



# **Appendix A Specification**

## **CPH037 Pharmacy-based Supervised Consumption of Methadone and Buprenorphine and Needle & Syringe Programme**

**Company/Organisation:** Derbyshire County Council

## Evaluation Approach

In assessing the response documents the Council will be seeking evidence of the Potential Provider's suitability to deliver the requirements of the contract.

- Responses will be evaluated in accordance with the Evaluation Approach detailed below.
- The provision of false information will disqualify organisations from further consideration.

### Specification

<b>Parts 1-8</b>	<b>Lot 1</b>	<b>Pharmacy Based Supervised Consumption of Methadone &amp; Buprenorphine</b>
<b>Parts 9-16</b>	<b>Lot 2</b>	<b>Pharmacy Based Needle and Syringe Programme</b>

### Accreditation requirements

**Providers shall complete Appendix B – Proposal Response to:**

**Express an Interest in becoming an accredited provider for:**

- **Lot 1** - Pharmacy Based Supervised Consumption of Methadone and Buprenorphine
- **Lot 2** - Needle and Syringe Programme
- **Lots 1 & 2** - Pharmacy Based Supervised Consumption of Methadone and Buprenorphine Service and Needle and Syringe Programme

**Confirm agreement to the stated requirements of the service(s).**

### Additional Information

The Council expressly reserves the right to require a Potential Provider to provide additional information supplementing or clarifying any of the information provided in response to the requests set out in documents. The Council may seek independent financial and market advice to validate information declared, or to assist in the evaluation.

Failure to provide the required information, make a satisfactory response to any question, or supply documentation referred to in responses, within the timescale given, may mean that your organisation will not be considered further.

## Instructions for Completion

- Responses and comments should be provided in English and should be as accurate and concise as possible.
- Proposal documents should be self-contained and supply all information, which are considered necessary for the accurate evaluation of their proposal.
- Technical and sales literature may be included as part of the proposal document but only as supporting evidence. Replies to questions must be, therefore, complete and not consist of references to such literature.
- The Council expressly reserves the right to require a Potential Provider to provide additional information supplementing or clarifying any of the information provided in response to the requests set out in this document. Failure to provide the required information within the timescale given may mean that your organisation will not be considered further.
- Failure to provide the required information, make a satisfactory response to any question/fully address the requirements of the specification, or supply documentation referred to in responses within the specified timescale may lead to your Tender being judged to be non-compliant.
- If you have any queries regarding how to complete this document please address them through the questions and answers stage of the Tender.

## Parts 1-8

# Lot 1 – Pharmacy-Based Supervised Consumption of Methadone and Buprenorphine

## Introduction

Pharmacists play an important role in the clinical care of patients prescribed opiate substitution therapy. Current clinical guidelines for the management of drug dependence<sup>1</sup> recommend that patients starting methadone or buprenorphine for the first time should take their daily dose of medication under the supervision of a professional (usually a pharmacist). The Prescriber determines the duration of supervision through an ongoing assessment of the patients' compliance and individual circumstances, with some patients requiring longer supervision periods than others. Daily supervised consumption is also recommended for those patients who are re-starting a prescription of methadone or buprenorphine after a break or who have a significant increase in their dose.

There are currently 142 community pharmacists accredited to provide supervised consumption in Derbyshire. Between April 2020 and January 2021, a total of 1,614 patients received supervised consumption across 112 pharmacies in Derbyshire, with 18,738 personal interactions taking place.

## Part 1 – Aims

1.1 The aims of this enhanced service are:

- a) To contribute to the clinical care of patients undergoing opiate substitution therapy
- b) To ensure the prescribed medication is taken, as directed, by the patient for whom it is intended
- c) To monitor the wellbeing of the patient during and following self-administration of prescribed medication
- d) To reduce the incidence of diversion of medication

<sup>1</sup> Department of Health (2017) *Drug Misuse and Dependence: UK Guidelines on Clinical Management*, 'Chapter 4: Pharmacological Interventions', London: Department of Health

- e) To reduce accidental ingestion of prescribed medication
- f) To provide regular contact with a healthcare professional able to feedback progress or concerns to the drug treatment provider

## Part 2 – Outputs

- 2.1 The desired outcomes of this service are:
- a) A reduction in drug-related deaths
  - b) Improved compliance with directions for administration of prescribed medication
  - c) Improved engagement with the drug treatment system
  - d) Reduced diversion of controlled drugs
- 2.2 The outputs will be:
- a) Basic demographic data on service users
  - e) Attendance and compliance data

## Part 3 - Delivery

- 3.1 Service description
- 3.1.1 The pharmacy shall offer the supervised self-administration of both methadone and buprenorphine (including buprenorphine/naloxone combination products). Where new medications (i.e. Buvidal) are prescribed, the pharmacy are expected to deliver this in line with the applicable guidance from NICE.
- 3.1.2 Supervision of self-administration of medication shall be carried out by a qualified pharmacist or a competent person who is registered with the General Pharmaceutical Council (GPhC).
- 3.1.3 The pharmacist shall dispense the medication and observe the patient while they swallow the medication (methadone) or allow the medication to dissolve sublingually (buprenorphine) as directed.
- Notes:
- Due to the risk of overdose, medication should not be dispensed to patients who present as intoxicated.
- In the case of buprenorphine, the patient should remain in the pharmacy until the medication is fully dissolved.
- 3.1.4 The patient will be registered onto the web-based monitoring system stipulated by the Council (currently PharmOutcomes) and all subsequent

dispensing activity (supervised, take-home or missed) recorded.

3.1.5 In regard to new patients, the pharmacist should:

- a) Explain the expectations of the pharmacy and patients in regard to confidentiality, privacy, behaviour, etc.;
- b) Give medication information at first dispensing event;
- c) Advise patients on safety and storage for any take-home doses of medication.

3.1.6 The pharmacist must contact the prescriber or keyworker if:

- a) A patient presents a prescription marked for the attention of a different pharmacy;
- b) The pharmacist has concern regarding the validity of the prescription;
- c) The patient misses one pick-up during dose titration;
- d) The patient misses three consecutive pick-ups once on stable dose;
- e) The patient continues to show intermittent contact, with regularly missed doses;
- f) The patient regularly presents to the pharmacy in an intoxicated state;
- g) The patient fails to comply with directed self-administration of medication;
- h) The pharmacist has concerns regarding a patient's physical or mental health;
- i) The pharmacist has concerns regarding risk to the service or others, including safeguarding concerns.

A record of any contact with the prescriber or keyworker should be entered on the patient medication record (PMR).

3.1.7 In the case of a patient transferring between pharmacies, the new pharmacy should contact the previous pharmacy to confirm recent dispensing.

3.1.8 The pharmacy shall provide water to the patient, to rinse mouth after taking medication or to wet mouth prior to consumption of buprenorphine.

3.1.9 Medication usage reviews shall be carried out as appropriate.

3.1.10 Patients shall be referred or signposted to other substance misuse, health or social care agencies as appropriate.

## 3.2 Inclusion and Exclusion Criteria

3.2.1 The pharmacy shall accept patients by agreement with the Derbyshire Recovery Partnership (DRP), including patients managed by GPs within 'shared care' arrangements with DRP.

- 3.2.2 Patients presenting prescriptions from substance misuse services (including primary care) outside of the Derbyshire County administrative area are outside of the remit of this service and will not constitute claimable activity.
- 3.2.3 Service users may be excluded from the service on a temporary or permanent basis at the discretion of the pharmacy manager. Behaviour or incidents which might lead to exclusion include:
- a) Acts or threats of violence towards pharmacy staff or others
  - b) Verbal abuse of staff or others
  - c) Shoplifting
  - d) Habitual over-intoxication.
- 3.2.4 It is expected that pharmacy managers shall employ a regime of escalation dependent on the seriousness of the incident or behaviour, with warnings given as appropriate.

### 3.3 Service Standards

- 3.3.1 The pharmacist delivering this service must have completed, be in the process of completing, or commit to completing (within six months), the Centre for Pharmacy Postgraduate Education open learning programme on *Substance Use and Misuse*.
- 3.3.2 The service shall be delivered in line with the General Pharmaceutical Council's *Standards of conduct, ethics and performance*. In particular, due to the stigma associated with illicit drug use, the following standards are emphasised:
- a) *3.2 Treat people politely and considerately*
  - b) *3.3 Not unfairly discriminate against people*
  - c) *3.5 Respect and protect people's dignity and privacy.*
- 3.3.3 Providers are expected to have appropriate clinical governance arrangements in place. In particular, pharmacies shall have in place:
- a) Appropriate standard operating procedures
  - b) Appropriate induction, training and development for staff
  - c) An appropriate incident reporting system that ensures the Council is informed of and has information in relation to any serious incident within 48 hours of the Provider becoming aware of its occurrence.
  - d) A complaints procedure
  - e) Safeguarding procedures.
- 3.3.4 The service will be delivered in line with national and local guidance, including:
- Department of Health (2017) Drug Misuse and Dependence: UK Guidelines on Clinical Management
  - NICE (2007) Technology appraisal guidance 114: Methadone and

buprenorphine for the management of opioid dependence.

- NICE (2007) Clinical guideline 51: Drug misuse – psychosocial interventions.
- NICE (2007) Clinical guideline 52: Drug misuse – opioid detoxification.

3.3.5 The service will be offered throughout the pharmacy's normal opening hours. No unreasonable time restrictions should be imposed on the patient when self-administration can be supervised. Any restrictions, such as latest acceptable time before closing should be clearly explained to the patient at first contact.

3.3.6 Supervised consumption should take place in a consultation room or, if unavailable, in an area which affords privacy to the patient. It is not appropriate for supervised consumption to take place over the counter in front of other customers.

## Part 4 – KPI's and Output Measures

- 4.1 Pharmacies are required to complete all required data fields in PharmOutcomes in line with the PharmOutcomes *Supervised Consumption Service Delivery Guide*.
- 4.2 The Council will conduct service user surveys on an annual basis to capture the patient experience of the service, including a focus on the issues of discrimination, dignity and privacy.

## Part 5 – Budget and Contract Term

- 5.1 The Council will pay a fee for the supervised consumption:
- a) Methadone: £2.30 per supervised consumption of a prescribed dose
  - b) Buprenorphine: £2.80 per supervised consumption of a prescribed dose
- 5.2 The fees the Council will pay with effect from 01 May 2025 for the supervised consumption:
- a) Methadone: £2.70 per supervised consumption of a prescribed dose
  - b) Buprenorphine: £3.50 per supervised consumption of a prescribed dose



## Part 6 – Reports and Contract Management

6.1 The Council will extract activity reports from the web-based monitoring system.

## Part 7 – Order and Invoices

Not Applicable – Invoiced through PharmOutcomes

## Part 8 – Response Requirements

8.1 Providers shall complete Appendix B – Response (Lot 1) to:

- Express an interest in providing the Pharmacy-based Supervised Consumption of Methadone & Buprenorphine service
- Confirm agreement to the stated requirements.

# Parts 9-16

## Lot 2 – Pharmacy-Based Needle and Syringe Programme

### Introduction

Injecting drug use is associated with a number of significant harms, including the transmission of viral hepatitis, bacterial infection, damage to the circulatory system and overdose.

A review of the effectiveness of needle and syringe programmes (NSPs)<sup>2</sup> concluded that there is evidence:

- that participation in NSPs reduces injection risk behaviours among injecting drug users, in particular self-reported sharing of needle and syringes, and frequency of injection
- to support the effectiveness of NSPs in reducing HIV infection among injecting drug users
- that access to sterile needles and syringes via pharmacies provides specific benefits in addition to those available through specialist NSPs

NICE public health guidance<sup>3</sup> recommends that community pharmacy-based NSPs are provided alongside specialist NSPs. The guidance also recommends that NSPs:

- Provide people who inject drugs with sufficient equipment to meet their needs, rather than being subject to an arbitrary limit
- Should not discourage people from taking equipment for others, but encourage those people to use the service themselves
- Provide advice relevant to the type of drug and injecting practices, especially higher risk practices such as injecting in the groin or neck
- Ensure people who use the programmes are provided with sharps bins and advice on how to dispose of needles and syringes safely

Currently there are 91 community pharmacies accredited to provide the NSP service in Derbyshire. Between April 2020 and January 2021, a total of 17,216 NSP transactions were

<sup>2</sup> Jones, L., Pickering, L. and Sumnall, H. et al (2008) *A review of the effectiveness and cost-effectiveness of needle and syringe programmes for injecting drug users*. Liverpool; John Moores University

<sup>3</sup> NICE (2014) Public health guidance 52: Needle and syringe programmes. NICE.

carried out with 2,851 service users across 46 pharmacies.

## Part 9 – Aims

### 9.1 The aims of the service are:

- a) To reduce the transmission of blood-borne viruses, particularly hepatitis C and HIV among injecting drug users
- b) To reduce the incidence of bacterial infection among injecting drug users
- c) To reduce other morbidity associated with injecting drug use
- d) To contribute to the local reduction of drug-related deaths
- e) To facilitate access to drug treatment services
- f) To reduce the nuisance and potential harm to the community caused by discarded used injecting equipment

### 9.2 The objectives of the service are:

- a) To reduce the level of direct and indirect sharing and re-use of injecting equipment
- b) To provide sufficient injecting equipment to allow the use of a new needle and syringe for every injection
- c) To offer harm reduction advice both verbally and via printed material
- d) To strongly encourage the return of all used injecting equipment for safe disposal
- e) To contribute to the local knowledge base about patterns of drug use
- f) To complement the specialist NSP provision

## Part 10 – Outputs

### 10.1 The desired outcomes of this service are:

- a) A reduction in the number of injecting drug users who report direct or indirect sharing of injecting equipment
- b) A reduction in the local prevalence of hepatitis C
- c) An increase in the number of injecting drug users who report using a new needle and syringe for every injection
- d) An increase in the amount of used injecting equipment which is returned for disposal
- e) A reduction in the reports of discarded injecting equipment found in the community

## 10.2 The outputs will be:

- a) Basic demographic data
- b) Injecting history data
- c) Transaction data

## Part 11 - Delivery

### 11.1 Service Description

The service shall be delivered in line with the *Derbyshire Pharmacy-based Needle & Syringe Programme Operational Guidelines in Appendix E*.

The service shall be operated by suitably trained pharmacy staff under the direction of a pharmacist.

They shall:

- 11.1.1 Register new service users on to the web-based monitoring system selected by the Council (currently PharmOutcomes).
- 11.1.2 Record subsequent transactions on the monitoring system
- 11.1.3 Offer injecting equipment on a 'pick and mix' basis
- 11.1.4 Encourage service users to take sufficient equipment to allow the use of a new needle and syringe for every injection
- 11.1.5 Give health promotion advice, including advice and information on how to reduce injecting related harms
- 11.1.6 Participate in specific harm reduction campaigns in conjunction with the Council or its commissioned integrated substance misuse service.
- 11.1.7 Refer service users to the integrated substance misuse service and other health and social care services as appropriate
- 11.1.8 Strongly encourage service users to return all used injecting equipment to the pharmacy for disposal
- 11.1.9 Accept and store returned equipment with due regard to safety
- 11.1.10 Maintain sufficient stock levels and order replacement stock in a timely manner

### 11.2 Inclusion and Exclusion Criteria

- 11.2.1 This service is available to anyone aged 18 years or above.
- 11.2.2 Service users may be excluded from the service on a temporary or permanent basis at the discretion of the pharmacy manager. Behaviour or incidents which might lead to exclusion include:
  - a) Acts or threats of violence towards pharmacy staff or customers
  - b) Verbal abuse of staff or customers
  - c) Shoplifting

d) Habitual heavy intoxication.

- 11.2.3 It is expected that pharmacy managers would employ a regime of escalation dependent on the seriousness of the incident or behaviour, with warnings given as appropriate.

### 11.3 Service Standards

- 11.3.1 The pharmacist overseeing the delivery of this service must have completed, be in the process of completing, or commit to completing (within six months), the Centre for Pharmacy Postgraduate Education open learning programme on *Substance Use and Misuse*.
- 11.3.2 Any pharmacy staff delivering the service shall have completed appropriate training.
- 11.3.3 The service should be offered in line with national and local guidance, including:
- NICE (2014) *Public health guidance 52: Needle and syringe programmes*
- 11.3.4 The service shall be delivered in line with the General Pharmaceutical Council's *Standards of conduct, ethics, and performance*. In particular, due to the stigma associated with illicit drug use, the following standards are emphasised:
- 3.2 *Treat people politely and considerately*
  - 3.3 *Not unfairly discriminate against people*
  - 3.5 *Respect and protect people's dignity and privacy*
- 11.3.5 Providers are expected to have appropriate clinical governance arrangements in place. In particular pharmacies shall have in place:
- a) Appropriate standard operating procedures
  - b) Appropriate induction, training and development for staff
  - c) An appropriate incident reporting system and comply with the Council's serious incident reporting procedures
  - d) A complaints procedure
  - e) Safeguarding procedures
- 11.3.6 Pharmacy staff shall be trained in the handling of clinical waste and the pharmacy shall have a needle-stick injury procedure in place.
- 11.3.7 Staff involved in the delivery of the service should be offered hepatitis B vaccination.
- 11.3.8 The service shall be offered throughout the pharmacy's normal opening hours.
- 11.3.9 The service shall be offered in a dedicated area of the pharmacy (if available), within the consultation room, or discretely at the main counter, if no alternative space is available.

## Part 12 – KPI's and Output Measures

12.1 Pharmacies are required to complete all required data fields in PharmOutcomes, in line with the PharmOutcomes Needle Exchange Service Delivery Guide.

12.2 Registration data to include:

- a) Initials
- b) Date of Birth
- c) Gender
- d) First part of postcode
- e) Primary drug injected
- f) Injection site
- g) Length of time injecting
- h) Hepatitis C testing status
- i) Treatment status

12.3 Transaction data to include:

- a) Type and number of needles and syringes issued
- b) Number of and size of sharps bins returned
- c) Advice given

The Council shall conduct service user surveys on an annual basis to capture the patients' experience of the service, including a focus on the issues of discrimination, dignity and privacy.

## Part 13 – Budget and Contract Term

13.1 The Council will pay a fee for NSP activity as detailed below:

A fee of £2.30 will be paid per NSP intervention.

13.2 Where new medications outside the scope of this specification have been prescribed, the Council shall work with the Local Pharmaceutical Committee to agree the charge per intervention.

## Part 14 – Reports and Contract Management

14.1 The Council will extract activity reports from the web-based monitoring system.

## Part 15 – Order and Invoices

Not Applicable – Invoiced through PharmOutcomes

## Part 16 – Response Requirements

16.1 Providers shall complete Appendix B – Response to:

- Express an interest in providing the Pharmacy Based Needle and Syringe Programme
- Confirm agreement to the stated requirements.

Please note pharmacies that are part of a chain will require their Head Office to sign up on their behalf for all branches that fall within the Council's administration area of Derbyshire. This is to reduce time and paperwork.