following the Commencement Date and whenever the procedure is updated by the Provider.

22.2 All complaints received by the Provider in relation to the provision of the Services shall be notified to the Purchaser as soon as reasonably practicable but in any event within five (5) Working Days of receipt.

23. **LIABILITY AND INDEMNITY**

23.1 Neither Party limits its liability for:

23.1.1 death or personal injury caused by its negligence or that of its employees, agents or subcontractors as applicable;

23.1.2 fraud and fraudulent misrepresentation; and

23.1.3 any other liability which cannot legally be limited.

23.2 Subject to clause 23.1, the total aggregate liability of the Provider and its respective affiliates to the Purchaser whether in contract, tort (including negligence), breach of statutory duty or otherwise arising out of or in connection with this Agreement will be a maximum of the total fees paid or payable under this Agreement.

23.3 Subject to clause 23.1, neither Party will be liable to the other Party for any indirect or consequential loss or damage including, without limitation, any indirect loss of business or profits in each case whether arising from negligence, breach of contract or otherwise.

24. **INSURANCE**

24.1 The Provider shall maintain in force (and/or procure that its sub-providers shall maintain in force) at its own cost appropriate indemnity arrangements (in accordance with clause 23.1.1) in respect of:

- employers' liability;
- clinical negligence where the provision or non-provision of the Services (or any other services under this Agreement) may result in a clinical negligence claim;

- public liability; and
- professional negligence.

25. TERMINATION

Termination upon expiry

25.1 This Agreement shall terminate upon the Expiry Date unless terminated earlier in accordance with clauses 25.2 to 25.3 of this Agreement.

Voluntary Termination

25.2 Either Party may terminate this Agreement at any time by giving no less than two (2) months' written notice to the other Party.

Termination on Default

25.3 Without prejudice to any other right or remedy it may possess the Purchaser shall be entitled upon the happening of any of the following events to immediately terminate this Agreement by written notice to the Provider:

25.3.1 the Provider ceases to carry on its business or substantially the whole of its business; or

25.3.2 the Provider is in persistent or repetitive breach of the regulatory compliance standards issued by a Regulatory Body or, Laws or, if applicable, NHS England; or

25.3.3 fails to comply with any applicable Laws; or

25.3.4 the Provider fails to notify the Purchaser as soon as possible, and in any event within five (5) Working Days, following a Provider change of control if it has a material impact on the provision of Service.

26. CONSEQUENCES OF TERMINATION AND EXPIRY

26.1 Upon expiry of this Agreement or on earlier termination, and without prejudice to any other provisions of the Agreement the Parties shall co-operate in achieving an orderly and efficient handover of the Services to the Purchaser or to any replacement provider.

27. TRANSFER OF UNDERTAKINGS (PROTECTION OF EMPLOYMENT) (TUPE)

27.1 The Parties agree that at the commencement of the provision of Services by the Provider, TUPE shall not apply so as to transfer the employment of any employees of the Purchaser or a third party to the Provider.

28. FORCE MAJEURE

28.1 Neither Party shall be in breach of this Agreement if there is a total or partial failure of performance by it of its duties and obligations under this Agreement occasioned by any Force Majeure Event.

29. NOTICES

29.1 Any notice or other document to be given under this Agreement shall be in writing and shall be deemed to have been duly given if sent to email addresses specified by the Purchaser's Authorised Officer and Provider's Authorised Officer.

30. RIGHTS OF THIRD PARTIES

30.1 Any person who is not a Party to this Agreement shall have no right under the Contracts (Rights of Third Parties) Act 1999 or otherwise to enforce any of the terms of this Agreement.

31. WAIVER

31.1 Neither Party shall be deemed to have waived the performance or breach of any provision of this Agreement unless it does so expressly in writing. No such waiver shall be deemed to be a waiver of any other past or future default or breach of such provision or any other provision of this Agreement.

31.2 No failure or delay by a Party in exercising any right under this Agreement shall be deemed to be a waiver of, or to otherwise prejudice, the exercise of that right.

32. SEVERABILITY

32.1 If any term of this Agreement is or becomes illegal, invalid or unenforceable in any jurisdiction, that will not affect the legality, validity or enforceability in that jurisdiction of any other term of this Agreement; or the legality, validity or enforceability in other jurisdictions of that or any other provision of this Agreement.

33. NO PARTNERSHIP

33.1 This Agreement does not create a partnership between the Parties and neither Party shall have any authority to act in the name or on behalf of, or otherwise bind, the other Party to any obligation.

34. CONFLICT BETWEEN PROVISIONS

If there is any conflict or inconsistency between any provision in the clauses of this Agreement and any provision in any Schedule to this Agreement, the provision of this Agreement shall take precedence to the extent of any conflict or inconsistency only.

35. ENTIRE AGREEMENT

35.1 This Agreement represents the entire Agreement between the Parties relating to its subject matter and supersedes and extinguishes any prior written or oral agreement between them concerning that subject matter notwithstanding the terms of any such prior agreement.

35.2 Each Party acknowledges that in entering into this Agreement, it has not relied on any representation, warranty or other assurance.

36. GOVERNING LAW AND JURISDICTION

36.1 This Agreement and any issues, disputes or claims arising out of or in connection with it (whether contractual or non-contractual in nature) shall be governed by, and construed in accordance with, the laws of England and Wales.

36.2 All disputes and claims arising out of or relating to this Agreement shall be subject to the exclusive jurisdiction of the courts of England and Wales to which the Parties irrevocably submit.

EXECUTED by **CENTRAL AND NORTH WEST LONDON NHS FOUNDATION TRUST:**

Signed (Authorised Officer) ……

Name/Position ……

Date ……

EXECUTED by **the Provider**:

Signed (Authorised Officer) ……

Name/Position ……..

Date ……..

SCHEDULE 1 SPECIFICATION

Supervised Consumption of Opioid Substitution Treatments and other medication - Pharmacy Specification

1. Introduction

This document sets out a Service Specification for a Supervised Consumption Service to Service Users who are prescribed Opioid Substitution Treatments (OST) and other medication where defined in the specification 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.

Pharmacists and Provider employees play a key role in supporting Service Users in complying with their prescribed regime, therefore reducing the incidents of accidental deaths through overdose.

For the purpose of the Agreement '**Supervised Consumption Services'** is defined as the observed consumption, by a Providers Pharmacist or their suitably trained pharmacy technician, of a Service User who is prescribed OST and/or other medication (where defined in the specification) where supervision has been requested by the Purchaser.

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) by the Purchasers local addiction service.

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 Provider 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 contact with a healthcare professional (the Providers 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.
- Liaising with the Purchaser (prescriber) or named recovery worker as appropriate, if the Service User appears intoxicated or when the Service User has missed doses[1], 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

[1] Please see missed dose section (4f)

There is a multidisciplinary approach to prescribing (including GP shared care prescribing) which is carried out in line with the recommendations of *Drug misuse and dependence guidelines on clinical management* (DH 2017[2]) and other central Guidance and includes the Providers pharmacist. The Providers pharmacists' 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.

In terms of the Services:

a) medicines for the management of opioid dependence where supervised consumption is required include:
   - Methadone 1mg/1ml oral solution standard (DTF) and sugar free (generic and trade name e.g. Physeptone®)
   - Buprenorphine 2mg and 8mg Oral Lyophilisates (generic and trade name Espranor®)
   - Buprenorphine 400microgram, 2mg and 8mg sublingual tablets (generic and trade name Subutex®)
   - Buprenorphine/Naloxone 2mg/0.5mg and 8mg/2mg tablets (generic and 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 the Services.

b) the Providers pharmacist or a suitably trained member of the Providers staff[3] 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 placed 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.

   - 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 manufacturer does not encourage this off-licence process and, if used, the Service User should be aware this is off-licence use and a Provider Standard Operating Procedure (SOP) should be in place. The Providers pharmacists and/or Provider staff are also advised to check this is covered within their Professional Indemnity Insurance.

c) Provider staff providing the Services will provide a user friendly, non-judgmental, Service User-centred and confidential service.

d) the Providers staff should ensure that the Service takes place in a private or quiet area of the pharmacy identified as safe to Provider staff and agreeable to the Service User.

e) Provider staff should make available to Service Users information about their medicines[4] and appropriate health promotion materials.

f) the Providers staff will promote safer practice to the Service User. As deemed appropriate this can include advice on sexual health and STIs, BBV transmission and Hepatitis B immunisation. Harm

[2] https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/673978/clinical_guidelines_2017.pdf

[3] As set out under 5 Accreditation

[4] Service User leaflets can be downloaded from the website www.patient.co.uk for individual OST medication.

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 local addiction services for supply of naloxone and further training and support in how to reduce the risk of overdose and DRDs.

g) Provider staff providing the Services will have SOPs in place for their individual premises. Examples of SOP's can be found on the National Pharmacy Association website.

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

i) Provider staff should abide by local arrangements for clinical governance. Any incident involving CDs within the scope of this Agreement should be reported to the Purchaser and the Local Controlled Drugs Accountable Officer (CDAO) for NHS England within three (3) Working Days.

j) the Provider will receive prompt payment for the Services provided. Please refer to Schedule 2 Contract Prices of the Agreement for payment details.

k) Providers will **not** be paid by the Purchaser for Service Users accessing the Services who come from outside the Purchasers commissioned area. Providers are advised to contact the service issuing the prescription to confirm payment arrangements for requests outside of the commissioned area.

l) **Safeguarding (adult and children)**: The Provider is already required to provide assurances concerning safeguarding vulnerable groups as part of their essential service's clinical governance requirements for community providers [5]. 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". The Providers staff that provide pharmaceutical services to children and vulnerable adults should be aware of safeguarding Guidance and the local safeguarding arrangements. The College of Provider 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[6].

The Purchaser will not be offering specific safeguarding training for this Service (unless agreed locally between the local commissioner and CNWL) but will be monitoring Provider compliance against the essential service and quality payment standards.

4. Service Description - summary

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 Provider 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. three (3) way agreements, **may** be set up (examples available upon request from the Purchaser) between the Purchaser (prescriber), Provider and Service User 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 pharmacist if the user does not comply with such agreements. This will

[5] PSNC & NHS Employers (2012) Clinical governance requirements for community pharmacy. Available at http://psnc.org.uk/wp-content/uploads/2013/07/Clinical_Governance_guidance_updated_final.pdf and as may be amended from time to time

[6] CPPE (2017) Safeguarding. Available at https://www.cppe.ac.uk/services/safeguarding and as may be amended from time to time

be agreed locally prior to the Service being delivered. The Provider can use their own terms of agreement but this must be approved through the local clinical governance arrangements or, as a minimum, between the Provider and the local clinical lead prior to their use. On certain occasions it may be decided that certain Service Users need a three (3) way agreement in place due to previous behaviour concerns. Individualised three (3) way agreements can be implemented in these circumstances in areas where wider three (3) way agreements are not used, if agreed between the Provider and prescriber/Purchaser/recovery worker.

d) Service Users are prepared for the provision of OST medications by the Purchaser and this should be reinforced by the Providers staff. This includes (but is not exclusive to) 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 (especially after three (3) days)
   v. Drug interactions
   vi. An explanation of supervised consumption and where and how this will occur and;
   vii. Opening and closing times of the Provider.

e) The Providers pharmacies must offer the Service throughout their opening times. Provider staff can discuss the best times for Service Users to attend, but at no time should a dose be refused to a Service User if they attend during the opening times of the Provider.

f) **Missed doses:**
Providers should notify the Purchaser when a Service User has:

Event	Provider Action	Provider to notify the purchaser within
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 Purchaser (prescriber) and sought their advice. 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.	2 Working Days of the event
Missed three (3) or more doses (equivalent to three (3) consecutive days of OST)	Please **do not dispense** the Service User's next dose until you have contacted the Purchaser (prescriber). The Purchaser 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 three (3) consecutive	1 Working Day of the event

	days have been missed is highlighted in the Royal Pharmaceutical Society's Medicines, Ethics and Practice[7] and should be adhered to. If the Purchaser confirms the prescription can continue then the current prescription, where the three (3) doses has been missed, **can** be used as long **as the Purchaser provides written confirmation e.g. via email.**	
Missed four (4) non-consecutive daily doses over a fourteen (14) day period or missing doses in a regular pattern	Counsel the Service User about the risk of missing doses and try to find out why they have missed their collections. This information must be shared with the Purchaser (prescriber) as part of the notification of such an event.	2 Working Days after the fourteen (14) day period
Has a certain pattern of missed doses e.g. every Monday	Counsel service user about risk of missing doses and try to find out why they have missed their collections. This information must be shared with the Purchaser (prescriber) as part of the notification of such an event.	2 Working Days of a pattern being identified

g) Information sharing – screening, risk assessment and referral. Provider staff should:
- feedback any appropriate information to the Purchaser with the agreement of the Service User, in accordance with their professional code of practice and local shared care agreements. This includes any concerns around the welfare of a child or adult.
- 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 Providers pharmacist has concerns about the Service Users' safety.
- signpost and/or refer Service Users to appropriate services in accordance with the essential service standard 5 (signposting)[8] for community pharmacies and any local agreements.

h) Providers pharmacists legal and professional responsibilities. Provider 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 OST 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.

[7] RPS Medicines, Ethics and Practice. The professional guide for pharmacists as amended from time to time

[8] Community Pharmacy England signposting available at https://cpe.org.uk/national-pharmacy-services/essential-services/signposting/

- co-operate with local Police CD liaison officers, the General Pharmaceutical Council (GPhC), local public health representatives, 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. Provider staff involved in the provision of this Service should have relevant knowledge and be appropriately trained in the operation of the Service to a standard agreed with the Purchaser. Training in the operation of the Service is provided by the Purchaser in the form of guidance, protocols and local workshops (at least once in an eighteen (18) month period). Delivery of these support services and training will be determined locally between the Purchaser, Local Pharmaceutical Committee (LPC), local commissioners and any other organisation or group that are considered to be a valid stakeholder in the Service's delivery e.g. Service User group.

b. The Providers Designated Pharmacist at the Providers premises (but all pharmacists should be encouraged to complete) must complete a Declaration of Competence (DoC) for "Supervised Consumption of Prescribed Medicines Service"[9] and complete the Certificate in Management of Drug Misuse Part 1 and Naloxone Saves Lives e-learning available from the CPPE website within 3 months of the Commencement Date. If the Provider does not have a full-time Designated Pharmacist, then at least 2 pharmacists who cover a minimum of 80% of the Providers opening hours should complete the DoC and CPPE programme. The DoC needs to be reviewed every two years by the pharmacists who have completed them.

c. Provider staff involved in the provision of the Service are aware of and operate within the local protocols agreed with the Purchaser. The pharmacy SOP must be based on these local protocols and must be regularly reviewed (see section 7b for further details)

d. Provider pharmacists who are new to the area and providing the Services will be allowed three (3) months to complete the CPPE training and meet the requirements of the Agreement.

e. The Provider will be invited by the Purchaser to attend at least one (1) meeting within an eighteen (18) month period to promote Service development and update the knowledge of Provider staff. This includes an awareness raising session about 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 Purchaser would encourage engagement from the Provider to support both service development and as a CPD update for the Provider's Staff.

6. Support

To ensure the effective management and development of the Service (including appropriate support for Provider staff) the Purchaser will put in place the following staffing structure:

Role	Responsibilities	Name	Contact details (e-mail/telephone)
Service Lead	to oversee the Agreement, performance monitoring and quality assurance		
Service Administrator	to validate claims and support the process of		

[9] https://www.cppe.ac.uk/services/docs/supervised%20consumption%20of%20prescribed%20medicines.pdf

	payments		
Single Point of contact	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 Provider referrals and guidance		

Support will also be provided through the Purchasers IT partners as set out below, who will provide the IT systems for processing Provider claims:

Borough/area	IT Partner/system
Hillingdon	PharmaOutcomes
Ealing	Neo 360
Brent	PharmaOutcomes
Hounslow	Neo 360
Milton Keynes	Neo 360

7. Performance and Quality Monitoring

a) The Provider must maintain accurate records on PharmaOutcomes/Neo 360 to ensure effective on-going Service delivery, audit and payment.

b) The Provider must review its SOPs and the referral pathways for the Service on a two-year cycle ***or*** when a significant change to the Services ***or*** a Patient Safety Incident dictates a need to review the SOP earlier.

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

d) The Provider will participate in any organised audit of service provision and co-operate with locally agreed or public health led assessments of Service User experience.

e) Periodic *Ad hoc* mystery shoppers will sample the quality of advice from the Service and inform training needs and Service development. Results of mystery shopping will be presented to the Provider, LPCs and local substance misuse/public health clinical governance forums when appropriate.

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

- **Service activity:** Volume of Service provision as measured by data in the local Provider 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 (in line with section 4f of this specification)
    b. DATIX review of Patient Safety Incidents (DATIX is the incident reporting system used by the Purchaser)
    c. review of SOPs and referral pathways on an annual basis

    d. maintaining a list of Provider staff attending local training events and pharmacist CPD relevant to the delivery of the Services e.g. completion of DOC's
    e. review of safeguarding training for Provider staff under the essential service arrangements and quality payments – safeguarding standards.
    f. a review of the health promotion material available for Service Users and how the Provider has promoted health promotion relevant to the Service User group
- **Service User experience:** Service User views on their experiences and satisfaction levels with the Service as measured through the Purchaser's Service User involvement mechanisms.

The 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. If the Provider fails to meet the quality standards they will be asked to work with the Purchaser on an improvement programme and monitored accordingly. If the Provider continues not to meet the quality indicators and standards **or** is not financially viable they **may** be given notice of termination (see Section 25: Termination).

SCHEDULE 2: CHARGES AND PAYMENT

PharmaOutcomes/Neo 360 has been commissioned by the Purchaser to act as an agent for processing claims associated with the delivery of this Service. Under this Agreement:

- PharmaOutcomes/Neo 360 is funded to provide access to Providers commissioned to provide the Services and process service payments on behalf of the Purchaser.

- Monthly claims (to be input by the Provider no later than the 6th calendar day of the next month for the previous months activity) are completed via the PharmaOutcomes/Neo 360 system. Failure to provide this information may result in non-payment, whilst consistent failure to do so over three (3) consecutive months may result in termination of the Agreement by the Purchaser (see Section 25: Termination).

Charges

Item	Cost (£)
Per administration of OST medication	

Payment Requirements:

The Provider will provide the Purchaser with the following information:

- **Name of their pharmacy**
- **Address of the pharmacy**
- **Bank details**
- **Contact name**

Payments to the Provider will be made via the Bank Automated Credit (BAC's) system. It is important to note that such payments are subject to successful validation of the claims data by the Purchaser

SCHEDULE 3: POLICIES

Patient_Safety_Incid
ent_Response_Policy

SCHEDULE 4: MANAGEMENT OF DATA

Management of data

Data subjects
The Personal Data processed by the Provider and/or the Purchaser concerns:

- recipients of the Service

Types of Personal Data
Personal Data will be Processed by the Provider under Article 6(1)(e) and Article 9(2)(h) of the GDPR and will include:

- data which identifies the recipients of the Service - such as name, contact details (which may include address, email address or phone number) and date of birth/age;
- data relating to the health of the recipient and details of any test or treatment provided by the Provider (special category data);
- financial data of the Parties in order to invoice and receive payment for Services.

Processing operations
Personal Data will be processed by the Provider and/or the Purchaser in order for:

- The Provider to provide the Services under this Agreement;
- The Provider to maintain records required for provision of the Service;
- The Provider to invoice and receive payment from the Purchaser; and
- quality assurance, performance management and contract management by the Purchaser.

Duration of Processing
The Personal Data processed by the Provider and/or the Purchaser will be subject to the above processing operations for the duration of the Agreement and subsequently where such retention is required by any applicable Law or for actual or prospective legal claims or as otherwise set out by either Party.