

Service Level Agreement and Service Specification for Pharmacy Supervised Consumption Darlington

Service Name	We Are With You in Darlington at STRIDE
Commissioner(s)	We Are With You on behalf of Darlington Borough Council
Provider Lead	We Are With You
Date Valid From	17/08/21
Date Review Due	16/08/22

Part A – Service Level Agreement

1. INTRODUCTION

This document defines the service requirements for the provision of a Supervised Consumption Service ('the Service') by the Community Pharmacy ('the Pharmacy') that must be met in order to receive payment in line with the Service Level Agreement in Part A) from We Are With You for provision of the Service as stated in the Service Specification in Part B). The Service will be provided to service users who are requiring supervised consumption of their medication for managing their substance misuse.

This Service Specification will, as required, be subject to continued review and amendment in consultation between We Are With You and a representation of local pharmacies. All Parties will be expected to cooperate fully with this review. All amendments to this Agreement, including the Service Specification will be evidenced in writing and signed by both We Are With You and the Pharmacy.

2. QUALITY STANDARDS

- 2.1 The Pharmacy will have an understanding of and will comply with Best Practice Guidance for Commissioners and Providers of Pharmaceutical Services for Drug Users (NTA, 2006); compliance with GPhC Code of Ethics and any locally set clinical governance and quality standards as agreed by the Pharmacy and We Are With You.
- 2.2 The Pharmacy will demonstrate a relevant quality assurance standard to We Are With You, or will work towards achieving such a standard within an agreed timescale. The quality assurance standards are specified in Appendix A as Pharmacy Assurance Framework.
- 2.3 We Are With You expects the Pharmacy to be able to provide evidence of full compliance with the obligations set out in this Service Level Agreement, We Are With You's quality standards arrangements, and other reasonable future arrangements deemed necessary as and when required. It would be expected that the pharmacy would follow GPhC clinical governance guidance. Any incidents or concerns would then be fed into We Are With You's clinical governance process.
- 2.4 All clinical governance, reported incidents and patient safety standards in regard to this enhanced Service will be monitored and audited by the Pharmacy.
- 2.5 The Pharmacy will ensure that We Are 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, arising directly from the negligence of the Pharmacy.

- 2.6 The Pharmacy will 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.
- 2.7 Incidents and near misses must be promptly reported to We Are With You on the same day that relates directly to the provision of this Service or as soon as the pharmacy becomes aware and the We Are With You service is open.

3. EXIT STRATEGIES AND SUSTAINABILITY

- 3.1 The Pharmacy accepts that We Are 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 28 days notice. Such reductions shall be timed to cause least disruption for service users. If We Are 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

4. ACCOUNTABILITY FOR POLICY AND PERFORMANCE.

- 4.1 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 Pharmacy's services.

5. CONFIDENTIALITY AND PROVISION OF INFORMATION.

- 5.1 The Pharmacy undertakes that they:
- Shall keep confidential all information concerning service users.
 - Shall keep safe at all times all papers and documents placed in their possession concerning service users.
 - Shall comply with the requirements of all legislation relevant to the service and in particular with the Data Protection Act 2018, Human Rights Act 1998 and Freedom of Information Act 2000.
- 5.2 We Are With You may require the pharmacist to supply any relevant information required to carry out monitoring and evaluation of the Service. Any service user information supplied must be anonymised where appropriate and will not be used for any purpose other than monitoring, evaluation and validation.
- 5.3 Each party shall comply with its respective obligations pursuant to applicable data

protection laws and/or regulations in relation to the processing of personal and/or special category data under this agreement, including but not limited to the General Data Protection Regulations and the Data Protection Act 2018.

6. EQUAL OPPORTUNITIES

- 6.1 The Pharmacy will 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. Staff should work in line with their own organisation's "Equal Opportunity Policy" and "Equality and Diversity Scheme". All aspects of the Service will be sensitive to the individual service needs of service users. Their cultural, religious and linguistic needs should be met and recognised, utilising resources and specific services for support where appropriate.

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.

7. FUNDING, PAYMENTS AND DEFAULT

- 7.1 See in Service Specification below.

Payment will be made monthly in arrears by We Are With You upon receipt of an invoice from the Pharmacy that arrives no later than the 5th day after the end of the month. Payments will only be made where We Are With You is satisfied that the Service has been provided in accordance with the terms of this Agreement and will make best endeavours to pay within 30 days of receipt of the Pharmacy's invoice.

- 7.2 We Are With You shall be entitled to suspend payment 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.

- 7.3 Following the exercise of rights in clause 7.2 above, We Are 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, We Are 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.

- 7.4 Without prejudice, if the Pharmacy fails to comply with the provisions of this Agreement We Are With You may serve a default notice stating the action required to remedy the default within a period of time (to be specified by We Are With You)

in which to take the action. If the Pharmacy remains in default following the expiry of the period specified We Are With You may proceed to terminate the Agreement.

7.5 The Service and payment may be varied or discontinued if:

- a) The Pharmacy and We Are With You agree, or
- b) A change in We Are 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 We Are With You service priorities that require either reduction in funding or discontinuation of funding.

We Are With You also has the option to terminate funding should the Pharmacy enter into receivership or become insolvent.

8. ARBITRATION

Any dispute, which cannot be resolved by negotiation, shall be referred to a nominated arbitrator for example the Chair of the Local Law Society.

9. NOTICES

9.1 Notices may be given personally and 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.

The Address for notice for We Are With You is:

We Are With You, Part Lower Ground Floor, Gate House, 1-3 St Johns Square,
London, EC1M 4DH

9.2 The address for notice for the Pharmacy is:

Insert Pharmacy address

10. TERMINATION

This Agreement will end at the end of the Term or earlier:

- a) On the dissolution of the Pharmacy
- b) On the expiry of at least one months' notice given by the Pharmacy to We Are With You of its intention to terminate the Agreement
- c) On the expiry of at least one months' notice given by We Are With You to the Pharmacy of its intention to terminate the Agreement
- d) In absence of the of regular accredited Pharmacist, Pharmacy Manager or Pharmacy Technician to oversee the Service.

11. THIRD PARTY RIGHTS

Nothing in this Agreement confers or purports to confer on any third party any benefit or any right to enforce any term of this Agreement.

12. SEVERABILITY

If any provision of this Agreement is held invalid, illegal or unenforceable for any reason by any court of competent jurisdiction, such provision shall be severed and the remainder of the provisions hereof shall continue in full force and effect as if this Agreement had been executed with the invalid illegal or unenforceable provision eliminated. In the event of a holding of invalidity so fundamental as to prevent the accomplishment of the purpose of this Agreement We Are With You and the Pharmacy shall immediately commence good faith negotiations to remedy such invalidity.

13. WAIVER

The failure of either We Are With You or the Pharmacy to insist upon strict performance of any provision of this Agreement or failure to exercise any right or remedy to which it is entitled hereunder shall not constitute a waiver thereof and shall not cause a diminution of the obligations of the other party Pharmacy under this Agreement or otherwise.

A waiver of any default shall not constitute a waiver of any subsequent default. No waiver of any of the provisions of this Agreement shall be effective unless it is expressly stated to be a waiver and communicated by either We Are With You or the Pharmacy to the other in writing.

14. ACCREDITATION

- 14.1 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 Part B.
- 14.2 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. Service may recommend the installation of a regular accredited person.
- 14.3 It is the responsibility of the Pharmacy to ensure that an accredited person is available to oversee the Service on a regular basis and if not We Are With You should be informed. Please update the document locally to reflect e.g. change in regular pharmacist and inform the service for key contact purposes. If no

accredited person is available to oversee on a regular basis please contact the service manager for advice.

Name	Job Title	Accreditation

AUTHORISATION

This Agreement is authorised by the following:-

For and on behalf of We Are With You:

Date	
Signed By	
Name	
Position	

For and on behalf of the Pharmacy:

Date	
Signed By	
Name	
Position	
Pharmacy Name and Address (please insert list of	

stores if a multiple and address to serve notice to if ever required)	
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Part B – Service Specification

1. Introduction

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

Daily contact allows not only a relationship to develop but also monitoring of client adherence and the opportunity to offer timely, supportive advice and responses on issues of concern. The Pharmacy thus has an important role to play and will contribute to the client'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 client choice, as part of an evolving treatment plan.

2. Aims

The aim of this 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

1. That 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.
2. That there should be greater involvement of primary care professions, such as General Practitioners and Community Pharmacists, in the care of more

stable drug misusers.

3. To ensure that the client takes the correct dose of medication prescribed by the Clinician.
4. To ensure that medication prescribed is not inappropriately directed onto the illegal market.

4. Principles of the scheme

This specification outlines the procedures for carrying out the Service and its administration. The 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 client.

The dispensing arrangements should take into account the client's social factors, such as employment and childcare responsibilities.

Supervision itself may create secondary dependence. Clients should not see this as a punishment and, once stabilised, clients should be trusted to take home their medication.

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

The client 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 clients' dignity and that of other pharmacy customers and staff safety.

5. Payment

Payment will be made to the Pharmacy on a per supervision basis. The payment schedule will be as follows:

Supervision of methadone and buprenorphine – £1.54 per supervision

This will be paid monthly in arrears (or as local variation) with the expectation that the Pharmacy will accept a minimum of 5 clients at any one time, subject to the service being able to refer 5 clients.

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.

6. Competencies and Training

We Are With You 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 provision of the Service.

Training for pharmacy staff will include appropriate related topics including basic drugs awareness, referral, health promotion, the 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 each participating pharmacy.

It is also a requirement for the accredited Pharmacist(s) and/or Pharmacy Technician(s) at each pharmacy to have completed in the last two years or go on to complete the latest CPPE Distance Learning Package on "Substance Use and Misuse" within 6 months of commencing service provision. 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 participating pharmacy to ensure their staff have been provided with appropriate training, this will include health and safety, an overall understanding of the Service, relevant SOPs and the importance of maintaining confidentiality.

In the event of changes to the accountable, accredited pharmacist or technician then We Are With You will be informed within 6 weeks of the situation. A new accountable pharmacist/technician will be allowed 3 months to complete the required CPPE training/DoC to take over as the replacement pharmacist.

The accredited/lead pharmacist must work at least three days a week in the pharmacy. Where locums or part time pharmacists predominantly operate a 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 We Are 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 We Are 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.

7. Prescriber Responsibilities

The Prescriber shall reach an understanding with the client 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 the most suitable/convenient pharmacy that is part of the scheme, with the client.

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

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

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

8. Referral Criteria/Liaison

Clients 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 client 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.

Observation will normally be for a period of 3 months. but may vary as discussed above and in 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 client 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). Please ensure checked, signed and a copy returned to the Prescribing Agency the same day on receipt.

9. 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 all pharmacy staff are trained, responsible and accountable.
- Pharmacy Technician's involved in the provision of this Service must be registered with the GPhC, have an up to date CPD portfolio and have a good knowledge of the Service.
- Ensure that 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 guidance in this document or appendices.
- Will make all reasonable efforts to accommodate all new supervised consumption clients 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 client is already banned from the premises or, there is an identifiable reason why it would be inappropriate for the client to be supervised at the pharmacy).

- An appropriate private area will be provided to protect the privacy and dignity of all clients. Supervision will never occur in the dispensary.
- Ensure all staff adhere to confidentiality.
- Respond 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.
- Will relay to the recovery co-ordinator and/or prescriber any appropriate concerns or comments they may have regarding a client's progress or conduct. This will be done in a manner not to breach confidentiality and maintain a good relationship with the client/pharmacy.
- All incidents will be reported to We Are With You in addition to any in-house incident monitoring procedures in the pharmacy and to the NHS Controlled Drug Accountable Officer as appropriate.
- Ensure 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 We Are 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 client first attends, the Pharmacy must check that the client meets the description given by the named contact; check the details of the 'Prescribed Treatment Agreement' and register the client on the Patient Medical Record (PMR) system. The pharmacy will establish an appropriate system to aid client identification when collecting medication subsequently.

The Pharmacy must take the client through the 'Prescribed Treatment Agreement'

and discuss/complete any relevant information, including:

- Opening hours for client to access services (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 client has missed three or more consecutive doses.
- Medication will not be dispensed if the Pharmacy suspects that there is drug and/or alcohol intoxication (client asked to return later or contact prescribing agency for assessment). Appendix A 'Signs and Symptoms of Intoxication' has been included to help in this determination. The client must be asked to return later or the Prescriber/Prescribing Agency contacted for assessment.
- Client must come in alone.
- Acceptable behaviour by the pharmacy and the client.

If a client has missed collecting doses the Pharmacy must contact the Prescribing Agency by telephone to inform of the missed dose. If the client misses 3 consecutive doses the Pharmacy must contact the Prescribing Agency and discuss the appropriateness of dispensing the dose.

If a client 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 client 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 clients must receive medication daily in accordance with the Prescribers

directions. Dispense instalments due on pharmacy closed days on a prior suitable day. If an instalment's collection day has been missed, please still dispense the amount due for any remaining day(s) of that instalment

It is 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, "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 client for whatever reason, any prescriptions that have not yet been started must be crossed and marked "INVALID". A note made on the client'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 Service delivery. 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.

Pharmacies must ensure that they have adequate insurance cover prior to commencing the Service.

10. Dispensing and Supervision

Supervision must never take place in the dispensary.

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, medication should be 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 client arrives at the Pharmacy.

When the client arrives, the accredited Pharmacist or authorised Pharmacy Technician must ensure that the client is correctly identified, interact with them to determine general health and suitability for collecting medication and receives his/her dose of medication. If a client presents as intoxicated (See Appendix A) please see the incident section below.

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

10.1 Methadone Liquid

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

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

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

If this is the client'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 clients should be in the early 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 client'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 client 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 client 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 client. The accredited Pharmacist or Authorised Pharmacy Technician will then observe the client 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 client should be observed until the tablet(s) have dissolved; the client should then open his/her 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.

Patients 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.

10.3 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 patient with a certain product (brand), the product cannot readily be exchanged with another product.

Note

Clients must not bring their own drinks into the pharmacy. There have also been reported cases of clients spitting their methadone into their drinks containers as a method of diversion.

All labels must be removed from the clients' dispensed containers, or have the client name obliterated indelibly, before throwing away, to maintain confidentiality.

After each dispensing the Pharmacy must then complete the data collection entry for that client 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. Note missed doses must be reported at the time as detailed above.

If the client 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 client CD return. That must be then destroyed following current guidance and best practice for a CD return. Please inform the Prescribing Agency and prescriber should this occur.

11. Incidents

You must contact the Prescribing Agency if:

- The client appears ill.
- The client misses a dose during titration or on a regular basis.
- The client misses three consecutive doses.
- Client does not consume whole dose.
- The client tries to avoid supervision of consumption.
- The client appears to be intoxicated with alcohol or drugs.
- The behaviour of the client 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 has to shut.
- Accidents or injuries.

Note

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

12. Key Contacts

If you have any concerns in relation to your contract or other issues please

contact:

Lead Clinical Pharmacist: emma.griss@wearewithyou.org.uk

Referrals can be made via secure NHSmail, post, or telephone.

Service contact details

Address

We Are With You in Darlington at STRIDE

26 Coniscliffe Road

Darlington

County Durham

DL3 7JX

Telephone: 01325 809 810

Secure email: withyou.darlington@nhs.net

13. 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



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)

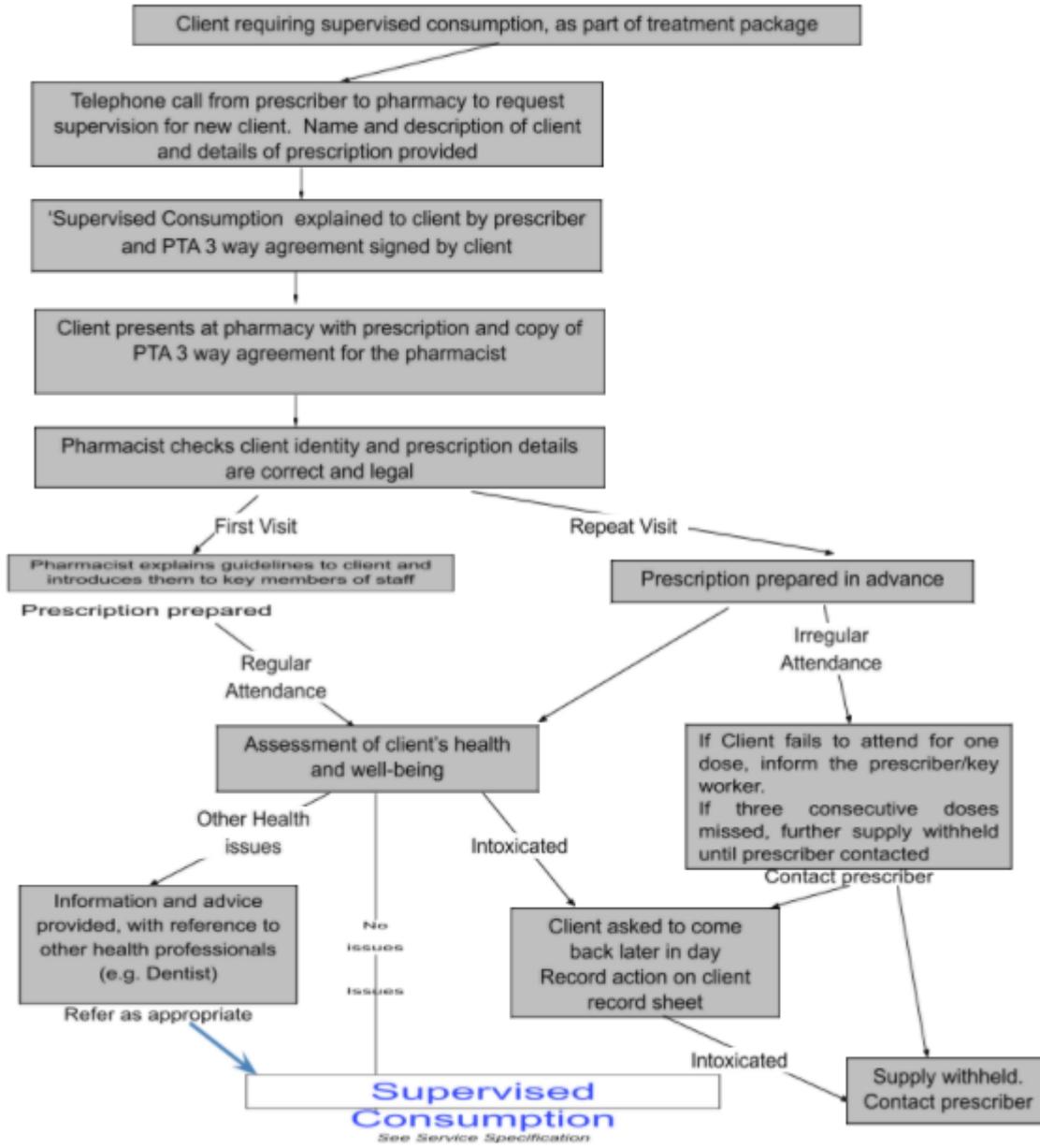
Pinpoint or constricted pupils
Sedation and drowsiness especially when taken with other depressants (e.g. benzodiazepines, alcohol, barbiturates)
Droopy eyelids
Slow speech

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 clients who, in line with the clinical guidelines, require supervised consumption.



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.

Client Name/Date of Birth:		Client Photograph:
Client ID number:		
WithYou Recovery Worker/Phone Number:		
Pharmacy Name/Address:		
Pharmacy Phone Number:		
GP Surgery/Phone Number:		
Pharmacy collection times:	E.g. M-F 9.30-4.30	

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 clients 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]

Client signature:

WithYou signature:

Pharmacy signature:

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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>	Client 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 clients treated with dignity and respect.		
Suitable data protection methods employed.		
Pharmacy/Client agreement in place (good practice).		
On observation pharmacy staff follow best practice when carrying out supervision (as detailed in SLA).		
Information is available to clients informing them how to make a complaint/compliment.		

Staff can give examples of regular interventions and signposting. Is there information available to handout to clients? 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 clients re NSP? Examples of signposting and interventions regularly.eg checking of client's sites, time elapsed since last use of exchange, understanding of appropriate kit. Is there harm minimisation discussion?		
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

Summary and Next Steps