SERVICE SPECIFICATION

Supervised Self Administration (SSA) of Methadone/Buprenorphine
April 2023 – March 2025

1. General Overview

1.1 Opioid substitute medication is recognised as an important element of specialist treatment for opiate dependency and the Community Pharmacist is well placed to deliver the supervised consumption element relating to this treatment.

1.2 The Department of Health and Social Care (DHSC), in *Drug misuse and dependence: UK guidelines on clinical management* (2017), recommends that new patients being prescribed opioid substitute medication such as methadone or buprenorphine should receive their medication by daily supervised consumption. This should last for approximately three months but is subject to individual circumstances; highly compliant patients may only spend weeks on supervised consumption, but longer periods may be required for patients who fail to respond to conventional treatment.

1.3 The council, in partnership with North Central London Integrated Care Board (NCL ICB) is seeking to commission a scheme for supervised consumption to be delivered at multiple local pharmacy sites whereby trained pharmacists deliver specialist supervision for consumption of methadone or buprenorphine at the point of dispensing to a service user who has been specifically prescribed to self-administer under the scheme.

1.4 Pharmacy services for drug users qualify as Locally Commissioned Services under 'The Contractual Framework for Community Pharmacy' and as such participation by community pharmacists in this service remains voluntary and guided by localised need. However, those who join the scheme will have a contractual obligation to adhere to these guidelines and to input as appropriate into the 'shared care' of substance users.

2. Aims and Purpose

2.1 The specialist service is to ensure that the service user consumes the medication safely as directed, to promote compliance with their treatment and mitigate against risk of diversion, in new patients or otherwise identified patients by:

- Dispensing in specified instalments (usually daily. Where agreed with the prescriber doses may be dispensed for the service user to take away to cover days when the pharmacy is closed)
- Ensuring each supervised dose is correctly consumed on site by the service user for whom it was intended.

3. Evidence Base

3.1 The DHSC *Drug Misuse and Dependence: UK Guidelines On Clinical Management* (2017) recognises that supervised consumption 'by an appropriate professional provides the best guarantee that a medicine is being taken as prescribed' and notes the reduction in drug related deaths involving methadone since the start of supervised consumption schemes, in the context of increased prescribing of methadone in general.

3.2 This service specification is supported by several key documents and publications:

- From harm to hope: A 10-year drugs plan to cut crime and save lives (Department of Health and Social Care) (2021)
- Preventing Drug and Alcohol Misuse: Effective Interventions (PHE) (2015)
- Drug Misuse and Dependence – UK Guidelines on Clinical Management (Department of Health and Social Care) (2017)
- Medications in Recovery: Best Practice in Reviewing Substance Misuse Treatment (PHE) (2013)
- Guidance for the use of substitute prescribing in the treatment of opiate dependence in primary care (Royal College of General Practitioners) (2011)
- NICE technology appraisal TA114 Methadone and buprenorphine for managing opioid dependence (2007)
- NICE Guidance NG64 – Drug Misuse Prevention: Targeted Interventions (2017)

4. Objectives and expected outcomes

To ensure compliance with the agreed treatment plan by:

4.1 Dispensing prescribed medication in specified instalments.

4.2 Ensuring each supervised dose is correctly administered to the patient for whom it was intended (as agreed with the prescriber, doses may be dispensed for the patient to take away to cover days when the pharmacy is closed).

4.3 Liaising with the prescriber, named key worker and others directly involved in the care of the patient (where the patient has given written permission).

4.4 Monitoring the patient'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 the patient appears intoxicated or when the patient has 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.

4.5 Improving retention in drug treatment.

4.6 Improving drug treatment delivery and completion.

4.7 To reduce the risk to local communities of:

- Overuse or underuse of medicines
- Diversion of prescribed medicines onto the illicit drugs market

- Accidental exposure to the dispensed medicine

5. Key Requirements

Service provision and referral pathways

5.1 Access to the service will be available to service users aged 18 years or over who are prescribed methadone or buprenorphine under the supervised self-administration scheme by Islington commissioned drug treatment providers or GPs only.

5.2 Pharmacies should not offer the supervised consumption service to service users unless specifically directed to do so and will be expected to evidence this with specific paperwork as outlined in this service specification.

5.3 Service users have the right to choose which participating Islington pharmacy they have their prescription dispensed and supervised at, although maximum patient numbers are still applicable. It is inappropriate for prescribers to direct patients to individual named pharmacies.

5.4 Service users will be encouraged to remain with the same pharmacy providing a valuable, constant and regular link with the same healthcare professional.

5.5 Where the service user does move to a different pharmacy this should be communicated clearly between the prescriber, the pharmacies involved and the service user both verbally and confirmed in writing.

Exclusion criteria

5.6 Service users may be excluded as a result of professional risk assessment and if they pose a serious risk to staff, other service users or members of the public. Where appropriate, work should be carried out to engage drug users in more appropriate services and a referral should be made where possible.

5.7 Service user exclusion decisions are made at the discretion of the pharmacist but within a structure of user's right and responsibilities. See Appendix 4.

Service approach and information

5.8 Pharmacies will offer a user-friendly, non-judgmental, service user centred and confidential service.

5.9 The pharmacy will provide support and advice to the service users, including referral to primary care or specialist substance misuse treatment providers where appropriate, utilising substance misuse treatment pathways as provided by commissioners.

5.10 The pharmacy will also offer interventions possibly including, but not limited to:

- Written and verbal advice about:
  - the supervised scheme
  - the medication itself: methadone/buprenorphine and/or other pharmacotherapy
  - alcohol use
  - risk of overdose
  - loss of tolerance following missed or uncollected doses
  - drug interactions

    - Pharmacy opening times

- Advice on a range of related issues including:
    - the prevention of drug related deaths (especially storage of any take home medication doses away from children, other family members)
    - overdose prevention
    - blood-borne virus infections
    - oral health, dental health
    - sexual health, contraception and safer sex
    - nutrition
    - minor infections, wound dressings
    - nicotine replacement therapy

5.11 The Substance Misuse Commissioning Team will provide details of relevant referral points which pharmacy staff can use to signpost service users who require further assistance.

5.12 The pharmacy will display health promotional materials for any promotional campaign linked to the service area or pathway as directed by the Joint Commissioning Team.

Location(s) of Service Delivery
5.13 SSA methadone/buprenorphine will be provided from the pharmacy premises commissioned to provide this service.

5.14 The pharmacy will provide the necessary level of privacy for service users, for example the availability of a private area or consultation room for discreet consumption.

Days / Hours of operation
5.15 For provision of this service pharmacies must be open at least 6 days per week (exceptional circumstances will be considered), with an accredited pharmacist present during these hours.

Response time, detail and prioritisation
5.16 This is an onsite service. Pharmacists are required to dispense NHS prescriptions with reasonable promptness.

Receiving a referral from substance misuse services or Islington GP
5.17 All individuals identified as requiring SSA will work with their prescriber/ lead worker to identify a participating Islington pharmacy with appropriately accredited pharmacy staff.

5.18 In advance of a referral, the pharmacy will receive a telephone call to confirm capacity in terms of the SSA service user threshold, at which point the pharmacy should confirm with the prescriber that they are commissioned to provide the services and have an accredited pharmacist.

5.19 A letter of introduction will be provided by the prescriber for any individual new to SSA services and/or new to the SSA commissioned pharmacy. A copy of the letter

of introduction will be emailed securely or faxed to the chosen pharmacy in advance to the service user presenting.

Service user presentation at the Pharmacy

5.20 When the service user presents to the pharmacy, the pharmacist should confirm their identity and request the original letter of introduction, which can happen via secure email to the prescribing agency. (Please note some individuals may not have any photographic identification and this should not be a barrier to the service).

5.21 If the pharmacist does not receive the letter of introduction from the service user or the service user does not attend, the pharmacist should inform the referring service or GP of this, as the service user may have taken the prescription to a different pharmacy.

5.22 All SSA prescriptions will detail the name and address of the pharmacy the service user has been referred to. Where an individual presents to a pharmacy that is different from the one detailed on the SSA prescription, it is recommended that the pharmacist contact the referring service or GP.

5.23 Once pharmacists receive the prescription, they should ensure this corresponds with the information on the letter of introduction. Any discrepancies or ambiguities should be confirmed with the referring service or GP.

5.24 Prescriptions for controlled drugs must adhere to the defined prescription requirements - please refer to the electronic BNF for full guidance. Prescribers must fulfil these requirements when issuing prescriptions, as a pharmacist may not legally dispense if this is not the case.

5.25 Pharmacists will be able to:

- Refer patients experiencing difficulties back to the referring service or GP for reassessment
- Withhold treatment if this is in the interest of service user safety; for example: during titration of doses, if the service user has missed doses or is intoxicated. The pharmacy should liaise and agree with the referring service or GP about the appropriate on-going treatment.
- Provide a routine assessment of stabilised service users for example for side effects, concordance issues, symptoms of withdrawal, intoxication and childcare issues.

6. Supervision requirements

6.1 Supervision should never take place in the dispensary for both professional and security reasons. There should be an agreed consultation area or private space available for supervised self-administration to ensure privacy and safety. Particular consideration should be given to the safety of staff using completely closed consultation rooms.

6.2 All labels must be removed from the service user’s dispensed containers before throwing away, to maintain patient confidentiality.

6.3 Pharmacies must have a standard operating procedure to cover all the processes involved in the scheme, which is readily available to, and understood by, all staff (and locum pharmacists) involved with the scheme.

6.4 A two-way agreement (Appendix 1) will be set up between the pharmacist and service user to agree how the service will operate, what constitutes acceptable behaviour by the service user, and what action will be taken by the pharmacist if the service user does not comply with the agreement. The pharmacist will ensure copies of two-way agreements (Appendix 1) are kept securely and retained for at least two (2) years for monitoring purposes.

6.5 The usual expectation is no more than one dose of medication should be taken away from the pharmacy on any single occasion (e.g. Saturday dose to be supervised in the pharmacy, Sunday dose to be taken away), except in exceptional circumstances i.e. bank holidays.

6.6 A pharmacy can provide a service to a maximum of 20 clients in total (this may be a combination of both methadone and buprenorphine clients). If a pharmacy wishes to provide a service above this level, a Risk Assessment must be carried out using the appropriate risk assessment tool in relation to each additional service user above 20 and submitted to the Substance Misuse Commissioning Team for consideration.

6.7 The pharmacy must request a copy of the risk assessment tool (Appendix 3) and submit the completed tool to commissioners prior to operating above the threshold of 20 service users. An action plan, agreed with the Substance Misuse Commissioning Team will be implemented by the pharmacy to address any concerns raised by the Risk Assessment prior to increasing the number of service users receiving the supervised administration service.

Guidance for the supervised administration of methadone

6.8 Methadone dispensed for supervised consumption will be licensed, and extemporaneously prepared methadone may not be supplied for SSA service users. A Guide to Good Practice in the Management of Controlled Drugs in Primary Care (2007)

6.9 The pharmacy will present the dispensed medicine to the service user in a suitable receptacle and will provide the service user with water to facilitate administration and/or reduce the risk of doses being held in the mouth.

6.10 Running balances must be maintained for methadone - this is good practice and the CD Accountable Officer (AO) is required to ensure that good practice is followed.

Guidance for the supervised administration of buprenorphine

6.11 Buprenorphine tablets should not be removed from the foil packaging until the service user presents for his/her supervised consumption dose.

6.12 If a dose is uncollected, the entry on the PMR should be annotated in such a way to alert the next pharmacist on duty of this missed dose. The prescription should also be annotated as ‘Not Dispensed’ or ‘ND’ to reflect this uncollected dose.

6.13 Buprenorphine tablets may be prescribed as ‘crushed’ or ‘not crushed’.

6.14 If ‘not crushed’, after careful removal from the foil blister place the tablets onto a piece of suitable paper with a centre crease. Fold the paper in half and hand to the service user; ensure that the tablets are placed under the tongue.

6.15 Observe the service user until the tablets have dissolved to ensure the dose is suitably administered. The service user will need to stay in the pharmacy until all of the tablet/residue has disappeared from their mouth and client has taken/swallowed water.

6.16 If ‘crushed’, use a tablet crusher to crumble the tablet but do not reduce to a powder and follow as 6.15.

6.17 Buprenorphine tablets put out for a service user may be returned to stock and used for that service user only on a subsequent supervision. If entered into the PMR but not collected, the entry should not be cancelled but annotated to show the medication has been put back into stock for subsequent administration.

7. Information Sharing

7.1 Pharmacists will share relevant information with other health care professionals and agencies, in line with locally, nationally, and legally determined confidentiality and information sharing arrangements.

7.2 If a service user on supervised consumption misses three consecutive doses, it is the duty of the pharmacist on the third day to contact the referring service to inform them of this, and to not dispense further doses to the service user unless the prescriber has been notified. Pharmacies should have systems in place to record missed/uncollected doses on the right-hand side of the instalment prescription and on the PMR so that the next pharmacist on duty is alerted of any missed doses.

7.3 Pharmacists will support the service user and the referring service/GP by monitoring continuity of care:

- Reporting when there is cause for concern where a service user has not collected a dose (in addition to the requirement to report when 3 consecutive doses are missed)
- When there is concern that a service user may have dropped out of treatment
- Reporting any other relevant concerns about the service user, including their behaviour or presentation
- Providing relevant information when requested by the referring service/GP.

Communication from prescriber

7.4 If the prescriber from the referring service or GP contacts the pharmacy with specific instructions (e.g. cancelling existing prescriptions) that prescriber must follow up any verbal instructions with a written confirmation. Community pharmacists should date, sign, print their name and stamp the communication and return it to that

prescriber via secure email or fax to acknowledge instructions and to confirm it has been actioned.

Communication from pharmacy
7.5 All verbal communication originating from the pharmacy with the referring service or GP (such as informing of missed doses, concerns about service user) must be recorded in writing by the pharmacist and the pharmacy request acknowledgement from the referring service or GP.

Communication with hospitals
7.6 The named clinical governance lead for the pharmacy should ensure that the pharmacy's contact details on NHS Choices are correct, as hospitals will use these if the client is unable to provide them with the details.

7.7 All communication with hospitals about SSA service users should be recorded clearly and communicated to drug treatment agencies as required.

7.8 Pharmacists should inform the referring service or GP immediately where they know an SSA service user is in hospital and share any other communications received from the hospital. Existing SSA prescriptions held within pharmacy should be cancelled by the prescriber verbally and then backed up with written correspondence (this includes situations where the hospital is enquiring about dose as another clinician is intervening) to reduce the risk of double dosing and overdose. Pharmacists should also record this clearly on the PMR system to alert other pharmacy colleagues. Where service users are discharged from hospital and present to the pharmacy for their SSA dose, they should be referred back to the referring service/GP (on a week day) or hospital ward (at weekends).

8. Training Requirements
8.1 All staff involved in the delivery of this service must have an appropriate level of accreditation to undertake these services. This includes any locum staff delivering the service. The Substance Misuse Commissioning Team will be informed on **ph.commissioning@islington.gov.uk** if there are more than two locums (without all the above qualifications) working in the pharmacy in a given period (over two weeks).

8.2 If a pharmacist who has undergone the training leaves the pharmacy, the obligation to meet training requirements will immediately transfer to the new employee pharmacist. It is the responsibility of the pharmacy to contact the Substance Misuse Commissioning Team immediately should there be any change in pharmacist or change in circumstances.

8.3 The contract will be terminated with any individual pharmacy who does not alert the Substance Misuse Commissioning Team of any change of circumstance within 48 hours of the change.

8.4 The contract to provide supervised administration services to the identified service user group is with the pharmacy contractor and not the individual pharmacist employees.

The pharmacy has a duty to ensure that pharmacists involved in the provision of the service have relevant knowledge and are appropriately trained in the operation of the service as demonstrated through continuing professional development and personal development plans.

8.5 Training required for pharmacists would be:

- Successful completion of the distance learning package 'Substance Use and Misuse" available from the Centre for Pharmacy Postgraduate Education (CPPE). Information is available from https//www.cppe.ac.uk
  - **Module** https://www.cppe.ac.uk/programmes/l?t=Substance-E-02&evid=53231
  - **Assessment** https://www.cppe.ac.uk/programmes/l?t=SubstanceEC-A-02&evid=54347
  - **Declaration of Competence** https://www.cppe.ac.uk/services/docs/supervised%20consumption%20of%20prescribed%20medicines.pdf
  -
  - Successful completion of the distance learning package "Safeguarding Adults and Children" available from the Centre for Pharmacy Postgraduate Education (CPPE). Information is available from https//www.cppe.ac.uk. **Modules:** https://www.cppe.ac.uk/programmes/l/safegrding_elfh-e-01

- Scanned copies of CPPE certificates will need to be submitted to the Substance Misuse Commissioning Team upon request.

8.6 The pharmacy has a duty to ensure that pharmacists involved in the provision of the service are aware of, and operate within, local protocols.

Locum Cover

8.7 When locum cover is being provided the pharmacist needs to ensure that the locum is given an adequate handover to dispense the medication safely. If there is to be a long-term locum (i.e. longer than for a one month period) then they will need to undergo training as outlined above.

9. Recording and reporting requirements

9.1 All pharmacy contractors will have on site access to the internet and be able to meet relevant electronic data requirements.

9.2 The pharmacy must maintain appropriate records to ensure effective on-going service delivery and compliance to audit requirements.

9.3 The Substance Misuse Commissioning Team will arrange an annual audit – this may include visits (by appointment) to each pharmacist to go over their controlled drug records and inspect the premises to ensure that they are fit for purpose, plus a service checklist, based on quality indicators.

9.4 Activity should be recorded within 72 hours of the activity via Pharmoutcomes.

9.5 Payment information will be generated based on activity data inputted by the pharmacy contractor. Data will not be considered for payment when entered to Pharmoutcomes retrospectively.

9.6 The above activity requirements, after consultation, will be subject to annual review and change by Substance Misuse Commissioning Team.

Incident reporting

9.7 Serious incidents and complaints relating to the pharmacy provider and/or delivery of this service should be reported to the Substance Misuse Commissioning Team immediately at ph.commissioning@islington.gov.uk

9.8 Incidents relating to controlled drugs should be reported to the CD accountable officer at NHS England immediately and backed up in writing as well as the Joint Commissioning Team. england.londoncdaccountableoffice@nhs.net

10. Monitoring

10.1 Pharmacy activity data generated from Pharmoutcomes will be used on a quarterly basis to report to Public Health Islington, NCL ICB and any other relevant commissioning group.

10.2 Activity data relating to this LCS (locally commissioned service) will be generated by commissioners on a regular basis to ascertain activity, local need and any performance issues.

10.3 Pharmacies will be monitored using the performance and quality standards outlined in Appendix 2.

10.4 Performance information will be sent to individual pharmacies on a regular basis and performance issues will be flagged to pharmacies where aspects of the service specification are not being met.

10.5 The Joint Commissioning Team will visit individual pharmacies where required to ensure the service specification is being met.

11. Continual Service Improvement Plan

11.1 The SSA service will be reviewed at regular intervals (usually bi-annually) and where appropriate in response to published guidance. Where necessary, service improvements will be incorporated into this SSA LCS by the Substance Misuse Commissioning Team, in consultation with the LPC.

11.2 The pharmacy shall ensure that it has a business continuity plan as part of emergency planning, for this enhanced service, to include:

- Short term major incidents
- Flu pandemic.

11.3 Emergency planning should include the following:

- Notification of any changes to contracted opening hours should be made to BOTH NHS England and the Substance Misuse Commissioning Team. The pharmacy contractor shall use all reasonable endeavours to resume provision of contracted services as soon as is practicable.
- Access to a list of drug service contact numbers (to advise of changes to opening hours and for liaison regarding clients using the substance misuse service).
- A procedure for advising substance misuse service users on the agreed process for medication collection if the pharmacy has to close.

11.4 Further guidance on emergency planning can be found:
- PSNC – http://www.psnc.org.uk/pages/pandemic_flu.html
- NPA – http://www.npa.co.uk/Resources/

12. Prices & Costs
12.1 Each supervised administration activity has an agreed fee attached to it. This is for each face-to-face supervised consumption activity.
- **Methadone supervision fee** = £2.25
- **Buprenorphine supervision fee** = £2.40

12.2 Fees cannot be claimed for dispensed medicines which the patient takes away or missed doses.

12.3 Fees cannot be claimed where the prescriber has not specifically directed for the consumption to be supervised.

12.4 Payment of the associated fees, for the provision of the above substance misuse service to the pharmacy, will authorised by the Substance Misuse Commissioning Team.

12.5 Payment information will be calculated via activity recorded by the pharmacy using the Pharmoutcomes. Activity should be recorded within seventy-two (72) hours to ensure that commissioners can ascertain borough activity in real time and to ascertain capacity of any given pharmacy at short notice.

12.6 Monthly activity reports, which will generate payment figures, will be generated on the first day of the following calendar month. Payment will not be made for activity added retrospectively following this date.

12.7 Where pharmacy contractors are temporarily unable to input activity using Pharmoutcomes, the Substance Misuse Commissioning Team should be alerted immediately in order to resolve the issue and agree an interim measure for recording and payment.

12.8 Payments will be authorised monthly following generation of a monthly report from Pharmoutcomes based on pharmacy daily input to reflect activity.

12.9 Input of daily activity information, will be taken as a true legal reflection of activity and pharmacy contractors will be paid at the agreed rate accordingly.

12.10 Activity should be entered via the Pharmoutcomes within 72 hours and activity data will be generated to inform monthly payment amount on the first day of the following month. Any activity inputted after this date will not be processed for payment **other than in exceptional circumstances which will be agreed with the Substance Misuse Commissioning Team at the time of initial non-reporting of the activity.**

12.11 The Substance Misuse Commissioning Team will obligate to process and make payments in a timely manner and shall notify the pharmacy if unavoidable delays occur. Any payment queries should be directed to the Substance Misuse Commissioning Team via email to ph.commissioning@islington.gov.uk

12.12 The Substance Misuse Commissioning Team shall notify the pharmacy as soon as possible if there are any queries relating to payment, performance or concern that the stated services have not been provided.

Appendix 1: Two Way Agreement Form

Supervised administration of Methadone or Buprenorphine at the Community Pharmacy

Between

And

Name of Pharmacy:
Address:

Telephone No:
Pharmacy supervised:
Consumption times:
Name of Patient:
Telephone No:

Name of Doctor:
Address:
Telephone No:
Name of Key worker:
Address:
Telephone No:

I, (the service user's name), **agree to take an active part in my treatment and to the following:**
a. The pharmacist will supervise consumption, at the pharmacy, of my daily doses of: - (delete as appropriate)
 Methadone
 Buprenorphine
b. I will attend to receive my supervised doses between the times agreed.
c. I will not request doses to take home other than when the pharmacy is closed.
d. If I miss a dose on the correct day I will not request it later; it cannot legally be supplied.
e. I will not request doses in advance of the date due.
f. I will not attend for supervised doses in the company of other people.
g. I will not attend for supervised doses under the influence of alcohol or non-prescribed medication.
If the pharmacist considers this to be case then I may be asked to return to the pharmacy later in the day.
h. I will not act in an aggressive or unreasonable manner.
i. I will not bring animals into the pharmacy.
j. I will respect the pharmacist's wishes if he/she has to ask me to wait a short time before supervising my medication.
k. I will not ask that other persons collect medication on my behalf, other than by prior arrangement.
l. I accept that any medication taken from the pharmacy and lost cannot be replaced.
m. A lapse of three days in attendance for supervised doses will require the pharmacist to withhold further doses until I have attended the prescriber and a new prescription issued or further dispensing authorised.
n. I will work with the pharmacist to achieve my treatment goals and agree to the sharing of information relating to my treatment with appropriate healthcare professionals and bodies such as Islington Joint Commissioning Team which will be used for their performance monitoring purposes.
o. I will treat all staff of the Community Pharmacy and GP surgery with respect.
p. If I am dissatisfied with the way I am treated at the pharmacy then a complaint can be made to the Joint Commissioning Team.

I, (the pharmacist's name), **agree to take an active part in the treatment of** (the service user's name) **and to the following: -**

a. I will work with the patient to achieve their treatment goals.
b. I will dispense patients prescriptions promptly, in turn and in accordance with the written instructions and undertakings listed above.
c. I will not dispense medication if I believe that it is unsafe for the patient at the time requested.
d. I will advise other pharmacists, including locum pharmacists, of this agreement
e. All staff at the pharmacy will treat the service user, (the service user's name), with respect

Additional conditions agreed to: -
I have read and understood the above information and wish to enter into this agreement.

Service user's name
Date
Pharmacist's name
Date

Appendix 2: Quality & Performance Standards

- The pharmacy displays health promotion material relating to: substance misuse treatment; harm reduction & related services available for the user group as well as promoting its uptake.
- The pharmacy displays health promotional materials provided by commissioners for any substance misuse or harm reduction campaigns - available from http://www.harmreductionworks.org.uk/

- Promotion materials will be checked during announced and unannounced monitoring visits.
- The pharmacy reviews its standard operating procedures - SOP (for this enhanced service) which incorporate business continuity and emergency planning, and the referral pathways for the service at least on an annual basis, or at a frequency agreed with the public health commissioning team.
- Emergency and business continuity plans readily available to all staff
- The pharmacy can demonstrate that pharmacists and staff involved in the provision of SSA maintain CPD relevant to this service as outlined in section 8.5
- The pharmacy participates in an annual Commissioner Led Audit organised audit of service provision.
- The pharmacist must ensure that CD records are made as promptly as possible.

Activity *Quality performance indicators*

- Recording of daily activity electronically via Pharmoutcomes within 72 hours
- Advise (promptly) of exceptional circumstances (e.g. software problems) and provide with action plan and timeline to resolve
- Up to date activity data available to commissioners via Pharmoutcomes
- Provide SSA services within the maximum patient threshold (set by Substance Misuse Commissioning Team)
- Advise (promptly) of exceptional circumstances where the pharmacy has provided services to over and above the agreed SSA maximum patient threshold.
- Submission of risk assessment by pharmacy
- Pharmacies approved for higher thresholds should evidence this by producing copies of the risk assessment

Appendix 3 Risk Assessment

Supervised Administration (Consumption of Prescribed Medicines)

Increase in Patient Threshold Risk Assessment

Enhanced Services

April 2023 – March 2025

Pharmacy **Telephone Number**

Address

Email

Current no of Patients receiving Supervised Administration

Proposed no of Patients receiving Supervised Administration

Please tick the relevant boxes and ensure all requested information is attached to your application

1. **Please state the enhanced services the pharmacy named currently provides** (tick boxes)

□ Supervised Self Administration of Methadone

□ Supervised Self Administration of Buprenorphine

□ Pharmacy Needle Exchange

□ Emergency Contraception

□ Palliative Care

□ Medicines Usage Review (MUR)

□ Minor Ailments Service

□ Medicines Reminder Devices

□ Stop Smoking

2. Please state how many clients you have: ……

3. Please state how many clients you wish to apply for……

4. Please state the number of dispensing items supervised administration currently constitutes per month

□	Less than 2,000	□	6,500 - 7,999
□	2,000 - 3,499	□	8,000 - 9,499
□	3,500 - 4,999	□	9,500 - 10,999
□	5,000 - 6,499	□	11,000+

5. Please state the current no. of dispensing support:

No of dispensing staff …….. Hours claimed on FP34 ……

6. Please state the times the pharmacy is open for supervised administration of medicines

Weekdays……
Weekends……

7. **Please state the times the pharmacy is open for other enhanced services**

Enhanced Service	**Opening Times - Weekdays**	**Opening Times - Weekends**
1.		
2.		
3.		
4.		
5.		
6.		
7.		
8.		

Training and accreditation

□ Copies of the pharmacists' completed CPPE Open learning Certificates "Substance use and misuse" and "Safeguarding Adults and Children" are enclosed.

□ Evidence of attendance at a local safeguarding event

Standard operating procedures

□ The pharmacy has the statutory required standard operating procedures (SOP) for Controlled Drugs, which includes the supervised administration (consumption of medicines) service.

□ The pharmacy is following good practice and reconciling controlled drug running balances

Identified Risks (refer to the NPSA Risk Management Matrix)

Risk	Score	Action Plan	Date of Completion

Continue on a separate sheet if required.

Declaration

Public Health Substance Misuse Commissioning Team has the right to undertake random checks by unannounced staff to verify the contents of any risk assessment application, prior to and, where applicable, after the application has been granted.

The pharmacy provider is aware any false declaration will lead to a suspension of the enhanced service.

Signed **Date**

Print Name

NPSA Risk Model Matrix

National Patient Safety Agency

Model matrix

For the full *Risk matrix for risk managers*, go to www.npsa.nhs.uk

Table 1 Consequence scores

Choose the most appropriate domain for the identified risk from the left hand side of the table Then work along the columns in same row to assess the severity of the risk on the scale of 1 to 5 to determine the consequence score, which is the number given at the top of the column.

	Consequence score (severity levels) and examples of descriptors				
	1	**2**	**3**	**4**	**5**
Domains	**Negligible**	**Minor**	**Moderate**	**Major**	**Catastrophic**
Impact on the safety of patients, staff or public (physical/ psychological harm)	Minimal injury requiring no/minimal intervention or treatment. No time off work	Minor injury or illness, requiring minor intervention Requiring time off work for >3 days Increase in length of hospital stay by 1-3 days	Moderate injury requiring professional intervention Requiring time off work for 4-14 days Increase in length of hospital stay by 4-15 days	Major injury leading to long-term incapacity/disability Requiring time off work for >14 days Increase in length of hospital stay by >15 days	Incident leading to death Multiple permanent injuries or irreversible health effects An event which impacts on a large number of patients

			RIDDOR/agency reportable incident An event which impacts on a small number of patients	Mismanagement of patient care with long-term effects	
Quality/complaints/audit	Peripheral element of treatment or service suboptimal Informal complaint/inquiry	Overall treatment or service suboptimal Formal complaint (stage 1) Local resolution Single failure to meet internal standards Minor	Treatment or service has significantly reduced effectiveness Formal complaint (stage 2) complaint Local resolution (with potential to go to independent review) Repeated failure to	Non-compliance with national standards with significant risk to patients if unresolved Multiple complaints/ independent review Low performance rating Critical report	Totally unacceptable level or quality of treatment/service Gross failure of patient safety if findings not acted on Inquest/ombudsman inquiry Gross failure to meet national standards

		implications for patient safety if unresolved Reduced performance rating if unresolved	meet internal standards Major patient safety implications if findings are not acted on		

Human resources/ organisational development/staffing/ competence	Short-term low staffing level that temporarily reduces service quality (< 1 day)	Low staffing level that reduces the service quality	Late delivery of key objective/ service due to lack of staff Unsafe staffing level or competence (>1 day) Low staff morale Poor staff attendance for mandatory/key training	Uncertain delivery of key objective/service due to lack of staff Unsafe staffing level or competence (>5 days) Loss of key staff Very low staff morale No staff attending mandatory/ key training	Non-delivery of key objective/service due to lack of staff Ongoing unsafe staffing levels or competence Loss of several key staff No staff attending mandatory training /key training on an ongoing basis
Statutory duty/ inspections	No or minimal impact or breech of guidance/ statutory duty	Breech of statutory legislation Reduced performance rating if	Single breech in statutory duty Challenging external recommendations/	Enforcement action Multiple breeches in statutory duty	Multiple breeches in statutory duty Prosecution

		unresolved	improvement notice	Improvement notices Low performance rating Critical report	Complete systems change required Zero performance rating Severely critical report
Adverse publicity/ reputation	Rumours Potential for public concern	Local media coverage – short-term reduction in public confidence Elements of public expectation not being met	Local media coverage – long-term reduction in public confidence	National media coverage with <3 days service well below reasonable public expectation	National media coverage with >3 days service well below reasonable public expectation. MP concerned (questions in the House) Total loss of public confidence
Business objectives/ projects	Insignificant cost increase/ schedule slippage	<5 per cent over project budget Schedule slippage	5–10 per cent over project budget Schedule slippage	Non-compliance with national 10–25 per cent over project budget	Incident leading >25 per cent over project budget Schedule slippage

				Schedule slippage Key objectives not met	Key objectives not met
Finance including claims	Small loss Risk of claim remote	Loss of 0.1–0.25 per cent of budget Claim less than £10,000	Loss of 0.25–0.5 per cent of budget Claim(s) between £10,000 and £100,000	Uncertain delivery of key objective/Loss of 0.5–1.0 per cent of budget Claim(s) between £100,000 and £1 million Purchasers failing to pay on time	Non-delivery of key objective/ Loss of >1 per cent of budget Failure to meet specification/ slippage Loss of contract / payment by results Claim(s) >£1 million
Service/business interruption Environmental impact	Loss/interruption of >1 hour Minimal or no impact on the environment	Loss/interruption of >8 hours Minor impact on environment	Loss/interruption of >1 day Moderate impact on environment	Loss/interruption of >1 week Major impact on environment	Permanent loss of service or facility Catastrophic impact on environment

Table 2 Likelihood score (L)

What is the likelihood of the consequence occurring?

The frequency-based score is appropriate in most circumstances and is easier to identify. It should be used whenever it is possible to identify a frequency.

Likelihood score	**1**	**2**	**3**	**4**	**5**
Descriptor	**Rare**	**Unlikely**	**Possible**	**Likely**	**Almost certain**
Frequency How often might it/does it happen	This will probably never happen/recur	Do not expect it to happen/recur but it is possible it may do so	Might happen or recur occasionally	Will probably happen/recur but it is not a persisting issue	Will undoubtedly happen/recur,possibly frequently

Note: the above table can be tailored to meet the needs of the individual organisation.

Some organisations may want to use probability for scoring likelihood, especially for specific areas of risk which are time limited. For a detailed discussion about frequency and probability see the guidance notes.

Table 3 Risk scoring = consequence x likelihood (C x L)

	Likelihood				
Likelihood score	**1**	**2**	**3**	**4**	**5**
	Rare	**Unlikely**	**Possible**	**Likely**	**Almost certain**
5 Catastrophic	5	10	15	20	25
4 Major	4	8	12	16	20
3 Moderate	3	6	9	12	15
2 Minor	2	4	6	8	10
1 Negligible	1	2	3	4	5

Note: the above table can to be adapted to meet the needs of the individual trust.

For grading risk, the scores obtained from the risk matrix are assigned grades as follows

1 - 3	Low risk
4 - 6	Moderate risk
8 - 12	High risk
15 - 25	Extreme risk

Instructions for use

1 Define the risk(s) explicitly in terms of the adverse consequence(s) that might arise from the risk.

2 Use table 1 (consequence scores) to determine the consequence score(s) (C) for the potential adverse outcome(s) relevant to the risk being evaluated.

3 Use table 2 (likelihood scores) to determine the likelihood score(s) (L) for those adverse outcomes. If possible, score the likelihood by assigning a predicted frequency of occurrence of the adverse outcome. If this is not possible, assign a probability to the adverse outcome occurring within a given time frame, such as the lifetime of a project or a patient care episode. If it is not possible to determine a numerical probability then use the probability descriptions to determine the most appropriate score.

4 Calculate the risk score the risk multiplying the consequence by the likelihood: C (consequence) x L (likelihood) = R (risk score)

5 Identify the level at which the risk will be managed in the organisation, assign priorities for remedial action, and determine whether risks are to be accepted on the basis of the colour bandings and risk ratings, and the organisation's risk management system. Include the risk in the organisation risk register at the appropriate level.

Appendix 4 Exclusion

In the event of an incident such as violent, aggressive or threatening behaviour towards pharmacy staff and the public, or theft, the pharmacist and their staff are not to put themselves in any risk of injury. It is not expected that pharmacy staff will accept threatening, violent or other abusive behaviour from Supervised Self Administration Clients.

In the event of such an incident the client should be asked to leave the premises with a verbal warning. The Pharmacist has the right to refuse a client access to the service on behavioural grounds.

If the client returns subsequently and there are no changes in behaviour the Pharmacist has the right to withhold services.

If a client does not leave voluntarily when requested, the pharmacist should call the police to escort the client from the premises.

If a client has been asked by the pharmacist to leave the premises or the pharmacist has had to call the police, the pharmacist will inform the treatment service immediately.