Service Level Agreement

and

Service Specification for Pharmacy Supervised Consumption of Medication

|  |  |
| --- | --- |
| Service Name | STARTSupporting Treatment and Recovery Together |
| Commissioner(s) | Foundations of Acklam Road, Middlesbrough, TS5 4EQ(**Foundations**) |
| Provider Lead | \*Insert Pharmacy Name (full company name and number if applicable) and primary address(the **Pharmacy**) |
| Pharmacy Location(s)  | \*insert each location at which the Services will be provided. |
| Contract Date From | 1st September 2020 |
| Contract Date End | 31st August 2023 |

**Part A - Service Level Agreement**

This agreement is between Foundations and the Pharmacy and shall commence on the date it is signed by both parties and shall continue until the Contract Date End unless terminated earlier in accordance with this agreement.

The Service Specification, for the avoidance of doubt, forms part of this agreement.

This is a Service Level Agreement for the supervised consumption of prescribed medicines for drug misusers by Community Pharmacies within Hartlepool.

1. **INTRODUCTION**

1. 1 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 Foundations 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 (**Clients**). The Services have been provided from the Contract Date Start and this contract shall be deemed to have taken effect on that date.

1.2 This Service Specification will, as required, be subject to continued review and amendment in consultation between Foundations and local LPC representing the interests of 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 Foundations and the Pharmacy.

**2. SERVICE DESCRIPTION**

2.1 This Service will require the Pharmacy to supervise the whole process of consumption of prescribed medicines at the point of dispensing in the pharmacy, ensuring that the dose has been administered to the Client.

2.2 The Pharmacy will offer user friendly, non judgemental, client centre, confidential service.

2.3 The Pharmacy will provide support and advice to the Client, including referral to primary care of specialist centres where appropriate.

**3. SERVICE STANDARDS**

2.1 The requirements of the Medicines Act and the Community Pharmacy Contract apply as usual.

2.2 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 Foundations.

2.3 The Pharmacy will demonstrate a relevant quality assurance standard to Foundations, or will work towards achieving such a standard within an agreed timescale.

2.4 Foundations expects the Pharmacy to be able to provide evidence of full compliance with the obligations set out in this Service Level Agreement, Foundations’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 Foundations’s clinical governance process.

2.5 The Pharmacy will operate to appropriate standards of clinical governance. The Pharmacy will be expected to provide suitable evidence to demonstrate the quality of service delivery for the supervised consumption of prescribed medications for drug users.

2.6 The Pharmacy will ensure that Foundations is indemnified and remains indemnified against any loss, damage, claim, action, or proceedings (including any interest, fine, penalty or legal and other professional costs) it may suffer or incur arising from or in relation to:

a. the Pharmacy’s breach or negligent performance or non-performance of this agreement;

b. the enforcement of this agreement;

c. any claim made by a third party (including for death, personal injury or damage to property) arising out of or in connection with the provision of the Services by the Pharmacy or any act or omission of the Pharmacy, its employees, agents or

SAVE THAT this indemnity shall not cover Foundations to the extent that a claim under it results from Foundation (START)’s gross negligence or wilful misconduct.

2.7 The Pharmacy will provide and maintain a safe and suitable environment for Clients, 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.

2.8 The Pharmacy shall also ensure that all personnel involved in the provision of the services have suitable skills, qualifications, and experience to enable them to properly perform the tasks assigned to them. The Pharmacy shall ensure that an accredited Pharmacist, Pharmacy Manager or Pharmacy Technician Accreditation regularly oversees the provision of the Services and in any event for no less than the majority of the working week. The designated Pharmacist has a duty to ensure that pharmacists and staff involved in the provision of the service – are aware of and operate within local protocols, have relevant knowledge and are appropriately trained.

2.9 Incidents and near misses must be promptly reported to Foundations on the same day that relates directly to the provision of this Service or as soon as the pharmacy become aware. All incidents involving a controlled drug must be reported to the PCT Accountable Officer. ***An incident is defined as any occurrence that is not consistent with the professional standards of care of the client or routine operation/policies of the organisation.***

2.10 The Pharmacy shall ensure the Services confirm with the Service Specification and are performed with a high level of care, skill, and diligence in accordance with best practice, shall ensure that it has all necessary licences and consents in relation to the Services, and shall not do or omit to do anything that may cause Foundations to lose any licence, authority or permission it requires.

2.11 The Pharmacy shall maintain throughout the term of this agreement all appropriate insurances that would be maintained by a reasonably prudent person carrying on the Services in order to cover the liabilities that may arise under or in relation to this agreement

Liability

2.12 Nothing in this agreement:

1. limits any liability that cannot be legally limited, including liability for death or personal injury caused by negligence or fraud;
2. limits the liability of a party under an indemnity given by it under this agreement;
3. limits the liability of a party to the extent that such is covered any payable out under a policy of insurance maintained by or for the benefit of that party;
4. limits the payment obligations of Foundations under this agreement; or
5. limits a party’s liability where such arises from its deliberate default.

2.13 Neither party shall be liable to the other for indirect or consequential losses, loss of profits, loss of sales or business, loss of agreements or contracts, or loss of anticipated savings.

2.14 Subject to clause 2.13 the liability of one party to the other under this agreement shall not exceed the total amount paid and payable to the Pharmacy under this agreement.

**3. EXIT STRATEGIES AND SUSTAINABILITY**

3.1 The Pharmacy accepts that Foundations 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.

3.2 Foundations shall endeavour to procure (but cannot guarantee) that any such reductions shall be timed to cause least disruption for Clients. If Foundations 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.

4.2 These meetings will be held at a time and place that do not disrupt the provision of the Pharmacy’s services.

4.3 The Services will be subject to performance monitoring, this may include self assessments and/or pharmacy visits as appropriate.

4.4 As a minimum the pharmacy must –

* Maintain accurate records
* Review standard operating procedures on an annual basis
* Demonstrate that pharmacists and staff involved can demonstrate CPD in respect of this service delivery
* Complete an incident report as appropriate

**5. CONFIDENTIALITY AND PROVISION OF INFORMATION.**

5.1 The Pharmacy undertakes that they:

• Shall keep confidential all information concerning Clients or persons connected to them.

• Shall keep safe at all times all papers, documents, materials, and other information placed in their possession or within their control concerning Clients or persons connected to them.

• Shall comply with the requirements of all legislation relevant to the service and in particular with the General Data Protection Regulation ((EU) 2016/679) as it applies in England, the Data Protection Act 2018, Human Rights Act 1998 and Freedom of Information Act 2000.

• Shall not use the confidential information of any Client or any person connected to them other than for performing its obligations under this agreement.

• Shall share information with professional agencies as reasonably required to ensure that appropriate services are provided and safe working practices are adopted.

5.2 Foundations 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.

**6. EQUAL OPPORTUNITIES**

6.1 The Pharmacy will adopt an equal opportunities policy relating to service provision, staffing and management of the organisation, with a view to preventing Discrimination as defined 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 Clients. Their cultural, religious and linguistic needs should be met and recognised, utilising resources and specific services for support where appropriate.

6.2 **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 Payments will be made pursuant to the Service Specification. Payment will be made monthly in arrears by Foundations 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 Foundations 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 undisputed invoice.

7.2 A fee should be claimed only where between 14 and 31 supervisions have taken place for each Client in the month relating to the claim.

7.3 Foundations shall be entitled to suspend payment and/or vary the amount of the payment if it considers the Pharmacy has committed a serious or persistent breach of the Agreement and shall forthwith notify the Pharmacy in writing accordingly.

7.4 Following the exercise of rights in clause 7.2 above, Foundations 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, Foundations 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.

7.5 Without prejudice, if the Pharmacy fails to comply with the provisions of this Agreement Foundations may serve a default notice stating the action required to remedy the default within a period of time (to be specified by Foundations) in which to take the action. If the Pharmacy remains in default following the expiry of the period specified Foundations may terminate the Agreement.

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

a) The Pharmacy and Foundations agree, or

b) By Foundations if change in Foundations 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 Foundations service priorities that require either reduction in funding or discontinuation of funding.

**8. ARBITRATION**

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

**9. NOTICES**

9.1 Notices must be given in writing (excluding fax or email) and 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.

9.2 The Address for notice for Foundations is: Foundations, Acklam Road, Middlesbrough, TS5 4EQ

9.3 The address for notice for the Pharmacy is : any address for the Pharmacy detailed in this agreement or its registered office or primary place of business from time to time.

**10. TERMINATION**

10.1 This Agreement will end the Contract Date End unless terminated earlier in accordance with this agreement.

10.2 Either party may terminate the agreement:

a) immediately if the other party commits a material or persistent breach of any of the terms of this agreement and (if the breach is remediable) fails to remedy the breach within 14 days of being notified in writing to do so;

b) immediately if the other party suspends or threatens to suspend payment of its debts, is unable to pay its debts as they fall due, or an order or resolution is made or for the winding up or dissolution of that party or for the appointment of an administrator, administrative receiver, or receiver; or

c) on one month’s written notice to the other.

10.3 Foundations may terminate this agreement immediately:

a) if there is an absence of an accredited Pharmacist, Pharmacy Manager, or Pharmacy Technician to oversee the Service;

b) if it is concerned as to the health or safety of Clients or any other person in the delivery of the Services.

c) pursuant to clause 7.5.

**11. THIRD PARTY RIGHTS**

11.1 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**

12.1 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 Foundations and the Pharmacy shall immediately commence good faith negotiations to remedy such invalidity.

**13. WAIVER**

13.1 The failure of either Foundations 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 Foundations 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 recommence on 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 Foundations should immediately be informed. Any change to the regular Pharmacist or Pharmacy Manager shall be immediately notified to Foundations in writing together with details of any replacement for key contact purposes. for key contact purposes. If no accredited person is available to oversee on a regular basis please contact the service manager for advice.

14.4 The Pharmacy shall immediately notify Foundations of any material change to local circumstances or matters that may impact on the provision of the Services or the performance of the Pharmacy’s obligations under this agreement.

This Agreement is authorised and executed by the following:-

**For and on behalf of Foundations**

|  |  |
| --- | --- |
| Signed |  |
| Date | 01-09-2020 |
| Name | Nicole Clark |
| Position | Clinical Partner |

**For and on behalf of the Pharmacy:**

|  |  |
| --- | --- |
| Signed |  |
| Date |  |
| Name: |  |
| Position |  |
| Pharmacy NameAnd Address (pleaseinsert address toservice notice toif ever required) |  |

**Part B - Service Specification**

**1. Introduction**

Community pharmacies are ideally placed to provide supervised consumption within an agreed and structured protocol. This allows relationships to develop between the Pharmacist and the Client whilst also providing opportunity to monitor client adherence to prescribing regimes and to offer advice and information at the point of contact. The pharmacy plays an important role in the review of prescribing practise by the prescribing service and the aim should be to reduce supervised consumption as soon as is safe and clinically appropriate to do so. However, this can and should be reinstated at times of crisis, relapse of by client choice.

**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**

• 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.

• 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.

• To ensure that the client takes the correct dose of medication prescribed by the Clinician.

• 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 from the Prescribing Agency through sharing of information and regular liaison.

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. General Responsibilities**

Standard Operating procedures should be available to all members of staff undertaking supervised consumption

Clients should be accepted for supervised consumption when they have been appropriately referred by the treatment provider – Foundations.

To work collaboratively with the client, treatment provider – Foundations, and key worker to ensure the objectives of the service are met.

To proactively share information, where appropriate, regarding any concerns

To have a designated named pharmacist at the pharmacy who will be responsible for the day to day running of the scheme.

To ensure prescriptions comply with necessary legal requirements

To inform pharmacies if, on an individual basis, use of an alternative strength methadone mixture has been approved

**6. Payment**

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

1. Supervision of methadone and buprenorphine £44.00 including VAT per client per month provided that between 14 and 31 supervisions have taken place for each client in the month relating to the claim. This will be paid monthly in arrears 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 inclusive of VAT, both Parties are aware of this. 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.

**7. Competencies and Training**

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. This will include engagement with the LPC and attendance at relevant events.

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.

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, including Locums, 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 Foundations 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 Foundations promptly.

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 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

**8. Responsibilities to clients**

To ensure the client is treated as an individual with respect and aiming to maintain confidentiality at all times.

At first contact confirm client understands of their responsibilities to the pharmacy within the client contract

To introduce themselves and any other key members of staff to new clients

To remind client when they are nearing the end of their prescription

Provide a copy of the pharmacy leaflet and opening times.

**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 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

**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 Foundations 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 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 Foundations 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.

• 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). 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 Medcation 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**

Prescriptions must clearly state “For Supervised Consumption” , processes must reflect the requirements of the Good Dispensing Practise for Controlled Drugs. If the prescriber requires that the Buprenorphine must be crushed prior to administration the prescription must state “to be crushed and supervised”

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.

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

Pharmacies must have a suitable quality assurance process for ensuring accuracy of measured doses

Child resistant closures should be used on all home doses where appropriate and advice given about safe-keeping of medication.

Does for consumption on days when the pharmacy are closed e.g., Sunday / Bank Holidays should be dispensed on a suitable prior day

**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.

**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.

**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

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. 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)