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**Service Level Agreement**

**Spark**

**Delphi Medical Consultants Ltd**

**Pharmacy Supervised Consumption Programme**

**1st April 2023 – 31st March 2024**

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| **Version** | **Date** | **Changed by** | **Reason for change** |
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| **Service** | Pharmacy Supervised Consumption |
| **Delphi Author** | Kayleigh Topping |
| **Provider** | Approved Pharmacies in Blackburn with Darwen |
| **Period of Service** | 1st April 2023 – 31st March 2024 |

1. **GENERAL OVERVIEW**

This specification sets out a model for an enhanced service for Supervised Consumption of Opiate Substitute Treatment (OST) and is between Delphi Medical Consultants Limited (the purchaser) as ‘Spark’ and Community Pharmacies of Blackburn with Darwen (the contractor) who are existing or new participants in the provision across Blackburn with Darwen. Participation by community pharmacies in this service remains voluntary and guided by localised need.

1. **SERVICE**
   1. **Overview of Service**

The specifications below outline the background, the Standard Operational Procedures and the administrative processes for the Supervised Self Administration Scheme for Opiate Substitute Treatment (OST) - Methadone, Buprenorphine, Espranor® oral lyophilisate and Buprenorphine-naloxone (Suboxone®).

Pharmacists participating in this service will be expected to take on the number of clients that they feel appropriate for their pharmacy within the parameters of good practice, taking into account all their community responsibilities.

One key element of drug treatment for opiate users is the prescribing of OST. Studies have shown that Methadone Maintenance Treatment reduces levels of injecting drug use and associated health problems, crime, and drug related death among those in treatment. Thus, the Clinical Guidelines believe it to be ‘an important part of drug misuse services’ (DoH, 1999:45). Prescribing substitute medications allows time for individuals to implement personal or social changes that can reduce the impact of their illicit drug use and is a key element to increase the opportunities of individuals to achieve their goals.

Pharmacists play a key and unique role in the care of the substance users.

‘Key’, in that through the supervision of consumption of OST, the pharmacist is instrumental in supporting drug users in complying with their prescribing regime, therefore reducing incidents of accidental death through overdose. Also, through supervision, pharmacists are able to keep the misdirection of controlled drugs to a minimum, which may help to reduce drug related deaths in the community.

The ‘unique’ role that pharmacists play in the treatment of drug users is the daily contact that they have with their patients, and their ability to monitor and offer advice on the patient’s general health and well-being. By integrating the pharmacists into the ‘shared-care’ service this gateway role can be developed to maximise the positive impact treatment has for patients.

It is therefore important that the service user attends the same pharmacy and that the pharmacist is supportive with an understanding attitude. The relationship between service user and pharmacist should ideally be friendly, but professional.

* 1. **Aims and Expected Outcomes**

To supervise the consumption of prescribed medicines at the point of dispensing in the pharmacy, ensuring that the dose has been consumed by the service user.

To offer a user-friendly, non-judgmental, client-centred and confidential service.

To liaise with the prescriber if there are concerns about the service user’s attendance for their prescription.

To provide support and advice to the service user, helping them access further advice or assistance. The service user will be referred to specialist treatment centres or other health and social care professionals where appropriate. This can continue with service users who move from supervised consumption to daily pick up and beyond.

To ensure compliance with the agreed treatment plan by:

* Dispensing in specified instalments (doses may be dispensed for the patient to take away to cover days when the pharmacy is closed)
* Ensuring each supervised dose is correctly consumed by the patient for whom it was intended

To reduce the risk to local communities of:

* Diversion of prescribed medicines onto the illicit drugs market
* Accidental exposure to the supervised medicines

Monitoring the service user’s response to prescribed treatment; for example, if there are signs of overdose, especially at times when doses are changed, during titration of doses, if they appear intoxicated or when they have missed doses and if necessary withholding treatment if this is in the interest of patient safety, liaising with the prescriber or named key worker as appropriate.

Pharmacies will strengthen this service by building good working relationships with the Spark service, working collaboratively to support promotional events, campaigns, warning message communication, treatment engagement and retention.

* 1. **Rationale for the Service**

Ensuring a safe and consistent approach of supervised consumption in Blackburn with Darwen that will standardise the process and result in a high level of service throughout the supervising pharmacies.

* 1. **Service Delivery** 
     1. **Location(s)**

This service is for residents of Blackburn with Darwen. The service will be delivered in approved community pharmacies only.

* + 1. **Days and Hours of Operation**

The service will operate during pharmacy opening hours.

* + 1. **Referral Criteria and Sources**

The service is for residents of Blackburn with Darwen aged 18 years and over identified as prescribed OST under the care of Delphi Medical Consultants Limited Substance Misuse Services.

Supervised consumption is specified on the prescription.

In the event a patient from out of area tries to access the supervised scheme, notification to the Spark prescribing team must be made with immediate effect.

Any person over 18 years old can be referred to Spark if they wish to access treatment on 01254 495014.

Young people under 18 years old should be signposted to the local specialised young people’s service Early Break. They can be contacted by telephone on 01254 222154 or by email at: [info@earlybreak.co.uk](mailto:info@earlybreak.co.uk).

* + 1. **Exclusion Criteria**

Where the service user lives outside of Blackburn with Darwen boundaries, excluding those of no fixed abode.

The service should display a zero tolerance approach; patients can be excluded for behaviour that has breached accepted rules and standards, at the discretion of the service, but within a structure of users' rights and responsibilities.

* + 1. **Essential Links to Other Services**

The pharmacy will be required to work with Spark and Public Sector bodies such as the NHS, Police, Probation.

The service provider will ensure:

* Collaborative and effective operational links with key workers and prescribers within the Spark treatment system in pursuit of a fully integrated seamless service for Blackburn with Darwen’s drug using population
* They support clients to engage with all relevant agencies with relevant signposting e.g. health, family support, education, employment services
* Clients are signposted to appropriate harm reduction and BBV screening services as appropriate

1. **SERVICE REQUIREMENTS** 
   1. **Operational**

A Standard Operating Procedure (SOP) for the service must be in place in the pharmacy, and the pharmacist must ensure that all staff, including locums, are aware of the content of the SOP, and have signed to confirm their understanding.

Participating pharmacists and pharmacy staff should be familiar with current national, regional, and local protocols and guidance.

The service user’s identity must be checked to ensure the prescription is dispensed to the correct person.

The pharmacist in charge will make an assessment that it is safe to supply the medication before supervising the dose, taking into consideration recently missed doses and intoxication from alcohol or drugs.

Supervision by the pharmacist should take place in a discreet area, or at times when the pharmacy is not likely to be busy, as agreed with the pharmacist.

Methadone – The daily amount should be dispensed according to good practice guideline. When the service user arrives, the measured dose should be poured into a suitable receptacle and consumed in the consultation area away from the main shop floor with water to facilitate its administration and/or reduce the risk of doses being held in the mouth.

Buprenorphine sublingual tablets – The pharmacy will prepare the dose. The service user may be provided with water in a disposable cup prior to issuing the dose, this may speed up the process of the medication dissolving under the tongue. The medication should be tipped directly under the tongue without handling. The service user will need to be supervised until the tablet has dissolved. This may take up to 10 minutes. When most of the tablet is dissolved, and only a chalky residue remains, talk to the service user to determine the dose has fully dissolved. The crushing of tablets is off-licence and therefore should not be undertaken unless the prescriber requires this. If required, the prescriber must write this on the prescription and both the prescriber and service user must be aware that this is off-licence.

Espranor oral lyophilisates – The pharmacy will prepare the dose. The oral lyophilisate should be removed from the blister pack with dry fingers and placed whole on the tongue until dispersed, which usually occurs within 15 seconds. The service user will need to be supervised until the lyophilisate has dissolved. Swallowing must be avoided for 2 minutes, and food and drink not consumed for 5 minutes after.

The pharmacist must be satisfied that the service user has taken the medication as prescribed and may request an oral cavity check if necessary.

Pre-packing of doses for supply the next day must be in line with a written procedure and be undertaken in line with current guidance for Good Manufacturing Practice. (National Prescribing Centre – A guide to good practice in the management of controlled drugs in primary care 3rd Edition December 2009)

If medication is dispensed for non-supervised consumption (e.g., Sundays, Bank Holidays) the service user must be provided with information regarding the safe storage of the medication and reminded of the danger it presents to others.

The pharmacist will receive notification from the prescriber in advance of a new service user presenting a prescription; where the prescriber has failed to contact the pharmacist in advance, the pharmacist should always contact the prescriber to confirm arrangements.

In the event of any changes to a service user’s prescription i.e. they are admitted to hospital for a short period of time, the prescriber will contact the pharmacy with details of how the prescription will be reinstated.

The decision to discuss a service user with the prescriber or the Substance Misuse Service is a professional one that should be made after considering the risk to the service user of non-disclosure and the damage that could be done to the supportive relationship between pharmacist and client.

If a pharmacist has any cause for concern relating to a service user, and the prescriber or drug worker is not available (e.g. after 5pm or at weekends), the pharmacist must use their professional judgement in deciding whether to supply. In the case of any concerns, report on the next working day to the prescriber/drug worker.

A pharmacy/patient agreement contract will state the terms of agreement set up between the pharmacist and patient (to agree how the service will operate, what constitutes acceptable behaviour by the client, and what action will be taken by the GP and pharmacist if the user does not comply with the agreement).

The instalment direction is a legal requirement and must be complied with; however, the Home Office has approved specific wording to be used which gives pharmacists a degree of flexibility when making a supply. The following wording allows a pharmacy to supply the balance of an instalment if the interval date is missed:

* Please 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.
* Consult the prescriber if three or more consecutive days of a prescription have been missed.
* Supervise consumption on collection days.
* Dispense daily doses in separate containers.

The pharmacy will maintain records of the service provided. All occasions where the service user fails to attend the pharmacy to collect a prescribed dose of medication will be recorded.

Internet access must be available for input of data onto PharmOutcomes.

Once a prescription is completed, the service called “Supervised Consumption – Supervision” will be completed on PharmOutcomes. If this is the first time the service user has presented at the pharmacy the service called “Supervised Consumption - Registration” will need to be completed as a one-off activity before the supervision can be entered. Any missed doses will need to be entered daily to the service called “Supervised Consumption – Missed dose” on PharmOutcomes.

The pharmacist will ensure timely and accurate completion of the agreed monitoring and performance tools, e.g. PharmOutcomes to support service administration and agreed payment mechanisms for activities.

The pharmacy will have appropriate health promotion material available for the users of the service and promotes its uptake.

The pharmacy will provide support and advice to the service user, including referral to Spark and other health and social care professionals where appropriate.

The pharmacy will deal with any complaints sensitively and will report any complaints, comments, or concerns to Spark as soon as possible.

Pharmacy staff must be aware of local child and vulnerable adult protection procedures. These must be followed at all times.

* 1. **When to Contact the Prescriber**

The pharmacy staff must contact the prescriber via phone in the following circumstances:

* The service user does not consume the whole dose under supervision.
* The service user appears to be ill.
* The service user tries to avoid supervision or the process for proper administration.
* If the incorrect dispensing of any controlled substance has occurred.
* Overdose has occurred.
* The service user has been seen selling, swapping, or giving away their controlled medication.
* The service user appears to be intoxicated. If the pharmacist considers the service user is grossly intoxicated, the prescriber must be contacted, and the dose withheld.
* Whenever a service user does not attend to pick up or take their prescribed OST, the prescribing service should be informed the same day, wherever possible and if three daily doses are missed the prescription should not be dispensed on the fourth or any subsequent day, as the service user may have reduced tolerance, until the prescribing team have been contacted (this is in addition to missed collection notification sent via PharmOutcomes) and the prescription authorised to be released by the prescriber.
* The service user displays clear signs of deterioration of physical and/or mental health.
* The pharmacy becomes aware of service user admission to or discharge from hospital.
* There are problems with the prescription – e.g. uncertainty about dates, validity, has been tampered with etc.
* The behaviour of the client is unacceptable and contrary to the service user/pharmacy agreement - ultimately only you can decide what behaviour is ‘unacceptable’. In circumstances where a dose is not administered, or you wish to cease future administrations, both the service user and prescriber must be made aware of this decision.
* Any patterns of non-attendance e.g. always missing the same day or regularly missing days should also be notified to the prescribing service so dispensing arrangements can be reviewed.
  1. **Brief Harm Minimisation and Health Promotion Interventions**

This will be undertaken by a pharmacist or other competent staff member and may encompass such areas as:

* + - Safe injecting techniques
    - Sexual health advice
    - Transmission of blood borne viruses
    - Wound site management
    - Nutrition
    - Safe storage and disposal of injecting equipment and substances (e.g., to avoid risk of injury to children)
    - Taking measures to reduce harm and prevent drug-related deaths.
    - Safe storage and use of OST.
    - Alcohol misuse

Advice will be consistent with relevant recognised guidelines and good practice and should be supported with appropriate harm minimisation materials or literature.

* 1. **Registration, Competencies and Training**

The contractor will have Standard Operating Procedures which will be reviewed along with the referral pathways for the service at least every two years.

The pharmacy should demonstrate that pharmacists (including locums) and pharmacy staff involved in the provision of the service will have sufficient knowledge of the service and are familiar with the requirements of this service specification.

Staffing and management structures will be streamlined and efficient with all staff having clear areas of responsibility.

Pharmacists must have successfully completed the CPPE Substance use and misuse e-course, e-assessment, Safeguarding Adults and Children e-learning and have declared their competency for the Supervised Consumption of Prescribed Medicines. The declaration will need to be confirmed on PharmOutcomes via enrolment.

The completion declaration for these courses must be no more than three years old. It is recommended that registered pharmacy technicians complete the same declaration.

The pharmacy will participate and co-operate in any Spark organised audit of the service provision or assessment of service user experience.

The pharmacy provides harm reduction information to each client that accesses the service.

The contractor will ensure that appropriate professional indemnity insurance is in place.

It is a requirement for pharmacies signing up to this agreement to comply with all the requirements of the essential services of the NHS Community Pharmacy Contractual Framework.

All training costs will be met by the contractor.

* 1. **Business Continuity**

The contractor will ensure that sufficient staffing is available in the pharmacy at all times for the effective running of the service, including planning for times of sickness, absences or any other occurrence that may jeopardise the delivery of the service to service users whilst continuing to meet the performance objectives and standards of the service as outlined in this agreement.

Delphi Medical has the right to withdraw the service from a pharmacy that is not staffed with regular pharmacists. Alternatively, Delphi Medical may impose additional conditions on the pharmacy for the pharmacy to remain providing the service.

* 1. **Additional Costs**

All additional costs will be met by the provider of the service.

* 1. **Safeguarding Children and Vulnerable Adults**

Pharmacists and pharmacy staff must be aware of Blackburn with Darwen child and vulnerable adult protection procedures; these must always be followed.

Children’s Social Care: **01254 666400**

Adults Social Care: **01254 585949** Out of hours: **01254 587547**

* 1. **Incident Reporting**

The pharmacy is required to have a robust incident reporting and investigation procedure in place.

Incidents relating to this service should be reported in line with the pharmacy’s incident reporting procedure. The pharmacy will provide a copy of the incident report to the Spark Service Manager.

The pharmacy will deal with any complaints sensitively and will report any complaints, comments, or concerns to the Spark Service Manager as soon as possible.

All serious incidents must be reported to Delphi Medical Consultants Limited for investigation.

* 1. **Insurance**

The provider must at its own cost maintain the required insurances with a reputable insurance company. The cover shall be in respect of all risks which may be incurred by the provider, arising out of the provider's performance of this contract, including death or personal injury, loss of or damage to property or any other such loss. Such policies must include cover in respect of any financial loss arising from any advice given or omitted to be given by the provider.

* 1. **Key Performance Indicators**
     1. **Data Collation/Reporting**

PharmOutcomes must be used to record all activity; no other reporting method will be accepted.

Data may be shared with other organisations e.g. LPC.

* + 1. **Contract Review Meetings**

Contract review meetings will be held on an annual basis. The meetings will be held on the pharmacy premises.

1. **CONTRACT VALUE**
   1. **Value**

The pharmacy will receive a fee of:

* £1.50 for every supervised dose of Methadone
* £2.50 for sublingual tablets Buprenorphine and Buprenorphine/Naloxone (Suboxone)
* £2.00 for Espranor oral lyophilisate

Contractors are responsible for entering accurate claims data onto PharmOutcomes. This must be done by no later than the end of the following month following the provision date. Please note PharmOutcomes has been configured to reject claims older than this timeframe.

Any activity recorded after this two month grace period may not be paid.

Please Note: Where the total daily dose of buprenorphine prescribed requires the dispensing of two tablets i.e 8mg & 2mg for a 10mg total daily dose, only one supervision fee may be claimed as this is not classed as two supervisions. The intention of the supervision fee is to cover the supervision of one dose regardless of the number of tablets required to make up that dose.

Payments can only be made to pharmacies who have signed up to this scheme and have agreed to provide the service outlined above. Payments are pharmacy not pharmacist based.

* 1. **Method of Payment**

Payment will be made by BACS on receipt of claim information from PharmOutcomes.

* 1. **Frequency**

Invoices with be paid monthly and within our payment terms of 30 days from the date of the invoice.

If you have any payment queries, please contact [finance@calico.org.uk](mailto:finance@calico.org.uk).

* 1. **Governance and Termination**

It is implicit in the service being provided that it is delivered to the standards specified and complies with the legal and ethical boundaries of the profession.

Should an issue be identified either through a visit or through any other means an action plan will be produced following the process below:

* The pharmacy alongside Delphi Medical will identify any issues and will agree upon an action plan summarising what action needs to be taken and by when.
* If any further action needs to be taken, this will be documented, and new timescales agreed.
* If the issues remain unresolved after this, the option to withdraw the service from the pharmacy may be exercised.

Please note that the pace with which the process progresses will be determined by the level of risk. In addition, any serious professional matters identified may be escalated to OHID or the GPhC.

This agreement may be terminated if either the pharmacy or Delphi Medical give the other party one month notice in writing during the duration of the contract.

If the pharmacy or Delphi Medical is in breach of the agreement, the agreement can be terminated with one month notice in writing or with immediate effect for a serious breach or incident (e.g. following a fitness to practice incident).

* 1. **Local Point of Contact**

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

**Spark**

BWD@calico.org.uk – Tel: 01254 495014

**Kayleigh Topping** (Delphi Senior Pharmacist)

ktopping@delphimedical.co.uk – Tel: 07583374079

**Gary Howarth** (Spark Service Manager)

gahowarth@delphimedical.co.uk – Tel: 07593100621

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On behalf of (Pharmacy Name and Address) –

Telephone number –

Email address –

The pharmacy is open \_\_\_\_\_\_\_\_\_\_ days a week.

I have read and understand the terms in the service specification and agree to provide the standard of the service specified.

|  |  |
| --- | --- |
| **Signed by Pharmacy** |  |
| Signature: |  |
| Name: |  |
| Position: |  |
| Date: |  |

On behalf of Delphi Medical Consultants Ltd. I commission the above pharmacy to provide the service detailed in the service specification for Pharmacy Supervised Consumption of Opiate Substitution Treatment.

|  |  |
| --- | --- |
| **Signed by Delphi** |  |
| Signature: |  |
| Name: |  |
| Position: |  |
| Date: |  |