**Service Level Agreement**

**Inspire Lancashire**

 **Supervised Consumption Programme**

**1st April 2022 – 31st March 2023**

1. **Background**
	1. Community pharmacies play an important role in the care of substance misusers. They enable service users to comply with their prescribed regime by supervised consumption of methadone, buprenorphine, Espranor (buprenorphine oral lyophilisate) or Suboxone (buprenorphine/naloxone). Supervised consumption reduces the diversion of Controlled Drugs which may lead to a reduction in drug-related deaths.
2. **Aims and intended service outcomes.**
	1. To ensure service user compliance with their prescribed regime by:
		* Dispensing medication in specified instalments as instructed on the prescription.
		* Supervising the consumption of prescribed medication in the pharmacy
	2. To reduce opportunity for diversion and illicit supply of controlled drugs.
	3. To provide regular contact with healthcare professionals for service users.
3. **Service outline**
	1. Supervised consumption provision is available to those aged 18 years and over who are prescribed opiate substitute treatment (OST) as part of a substance misuse treatment programme where:
		* Supervised consumption is specified on the prescription.
		* Prescribing is undertaken by a prescriber at a CGL base or by a GP with Special Interest (GPwSI)/GPs participating in formal Shared Care arrangements within the North & Central Lancashire area.
		* the individual is usually resident within the North & Central Lancashire area
	2. The service will require the pharmacist to supervise the consumption of prescribed medications when indicated by the prescriber, ensuring that the dose has been administered appropriately to the service user.
	3. The prescribing service will contact the service users chosen pharmacy prior to the service user attending the pharmacy, to ensure the pharmacy has capacity to take on a new service user. The pharmacy will be provided with the service users’ details.
	4. The service user’s recovery worker will be responsible for obtaining the service users agreement to supervised consumption.
	5. Terms of agreement between the prescribing agency, pharmacist and service user should be discussed and agreed. This should detail how the service will operate, what is considered acceptable behaviour by the service user and what will happen if the agreement is breached. Signatures should be obtained confirming this and a copy of the information given to the service user and a copy kept by the pharmacy. The service user should be provided with any relevant pharmacy information at this time (e.g., opening hours). Appendix C provides a copy of a suggested template which can be adopted by the Pharmacy.
	6. The pharmacy will provide support and advice to the service users, including referral to other primary care services or specialist substance misuse services where appropriate.
	7. The pharmacy will continue to provide advice and support to service users who are moving from supervised consumption to daily pick-up and beyond; this may include referral back to the prescriber where appropriate.
	8. 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.
	9. Methadone: The pharmacy will present the medicine to the service user in a suitably labelled receptacle and will provide the service user with water to facilitate administration and/or reduce the risk of doses being held in the mouth. If a service user’s dose is measured out in advance of their visit, then suitable containers with lids should be used. These shall be individually labelled as per normal labelling regulations. Prior to disposal of these containers, all identifying labels shall be removed/anonymised.
	10. Buprenorphine and buprenorphine/naloxone: The pharmacy will prepare the dose. The service user will 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. Offer a further drink of water.

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.

* 1. Espranor: 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.
	2. If a service user misses three consecutive doses of OST, the prescribing service must be contacted (this is in addition to missed collection notification sent via PharmOutcomes) and no further doses dispensed unless advised by the prescriber. Any patterns of non-attendance e.g. always missing the same day or regularly missing days should also be advised to the prescribing service so dispensing arrangements can be reviewed.
	3. 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:

1. Please dispense instalments due on pharmacy closed days on a prior suitable day.

2. If an instalment’s collection day has been missed, please still dispense the amount due for any remaining day(s) of that instalment.

3. Consult the prescriber if 3 or more consecutive days of a prescription have been missed.

4. Supervise consumption on collection days.

5. Dispense daily doses in separate containers.

1. **Data Recording & Information Sharing**
	1. 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.
	2. Internet access must be available for input of data onto PharmOutcomes.
	3. 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.
	4. Any missed doses will need to be entered daily to the service called “Supervised Consumption – Missed dose” on PharmOutcomes. In addition, the prescribing service should be notified of all missed doses via the missed collection notification function on PharmOutcomes.
	5. The prescribing service should be contacted directly via telephone, if the service user has not attended for three days or you have an immediate concern for that service user, and supply stopped and not started again without the agreement of the prescriber or recovery worker.
	6. All provisions will be recorded on PharmOutcomes. These records will be operated together with the Controlled Drug Records required by legislation.
	7. The pharmacy providing the dispensing service will contact the prescribing service in any of the following circumstances:
* Drug related death in pharmacy premises
* Overdose
* Incorrect dispensing of any controlled substance
* The service user is seen to be selling, swapping, or giving away their controlled medication.
* Following three consecutive failures to attend. Where three consecutive doses have been missed, the pharmacist will not supply a further dose unless agreed by CGL and the service user should be referred back to CGL drug services to be clinically re-assessed.
* Breach of the 3-way agreement which the service user has signed.
* Any other occasion when the pharmacist is concerned about the service user’s well-being.
* Refuses to consume their dose as prescribed.
* Is collecting erratically (even if not breaching the 3-day rule)
* Is under the influence of drugs/alcohol resulting in the pharmacist making a professional judgement decision not to dispense a dose.
* Shows clear signs of deterioration of physical and/or mental health.
* Has been violent or has threatened violence.
* Is involved in a serious or untoward incident that affects or may affect the expected outcome of the treatment.
* Becomes aware of service user admission to or discharge from hospital.
	1. Pharmacists will share relevant information with other health care professionals and agencies, in line with locally determined confidentiality arrangements. The service user should be informed that information is being shared (unless to do so would put another person at risk e.g., in the case of suspected child abuse)
1. **Brief Harm Minimisation and Health Promotion Interventions**
	1. 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
	2. Advice will be consistent with relevant recognised guidelines and good practice and should be supported with appropriate harm minimisation materials or literature.
2. **Accessibility**
	1. Selection of the pharmacy to provide treatment will be the decision of the service user, subject to the nominated pharmacy agreeing to commence treatment.
	2. Pharmacists will be required to provide on-going support during the period of the Supervised Administration Programme, which will usually be for at least the first 4 weeks of prescribing, or until the service user transfers to another pharmacy with the authorisation of the prescriber.
	3. The pharmacy will ensure that there are no unreasonable or strict time restrictions imposed on the service user.
	4. The pharmacist in charge will take appropriate steps to ensure they are confident of the identity of the service user before supervising each dose.
	5. 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.
3. **Service requirements and duration**
	1. This service specification is valid from 1st April 2021 – 31st March 2022.
	2. The pharmacy will offer a user-friendly, non-judgmental, patient-centred, and confidential service.
	3. The service will be delivered in a consultation area in the pharmacy which ensures a sufficient level of privacy and safety and meets Medicines Use Review premise requirements.
	4. Pharmacists and staff involved in the provision of the service must be aware of and operate within any locally agreed protocols and follow their company Standard Operating Procedures that cover the provision of this service.
	5. Pharmacists and staff involved in the provision of the service must have relevant knowledge and be appropriately accredited in the operation of the service.
	6. The Contract Manager must be informed of any changes to personnel which impacts service delivery or availability. Every effort should be made to ensure service continuity.
4. **Safeguarding and Governance**
	1. Pharmacy staff must be aware of local child and vulnerable adult protection procedures; these must always be followed.
	2. It is implicit in the service being provided that it is delivered to the standard specified and complies with the legal and ethical boundaries of the profession.
	3. Should an issue be identified either through a visit by the Contract Manager or through any other means an action plan will be produced following the process below:
		* CGL will identify any issues and will agree points for action with the named pharmacist, and an action plan will be created.
		* The Contract Manager will send a written report to the named pharmacist within two weeks of the visit summarising what action needs to be taken and by when.
		* The Contract Manager will contact the pharmacy again once the agreed timescales have elapsed to confirm that the action plan has been completed.
		* 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 Public Health England or GPhC.

1. **Required Training**
	1. The lead pharmacists providing the service are required to successfully complete:
		* CPPE Substance Use and Misuse (Modules 1 – 4) and the associated learning
		* CPPE Safeguarding Children and Vulnerable Adults and the associated learning.
	2. All pharmacists will be required to complete the CPPE Declaration of Competence for Supervised Consumption of Prescribed Medicines. The declaration will need to be confirmed on PharmOutcomes via enrolment.
	3. The training requirements must be met within three months of joining the service and updated every three years.
	4. A representative from the pharmacy may be required to attend an annual training event.
	5. The lead pharmacists will be responsible for identifying staff training needs and for recording their own Continuing Professional Development, and cascading training to all staff where appropriate.
2. **Quality indicators**
	1. The pharmacy will have standard operating procedures relating to this service. The pharmacist will review these standard operating procedures and the referral pathways for the service on an annual basis.
	2. The pharmacist will attend required training and accreditation events relating to this service.
	3. The pharmacist has completed the required training.
	4. The pharmacist has undertaken CPD relevant to this service, and pharmacists (including locums) and staff involved in the provision of this service have sufficient relevant knowledge and are familiar with the requirements of this service specification.
	5. The pharmacy has a complaints procedure in place.
	6. The pharmacy co-operates with any local assessment of service and service user experience, including use of “mystery customers” and audits.
3. **Incidents and complaints**
	1. The pharmacy is required to have a robust incident reporting and investigation procedure in place.
	2. 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 Contract Manager.
	3. The pharmacy will deal with any complaints sensitively and will report any complaints, comments or concerns to the Contract Manager as soon as possible.
	4. Inspire will conduct their own internal investigation in relation to any reported pharmacy incidents and complaints. See Appendix D for further details.
4. **Use of Locum Pharmacists**
	1. The pharmacy has a duty to ensure that staff and other pharmacists (including locums) involved in the provision of the service have relevant knowledge and are appropriately trained in the operation of the service to ensure the smooth continuation of the service in the absence of the regular pharmacist.
	2. Where possible, the pharmacy should ensure it is staffed by a regular pharmacist/s. Should the pharmacy be in a position where the pharmacy will be run on different locum pharmacists for more than a month, the Contract Manager must be informed.
	3. CGL has the right to withdraw the service from a pharmacy that is not staffed with regular pharmacists. Alternatively, CGL may impose additional conditions on the pharmacy for the pharmacy to remain providing the service.
	4. The pharmacy should ensure that there are adequate support staff, including staff specifically trained to support this service in the pharmacy at all times in order to support the pharmacist (including locum pharmacist) in the operational elements of the service and to help ensure the safe and smooth running of the service.
	5. The pharmacy will ensure that appropriate professional indemnity insurance is in place.
	6. 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.
5. **Payment arrangements**

|  |  |
| --- | --- |
| **Service Provided** | **Fee** |
| Supervised Consumption- Supervision Methadone | £1.65 per dose |
| Supervised Consumption- Supervision Buprenorphine | £2.30 per dose |
| Supervised Consumption – Supervision Buprenorphine/naloxone | £2.30 per dose |
| Supervised consumption – Supervision Espranor | £1.75 per dose |

* 1. Payments will be made monthly upon input of the data onto PharmOutcomes. Invoices will be generated automatically by PharmOutcomes on the 7th of the month. The service contract and financial details will need to be completed and returned before any payments will be made.
	2. Fees will be paid based on submitted claims into a bank account specified by the pharmacy.
	3. The pharmacy is responsible for entering accurate claims data on the correct website.
1. **Audit**
	1. The pharmacy will participate in audits of this service provision organised by the Contract Manager, as and when required, and deliver identified action points reported on the audit within the agreed timescale.
	2. The Contract Manager may employ mystery shoppers as part of this audit.

**Appendix 1: Local Contact Information**

**East Lancashire:**

Jane Allen GP & Pharmacy Quality & Governance Lead 07788 317838

**North, Central & West Lancashire**

Katie Egan Integrated Care Lead 07741 662171

**Clinical and Medical Support:**

Andy Lane Lead Clinician 07827 843565

Diane Rapley Regional Lead for Nursing 07507 847530

**Finance Queries:**

 Damilare Ajeleti Finance and Contracts Coordinator 07552844045

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**Appendix B Application to join the Supervised Consumption Scheme for Lancashire Area**

**SUPERVISED CONSUMPTION SERVICE SPECIFICATION valid from 1st April 2022– 31st March 2023.**

**AGREEMENT**

I apply to be paid for the supervision of methadone, buprenorphine, Espranor (buprenorphine oral lyophilisate) or Suboxone (buprenorphine/naloxone) prescribed medication in the pharmacy premises as named below in line with the Supervised Consumption Service Specification and agree to submit monthly activity on PharmOutcomes by the 5th of each month.

The pharmacy will provide supervised self-administration of:

1. Methadone
2. Buprenorphine
3. Buprenorphine/naloxone
4. Espranor

The pharmacy is open …………. days a week.

I will claim the fees appropriate to this number of days opening following supervision of the prescribed medication as detailed above.

**SIGNED**

**for and on behalf of**

**the CONTRACTOR**

|  |  |
| --- | --- |
| **Pharmacy Name** |  |
| **Address** |  |
| **Print Name** |  |
| **Signature**  |  |
| **Job Title**  |  |
| **Date** |  |

**Appendix C Three Way Agreement**

  

 INSPIRE LANCASHIRE DRUG AND ALCOHOL SERVICES THREE WAY AGREEMENT

**CLIENT NAME: DOB:**

**This is a formal agreement between the client, prescribing agency and pharmacy.**

1. My prescription will be decided by my prescribing doctor, my key worker and me.

2. When attending the pharmacy:

I will be expected to show some form of identification.

If my prescription is for ‘supervised consumption’ I will be asked where in the pharmacy I would like to consume my medication.

3. I will attend the named pharmacy in person, at the times advised by the pharmacist and convenient to myself.

4. The pharmacist & prescribing service have the right to refuse to see me if they believe I am intoxicated.

5. All parties involved in this treatment plan will be treated with respect and dignity at all times.

6. I understand that I can only obtain prescriptions for my medication from the Prescribing Service named in this contract. I cannot have my prescriptions dispensed by another pharmacy without negotiating this with my keyworker. Any changes required due to work or holiday arrangements will need to be negotiated with my key worker, with a least 14 days’ notice of changes required.

7. I am responsible for all medications prescribed to me and, if I should lose them or take them other than as directed, they may not be replaced.

8. I will make sure to dispose of all empty medication bottles safely by rinsing them out and returning them to my pharmacy.

9. I understand that I must collect my prescription on the specified days. If I am unable to collect my prescription at all I need to notify my keyworker who will advise the pharmacy. I understand that no-one else can collect my medication unless pre-arranged with key-worker.

10. I understand that if I do not collect my prescription for, **three or more consecutive days** if I am on daily pick-up or if a missed pick-up results in **three missed doses** the pharmacy will not dispense my medication until my treatment has been reassessed. If this happens the pharmacist will contact my keyworker and I will need to contact my key worker to have my treatment reviewed. The pharmacist will also advise my key worker on each occasion I miss my collection.

11. I understand that if I miss a day of medication during the titration phase of the prescription, the pharmacist will need to consult with a prescriber before my next dosage can be dispensed.

12. All persons involved in my treatment are expected to provide this service as discreetly as possible.

13. I understand that information will need to be shared between all those involved in my treatment as outlined below:

14. In the circumstance where I may use a needle exchange service at the pharmacy dispensing my medication, this will remain confidential and anonymous except where a situation arises that puts my health or others at risk, in which case there will be a duty of care to share information.

**Inspire Keyworker:**

**Pharmacist**:

My contract will commence on: ……………………………………………….. [CGL to enter start date]

* I will attend the pharmacy named below, at a pre-arranged time if appropriate.

(Pharmacist to state appropriate time) ………………………………………………

* I have read, and agree to this contract.

**CLIENT**

**NAME:**

**ADDRESS:**

**PHONE NUMBER:**

**SIGNATURE &**

**DATE**

**KEYWORKER**

**NAME:**

**ADDRESS:**

**PHONE NUMBER**

**PHARMACIST**

**NAME:**

**ADDRESS:**

**PHONE NUMBER**

Key worker to ensure that signed copies by all parties go to:

* Pharmacy
* Client (if requested)
* G.P. [If client is shared care]

Original to be filed in the client’s case notes.



Dear \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_(Pharmacist)

**Re: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_DOB\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

I wish to introduce the above named client to you who has been assessed by our service and is commencing on\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. The dispensing regime is Daily Supervised Consumption. Please see enclosed a copy of the 4 Way Agreement signed by all relevant parties. Please sign a copy and fax back to the service on fax no --------------------------------------------------------.

Please note that I shall inform you of any changes in his/her prescription. If you have any queries, please do not hesitate to contact me on the above telephone number.

Yours sincerely,

**Appendix D - Primary Care Governance Flowchart – Incident Reporting**

Time since incident

**Incident or near miss occurs**

**Investigated and learning shared by Inspire responsible person**

**Relevant lessons learnt or actions shared in Integrated Governance Team Meeting where applicable**

**30 working daysdays**

**Investigation methods, good practice, lessons learnt, and relevant actions recorded on datix**

**Incident investigation completed with involvement from Primary Care Service**

**24 Hours**

**Internal investigation details provided to CDAO as required**

**Confirmation email & reference number received from Controlled Drugs Accountable Officer (CDAO) uploaded onto Datix incident report**

**e.g. lost prescriptions; prescribing, dispensing or administration errors**

**Where incident falls under Reporting Controlled Drugs Concern – online reporting completed by staff member (www.cdreporting.co.uk)**

**Inspire will report to CQC**

**Where the incident is CQC reportable**

**Inspire will report to their Commissioning Body**

**Where the incident falls under a Serious Reportable Incident**

**Inspire staff member notified of the incident**

**Datix report** **completed**

**1 Hour**

**Pharmacy or Surgery notifies Inspire of**

**Incident**