

Name Address Teresa Gerrard
Finance Manager
Corporate Procurement
County Hall

Matlock

Derbyshire DE4 3AG

Tel: 01629 536805 Please ask for: Caroline May

Ref: CPH080

Insert pharmacy address (or head office address) including email address

[Insert date]

**Dear Sirs** 

## Award of Contract for the Provision of Community Pharmacy Naloxone Service

Following your submission for the supply of the above-stated programme to Derbyshire County Council ("the **Council**"), we are pleased to award this Contract to you as set out in tender documents Appendix B (Expression of Interest) and Appendix E (List of Branches) attached to this Award Letter at Annex 3 (amend as appropriate – delete if not group pharmacy).

The following documents form the contract between the Council and your Company (as "the **Provider**") for the provision of the Services ("the **Contract**"):

- (a) This letter ("Award Letter")
- (b) The Terms and Conditions at Annex 1 ("Conditions")
- (c) The Specification at Annex 2

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(d) The Expression of Interest at Annex 3 including List of Branches (delete if not group pharmacy)

Unless the context otherwise requires, capitalised expressions used in this Award Letter have the same meanings as in the Conditions.

In the event of any conflict between this Award Letter and the Conditions, this Award Letter shall prevail. Please do not attach any Provider terms and conditions to this Award Letter, as they will not be accepted by the Council and may delay the conclusion of the Contract.

We thank you for your co-operation to date and look forward to forging a successful working relationship resulting in a smooth and successful delivery of the Services.

Please confirm your acceptance of the award of this Contract by signing and returning the enclosed copy of this letter to <a href="mailto:publichealth.procurement@derbyshire.gov.uk">publichealth.procurement@derbyshire.gov.uk</a> within (7) days from the date of this letter. No other form of acknowledgement will be accepted. Please remember to quote the reference number above in any future communications relating to this Contract.

Yours faithfully,

**Teresa Gerrard** 

## **Finance Manager – County Procurement Commissioning, Communities and Policy**

**SIGNED** for and on behalf of DERBYSHIRE COUNTY COUNC A GELLANA



**Signature** 

**Teresa Gerard - Finance Manager** 

Date:

The Council representative in respect of this Contract is:

Name:

Caroline May **Procurement Officer** caroline.may@derbyshire.gov.uk

We accept the terms and conditions as set out in this Contract.

**SIGNED** for and on behalf of the **NAME OF PHARMACY** 

	Signature		
	Authorised Signatory's Name		
	Title		
	Date		
Please confirm	the contact details for your representative in respect of this Contract:		
Name:			
Email:			
Phone number	<b>r</b> :		

#### Annex 1

#### **Terms and Conditions**

## 1. Definitions and Interpretation

#### 1.1. In these terms and conditions:

"Agreed means the purpose of the processing of Personal Data as set out in Clause

**Purpose**" 14.1 of this Contract;

"Approved The Council's commissioned contractor to procure and supply Take Home Supplier" Naloxone kits to Community Pharmacies.

"Charges" means the charges for the Services as specified in Part 5 of the

Specification;

"Competent means any body that has authority to issue standards or recommendations

**Body**" means any body that has authority to issue standards or recommendations with which either Party must comply and, for the avoidance of doubt, includes a Regulatory Body;

"Confidential means any information which has been designated as confidential by either Party in writing or that ought to be considered confidential (however it is conveyed or whatever media it is stored) including information which relates to the business affairs, properties, assets, trading practices and commercially sensitive information of either Party and any personal data

(within the DPA 2018);

"Data have the meaning given in the UK GDPR;

Controller,
Data Subject,
Personal Data,
Personal Data
Breach, Data
Protection
Officer"

"Data Protection Legislation" means (i) all applicable UK law relating to the processing of personal data and privacy, including but not limited to the UK GDPR, and the Data Protection Act 2018 to the extent that it relates to processing of personal data and privacy; and (ii) (to the extent that it may be applicable) the EU GDPR). The UK GDPR and EU GDPR are defined in section 3 of the Data Protection Act 2018;

"DPA 2018" means the Data Protection Act 2018;

"EIR" means the Environmental Information Regulations 2004;

"FOIA" means the Freedom of Information Act 2000;

"Good Clinical Practice"

means using standards, practices, methods and procedures conforming to the Law and using that degree of skill and care, diligence, prudence and foresight which would reasonably and ordinarily be expected from a skilled, efficient and experienced clinical services provider, or a person providing services the same as or similar to the Services, at the time the Services are

provided, as applicable;

"Goods and means the Take Home Naloxone Kits and the associated services that the Services" Provider orders:

#### "Guidance"

means any applicable local authority, health or social care guidance, direction or determination which the Council and/or the Provider have a duty to have regard to including (but not limited to) any document published under section 73B of the NHS Act 2006 and any guidance or policies included in the Specification or notified to the Provider in writing;

## "Indirect Losses"

means:

- (i) loss of profits (other than profits directly and solely attributable to the provision of the Services);
- (ii) loss of use:
- (iii) loss of production;
- (iv) increased operating costs;
- (v) loss of business:
- (vi) loss of business opportunity;
- (vii) loss of reputation; (viii) loss of goodwill; or
- (ix) any other consequential or indirect loss of any nature, whether arising in tort or on any other basis;

"Law"

Means any law, statute, subordinate legislation within the meaning of Section 21(1) of the Interpretation Act 1978, bye-law, right within the meaning of the European Union (Withdrawal) Act 2018 as amended by European Union (Withdrawal Agreement) Act 2020, regulation, order, regulatory policy, mandatory guidance or code of practice, judgment of a relevant court of law, or directives or requirements of any regulatory body with which the Supplier is bound to comply;

# "National Standards"

means those standards applicable to the Provider under any Law and/or Guidance as amended from time to time:

# "Permitted Recipients"

means the Parties to this Contract, the directors, officers, staff and employees of each Party, any third parties engaged to perform obligations in connection with this Contract;

#### "Pharmacy"

means any premises from which the Provider delivers the Services;

# "Protective Measures"

appropriate technical and organisational measures designed to ensure compliance with obligations of the Parties arising under Data Protection Legislation and this Agreement, which may include: pseudonymising and encrypting Personal Data, ensuring confidentiality, integrity, availability and resilience of systems and services, ensuring that availability of and access to Personal Data can be restored in a timely manner after an incident, and regularly assessing and evaluating the effectiveness of the measures adopted by it including those outlined in Schedule 3 (Data Processing);

# "Regulatory Body"

means any body carrying out regulatory or registration functions in relation to the Provider and/or the Services, including the General Pharmaceutical Council ("**GPhC**");

# "Serious Incident"

means an incident or accident or near-miss where a person suffers serious injury, major permanent harm or unexpected death on the Provider's premises or where the actions of the Provider, its Staff or the Council are likely to be of significant public concern;

#### "Services"

means the services to be supplied by the Provider to those eligible under this Contract as set out in the Specification attached to this Award Letter at annex 2 and the tender document Appendix E ("Branches Spreadsheet") attached to this Award Letter at Annex 3:

"Service User" means a person eligible to receive the Services;

"Specification" means the specification for the Services attached at Annex 2;

"Staff" means all persons employed by the Provider to perform its obligations under

this Contract together with the Provider's servants, agents, suppliers and sub-contractors used in the performance of its obligations under this

Contract;

"Supervisory means the real to this Contra

means the relevant supervisory authority in the territories where the Parties

to this Contract are established;

"**Term**" means the term of this Contract as set out in Clause 2.

1.2. The headings in these terms and conditions shall not affect the interpretation of this Contract.

- 1.3. References to any statute or statutory provision include a reference to that statute or statutory provision as from time to time amended, extended or re-enacted.
- 1.4. Use of the singular includes the plural and vice versa.
- 1.5. Use of the words and phrases "including", "for example" and "in particular" (and variants of each) shall be construed as illustrative and without limitation to the generality of the related general words unless expressly stated to the contrary.

#### 2. Term

2.1. This Contract shall commence on 1 April 2024 ("the **Commencement Date**") and shall continue until terminated in accordance with the provisions of this Contract.

#### 3. Services

- 3.1 In consideration of the Council's agreement to pay the Charges, the Provider shall supply the Services subject to and in accordance with the Contract.
- 3.2 The Provider shall comply with all applicable Laws as well as all National Standards, regulations, Guidance, direction or determination which the Council and/or the Provider have a duty to have regard to and the Provider shall notify the Council in the event of a conflict between such compliance and any provision of this Contract.
- 3.3 The Provider shall provide the Services with reasonable skill and care in accordance with the best practices prevailing in the industry-sector of which the Services form part.
- 3.4 The Provider shall provide all equipment necessary for the proper performance of the Services and warrants that such equipment is fit for the purposes for which it will be required.

#### 3.5 The Provider warrants:

3.5.1 that it has completed the NHS Data Security and Protection Toolkit (**DSPT**) and is currently marked as having achieved either "Standards Met" or "Standards Exceeded" on the NHS Digital DSPT website;

- 3.5.2 that it will continue to complete the DSPT on an annual basis throughout the Term of the Contract and will continue to achieve either "Standards Met" or "Standards Exceeded" on the NHS Digital DSPT website; and
- 3.5.3 that it will notify the Council immediately in writing in accordance with Clause 19.7 if it fails at any time to be marked as having achieved either "Standards Met" or "Standards Exceeded" on the NHS Digital DSPT website.
- 3.6 The Provider acknowledges that any failure to complete the DSPT on an annual basis or to be marked as having achieved either "Standards Met" or "Standards Exceeded" on the NHS Digital DSPT website constitutes a material breach of the Contract entitling the Council to terminate the Contract with immediate effect in accordance with Clause 10.2.
- 3.7 The Provider warrants that any Staff assigned to the performance of the Service has all such experience, skills and qualifications necessary for the proper performance of the Service.
- 3.8 If the Council reasonably believes that any of the Provider's Staff are unsuitable to undertake work in respect of the Contract, it may, by giving written notice to the Provider:
  - 3.8.1 direct the Provider to end the involvement in the provision of the Services of the relevant person(s); and/or
  - 3.8.2 require that the Provider replace any person removed under this Clause with another suitably qualified person;
  - and the Provider shall comply with any such notice.
- 3.9 The Provider must provide to the Council all of the information reasonably requested by the Council in connection with the provision of the Services. In the absence of any timescale for the provision of such information, it shall be provided within 14 days of request.
- 3.10 The Provider shall not make any material changes to the Services without the prior consultation and agreement of the Council.
- 3.11 The Provider must carry out the Services in accordance with all applicable Laws and Good Clinical Practice and must, unless otherwise agreed with the Council in writing:
  - 3.11.1 comply, where applicable, with the registration and regulatory compliance guidance of any appropriate Regulatory Body;
  - 3.11.2 respond, where applicable, to all requirements and enforcement actions issued from time to time by any appropriate Competent Body;
  - 3.11.3 consider and respond to the recommendations arising from any audit or Serious Incident report;
  - 3.11.4 comply with the recommendations issued from time to time by a Competent Body.
- 3.12 The Provider acknowledges that it is not appointed on an exclusive basis and that the Council does not provide any guarantee or other assurance as to the volume of Services that may be required from the Provider under this Contract.
- 3.13 Except where required by Law, the Provider shall not be required to provide or to continue to provide Services to any Service User:
  - 3.13.1 who in the reasonable professional opinion of the Provider is unsuitable to receive the relevant Service, for as long as such unsuitability remains;

- 3.13.2 who displays abusive, violent or threatening behaviour unacceptable to the Provider and/or the Provider's Staff (acting reasonably and taking into account the mental health of that Service User); or
- 3.13.3 where expressly instructed not to do so by an emergency service provider who has authority to give such instruction, for so long as that instruction applies.
- 3.14 If the Provider proposes not to provide or to stop providing a Service to any Service User under Clause 3.13:
  - 3.14.1 where reasonably possible, the Provider must explain to the Service User, taking into account any communication or language needs, the action that it is taking, when that action takes effect, and the reasons for it; and
  - 3.14.2 the Provider must tell the Service User of the right to challenge the Provider's decision through the Provider's complaints procedure and how to do so;

provided that nothing in this Clause 3.14 entitles the Provider not to provide or to stop providing the Services where to do so would be contrary to the Law.

- 3.15 In respect of the services to be delivered:
  - 3.15.1 The Provider must only use the Goods and Services ordered from the Council's Approved Supplier in the delivery of the Services (unless agreed otherwise in writing by the Council);
  - 3.15.2 The Council shall not be liable to the Provider for any Charge for the Services if these are delivered with goods and services that are not ordered by the Provider in accordance with Clause 3.15.1:
  - 3.15.3 The Provider shall place orders for Goods and Services in accordance with the ordering procedure required by the Approved Supplier;
  - 3.15.4 The Provider must only order the specified amount of Goods and Services at any one time in order to avoid any unnecessary expenditure being incurred by the Council;
  - 3.15.5 The Provider agrees to comply with any obligations or requirements relating to the Provider in respect of the Supply of the Goods and Services at all times:
  - 3.15.6 Without prejudice to any other right or remedy it may have, the Council shall be entitled to recover the Charges, from the Provider in accordance with Clause 6.4 of this Contract, should the Provider be in breach of this Clause 3.15;
  - 3.15.7 Subject to the limitations set out in Clause 8, the indemnity given by the Provider to the Council in Clause 7 of this Contract shall cover the Provider's acts, omissions, default and negligence arising out of or in connection with this Clause 3.15.
- 3.16 The Provider shall ensure that its details on Pharmoutcomes for each Pharmacy are up to date and correct and shall inform the Council promptly of any changes in ownership of any Pharmacy.

# 4. Compliance with GPhC Standards and Registration, and Incident Reporting Requirements

- 4.1 The Provider (or any pharmacist, at the time of delivering the Service for, or on behalf of, the Provider) must be registered with the GPhC.
- 4.2 The Provider must comply with GPhC regulations and procedures at all times throughout the term of this Contract, including all reporting obligations.

- 4.3 The Provider shall have in operation clear procedures for dealing with Serious Incidents. These procedures should make sure that 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. This information shall include information on what action will or has been taken by the Provider as a result of the Serious Incident.
- 4.4 The Provider shall maintain a proper record of all Serious Incidents received in relation to the Service, including the way in which complaints in respect of those Serious Incidents have been dealt with or resolved.

## 5. Safeguarding Children and Vulnerable Adults

- 5.1 The Provider confirms that it has appropriate safeguarding policies in place which will be adhered to. This warranty is given on the Commencement Date and repeated on every day during the term of this Contract.
- 5.2 If requested by the Council, the Provider shall provide within 7 days evidence to the Council that it is addressing any safeguarding concerns.
- 5.3 If requested by the Council, the Provider shall participate in the development and implementation of any local multi-agency safeguarding quality indicators and/or plan.

## 6. Charges, Payment and Recovery of Sums Due

- 6.1 The Charges for the Services shall be the full and exclusive remuneration of the Provider in respect of the supply of the Services. Unless otherwise agreed in writing by the Council, the Charges shall include every cost and expense of the Provider directly or indirectly incurred in connection with the performance of the Services. The Charges are exclusive of Value Added Tax (VAT) which shall be charged at the prevailing rate and is payable by the Council following the receipt of a VAT invoice.
- 6.2 The Provider shall submit claims for payment of the Charges in respect of Services provided to Service Users by the end of each month via a web-based system made available by the Council (currently PharmOutcomes) or as otherwise directed by the Council. Payment under each invoice shall only become due once the Council has received from the Provider all information required under the Contract via the web-based system. The Council shall pay each such undisputed invoice within 30 days of receipt of the invoice generated from the Council's internal accounting system.
- 6.3 If there is a dispute between the Parties as to the amount invoiced, the Provider shall continue to provide the Services and the Council shall pay any undisputed amount. Any disputed amounts shall be resolved through the dispute resolution procedure detailed in Clause 15.
- 6.4 The Council retains the right to refuse to pay any Charges, or to claim it back, at any time, if the Provider fails to provide the Services reasonable skill and care in accordance with Good Clinical Practice.
- 6.5 The Council shall not be liable to pay any Charges if it is invoiced more than six months after the end of the month in which the relevant Services were performed or if relevant reports are more than six months overdue.
- 6.6 The Council shall not be liable for any payment that is made incorrectly as a consequence of the Provider's payment information on Pharmoutcomes being

incomplete, inaccurate or out of date whether this is results from a change in ownership of the Provider or of any Pharmacy or otherwise.

#### 7. Indemnities

7.1 The Provider shall indemnify and keep indemnified the Council against all direct actions, proceedings, costs, claims, demands, liabilities, losses and expenses whatsoever, whether arising in tort (including negligence), default or breach of this Contract, or breach of its statutory duty or breach of an obligation under Data Protection Legislation, save to the extent that the same is directly caused by or directly arises from the negligence, breach of this Contract or breach of statutory duty or breach of an obligation under Data Protection Legislation by the Council.

## 8. Limitation of Liability

- 8.1 Neither Party shall be liable to the other Party (as far as permitted by Law) for Indirect Losses in connection with this Contract.
- 8.2 Each Party must at all times take all reasonable steps to minimise and mitigate any losses for which it is entitled to be indemnified by or bring a claim against the other Party pursuant to this Contract.
- 8.3 Subject to Clause 8.5, the Council's liability under this Contract shall be limited to the Charges.
- 8.4 Subject to Clause 8.5, the Provider's liability under this Contract shall be limited to the Charges.
- 8.5 Nothing in this Contract will exclude or limit the liability of either Party for death or personal injury caused by its negligence, fraud or fraudulent misrepresentation or any other liability that cannot be legally limited.

#### 9. Insurance

- 9.1 The Provider undertakes to effect and maintain in force at its own cost with reputable insurers the following insurance policies at all times during the life of this Contract for each and every claim:
  - 9.1.1 public liability (third party) insurance for a minimum of £5,000,000 (five million pounds):
  - 9.1.2 employer's liability insurance for a minimum of £10,000,000 (ten million pounds);
  - 9.1.3 professional indemnity insurance for a minimum of £5,000,000 (five million pounds) each
  - 9.1.4 product liability insurance for a minimum of £5,000,000 (five million pounds);
  - 9.1.5 medical malpractice insurance for a minimum of £5,000,000 (five million pounds).
- 9.2 The Provider undertakes to maintain in force at its own cost the professional indemnity insurance and medical malpractice insurance for a period of six (6) years beyond the life of the Contract, to begin on the expiry date or termination of this Contract (howsoever arising).

#### 10. Termination

- 10.1 Either Party may terminate this Contract in whole or part for any reason and at any time by giving the other Party one month's written notice.
- 10.2 The Council may terminate this Contract in whole or in part by written notice to the Provider with immediate effect if the Provider:
  - 10.2.1 is in material breach of any obligation under this Contract which (in the Council's reasonable opinion) is not capable of remedy;
  - 10.2.2 is in breach of any obligation under this Contract which is capable of remedy and that breach is not remedied within 14 days of the Provider receiving notice specifying the breach and requiring it to be remedied;
  - 10.2.3 breaches any of the provisions of Clauses 9 (Insurance), 12 (Confidentiality), 14 (Data Protection) or 16 (Bribery);
  - 10.2.4 becomes insolvent, or if an order is made or a resolution is passed for the winding up of the Provider (other than voluntarily for the purpose of solvent amalgamation or reconstruction), or if an administrator or administrative receiver is appointed in respect of the whole or any part of the Provider's assets or business, or if the Provider makes any composition with its creditors or takes or suffers any similar or analogous action (to any of the actions detailed in this Clause) in consequence of debt in any jurisdiction.
- 10.3 Subject to Data Protection Legislation, upon termination or expiry of the Contract, the Provider shall (at no cost to the Council) at the written request of the Council either return or securely destroy all requested documents, information and data to the Council as soon as reasonably possible upon request.
- 10.4 The Council shall have no liability in respect of any costs incurred by the Provider after the date of expiry or termination.

## 11. Review Meetings, Reports and Records

- 11.1 At the reasonable request of the Council, representatives from the Council and the Provider shall meet to review the performance of the Provider in delivering the Services, the costs of the Service, forward planning and any further matters which either Party wishes to review.
- 11.2 The Provider shall submit such information and reports as required by the Specification via the web-based system made available by the Council (or such other format as determined by the Council), within the timescales and in the format specified by the Council and the Provider shall provide such further information as reasonably requested by the Council.
- 11.3 The Provider shall maintain for at least 6 years from the end of the Contract, or as long a period as may be agreed between the Parties in writing, full and accurate records of the Services supplied under the Contract and all payments made by the Council. The Provider shall on request afford the Council or the Council's representatives such access to those records as may be reasonably requested by the Council in connection with the Contract.

## 12. Confidentiality

- 12.1 Each Party shall:
  - 12.1.1 treat all Confidential Information belonging to the other Party as confidential and safeguard it accordingly; and

- 12.1.2 shall not disclose any Confidential Information belonging to the other Party to any other person without the prior written consent of the other Party except where disclosure is otherwise expressly permitted by the provisions of this Contract.
- 12.2 Clause 12.1 shall not apply to any disclosure of information:
  - 12.2.1 required by any applicable Law, including FOIA and EIR;
  - 12.2.2 that is reasonably required by persons and to such extent as may be necessary for the performance of the Contract;
  - 12.2.3 where such information is already generally available or in the public domain, other than as a result of unauthorised disclosure;
  - 12.2.4 which is lawfully already in the possession of the receiving Party, prior to its disclosure by the disclosing Party; or
  - 12.2.5 by the Council to any other department, office or agency of the Government.
- 12.3 The Parties acknowledge that the Contract is not Confidential Information and may be published in whole or redacted by the Council if necessary. The Council may consult with the Provider to inform its decision regarding any publication or redactions but shall have the final decision in its absolute discretion with regards to any publication or redactions.

#### 13. Freedom of Information

- 13.1 The Parties acknowledge that each is subject to the requirements of the FOIA and the EIR and shall assist and co-operate with one another to enable each Party to comply with these information disclosure requirements, where necessary.
- 13.2 If either Party receives a request for information under the FOIA which relates to the Services covered by this Contract it shall promptly (and in any event within 2 Working Days) inform the other Party of the request.
- 13.3 The Parties will cooperate with one another in responding to a request for information by processing information or environmental information (as the same are defined in the FOIA) in accordance with a records management system that complies with all applicable records management recommendations and codes of conduct issued under section 46 of the FOIA, and providing copies of all information requested by the other Party within 5 Working Days of such request and without charge.

#### 14. Data Protection

- 14.1 The Parties agree that in relation to:
  - 14.1.1 Personal Data processed by the Provider in providing Services under this Contract (for example, patient details, medical history and treatment details), the Provider shall be the sole Data Controller; and
  - 14.1.2 Personal Data, the processing of which is required by the Council for the purposes of quality assurance, performance management and contract management the Council and the Provider will be independent Data Controllers;

together the "Agreed Purpose".

- 14.2 Where the Council requires information under Clause 14.1.2 above, the Provider shall consider whether the requirement can be met by providing anonymised or aggregated data which does not contain Personal Data. Where Personal Data must be shared in order to meet the requirements of the Council, the Provider shall provide such information in pseudonymised form where possible.
- 14.3 Each Party shall comply with all the obligations imposed on a Data Controller under the Data Protection Legislation in relation to all Personal Data that is processed by it in the

- course of performing its obligations under this Contract.
- 14.4 Each Party shall designate its own Data Protection Officer if required by the Data Protection Legislation.
- 14.5 Any material breach of the Data Protection Legislation by one Party shall, if not remedied within fourteen (14) days of written notice from the other Party, give grounds to the other Party to terminate this Contract with immediate effect.
- 14.6 In relation to the Processing of any Personal Data, each Party shall:
  - 14.6.1 ensure that it has all necessary notices and consents in place to enable lawful sharing of Personal Data to the Permitted Recipients for the Agreed Purpose;
  - 14.6.2 give full information to any Data Subject whose Personal Data may be processed under this Contract of the nature of such Processing;
  - 14.6.3 process the Personal Data only for the Agreed Purpose;
  - 14.6.4 not disclose or allow access to the Personal Data to anyone other than the Permitted Recipients;
  - 14.6.5 ensure that all Permitted Recipients are reliable and have had sufficient training pertinent to the care and handling of Personal Data;
  - 14.6.6 ensure that all Permitted Recipients are subject to written contractual obligations concerning the Personal Data (including obligations of confidentiality) which are no less onerous than those imposed by this Contract;
  - 14.6.7 ensure that it has in place Protective Measures which are appropriate to protect against unauthorised or unlawful Processing of Personal Data and against accidental loss or destruction of, or damage to, Personal Data in accordance with Article 32 of the UK GDPR:
  - 14.6.8 not transfer any Personal Data outside the UK unless the transferring Party ("the **Transferor**") ensures that:
    - the destination country has been recognised as adequate by the UK government in accordance with Article 45 UK GDPR or section 74 of the DPA 2018;
    - (b) the Transferor has provided appropriate safeguards in relation to the transfer (whether in accordance with UK GDPR Article 46 or section 75 of the DPA 2018) as determined by the Council;
    - (c) the Data Subject has enforceable rights and effective legal remedies;
    - (d) the Transferor complies with its obligations under Data Protection Legislation by providing an appropriate level of protection to any Personal Data that is transferred (or, if it is not so bound, uses its best endeavours to assist the other Party in meeting its obligations); and
    - (e) the Transferor complies with any reasonable instructions notified to it in advance by the other Party with respect to the processing of the Personal Data
  - 14.6.9 assist the other Party (at its own cost) in responding to any request from a Data Subject and in ensuring its compliance with all applicable requirements and obligations under the Data Protection Legislation with respect to security, breach notifications, impact assessments and consultations with supervisory authorities or the UK's Information Commissioner's Office.
- 14.7 Each Party shall notify the other Party without undue delay on becoming aware of any Personal Data Breach under this Contract.

## 15. Dispute Resolution

- 15.1 The Parties shall attempt in good faith to negotiate a settlement to any dispute between them arising out of or in connection with the Contract within such reasonable time as agreed between the Parties. Such efforts shall involve the escalation of the dispute to an appropriately senior representative of each Party, if necessary.
- 15.2 If the dispute is not resolved under Clause 15.1 then either Party may commence or continue court proceedings in respect of such unresolved dispute.
- 15.3 Notwithstanding any dispute, the provision of the Services shall not be suspended, ceased or delayed and the Provider (and its Staff) shall comply fully with this Contract at all times.

#### 16. Bribery

- 16.1 Each Party warrants it shall (and will ensure its Staff shall) comply with the Bribery Act 2010 at all times and shall notify the other Party immediately if a breach of this Act is suspected or known.
- 16.2 Each Party shall maintain its own policies and procedures to ensure compliance with any relevant requirements and will enforce them where appropriate.
- 16.3 Either Party may terminate this Contract by written notice with immediate effect if the other Partyor its Staff (whether acting or not with the Provider's knowledge) breaches the Bribery Act 2010.

#### 17. Audit and Inspection

- 17.1 The Provider must comply with all reasonable written requests made by the Council, the National Audit Office, the GPhC or other Regulatory Body, in respect of entry to the Provider's premises and/or the premises of any sub-contractor for the purposes of auditing, viewing, observing or inspecting such premises and/or the provision of the Services, and for information relating to the provision of the Services. The Provider must provide the Council with all reasonable co-operation and assistance in relation to such requests, including access to information and to Staff, unless it would materially and adversely affect the provision of the Services.
- 17.2 The Provider shall provide such reasonable co-operation and assistance in relation to any audit, including providing:
  - 17.2.1 all reasonable information requested within the scope of the audit;
  - 17.2.2 reasonable access to the Provider's premises and/or the premises of any subcontractor; and
  - 17.2.3 access to its Staff.
- 17.3 The Council shall use its reasonable endeavours to ensure that reasonable written notice is given of any audit and that the conduct of any audit undertaken within its control does not unreasonably disrupt the Provider or delay the provision of the Services.

#### 18. Complaints

18.1 If a complaint is received about the standard of the provision of the Services or about the manner in which any of the Services have been supplied or work has been performed or about the materials or procedures used or about any other matter connected with the performance of the Provider's obligations under this Contract, then the Council may take any steps it considers reasonable in relation to that complaint, including investigating the complaint and discussing the complaint with the Provider, and any appropriate Competent Body. Without prejudice to any other rights the Council may have under this Contract, the Council may, in its sole discretion, uphold the complaint and take any reasonable action in connection with this Contract as a consequence.

#### 19. General

- 19.1 A person who is not a party to the Contract shall have no right to enforce any of its provisions which, expressly or by implication, confer a benefit on him, without the prior written agreement of the Parties and the Contracts (Rights of Third Parties) Act 1999 shall not apply.
- 19.2 The Contract cannot be varied except in writing signed by a duly authorised representative of both Parties.
- 19.3 The Provider must not assign, delegate, transfer, sub-contract, novate, charge or otherwise dispose of all or any of the rights or obligations under this Contract without the prior written consent of the Council.
- 19.4 The Contract contains the whole agreement between the Parties and supersedes and replaces any prior written or oral agreements, representations, or understandings between them. The Parties confirm that they have not entered into the Contract on the basis of any representation that is not expressly incorporated into the Contract. Nothing in this Clause shall exclude liability for fraud or fraudulent misrepresentation.
- 19.5 Any waiver or relaxation either partly, or wholly of any of the terms and conditions of the Contract shall be valid only if it is communicated to the other Party in writing and expressly stated to be a waiver. A waiver of any right or remedy arising from a breach of contract shall not constitute a waiver of any right or remedy arising from any other breach of the Contract.
- 19.6 If any provision of the Contract is prohibited by Law or judged by a court to be unlawful, void or unenforceable, the provision shall, to the extent required, be severed from the Contract and rendered ineffective as far as possible without modifying the remaining provisions of the Contract and shall not in any way affect any other circumstances of or the validity or enforcement of the Contract.
- 19.7 Any notice to be given under the Contract shall be in writing and may be served by personal delivery, pre-paid post or e-mail to the address of the relevant representative of the Party as set out in the Award Letter, or such other address as that Party may from time to time notify to the other Party in accordance with this Clause. Notices may be served by email only if the original notice is then sent to the recipient by personal delivery or pre-paid post in the manner set out in this Clause.
- 19.8 This Contract shall be governed by and interpreted in accordance with English Laws and the Parties submit to the jurisdiction of the Courts of England.

## Annex 2

## The Specification



# Appendix A Specification draft

# CPH080 Provision of Community Pharmacy Take Home Naloxone Service

Company/Organisation: Enter Tenderer's Name

## **Evaluation Approach**

In assessing the response documents the Council will be seeking evidence of the potential providers 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.

## **Service Delivery Requirements**

Providers shall complete Appendix B – Proposal Response to Express an interest in becoming an accredited provider for the Provision of Community Pharmacy Naloxone Service.

## **Service Eligibility**

Only Pharmacies that are currently commissioned by Derbyshire County Council to provide the Supervised Consumption of Methadone or Buprenorphine service and/or Needle and Syringe Exchange and are eligible to deliver the Community Pharmacy Naloxone Service. This is because under regulations that came into force in October 2015<sup>(1)</sup>, people working in or for drug treatment services can, as part of their role, supply naloxone, for use to save a life in an emergency opioid overdose, without a prescription. Under these regulations, pharmacies that are commissioned by local authorities<sup>(2)</sup>, to provide needle and syringe programmes, or drug opioid substitution treatments, are permitted to issue naloxone without prescription.

## Confirm agreement to the stated requirements of the service.

- (1). PHE (2017) Take-home naloxone for opioid overdose in people who use drugs. Public Health England
- (2). PHE (2019) Widening the availability of naloxone. Available here: Widening the availability of naloxone GOV.UK (www.gov.uk)

#### 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 the response to the requests set out in documents. The Council may seek independent financial and market advice to validate information declared, or to assist 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.

## **Definitions**

CPR	Cardiopulmonary Resuscitation		
DCC	Derbyshire County Council		
DRD	Drug Related Deaths		
GPhC	General Pharmaceutical Council		
NSP	Needle and Syringe Programme		
POM	Prescription Only Medicine		
Qualified Provider	are defined as pharmacies that are commissioned by Derbyshire County Council to provide needle and syringe exchange or opioid substitution therapy.		
SMS	Substance Misuse Services		
SOP	Standard Operating Procedure		
THN	Take Home Naloxone		

# **Specification**

## Introduction

Naloxone is the emergency antidote for an overdose caused by heroin or other opiates or opioids, such a methadone, morphine or fentanyl. The main life-threatening effect of heroin and other opioids is overdose, which causes a severely reduced respiratory rate, leading to severe hypoxia, which if not treated as an emergency can be fatal. Naloxone blocks the effects of opioids and reverses the respiratory depression. Its use is widespread across emergency departments and ambulance services, and many thousands of lives have been saved through the professional emergency use of Naloxone.

Drug Related Deaths (DRD) in the UK are at the highest level since recording began, increasing by over 60% in the 10 years to 2020<sup>(1)</sup>. The majority of DRD relate to accidental overdose of opioids, primarily heroin<sup>(2)</sup>. Take Home Naloxone (THN), involves providing people at risk of opioid overdose, and those who may encounter them, with a supply of naloxone, to use in non-clinical situations, as an emergency response to an overdose, whilst waiting for emergency services to arrive. THN is an evidenced based approach to reducing DRD. THN is routinely offered to people who are at risk of an opioid overdose<sup>(1)</sup>, in Derbyshire THN is currently provided by specialist substance misuse treatment centres and some hospitals.

Local evidence demonstrates that a sizeable proportion of people at risk of DRD are not currently in contact with substance use services. Further evidence indicates that in Derbyshire, there are a significant number of localities, that have individuals and communities that are at risk of opioid overdose, and that that would not be able to access THN without some form of transport.

Alternative approaches to the provision of THN to this disadvantaged population are therefore required. Community Pharmacies play a vital part in the national approach to the care and management of patients with opioid misuse problems in the UK. Community Pharmacies provide Needle and Syringe Exchange, and Opioid Substitution Therapy, which are both essential components of the multiagency approach to the management of substance use disorders. Pharmacies are familiar and acceptable services, and with their wide geographic availability, pharmacies are an ideal setting to access people at risk of DRD and provide THN.

Naloxone is a prescription-only medicine, so pharmacies cannot sell it over the counter. But under regulations that came into force in October 2015<sup>(3)</sup>, people working in or for drug treatment services can, as part of their role, supply naloxone, for use to save a life in an emergency opioid overdose, without a prescription. Under these regulations, pharmacies that are commissioned by local authorities<sup>(4)</sup>, to provide needle and syringe programmes, or opioid substitution treatments, are permitted to issue naloxone without prescription.

Derbyshire County Council are seeking to expand the provision of THN, via community pharmacies that are currently commissioned to provide needle exchange or opioid substitution, for the financial year 2024/25.

#### References:

- 1. Office for National Statistics (2021) Deaths Related to Drug Poisoning in England and Wales: 2020 Registrations Deaths related to drug poisoning in England and Wales Office for National Statistics (ons.gov.uk) accessed 12/07/2022.
- 2. O'Halloran C., Cullen K., Njorogea J., Jessop L., Smith J., Hope V., and Ncube F., (2017) The extent of and factors associated with self-reported overdose and self-reported receipt of naloxone among people who inject drugs (PWID) in England, Wales and Northern Ireland. International Journal of Drug Policy, 46, 35-40
- 3. PHE (2017) Take-home naloxone for opioid overdose in people who use drugs. Public Health England
- 4. PHE (2019) Widening the availability of naloxone. Available here Widening the availability of naloxone GOV.UK (www.gov.uk)

## Part 1 – Aims

The primary aim of this pharmacy service is to contribute to a reduction in drug related deaths (DRD) within Derbyshire by:

- a. increasing awareness of overdose risk and the role of naloxone to people at risk of overdose, and offer, and supply THN.
- b. providing education about overdose awareness and what to do in emergency situations, including how to use THN.
- c. providing a convenient supply of replacement THN following emergency use or expiry date.
- d. supporting other relevant harm reduction initiatives (such as needle and syringe exchange).
- e. promoting the role that pharmacies can play in helping to reduce DRD.

## Part 2 – Outputs

The expected outputs of this service are:

- a. provision of harm reduction messages.
- b. Increase in availability of THN in the community for emergency use in opioid overdose.
- c. Increase in awareness of symptoms of opioid overdose and how to respond in an emergency.
- d. Provision of education in the appropriate use of THN in the situation of opioid overdose.
- 2.1 The desired outcomes of this service are:
  - a) A reduction in drug-related deaths.
  - b) Improved knowledge skills and confidence for use of THN in services users.
  - c) Improved knowledge skills and confidence regarding DRD reduction amongst

services users.

## Part 3 - Delivery

## **Service Description**

THN can be supplied to any individual aged 18 or over with the instruction that "supply shall be for the purpose of saving life in an emergency".

The primary target groups for the issue of THN supply are those individuals accessing the Supervised Consumption of Methadone and Buprenorphine service, and or Needle and Syringe Exchange service. For such individuals it is appropriate for a pharmacy to consider offering a new supply at frequent intervals, and THN could be offered on every visit, using the principles of 'opt-out'. It is envisaged that such prompts may encourage individuals to always carry THN with them. For these individuals THN should be available and provided on every initial interaction from service commencement date unless an individual declines and states that they do not wish to accept the offer of THN supply. Once an individual has been issued with a THN kit, the pharmacist should periodically review whether a replacement kit is needed.

THN can also be made available to individuals who are not accessing opioid replacement therapy or needle exchange services, as any member of public over the age of 18 is eligible to be issued with THN on request. Full details of eligibility and exclusion criteria are provided below in the specification.

As part of this service, THN can be offered in either Intranasal (such as Nyxoid 1.8mg nasal spray, or "Pebble" 1.26mg nasal spray) or Intramuscular (such as Prenoxad 2mg/2ml preloaded syringe) formulations. All supplies must be within the expiry date and the recipient must be made aware of the expiry date, and that they should return to the pharmacy for further supply if their kit is used, damaged, or expired.

The THN kit issued will be determined by patient choice and availability:

In delivering this service the Provider will demonstrate compliance with all relevant national standards for service quality and clinical governance including compliance with their obligations under Schedule 4 of the Pharmaceutical Services Regulations (Terms of Service of NHS pharmacists) in respect of the provision of essential services and an acceptable system of clinical governance.

## **Staff Training**

Pharmacy staff supplying THN must be appropriately trained prior to them being able to deliver this service.

All pharmacy staff providing the service must complete the free Addiction Professionals Educational Resources FreeLearn: Naloxone Saves Lives online learning package, which can be accessed through the following link <a href="https://www.ap-elearning.org.uk/">https://www.ap-elearning.org.uk/</a>. The Pharmacy must keep a log of staff who have completed training in a training record, including copies of the certificates of completion. It is important to note that since this training package was created, a new formulation of intranasal naloxone has been made available, similarly, there is potential that additional licensed formulations may become available during the time of this contract.

Which formulation is supplied may therefore vary and it is essential that the training provided to the individual collecting the naloxone is appropriate for the type of supply made. The current three types of naloxone available as THN are:

- Intramuscular, i.e., "Prenoxad" pre-filled syringe. Product specific training and information can be found here: Prenoxad Injection
- Intranasal, i.e., Nyxoid 1.8mg nasal spray. Product specific training and information can be found here: Nyxoid 1.8 mg nasal spray, solution in a single-dose container -Summary of Product Characteristics (SmPC) - (emc) (medicines.org.uk)
- Intranasal, i.e., "Pebble" 1.26mg nasal spray Product specific training and information can be found here: <u>Naloxone 1.26mg Nasal Spray | How to respond to an opioid</u> <u>overdose by using Naloxone</u>

Additional training resources may be available on request from the Council's approved THN Supply and Service contractor, and Council representatives will be available to provide further support to train pharmacy staff if requested by the Pharmacy within the first three months of this contract being published.

The Responsible Pharmacist on duty at any time will retain professional responsibility and the Pharmacy shall retain liability for the Service.

# Education / knowledge requirements for THN recipients that should be provided in conjunction with THN supply

Pharmacy staff members delivering this service must be satisfied that the individual attending the pharmacy to collect a THN kit has a comprehensive understanding of the instructions on how to administer THN prior to issuing a kit. Some recipients may have an existing knowledge and decline education, in such circumstances the Pharmacy staff must be satisfied that the recipient has the required level of knowledge set out in this education requirement section before supplying THN.

Education can be delivered verbally by pharmacy staff, or individuals can be shown the training videos as accessed through the individual links provided above.

The pharmacy must ensure that individuals accessing the service are treated with respect and dignity, and interactions with individuals must take place in a designated consultation room to ensure their privacy and safety.

Pharmacy staff will supplement education provided by offering information on how to access information leaflets or training resources if needed.

## Knowledge required by the THN recipients should include:

## 1. How to identify and respond to an overdose:

- Can identify the symptoms of an opioid overdose. These include:
  - Their breathing or heartbeat slows or stops.
  - Changes to facial colour, becoming extremely pale and/or feels clammy to the touch.
  - They cannot be woken or are unable to speak. or their body becomes limp.
  - o Their fingernails or lips have a purple or blue colour.

- They start vomiting, making gurgling noises, an overdose can often be mistaken for snoring.
- Understand the common factors that increase overdose risk. These include:
  - o use of substance by injecting.
  - o unpredictable and variable strength / potency of drugs.
  - using multiple substances at the same time (including alcohol and prescribed medications).
  - being physically unwell.
  - o loss of tolerance (after a break or reduced use for a period of time).

## 2. How to store, carry, and administer THN in the preparation form issued:

- Know how to administer THN (depending on the type of kit issued see below).
- Understand the possible side effects of THN, including withdrawal.
- Understand the safe storage requirements of THN, stressing the importance of carrying the THN supply with them, ideally at all times.
- Know how to open the THN pack and not to do so except for emergency use.
- Know how to dispose of unwanted, expired or used packs and how to source replacements.

# 3. Understand the actions to take if witnessing a suspected opioid overdose, including:

- Ensure personal safety first.
- How to support the overdose casualty until emergency services arrive.
- Place the casualty in the recovery position, if breathing.
- Place the casualty on their back and commence CPR if not breathing.

#### 4. Understand the importance of calling 999 for an emergency ambulance:

- Naloxone has a shorter half-life (and thus duration of action) than most opioids.
- This means that the casualty may again become oversedated after the naloxone wears off, as such emergency service review and intervention is always recommended.

# Specific education must also be provided to individuals accessing the service based on the type of THN they are provided with.

If supplying Intramuscular THN (i.e. Prenoxad), the following must be explained:

- i. Inject naloxone into the thigh or upper arm muscle.
- ii. Repeat naloxone injections at 2-minute intervals in doses of 0.4mg until breathing commences Please note: each prefilled syringe contains five x 0.4mg doses.
- iii. If the patient is still non-responsive and the ambulance services have not arrived, additional Naloxone doses can continue to be given at 2-minute intervals if there are other kits available to use.
- iv. Wait with the casualty until the ambulance arrives and safely dispose of the naloxone kit to paramedics.
- v. Videos that can be used for patient education for Prenoxad can be found here: Prenoxad Injection

**If supplying Intranasal THN** (i.e. Nyxoid 1.8mg nasal spray, or Pebble 1.26mg nasal spray), the following must be explained:

- i. Give one dose into the nostril immediately on suspecting an opioid overdose while waiting for emergency services.
- ii. Repeat chest compressions and rescue breaths until breathing commences.
- iii. If the first dose does not have an effect, a second dose should be given after 2–3 minutes in the other nostril.
- iv. If the first dose works well but the patient later worsens a second dose should be given immediately in the other nostril.
- v. Videos that can be used for patient education for Nyxoid 1.8mg nasal spray, can be found here: Nyxoid 1.8 mg nasal spray, solution in a single-dose container Audio and Video (emc) (medicines.org.uk)
- vi. Videos that can be used for patient education for Pebble 1.26mg nasal spray can be found here: <u>Guidance for UK Healthcare professionals and drug service workers</u> | Naloxone United Kingdom

The above areas and the process of using the THN kit should be explained and demonstrated using a sample kit and the individual's understanding noted. This should be done each time a kit is issued or replaced.

Pharmacy staff must also make individuals aware that THN has a maximum shelf life of three (3) years. When a kit is issued this should be explained to the individual and the expiry date noted and told to them. Recipients of THN should be encouraged to return the kit to the service once this expiry date is close, to collect a further supply.

#### Provision of additional Harm Reduction Information

Pharmacists and pharmacy staff should offer harm reduction advice within their competencies that may include:

- The benefits of being in drug treatment being on an opioid substitution programme (i.e., methadone or buprenorphine) reduces the risks to people that misuse opioids.
- The factors that increase risks of accidental overdose.
- The importance of not using drugs alone, as no one would be able to call for help or administer THN.

Public Health may occasionally supply pharmacies with harm reduction material, for distribution to the Client population. This will normally be carried out as part of a county-wide campaign, e.g., to raise awareness of issues such as overdose or hepatitis C.

In addition, Public Health will notify pharmacies of any urgent health warnings (e.g., possible contaminated street drugs, botulism, or anthrax infection risks, etc.), which require communication to the Client population. The Derby and Derbyshire Local Drug Information System considers all substance use related risks, using National set criteria, and distributes

alerts to local professionals.

## Registration

On an individual's first visit, they should be registered on the web-based monitoring system, PharmOutcomes. Registration should be done in a consultation room to ensure privacy. If access to PharmOutcomes is not available during registration or data entry at a later point is preferred, an individual's data may be temporarily recorded on paper and updated onto the system later.

Refusal by the client to supply any of the requested data items should not preclude their use of the Take Home Naloxone Service. Any missing data fields may be attempted to be completed at a later visit.

Data fields to be entered onto PharmOutcomes on registration are as follows:

- Name/Initials
- Date of Birth
- Address
- Post Code
- Gender

## **Recording Transactions**

On each transaction the Pharmacy staff member supplying the THN to an individual must confirm and record the following on the PharmOutcomes System:

- The date of the transaction.
- Confirmation that the individual is over the age of 18 years old. Identification is not required to prove this, but an individual must provide verbal assurance.
- Confirmation that the individual has received the required education on THN as specified above.
- Confirmation of the type of THN supplied (i.e., type of Intramuscular or Intranasal), including the batch number and expiry date.

## **Eligibility criteria:**

The main intention for the Provision of Community Pharmacy Take Home Naloxone Service is to ensure sufficient supplies are available in community settings to enable emergency responses to overdose situations and save lives. As such pharmacy staff can use their judgement about eligibility. Legally there are no restrictions on who THN can be supplied to as long as supply is made for the purpose of saving a life in an emergency. In practice the groups most likely to be supplied THN include:

- Any drug user at risk of overdose.
- ii. Clients receiving opioid replacement therapy or injection equipment.
- iii. Prison leavers with a history of drug use.
- iv. Carers, friends, and family members of a drug user at risk of overdose.
- v. Any individual working in an environment where there is a risk of overdose for

- which the THN may be useful.
- vi. Any other group where exemptions currently apply or where an exemption comes into force during the term of this contract.
- vii. Individuals aged 18 and over. Given that THN is supplied with the purpose of saving life, proof of age and identity is not required for supply to be made. If the person seeking supply is clearly under 18 then the notes within the exclusion criteria should be followed.

Individuals who have been supplied the THN by a commissioned drug treatment service, including pharmacies, should not supply it to others. However, in an emergency, anyone can use any available naloxone to save a life<sup>(1)</sup>.

Although this specification seeks to ensure that residents of Derbyshire County (excluding Derby City), have access to THN, it would not be appropriate to refuse to provide THN based on address. It is also anticipated that a sizeable number of people at increased risk for overdose that may need THN may also be homeless or have no fixed abode.

#### **Exclusion Criteria:**

Pharmacies should not issue THN kits to the following:

- i. Individuals whose behaviour breaches acceptable standards, as deemed by the pharmacy, or where their actions or behaviour have posed a risk to staff or others.
- ii. People under the age of 18: given the complexity of THN supply to a person under the age of 18, it is advisable that such young people are signposted to other support services. Derbyshire County Council contracts with organisations listed below to support young people:
  - i. Change Grow Live (CGL), to deliver the Children and Young People's Specialist and Targeted Substance Use Service, contact details of which can be found here <a href="https://www.changegrowlive.org/young-peoples-service-derbyshire">https://www.changegrowlive.org/young-peoples-service-derbyshire</a>
  - ii. Action for Children, to deliver the Children Affected by the Substance Use of Others service (Space4U), contact details of which can be found here <a href="https://services.actionforchildren.org.uk/derbyshire/space-4-u/">https://services.actionforchildren.org.uk/derbyshire/space-4-u/</a>.

## **Naloxone Supply to Pharmacies**

The THN issued through the service shall be provided to the Pharmacy by an external supply and service contractor commissioned by the Council.

The Council shall confirm details of this supplier and shall arrange for them to contact the Pharmacy to outline ordering and delivery processes and procedures once contractual arrangements are in place between the Council and the Pharmacy.

To reduce the likelihood of loss of waste, stock holding on site can be kept to a minimum as the Council's contracted THN supplier will have a fast and efficient ordering and delivery system in place. To maintain continuity of service, Pharmacies should order and hold a stock of 10 THN kits, which would normally be five (5) kits each of Intramuscular (i.e. Prenoxad®) and Intranasal (i.e., at either 1.8mg dose Nyxoid® or 1.26mg dose Pebble), unless agreed otherwise with the

Council. The stock issued through the Council's contracted THN supplier must only be used for the provision of this service. If, during the duration of this contract, an individual pharmacy believes that they should hold a stock level that differs from this, this should be discussed in the first instance with the Council.

Once any of these kits are provided to individuals using the service, replacement stock must be ordered from the supplier.

Any THN that passes its expiry date must not be provided to individuals and must be disposed of. Any expired supplies held by the Pharmacy, or returned to the Pharmacy by individuals, should immediately be placed in sharps collection bins for clinical waste collection and disposal.

Deliveries must be signed for by pharmacy staff and the delivery note retained.

#### Clinical and Cost Effectiveness

Pharmacies will:

- Comply with their obligations under Schedule 4 of the Pharmaceutical Services Regulations (Terms of Service of NHS pharmacists) in respect of the provision of essential services and an acceptable system of clinical governance.
- Demonstrate the principle of 'best value' through continuous improvement taking into account a combination of effectiveness (successful outcomes), efficiency (high productivity) and economy (costs).
- Ensure there is designated clinical leadership and accountability, and clear clinical protocols for effective clinical governance.
- Ensure staff are appropriately supported and supervised, including clinical supervision.

## Expectations in relation to equality, diversity, and inclusion

Pharmacies must ensure that all communities within Derbyshire can engage with and use this service, through:

- Ensuring the service offers equitable access to treatment and care.
- Ensure the service meets the duties of the Equality Act 2010, including assisting the Council to meet the public sector equality duty for all the 9 protected characteristics of:
  - a) Age
  - b) Disability
  - c) Gender re-assignment plus gender identity
  - d) Marriage and civil partnership
  - e) Pregnancy and maternity
  - f) Race and ethnicity
  - g) Religion and belief, including non-belief plus cultural background
  - h) Sex

i) Sexual orientation

## Safeguarding

The pharmacy shall ensure that local safeguarding procedures are followed in a timely and appropriate manner and adhere to statutory and non-statutory guidance in line with the local Safeguarding Children Board and Safeguarding Adults Board policies and procedures:

- Derby and Derbyshire Safeguarding Children Procedures <a href="https://derbyshirescbs.proceduresonline.com/index.htm">https://derbyshirescbs.proceduresonline.com/index.htm</a>
- Derby and Derbyshire Adults Protection Policy and Procedures. https://www.derbysab.org.uk/

All staff operating the service must have an up-to-date Disclosure and Barring Service check.

## **Serious Untoward Incidents**

The Pharmacy shall ensure that any Serious Untoward Incidents that occur as a result of the delivery of this service should be actioned appropriately in line with the Serious Incidents (SI) policy which is attached as an appendix to this specification.

## **Exit Planning**

This will be a rolling annual contract commencing on the 1 April 2024. If the Council terminates this rolling contract, the Pharmacy must no longer provide individuals with THN past the contract expiry date.

Any unused doses of THN held by the Pharmacy must be disposed of in line with the Pharmacies standard practices.

1. PHE (2019) Widening the availability of naloxone. Available here Widening the availability of naloxone - GOV.UK (www.gov.uk)

## Part 4 - KPI's and Output Measures

Pharmacies are required to complete all required data fields in PharmOutcomes and performance will be monitored as detailed in the table below;

Outcome	Output	Measure	Frequency
Improved	Number of	PharmOutcomes	Monthly
awareness and	individuals trained	data	
availability of THN in	and supplied with		
Derbyshire	THN.		

The Council may conduct service evaluation through site visits to Pharmacies and may undertake surveys on an annual basis to capture individuals experience, including a focus on

the issues of discrimination, dignity, and privacy.

## Part 5 – Budget and Contract Term

The contract will be a rolling annual contract and will commence on 01 April 2024. The Council may choose not to continue the rolling contract on an annual basis and will inform Pharmacies as to any decision made.

Pharmacies can opt to provide this service at any point throughout the financial year by completing an Expression of Interest and signing a contract. The end date of all contracts shall be the end of the financial year in which they sign a contract to deliver the service.

The Council will pay a one-off fee of £250.00 to all eligible pharmacies who sign up to deliver this service, to cover programme set up and ensure pharmacy staff complete the required training as set out in this specification. Pharmacies must invoice the Council through the process set out in Part 7 of this specification to claim this. This fee is only available to individual Pharmacies once.

The Council will also pay £13 per transaction of THN. Pharmacies will need to submit claims through the PharmOutcomes system for transactions, and invoices will be generated for the Council automatically through PharmOutcomes for this. Transactional costs will cover:

- Pharmacy staff time and associated costs for the THN activity.
- Record keeping activities to include PharmOutcomes data entries.
- Completion of relevant training to ensure maintenance of confidence and competence when supporting people who use substances.

Claims for transaction payment are generated automatically in monthly arrears once inputted by the pharmacy into the PharmOutcomes system. All claims are to be submitted via PharmOutcomes within one (1) month of the transaction taking place. The Council will not pay any claims submitted beyond the one (1) month allowable timescale.

It is the responsibility of the Pharmacy to ensure that their details are up to date in the PharmOutcomes system, and the Council is not liable for any incorrect payments made as a result of Pharmacy details being incorrect.

Pharmacies must also contact the Council in the event of changes of ownership, as new contracts will need to be issued to enable the Pharmacy to continue to deliver the service. The Council is not liable for any payments made incorrectly if Pharmacies do not inform us of changes in ownership.

## Part 6 - Reports and Contract Management

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

## Part 7 – Order and Invoices

#### Invoices

An Invoice will need to be submitted to the Council by each Pharmacy to claim the £250.00 sign-up fee, covering programme set up and ensuring pharmacy staff complete the required training as set out in this specification.

The Council requires the ability to raise electronic orders, receive electronic invoices and that:

•Invoices always quote the purchase order number and a contact name.

Submission of a signed contract will be taken as confirmation that your organisation can comply with the stated ordering and invoicing requirements.

Once the Council has received a signed copy of the contract from the Pharmacy, the Pharmacy will be contacted by email with a Purchase Order (PO) Number. The Pharmacy may be requested to provide additional information to the Council to be registered as a vender and receive a PO. The Pharmacy will then need to send an email to the Council (ASCH.Public.Health@derbyshire.gov.uk) containing an invoice for the £250.00 sign-up fee quoting the PO provided. The invoice will then be processed and paid.

## Part 8 – Response Requirements

Providers shall complete Appendix B – Expression of Interest and email it to <a href="mailto:publichealth.procurement@derbyshire.gov.uk">publichealth.procurement@derbyshire.gov.uk</a> to:

- Express an interest in providing the Community Pharmacy Naloxone Service.
- Confirm agreement to the stated requirements.

A contract will then be forwarded for signature.

## Annex 3

## **Expression of Interest**

## Annex 4

## **List of Branches**