

Service Level Agreement and Service Specification for Pharmacy Supervised Consumption

Location:

Service Name	We Are With You in Rotherham
Commissioner(s)	We Are With You on behalf of Rotherham Metropolitan Borough Council
Provider Lead	We Are With You
Date Valid From	01/04/2023
Date Review Due	30/09/2023

THIS AGREEMENT is made on 1/4/2023

BETWEEN:

(1) **WE ARE WITH YOU**, a private company limited by guarantee, incorporated in England and Wales with company number 02580377, and a charity registered in England with registration number 1001957 and in Scotland with registration number SCO40009, whose registered office is at Part Lower Ground Floor, Gate House, St. John's Square, London EC1M 4DH ("**With You**"); and

(2) The entity whose details are included in clause 18, hereinafter referred to as the "**Pharmacy**"

each a "**Party**" and together the "**Parties**".

WHEREAS:

- i. With You wish to enter into a Service Level Agreement (the "**Agreement**") with the Pharmacy under which a Supervised Consumption Service (the "**Service**") will be provided by the Pharmacy, in line with the provisions specified in Schedule 1 (Service Level Agreement) of this Agreement.
- ii. The Pharmacy will receive payment (the "**Fees**") from With You for the provision of the Service as specified in Schedule 2 (Funding, Payment of Fees and Default) of this Agreement.
- iii. The Service will be provided to service users who are requiring supervised consumption of their medication for managing their substance misuse.
- iv. The specifications detailed in Schedule 4 (Service Specification) of this Agreement, as well as any other provisions in this Agreement, will be subject to continued review and amendment in consultation between With You and the Pharmacy, as and when required. The Parties shall be expected to cooperate fully with any of these reviews. All amendments to this Agreement shall be evidenced in writing and signed by both Parties.

1. COMMENCEMENT AND DURATION

1.1. This Agreement shall commence on (or shall be deemed to have commenced on) the date of this Agreement (the "**Commencement Date**") and shall, subject to the other provisions of this Agreement, continue indefinitely unless terminated in writing by either Party in accordance with clause 10.

1.2. The Parties may agree to review this Agreement from time to time, as specified in section iv. above.

2. FEES

2.1. With You shall pay the Fees in accordance with the invoicing and payment provisions set out in Schedule 2 (Funding, Payment of Fees and Default).

3. LIABILITIES

3.1. Neither Party limits its liability for: (i) death or personal injury caused by its negligence or that of its employees, agents or subcontractors as applicable; (ii) fraud and fraudulent misrepresentation; and (iii) any other liability which cannot legally be limited.

3.2. Subject to clause 3.1, the total aggregate liability of one Party to the other, whether in contract, tort (including negligence), and 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.

3.3. The Pharmacy shall ensure that With You is indemnified against any claim arising from a service user or any person acting on behalf of the service user arising from the provision of the Service, and arising directly from the negligence of the Pharmacy.

3.4. Subject to clause 3.1, neither Party shall be liable to the other 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.

4. INTELLECTUAL PROPERTY RIGHTS

4.1. All Intellectual Property Rights belonging to a Party prior to the execution of this Agreement shall remain vested in that Party.

4.2. All Intellectual Property Rights and all other rights in any documents or materials produced pursuant to this Agreement shall belong to With You.

4.3. Subject to clause 4.1, each Party will grant to the other a non-exclusive, non-transferable and revocable right to use and reproduce its name and trademark solely as necessary to permit the other's performance of its obligations under this Agreement. Use of the name and trademark will be agreed between the Parties and consent to such use will not be unreasonably withheld.

4.4. Neither Party shall use any name or trademark belonging to the other Party in any way that may damage the goodwill of the other Party.

4.5. Each Party shall indemnify the other Party against all costs, expenses, claims, losses and damages arising directly or indirectly from any claim by a third party that any Intellectual Property supplied by such Party infringes the trademark, patent, copyright, design or other intellectual property right of such third party.

5. CONFIDENTIALITY

5.1. The Parties agree that each shall treat confidentially the terms and conditions of this Agreement and all information provided by each Party to the other regarding its business and operations. All confidential information provided by a Party shall be used by the other party solely for the purpose of rendering or obtaining the Service pursuant to this Agreement and, except as may be required in carrying out this Agreement, shall not be disclosed to any third party without the prior consent of such providing Party.

5.2. This clause 5. shall not be applicable to any information that is publicly available when provided or thereafter becomes publicly available other than through a breach of this Agreement, or that is required to be disclosed by or to any Regulatory Authority, any auditor of the Parties, or by judicial or administrative process or otherwise by applicable law.

6. DATA PROTECTION

6.1. The Parties acknowledge and agree that, for the purpose of providing the Service under this Agreement, With You acts as Data Controller and the Pharmacy acts as an independent Data Controller. Each Party shall be responsible for their compliance with all obligations and duties under Data Protection Law, as defined in Schedule 3 (Data Protection) of this Agreement, in respect of any personal data which they may process under this Agreement.

6.2. The processing of personal data carried out under this Agreement shall be subjects to the provisions contained in Schedule 3 (Data Protection).

7. DISPUTE RESOLUTION

7.1. If any dispute arises out of this Agreement or in relation to the Pharmacy's provision of the Service as applicable under this Agreement, the Parties shall attempt to settle it by negotiation and seek in good faith to resolve the dispute within thirty (30) days of the issue being referred, escalating it within their respective organisations as necessary for this purpose.

7.2. If the Parties are unable to settle any dispute by negotiation within thirty (30) days, the Parties shall refer the dispute to mediation in accordance with the Centre for Effective Dispute Resolution (CEDR, <https://www.cedr.com/>) Model Mediation Procedure. Notwithstanding, nothing in this clause shall prevent the Parties commencing or continuing court proceedings at any time.

8. ASSIGNMENT/SUBCONTRACTING

8.1. Neither Party shall assign, transfer, charge or otherwise deal with all or any of its rights under this Agreement without the prior written consent of the other Party. No such permitted assignment shall relieve either Party of any of its obligations under this Agreement.

9. NOTICES

9.1. Notices may be given by recorded delivery post to any address given for that purpose. A notice given by post will be deemed to have been served the first working day after it was posted.

9.2. Notices may also be given by electronic mail, in which case a notice will be deemed to have been served on the date when it was sent. If the Party serving the notice receives a machine-generated message that delivery of the electronic mail has failed, the Party serving the notice must contact the other Party without delay.

9.3. When serving a notice by recorded delivery post:

9.3.1. The address for notice for With You is - We Are With You, for the attention of the Company Secretary, Part Lower Ground Floor, Gate House, 1-3 St Johns Square, London EC1M 4DH.

9.3.2. The address for notice for the Pharmacy is - .

10. TERMINATION

10.1. Either Party may terminate this Agreement at any time on giving not less than one (1) months' written notice to the other Party.

10.2. Without prejudice to its other rights or remedies which the Parties may have, either Party may terminate the Agreement immediately by written notice to the other Party, if the other Party:

10.2.1. fails to pay any amount due under this Agreement on the due date for payment and remains in default not less than one (1) month after being notified in writing to make such payment;

10.2.2. commits a material breach of any of the terms of this Agreement and (if such a breach is remediable) fails to remedy that breach within one (1) month of that Party being notified in writing of the breach;

10.2.3. repeatedly breaches any of the terms of this Agreement in such a manner as to reasonably justify the opinion that its conduct is inconsistent with it having the intention or ability to give effect to the terms of this Agreement; or

10.2.4. is unable to pay its debts or becomes insolvent, is the subject of any order made or a resolution passed for the administration, winding-up or dissolution (otherwise than for the purpose of a solvent amalgamation or reconstruction), has an administrative or other receiver, manager, trustee, liquidator, administrator, or similar officer appointed over all or any substantial part of its assets, enters into or proposes any composition or arrangement with its creditors generally or is the subject of any events or circumstances analogous to the foregoing in any applicable jurisdiction.

10.3. On termination of this Agreement for any reason:

10.3.1. With You shall, except where the Agreement is terminated due to the Pharmacy's material or repeated breach, immediately pay all of the Pharmacy's outstanding unpaid invoices and, in respect of the Service supplied but for which no invoice has been submitted, the Pharmacy will submit an invoice, which shall be payable immediately on receipt; and

10.3.2. the accrued rights, obligations and liabilities of the Parties as at termination and the continuation of any provision expressly stated to survive or implicitly surviving termination, shall not be affected.

10.4. The following clauses shall survive termination of this Agreement and shall continue with full force and effect:

- a) Clause 3. Liabilities
- b) Clause 4. Intellectual Property Rights
- c) Clause 5. Confidentiality
- d) Clause 6. Dispute Resolution
- e) Clause 13. Publicity
- f) Clause 15. Governing Laws and Jurisdiction
- g) Schedule 3 Data Protection

11. THIRD PARTY RIGHTS

11.1. Save as otherwise expressly provided in this Agreement, no term of this Agreement is intended to confer a benefit on, or be enforceable by, any person who is not a party to this Agreement (whether under the Contracts (Rights of Third Parties) Act 1999 or otherwise).

12. NO PARTNERSHIP

12.1. 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.

13. SEVERABILITY

13.1. If any provision of this Agreement is or becomes invalid, illegal 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.

14. WAIVER

14.1. 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.

14.2. 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.

15. PUBLICITY

15.1. Each Party shall obtain written approval from the other prior to making any press release or public statement or announcement regarding this Agreement or any ancillary matter unless the release, statement or announcement is required by law. Any such required announcement shall in any event be issued only after prior consultation with the other Party as to its contents.

16. ENTIRE AGREEMENT AND AMENDMENTS

- 16.1. 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.
- 16.2. Each Party acknowledges that in entering into this Agreement, it has not relied in any representation, warranty or other assurance.
- 16.3. The Agreement may only be amended or varied by a document in writing signed by a duly authorised person on behalf of each Party.


17. GOVERNING LAWS AND JURISDICTION

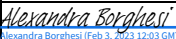
- 17.1. This Agreement is governed by and shall be construed in accordance with the laws of England and Wales, and the Parties agree to submit to the exclusive jurisdiction of the courts of England and Wales.

18. AUTHORISATION

This Agreement is authorised by the following:-

For and on behalf of We Are With You:

Date	Feb 3, 2023
Signed by	 <small>Paul Hughes (Feb 3, 2023 12:56 GMT)</small>
Name	
Position	Executive Medical Director

Date	Feb 3, 2023
Signed by	 <small>Alexandra Borghesi (Feb 3, 2023 12:03 GMT)</small>
Name	Alexandra Borghesi
Position	Company Secretary & DPO

For and on behalf of the Pharmacy:

Date	
Signed by	
Name	
Position	
Email address	

Pharmacy registered address	
Company no.	

Schedule 1

Service Level Agreement

1. Quality Standards

- 1.1. The Pharmacy must have an understanding of, and must comply with, Best Practice Guidance for Commissioners and Providers of Pharmaceutical Services for Drug Users (NTA, 2006); compliance with the General Pharmaceutical Council (GPhC) Code of Ethics; and any locally set clinical governance and quality standards as agreed by the Pharmacy and With You.
- 1.2. The Pharmacy must demonstrate a relevant quality assurance standard to With You, or must work towards achieving such a standard within an agreed timescale. The quality assurance standards are specified in Appendix A (Pharmacy Assurance Framework).
- 1.3. With You expects the Pharmacy to be able to provide evidence of full compliance with the obligations set out in this Agreement, With You's quality standards arrangements, and other reasonable future arrangements deemed necessary as and when required.
- 1.4. All clinical governance, reported incidents and patient safety standards in regard to the Service provided by the Pharmacy under this Agreement shall be monitored and audited by the Pharmacy on a regular basis.
- 1.5. Incidents and near misses must be promptly reported to With You on the same day that relates directly to the provision of the Service under this Agreement, or as soon as the Pharmacy becomes aware. Any incidents or concerns relating to the provision of the Service by the Pharmacy will be fed into With You's clinical governance process.
- 1.6. The Pharmacy shall provide and maintain a safe and suitable environment for service users, comply with all statutory requirements, legislation, department of health guidelines, professional codes of practice and all health and safety regulations. The Pharmacy may also be required to complete a clinical waste audit annually or when required by the waste contractor.
- 1.7. Throughout the term of this Agreement, and for as long time thereafter as may be regarded as necessary and customary in the health care sector, the Pharmacy shall maintain an appropriate public liability and professional negligence insurance, to include the provision of the Service, with an authorised insurance carrier of good standing.

2. Exit Strategies and Sustainability

2.1. The Pharmacy accepts that With You is unable to guarantee future funding and may, owing to budgetary considerations, be obliged to reduce funding by the giving of not less than 1 month notice. Such reductions shall be timed to cause least disruption for service users. If With You invokes this clause to reduce payment, then the Pharmacy shall be entitled to cease providing the Service without further notice at its sole discretion and incurring no penalty.

3. Accountability for Policy and Performance

3.1. Representatives of the Pharmacy may be required to attend policy and performance meetings and shall be obliged to attend to answer questions relating to the Service and to account for funding received. These meetings will be held at a time and place that do not disrupt the provision of the Service by the Pharmacy.

4. Equal Opportunities

4.1. The Pharmacy shall adopt an equal opportunities policy relating to service provision, staffing and management of the organisation, which is consistent with the definition of *discrimination* stated below, and which complies with all relevant statutory obligations:

Discrimination - *Through either direct or indirect action, giving less favourable treatment or applying an unjustified requirement because of age, race, gender, disability, sexual orientation, marital status, and blood borne virus status, irrelevant convictions, ethnic origin or religious belief.*

4.2. Staff should work in line with their own organisation's policies and procedures in relation to equal opportunities. All aspects of the Service will be sensitive to the individual needs of service users. Their cultural, religious and linguistic needs should be met and recognised, utilising resources and specific services for support where appropriate.

5. Accreditation

5.1. Accreditation for the Pharmacy to provide the Service is based on the presence and control of an accredited Pharmacist, Pharmacy Manager or Pharmacy Technician as defined in Schedule 4 (Service Specification) of this Agreement.

5.2. Accreditation for the Pharmacy to provide the Service will cease and the Service suspended if there is no regular accredited person available to oversee the Service the majority of the working week.

5.3. It is the responsibility of the Pharmacy to ensure that an accredited person is available to oversee the Service at all times. If any changes occur, the Pharmacy must notify With You and follow the provisions in Schedule 4 (Service Specification).

Schedule 2

Funding, Payment of Fees and Default

1. With You shall pay the Fees to the Pharmacy monthly in arrears upon receipt of an invoice from the Pharmacy that arrives no later than the 5th day after the end of the month. The Fees shall only be paid where With You is satisfied that the Service has been provided in accordance with the terms of this Agreement and shall make best endeavours to pay within 30 days of receipt of the Pharmacy's invoice.
2. With You shall be entitled to suspend payment of the Fees and/or vary the amount of the payment if it considers the Pharmacy has committed a serious breach of the Agreement and shall forthwith notify the Pharmacy in writing accordingly.
3. Following the exercise of rights in clause 2. above, With You shall immediately investigate the grounds for suspension or variation and report to the Pharmacy every 30 days until such investigation is complete. When the investigation is complete, With You shall immediately notify the Pharmacy of the outcome and, where appropriate, within 30 days pay any sums to the Pharmacy that were suspended or varied.
4. If the Pharmacy fails to comply with the provisions of this Agreement, With You may serve a default notice stating the action required to remedy the default within a period of time (to be specified by With You) in which to take the action. If the Pharmacy remains in default following the expiry of the period specified, With You may proceed to terminate the Agreement in line with the provisions in clause 10 of this Agreement.
5. The Service and payment of the Fees may be varied or discontinued if:
 - i. The Pharmacy and We Are With You agree, or
 - ii. A change in With You service priorities is required either by changes in legislation or by other circumstances, including the cessation or reduction of the budget or other changes in With You service priorities that require either reduction in funding or discontinuation of funding.
6. Payment of Fees will be made by With You to the Pharmacy in line with the following payment schedule:

Type of Supervised Consumption	Fees per Supervision (£) ¹
Methadone	1.94
Sublingual tablets (buprenorphine, Subutex, Suboxone)	1.94
buprenorphine oral lyophilisate 2mg and 8mg (Espranor®)	1.94

¹Update locally.

The Pharmacy will be expected to accept a minimum of five (5) service users at any one time (subject to With You being able to refer five (5) service users).

The Service as outlined is VAT exempt, both Parties are aware of this exemption. However, if in the future the VAT status was to change then the Pharmacy would be made aware of this change, and an opportunity to renegotiate the terms of the Agreement would be made available.

Schedule 3

Data Protection

1. This Schedule 3 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.
2. The Parties shall ensure that:
 - 2.1. They comply at all times with all applicable data protection and privacy legislation in force from time to time in the United Kingdom, including the retained EU law version of the General Data Protection Regulation ((EU) 2016/679) (UK GDPR); the Data Protection Act 2018 (DPA 2018); and the Privacy and Electronic Communications Regulations 2003 (SI 2003/2426) as amended, and all other applicable law about the processing of personal data, including where applicable the guidance and codes of practice issued by the Information Commissioner's Office, all as amended from time to time ("**Data Protection Law**").
 - 2.2. All necessary privacy notices and consents are in place to enable the lawful processing (including sharing) of personal data by the Parties - which includes their employees, subcontractors, directors, trustees or other third parties authorised to process personal data under this Agreement – and that they are reliable and have sufficient training relevant to the care and handling of personal data, and that they are subject to contractual obligations concerning privacy and confidentiality.
 - 2.3. They have adequate technical and organisational measures in place 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 UK GDPR.
3. The Parties shall not transfer any personal data, processed under this Agreement, outside the European Economic Area (EEA).
4. The Pharmacy shall notify With You without undue delay, and in any case within 48 hours of receipt, of any request received by service users or other third parties in relation to this Agreement. Specifically, any request received by the Pharmacy by parties exercising their rights under Articles 15 to 23 of the UK GDPR to include, but not exclusive of, the right of access (Subject Access Request); the right to rectification; the right to erasure; the right to restriction of processing; and the right to data portability.
5. Each Party shall notify the other Party without undue delay, and in any case within 48

hours of becoming aware of any personal data breach or data security incident occurred under this Agreement.

6. The notifications referred to in sections 4. and 5. above should be made to the relevant Party's Data Protection Officer (where one is appointed) or Caldicott Guardian, contacts details as below:

With You	Data Protection Officer: Alexandra Borghesi, Company Secretary & DPO, data.protection@wearewithyou.org.uk
	Caldicott Guardian: Paul Hughes, Executive Medical Director, caldicott@wearewithyou.org.uk
Pharmacy	Data Protection Officer: Caldicott Guardian:

Details of Processing

1. Data Subjects	The recipients of the Service (service users).
2. Types of Personal Data	<ul style="list-style-type: none"> - 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 Pharmacy (special category data); - service users' GP details (including name and practice details) where required.
3. Lawful Basis for Processing	<p>Under this Agreement:</p> <ul style="list-style-type: none"> - Personal data will be processed under Article 6(1)(a) ("consent") and 6(1)(b) ("performance of a contract") of the UK GDPR. - Special category data will be processed under Article 9(2)(a) ("consent") and 9(2)(h) ("provision of health and social care") of the UK GDPR; and section 2(2)(d) ("the provision of health care or treatment") of Part 1, Schedule 1 of the DPA 2018.
4. Purpose of Processing	<p>The Pharmacy shall process personal data and special category data to:</p> <ul style="list-style-type: none"> - Provide the Service under this Agreement - Maintain records required for provision of the Service - Invoice and receive payment from With You.

	<p>With You shall process personal data and special category data to:</p> <ul style="list-style-type: none"> - Enable the provision of the Service by the Pharmacy - For quality assurance purposes, to monitor the Pharmacy's performance under this Agreement and for contract management purposes.
5. Duration of Processing	<p>The Parties shall process personal data and special categories data for the duration of this Agreement and subsequently where retention of personal data or special category data is required by applicable law or for actual or prospective legal claims or as otherwise set out in writing by either Party.</p>
6. Deletion	<p>Unless otherwise required by law, the Pharmacy shall, upon termination or expiry of the Agreement for whatever reason, or at the request of With You, either securely delete or return all personal data and special category data to With You. If required by law to retain a copy of such data, the Pharmacy shall inform With You what data is being retained and the lawful basis provided for in Data Protection Law that justify such retention.</p>

Schedule 4

Service Specification

1. Introduction

Community pharmacies are ideally placed to provide supervised consumption (SC) to service users within an agreed and structured protocol.

Daily contact allows not only a relationship to develop but also monitoring of service user adherence and the opportunity to offer timely, supportive advice and responses on issues of concern. The Pharmacy therefore has an important role to play and will contribute to the service user's review by the prescribing service.

The Pharmacy must be aware that supervision aims to liberalise as soon as safe and clinically appropriate to do so, but may be reinstated at times of crisis, relapse or by service user's choice, as part of an evolving treatment plan.

2. Aims

The aim of the Service is to minimise the possible harmful effects of supply of substances liable to misuse by both increasing adherence and reducing supplies leaking into the illicit market.

This Service supports adherence with [Drug Misuse and Dependence UK Guidelines on Clinical Management](#), published by the Department of Health; and [Methadone and Buprenorphine for the Management of Opioid Dependence](#) (TA114) published by National Institute for Health and Clinical Excellence (NICE).

3. Objectives

- b) There should be well managed models of care pharmacy pathway with associated counselling and care programmes for substance misusers, aimed at immediate harm minimisation, with the ultimate goal of recovery wherever possible.
- c) There should be greater involvement of primary care professions, such as General Practitioners and Community Pharmacists, in the care of more stable drug misusers.
- d) To ensure that the service user takes the correct dose of medication prescribed by the Clinician.
- e) To ensure that medication prescribed is not inappropriately directed onto the illegal market.

4. Principles of the Service

This Service Specification outlines the procedures for carrying out the Service and its

administration. The Service Specification has been separated into Pharmacy and Prescriber responsibilities.

Supervised consumption is recommended for new prescriptions. The duration of supervision will be based on an individual risk assessment for, and with, each service user. The dispensing arrangements should take into account the service user's social factors, such as employment and childcare responsibilities.

Supervision itself may create secondary dependence. Service users should not see it as a punishment but as a supportive measure and one in which a therapeutic relationship can be developed.

Pharmacies are supported by the Prescribing Agency through sharing information and regular liaison.

The service user enters into a contract with the Pharmacy to ensure appropriate engagement. See Appendix C for *Three Way Prescribed Treatment Agreement*.

There must be a designated area in the Pharmacy i.e. consultation area/room, that has been passed as suitable for delivering professional services as part of the Community Pharmacy Assurance Framework Monitoring Visits, that takes into account both the service user's dignity, that of other customers of the Pharmacy and its staff safety. Supervision must never occur in the dispensary.

5. Competencies and Training

With You's training events will be held regularly (at least annually) and the content will be available to all of the Pharmacy team, even if they are not currently involved in the provision of the Service under this Agreement.

Training for the Pharmacy staff will include appropriate related topics including basic drugs awareness, referral, health promotion, and harm minimisation approach to treatment, feedback on learning from incidents, developments, and national guidance.

Attendance at the first session on initiation of accreditation and service provision and then at least one session per year is compulsory for the Accountable Pharmacist(s) and/or Pharmacy Technician(s) accredited to oversee the Service in the Pharmacy.

It is also a requirement for the accredited Pharmacist(s) and/or Pharmacy Technician(s) at the Pharmacy to have completed, in the last two years, or go on to complete, within 6 months of commencing the provision of the Service, the latest [CPPE training on "Substance Use and Misuse"](#). Pharmacists must incorporate this to complete a CPPE Declaration of Competence (DoC) for Supervised Consumption of Prescribed medicines and ensure it is reviewed regularly.

It is the responsibility of the accredited Pharmacist(s) and/or Pharmacy Technician(s) of the Pharmacy to ensure their staff have been provided with appropriate training. This will include Health & Safety, an overall understanding of the Service, relevant SOPs and the importance of maintaining confidentiality.

In the event of changes to the accountable and accredited pharmacist or technician, the Pharmacy shall notify With You within six weeks of the date of change. A new accountable pharmacist/technician will be allowed three months to complete the required CPPE training/DoC to take over as the replacement pharmacist.

The Pharmacy must update the below document locally to reflect any changes in the regular pharmacist and ensure With You is kept informed, for key contact purposes. If no accredited person is available to oversee on a regular basis, the Pharmacy must contact With You’s management for advice.

Change Date:	Name:	Job Title:	Accreditation:

The accredited/lead pharmacist must work at least three days a week in the Pharmacy. Where locums or part time pharmacists predominantly operate the Pharmacy, the area manager pharmacist or equivalent must nominate a lead technician/manager to act as a contact in this store. This must be communicated to With You promptly.

The Responsible Pharmacist on duty at any time will retain professional responsibility and liability for the Service. In line with this, the Pharmacy employing locums must ensure the locums employed are suitably trained as described to operate a supervised consumption service. Locums must be encouraged to attend the training events put on by With You.

The lead pharmacist/registered technician must ensure all their staff are fully trained on the supervised consumption scheme and relevant SOPs, health and safety and other associated aspects.

Where PharmOutcomes or similar is used it is imperative that communication section is regularly checked on there and actions requested implemented. This is because it may be employed to send critical alerts and updates. Failure to do this could jeopardise payment.

6. Prescriber Responsibilities

The Prescriber shall reach an understanding with the service user that their prescriptions will be dispensed at a designated Community Pharmacy. This will be recorded in the Prescribed Treatment Agreement. The Prescribing Agency must negotiate with the service user the most suitable/convenient pharmacy that is part of the scheme.

The Pharmacy shall be contacted in advance by the Prescribing Agency to ascertain if the Pharmacy has space to take the service user and that there are no historical issues e.g. a ban. If the Pharmacy is able to take the service user, the Prescribing Agency will discuss the dispensing arrangements for the service user.

If the Pharmacy accepts the service user, the Prescribing Agency must complete a Prescribed Treatment Agreement and a copy will be presented to the Pharmacist by the service user at first visit or faxed/emailed in advance (see Appendix C). The Pharmacy will sign and retain a copy of the Prescribed Treatment Agreement on site for the duration of treatment.

The Prescribing Agency must provide feedback to the Pharmacy, when appropriate, on service user issues flagged up by the Pharmacy.

7. Referral Criteria/Liaison

Service users may be re-referred for supervised consumption if:

- Collections are erratic.
- Drug testing results or disclosures of on top use.
- There is concern that the prescribed drug is being diverted or used inappropriately.
- The service user shows a continued and unstable pattern of drug misuse.
- There are broader concerns such as safeguarding e.g. to reduce the chance of accidental consumption by children.

The length of time an individual is under supervision, and when that is instigated, will vary and be dependent on an assessment, as provided for in the Drug Misuse and

Dependence, UK Guidance on Clinical Management 2017.

It is important that close links are maintained between the Prescribing Agency and Pharmacy involved in the Service. To avoid any confusion or 'mixed messages' each service user will have a named recovery coordinator.

The Pharmacy will be sent an External Delivery Log with any prescriptions sent by delivery or post (see Appendix D). The Pharmacy shall check, sign and send a copy to the Prescribing Agency the same day of receipt.

8. Accredited Pharmacist/Pharmacy Technician Responsibilities

There is a professional requirement for all participating pharmacies to put in place and operate written standard operating procedures covering this locally commissioned enhanced service.

The lead accredited Pharmacist/Pharmacy Technician will ensure that:

- All the Pharmacy staff are trained, responsible and accountable.
- The Pharmacy Technician's involved in the provision of the Service is registered with the GPhC, has an up to date CPD portfolio and have a good knowledge of the Service.
- All dispensing is in accordance with all legal requirements and practice guidance for pharmacists providing instalment dispensing services to drug misusers, as well as Supervised Consumption Scheme Operational Guidelines as detailed within this document.
- The lead pharmacist uses an SOP from their own organisation, providing it is not contrary to the provisions in this Agreement.
- All reasonable efforts are made to accommodate all new supervised consumption service users who are referred by the treatment provider. Lead pharmacists will not decline new referrals for SC unless they have reached capacity or there is a valid professional clinical reason for refusal (i.e. the service user is already banned from the premises or, there is an identifiable reason why it would be inappropriate for the service user to be supervised at the Pharmacy).
- The Pharmacy responds to requests from the Prescribing Agency to discuss any clinical issues or queries within the same working day and ideally at an interval of no more than 4 hours after the initial request. The Prescribing Agency will endeavour to respond in a timely manner whilst prioritising service user need.
- Any appropriate concerns or comments they may have regarding a service user's progress or conduct are relayed to the recovery co-ordinator and/or prescriber. This will be done in a manner not to breach confidentiality and maintain a good relationship with the service user/Pharmacy.

- All incidents are reported to With You in addition to any in-house incident monitoring procedures in the Pharmacy, and to the NHS Controlled Drug Accountable Officer as appropriate.
- All records are adequately maintained.
- All details are entered onto the web-based recording platform/or paper recording and faxed/posted in an accurate and timely manner.

The Service will operate every day the Pharmacy is open. If the Pharmacy put in an application to reduce their opening days or times, then With You must be informed at the time of application.

The Pharmacy will take part in audit activity, including visits, and agree to share information regarding substance misuse data to allow discussion and improvement of services. An example of the audit is attached in Appendix E.

When the service user first attends, the Pharmacy must:

- check that the service user meets the description given by the named contact;
- check the details of the Prescribed Treatment Agreement and register the service user on the Patient Medical Record (PMR) system.

The Pharmacy will establish an appropriate system to aid service user identification when collecting medication subsequently.

The Pharmacy must take the service user through the Prescribed Treatment Agreement and discuss/complete any relevant information, including:

- Opening hours for the service user to access the Service (this must be as flexible as possible to encourage retention). This section should be completed by the Pharmacy.
- The Pharmacy's right to contact the prescriber and/or named contact or other relevant healthcare professional.
- Missed doses cannot be dispensed at a later date.
- Medication will not be dispensed if a service user has missed three or more consecutive doses.
- Medication will not be dispensed if the Pharmacy suspects that there is drug and/or alcohol intoxication (service user is asked to return later or contact prescribing agency for assessment). Appendix A 'Signs and Symptoms of Intoxication' has been included to help the Pharmacy in this determination. The service user must be asked to return later or the Prescriber/Prescribing Agency contacted for assessment.
- Service user must come in alone.
- Acceptable behaviour by the Pharmacy and the service user.

If a service user has missed collecting doses, the Pharmacy must contact the Prescribing Agency by telephone to inform of the missed dose. If the service user misses three consecutive doses, the Pharmacy must contact the Prescribing Agency and discuss the appropriateness of dispensing the dose.

If a service user has missed collecting three or more consecutive doses and it is not possible for the Pharmacy to speak to the Prescribing Agency at that time, as it is outside normal opening hours, the Pharmacy will not dispense the dose.

Where the Pharmacy has not dispensed a daily dose of medication, entries must be made on the relevant data collection form(s).

The Pharmacy must also contact the Prescribing Agency if the service user fails to attend regularly to collect their medication within any two-week period.

The risk of death during methadone induction is nearly seven-fold greater during initiation than once on methadone maintenance. Therefore, extra caution must be exercised during the first two weeks and any doses missed must be reported to the Prescribing Agency, service manager or prescriber.

All service users must receive medication daily in accordance with the prescriber's directions. The Pharmacy must dispense instalments due on Pharmacy closed days on a prior suitable day. If an instalment's collection day has been missed, the Pharmacy must still dispense the amount due for any remaining day(s) of that instalment.

It is a recommended good practice for pharmacists to supply multiple doses in separate containers. To reinforce this practice, additional Home Office wording can be added to the prescription e.g. "Dispense daily in separate containers". Where the decision is made by the pharmacist not to do this, a suitable measuring device should be supplied.

Where the dispensing service has been terminated for a service user for whatever reason, any prescriptions that have not yet been started must be crossed and marked "INVALID". A note must be made on the service user's Patient Medication record (PMR) and destroyed in the presence of a witness and placed in confidential waste.

Locum pharmacists must be made aware of this Service and the procedures in advance of them providing locum cover. A Supervised Consumption Pathway (Appendix B) has been provided to support delivery of the Service. It is essential that the Service runs smoothly and all records are kept up to date. The presence of a locum pharmacist is not a valid reason for the Service Specification not to be followed.

9. Dispensing and Supervision

Doses of medication can be made up in advance each day (assuming the pharmacist is

in possession of a current prescription). Where prepared in advance, it is recommended, or when for take home, that medication is dispensed into an appropriate child resistant container labelled in accordance with the requirements of the Medicines Act, and must be stored in the CD cabinet until the service user arrives at the Pharmacy.

When the service user arrives, the accredited Pharmacist, locum or authorised Pharmacy Technician, must ensure that the service user is correctly identified and interact with them to determine general health and suitability for collecting medication and receiving their dose of medication. If a service user presents as intoxicated (See Appendix A) the provisions in section 10 below (Incidents) must be followed.

The accredited Pharmacist or Authorised Pharmacy Technician must show the medication to the service user and confirm strength and dose.

9.1 Methadone Liquid

Methadone must be consumed directly from the service user's labelled dispensing bottle.

The accredited Pharmacist or authorised Pharmacy Technician shall observe the consumption of methadone by the service user. The service user should then be offered a drink of water (also helps prevent tooth decay) and engage in conversation with the service user. This is to ensure that the methadone has been swallowed.

9.2 Buprenorphine Sublingual Tablets (Buprenorphine e.g. Subutex®)

If this is the service user's first dose of buprenorphine, the pharmacist should explain they must have waited at least 8 hours since their last heroin use or at least 24 hours since their last dose of methadone. Ideally service users should be in the initial stages of withdrawal before taking their first dose. This is to minimise the risk of precipitated withdrawal. This is what happens when buprenorphine displaces the opioid before the opioid is out of their system. It is the service user's responsibility to assess his or her own withdrawal state and readiness for the first dose.

A drink of water should be supplied to the service user prior to dose to moisten the mouth (this aids dissolution of the tablet).

It should be explained that the tablet(s) must be dissolved under the tongue to absorb the active ingredient and the service user should avoid swallowing (both the tablet(s) and saliva whilst dissolving).

The accredited Pharmacist or Authorised Pharmacy Technician will place the tablet(s) into a pot and hand to the service user. The accredited Pharmacist or Authorised

Pharmacy Technician will then observe the service user placing the tablet(s) under the tongue to dissolve. The accredited Pharmacist or Authorised Pharmacy Technician can ask to observe the tablets in situ under the tongue before they begin to dissolve (to ensure tablets have been placed under the tongue). The service user should be observed until the tablet(s) have dissolved; the service user should then open their mouth to confirm the tablet(s) has dissolved. Supervision is most important in the first three minutes during which time the majority of the tablet will have dissolved and the risk of diversion greatly reduces. It should be noted that different brands of buprenorphine have different dissolution rates.

Service users should be advised that excessive saliva production may reduce the effectiveness of the drug and is not desirable. Saliva should be ideally kept in the mouth and not swallowed.

Crushing of buprenorphine prior to administration is not recommended but it may be required in exceptional circumstances. It should be noted though that this is an off-label use.

9.3 Buprenorphine oral lyophilisate 2mg and 8mg (Espranor®)

The route of administration for Espranor® is on the tongue, not under it.

Administration is oromucosal. The oral lyophilisate should be taken from the blister unit with dry fingers, and placed whole on the tongue until dispersed, which usually occurs within 15 seconds, and then absorbed through the oromucosa. Swallowing should be avoided for 2 minutes. The oral lyophilisate should be taken immediately after opening the blister. Patients should not consume food or drink for 5 minutes after administration.

Pharmacists must advise patients that the oromucosal route of administration is the only effective and safe route of administration for this medicinal product. If the oral lyophilisate, or saliva containing buprenorphine are swallowed, the buprenorphine will be metabolised and excreted and have minimal effect.

Espranor® is not interchangeable with other buprenorphine products. Different buprenorphine products have different bioavailability. Therefore, the dose in mg can differ between products. Once the appropriate dose has been identified for a service user with a certain product (brand), the product cannot readily be exchanged with another product.

IMPORTANT NOTE

Service users must not bring their own drinks into the Pharmacy. There have been reported cases of service users spitting their methadone into their drinks containers as a method of diversion.

All labels must be removed from the service user's dispensed containers, or have their name obliterated indelibly, before throwing away, to maintain confidentiality. It is also good practice to rinse out any methadone container before disposal.

After each dispensing, the Pharmacy must then complete the data collection entry for the service user in accordance with instructions as well as making the appropriate entries into the CD register and on the prescription. In the case of PharmOutcomes this is typically done at the end of the prescription. It is imperative that full details are recorded, including where there have been any issues causing concern. Missed doses must be reported at the time as detailed above.

If the service user declines any medication, the Pharmacy must contact the Prescribing Agency for further advice and record on the data collection site.

If only a partial amount of methadone is consumed, enter in the CD register the full dispensed dose and record the unconsumed quantity as a service user CD return. That must be then destroyed following current guidance and best practice for a CD return. The Pharmacy must inform the Prescribing Agency and the prescriber should this occur.

10. Incidents

The Pharmacy must contact the Prescribing Agency if:

- The service user appears ill.
- The service user misses a dose during titration or on a regular basis.
- The service user misses three consecutive doses.
- Service user does not consume whole dose.
- The service user tries to avoid supervision of consumption.
- The service user appears to be intoxicated with alcohol or drugs.
- The behaviour of the service user is unacceptable, e.g. shoplifting/verbal and/or physical abuse.
- There is any doubt whether it is safe to supply the dose.
- If there is a dispensing error.
- Due to unforeseen circumstances the Pharmacy must shut.
- Accidents or injuries.

IMPORTANT NOTE

- Missing doses may result in a drop in Opiate tolerance with increased risk of accidental overdose.
- Service users stable on medication should be alert and coherent.
- Only the pharmacist can decide what behaviour is unacceptable.

11. Key Contacts

a. Referrals (via secure NHSmail or telephone)

Contact Name(s) (if applicable):	
NHSmail address:	withyou.rotherham@wearewithyou.org.uk
Telephone Number(s):	08081753981

b. General queries about this Agreement

Contact Name(s):	Emma Griss
Email address:	emma.griss@wearewithyou.org.uk
Telephone Number(s):	07855000733

12. References

- Drug Misuse and Dependence UK Guidelines on Clinical Management, published by the Department of Health 2017.
- Methadone and Buprenorphine for the Management of Opioid Dependence (TA114) published by National Institute for Health and Clinical Excellence (NICE).
- Royal College of General Practitioners (RCGP). Guide to Management of Substance Misuse in Primary Care (2013).

Appendix A

Signs and Symptoms of Intoxication

3

Alcohol

Slurred speech
Blood shot eyes
Dilated pupils with sluggish response to light
Loss of co-ordination
Smell of alcohol on breath
Drowsiness and sedation especially if taken with another depressant e.g. benzodiazepines
Lateral nystagmus (spontaneous, rapid, rhythmic eye movements)
Irritability

Benzodiazepines

Drowsiness and sedation especially if taken with another depressant e.g. alcohol
Loss of co-ordination
Slurred speech
Droopy eyelids
Dizziness
Poor comprehension
Irritability

Opiates (Heroin)

Pinpoint or constricted pupils
Sedation and drowsiness especially when taken with other depressants (e.g. benzodiazepines, alcohol, barbiturates)
Droopy eyelids
Slow speech

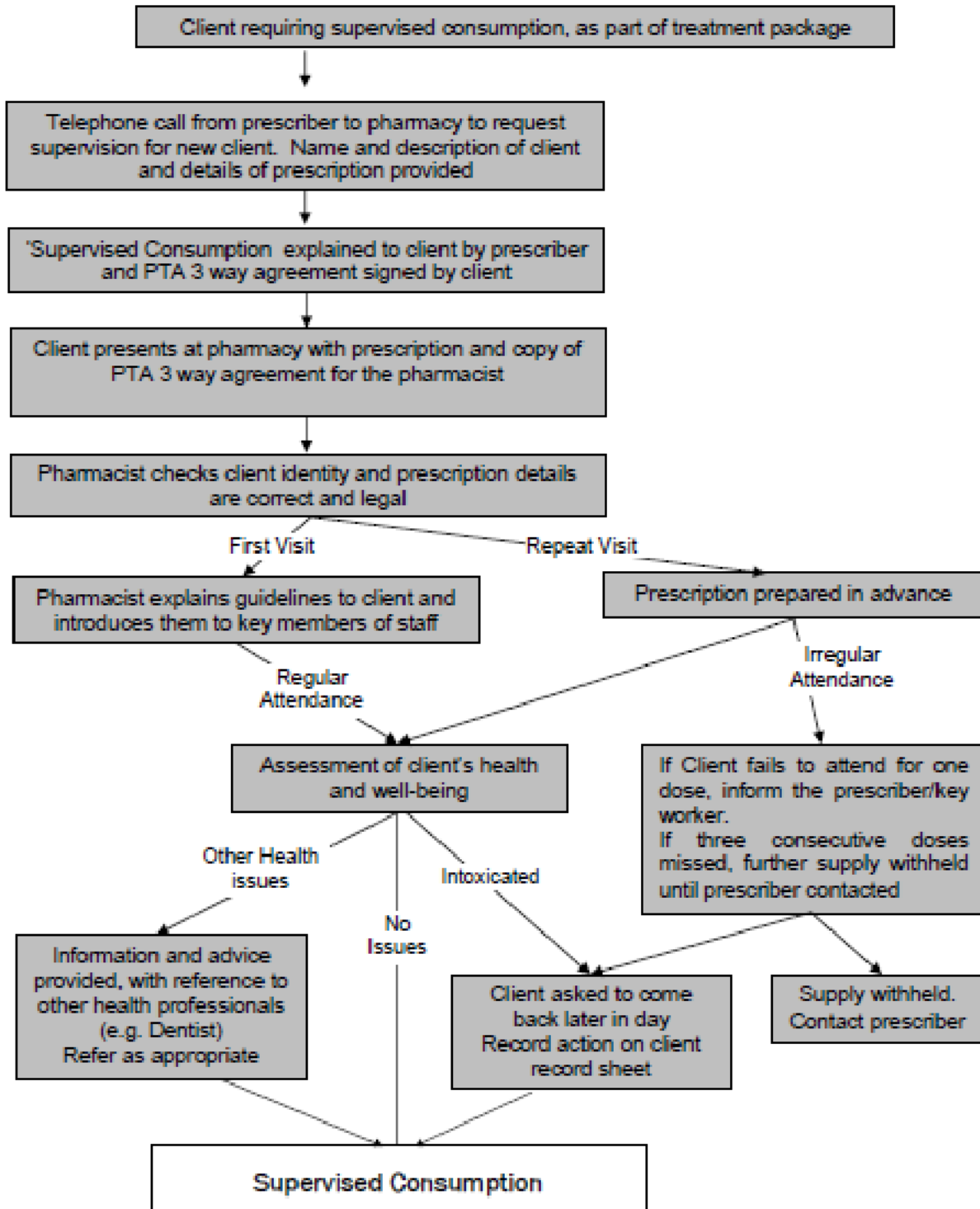
Stimulants (Amphetamine and Cocaine)

Dilated pupils
Brisk reflexes
Fine tremor of limbs
Blurred vision
Irrational behaviour
Confusion

Appendix B

Supervised Consumption Pathway

This is the pathway for service users who, in line with the clinical guidelines, require supervised consumption.



Appendix C

Prescribed Treatment Agreement

This agreement is to help you to understand what you can expect from We Are With You, your pharmacist and your GP (if shared care). It also gives you information on how you can best help us to help you.

Service user Name/Date of Birth:		Service user Photograph:
Service user ID number:		
We Are With You Recovery Worker/Phone Number:		
Pharmacy Name/Address:		
Pharmacy Phone Number:		
GP Surgery/Phone Number:		
Pharmacy collection times:	<i>[for example: M-F 9.30-4.30]</i>	

We Are With You will...

- Fully support you in your recovery programme and in the decisions you make with regard to your medication in a way that helps to keep you safe and well.
- Treat you with respect, courtesy, understanding, kindness, compassion and honesty at all times and not judge you if you stumble or lapse in your recovery plan.
- Keep you fully informed of your treatment options and provide information about medication, potential benefits and risks.
- Respect that you have the right to decline or accept the treatment offered to you after being fully informed about risks (including monitoring requirements, adverse effects of treatments) and benefits of treatment.
- Discuss and exchange information on your state of health, attendance and other factors relating to your treatment, with the aim of improving your treatment and reduce the risk of harm.
- Communicate with providers who may be treating you for other conditions as agreed with you to support your recovery.
- Provide you with advice on safe storage of your medication (including providing a lockable box if necessary)

- Provide you with naloxone to use if you or someone you know has an opioid overdose, and train you on how to use it.

Your Pharmacy will...

- Advise you of the opening times, and the best time to collect your medication to minimise your wait
- Confirm your identity each time you attend and respect your confidentiality.
- Dispense your medication in a bottle, disposable cup or box labelled with your medication and dose.
- If your medication is supervised the pharmacy will:
 - take you into a private area of the pharmacy so that you can take your medication in private
 - give you a drink of water in a disposable cup after you have taken your medication if appropriate.
 - ask you to stay until your medication has been absorbed (if you are prescribed buprenorphine)
- Share information with We Are With You and your GP (if shared care) about your attendance and health.

Help us to help you by...

- Treating the staff and other service users at We Are With You, your pharmacy and GP practice with respect and adhere safely to your treatment program and recovery plan.
- Attending appointments with your Recovery Worker and prescriber and letting us know if you cannot attend.
- Engaging in psychosocial activities and groups so that you can maximise your chance of recovery.
- Attending your appointments and pharmacy without being under the influence of drugs or alcohol.
- Informing us if you wish to change your regular pharmacy
- Informing us if your contact details change e.g. phone number so we can contact you.
- Picking up your medication as agreed. Your pharmacist will not be able to dispense missed doses, and if you miss more than 3 days may withhold any further doses until they contact We Are With You (or your GP if shared care).
- Taking your medication at the dose agreed, without stockpiling any for future use, or giving to anyone else. Any unused medication must be returned to your pharmacy.
- Collecting your medication in person. Your pharmacist cannot normally supply to a representative unless this has been previously agreed in writing.
- Keeping your medication safely stored and out of sight of children. It may not be possible to replace medication that is lost, stolen or spilt.

- Informing the DVLA of your medication (if you drive).
- Giving We Are With You (or your GP if shared care) at **least 14 days' notice** if you need changes made to your prescription, for example, if you are going on holiday.

Information Sharing and Consent (shared care only)

In order to provide you with a continuity of care and service your GP will (where systems allow) be provided with access to your We Are With You Clinical records. Records held within the shared care system are accessible by all GPs within your area however only GPs at your registered practice are permitted to view these records. Access to these records will be available throughout your time in shared care and will be removed if you leave shared care or when you leave treatment (whichever occurs first).

Consent to the use of a photograph for identification:

We Are With You, your pharmacy and GP (if shared care) confirm that your photograph and personal information contained within this agreement will be used for the sole purpose of identifying you during prescribed treatment and stored securely at all times. It will not be issued to, or viewed by any individuals or agencies outside this agreement.

I agree to my photograph being used for the purposes stated above: [Y] [N]

Service user signature:	We Are With You signature:	Pharmacy signature:

Date naloxone supplied:	
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Appendix D

Prescription Log: External Delivery

Dear Pharmacist/GP/Other at Pharmacy/Surgery/Service name and location

Please find enclosed the prescription(s) listed in the table below.

Please complete the 'Received By' column to confirm receipt and send a copy of this form to Service Contact Details e.g. postal address, fax number, email address.

Date	Prescription Serial No <i>(First/Last numbers if all scripts in between are checked and correct)</i>	Service user ID/Date of Birth & Initials <i>(if applicable)</i>	Recovery Worker Name <i>(not applicable if 'blank' prescription)</i>	Recovery Worker Contact Number <i>(not applicable if 'blank' prescription)</i>	Comments <i>(e.g. holiday prescription, replacement prescription, request to destroy previous prescriptions)</i>	Received by <i>(Name & Signature)</i>

<i>To be completed by an Administrator</i>					
<i>Date Posted</i>		<i>Delivery Service</i>		<i>Delivery Reference</i>	

Appendix E

Quality Assurance Standards Framework for Supervised Consumption and Needle Syringe Provision

Pharmacy Site		ODS Code	
Authorised Person/Responsible Pharmacist at Site Overseeing Provision		Branch Manager	
Date of Audit		Audit Completed by	

Verification Check	Y/N/NA *	Comments
Signed SLA in place and been received by We Are With You?		
Copy of SLA available in pharmacy, read and signed off by all participating staff in store that day.		
DOCs (Declaration of Competencies) been completed by authorised pharmacist.		
Relevant SOPs in place?		
Private professional area/consultation room suitable for delivering service utilised for SC/NSP. Should be clean and safe and not utilised as a stockroom/staff room.		
Observation during visit and feedback indicates service users treated with dignity and respect.		
Suitable data protection methods employed.		
Pharmacy/Service user agreement in place (good practice).		
On observation pharmacy staff follow best practice when carrying out supervision (as detailed in SLA).		
Information is available to service users informing them how to make a complaint/compliment.		

Verification Check	Y/N/NA *	Comments
Staff can give examples of regular interventions and signposting. Is there information available to handout to service users? Is there information on how to access treatment services available from staff?		
Last 3 months of reporting on line demonstrates prompt timely (ideally within 24h) accurate data capture and recording.		
*All staff involved in service provision have been appropriately trained/briefed by authorised person. Evidence?		
On checking the CD cupboard that day's SC are prepared in advance and are stored securely.		
Evidence of good practice utilised to minimise infection spread e.g. use of disposable cups.		
Labels are removed and placed in confidential waste and clinical waste disposed securely.		
If using a methadone pump ensure there is an SOP for its operation and equipment accuracy has been validated as to manufacturer's guidelines.		
Sharps and returns stored safely in a designated area.		
In NSP sites check stock is adequate and appropriate.		
What are returns levels? On checking return bins do these contain only appropriate waste (i.e. from outside is there any evidence that other waste is contained than black returns bins?		
Are staff engaging with service users re NSP? Examples of signposting and interventions regularly.eg checking of service user's sites, time elapsed since last use of exchange, understanding of appropriate kit. Is there harm minimisation discussion?		

Verification Check	Y/N/NA *	Comments
Staff are aware of safeguarding leads and contact details locally and can show these to auditor.		
In NSP sites the NSP logo sticker is clearly displayed externally.		
<p>Fitness to Practice. The Pharmacy Manager must provide a declaration that the following fitness to practice documents are up to date across the practice:</p> <ol style="list-style-type: none"> 1. Professional Indemnity arrangements 2. Safeguarding Training regarding children and adults and evidence can be provided. 3. Evidence of CPD 4. Evidence of public liability insurance 		

* **Y = meets expected standard. No action required.**

N = doesn't meet expected standard.

NA = not applicable.

Summary and Next Steps











Rotherham - SLA Supervised Consumption(V6.4.6 June 2022) (1)

Final Audit Report

2023-02-03

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-  Document e-signed by Alexandra Borghesi (alexandra.borghesi@wearewithyou.org.uk)
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2023-02-03 - 12:56:33 PM GMT
-  Document e-signed by Paul Hughes (paul.hughes@wearewithyou.org.uk)
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