**Service Level Agreement for Community Pharmacy Emergency Naloxone Administration Programme (ENAP)**

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| Service Name/Location | Likewise Sheffield |
| Version | V2.0 |
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| Date Valid From | 1st July 2024 |
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| On behalf of Contractor:  Organisation’s Name  Name  Signature  Date  Position  Address  *(if a multiple, list all relevant and lead address for notices to be sent to)* | X  X  X  X  X  X  X  X  X  X  X |
| On behalf of Commissioner  Service  Name  Signature  Date  Position  Address | **Humankind Charity,** (Humankind)a UK Registered Company No. 182 0492 and a Registered Charity No. 515 755, VAT No. 334 6763 43, whose Registered Office is Inspiration House, Unit 22, Bowburn North Industrial Estate, Durham DH6 5PF  Likewise Sheffield  Jo Byrden    Friday 1st July 2024  Assistant Director, Likewise Sheffield  Portland House, 243 Shalesmoor, Moorfields, Sheffield S3 8UG |

# Introduction

This document sets out a Service Specification for the Community Pharmacy Emergency Naloxone Administration Programme (ENAP). Pharmacies are well placed to be able to provide ENAP and other relevant information on harm reduction as part of the local harm reduction strategy to prevent drug related deaths. They can also signpost to other relevant substance misuse services and facilitate increases in the number of people who have access to naloxone by Pharmacies working both in partnership with Humankind and as a standalone service where appropriate.

Any person can administer naloxone for the purpose of saving a life. This SLA outlines the training to support this and the monitoring to support governance and evidence-based provision from a community pharmacy setting.

This ENAP will use Nyxoid® intranasal spray (sprayed into the nose) nasal spray.

# Governance

* 1. This document supersedes all previous working agreements.
  2. The Pharmacy must adhere to relevant legislative requirements including the Human Medicines Regulations 2012, best practice guidance and the standards set, for example by the General Pharmaceutical Council (GPhC) and Royal Pharmaceutical Society (RPS), as well as Public Health England (PHE) [Widening the Availability of Naloxone Guidance](https://humankindcharity.sharepoint.com/sites/HMK_ClinicalDepartment/Shared%20Documents/General/Workstreams/SLAs/1%09https:/www.gov.uk/government/publications/widening-the-availability-of-naloxone/widening-the-availability-of-naloxone) , the ‘[Drug Misuse and Dependence UK Guidelines on Clinical Management (2017)](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/673978/clinical_guidelines_2017.pdf)’ and [Community pharmacy: delivering substance misuse services](https://www.gov.uk/government/publications/community-pharmacy-delivering-substance-misuse-services/community-pharmacy-delivering-substance-misuse-services) published by the Department of Health.
  3. Humankind and the Pharmacy will fully adhere to their respective obligations set out in this document.
  4. Both Parties agree to share relevant information regarding substance misuse data to allow safe and high-quality Service provision/improvements and in line with the local PharmOutcomes licence agreement which detail data controller/processing/ sharing details.
  5. Each party shall comply with its respective obligations pursuant to applicable data protection laws and/or regulations in relation to the processing of personal and/or special category data under this agreement, including but not limited to the General Data Protection Regulations and the Data Protection Act 2018.
  6. The Pharmacy will demonstrate relevant agreed Quality Standards to Humankind or will work towards achieving such a standard within an agreed timescale. If the Pharmacy remains in default following the expiry of the period specified, Humankind may proceed to terminate the Agreement.
  7. The Pharmacy will take part in reasonably requested audit activity including the facilitation of Quality Assurance visits as agreed between all parties.
  8. Should the Pharmacy not work in line with the agreed standards, Humankind shall immediately investigate and may review payment, and in the case of suspension or variation, report to the Pharmacy every 30 days until such investigation is complete. When the investigation is complete, Humankind shall immediately notify the Pharmacy of the outcome.
  9. Any incidents or concerns must be reported immediately and appropriately actioned in accordance with respective organisations incident reporting processes.
  10. Issues pertaining to concerns, incidents, indemnity, performance, disputes, confidentiality, and data handling, which include safeguarding issues, must be promptly reported to Humankind, usually within one working day as appropriate as soon as the Pharmacy become aware.
  11. The Pharmacy must demonstrate they have appropriate insurance in place to be able to offer the Service and must ensure that Humankind is indemnified against any claim arising from the provision of the Service, and in the case of negligence of the Pharmacy: this liability may not be transferred.
  12. The health and safety of Pharmacy staff (and any associated indemnity issues), remain the responsibility of the Pharmacy.
  13. Any dispute, which cannot be resolved by negotiation, shall be referred to a nominated arbitrator for example the Local Authority Commissioner for Substance misuse Services or Chair of the Local Law Society.
  14. Representatives of the Pharmacy (Community Pharmacy South Yorkshire) and Humankind are required to attend regular review meetings, which should occur at least once a year and may be called by either party, usually giving 14 days’ notice.

# Funding, Notices and Termination

* 1. Payment for this scheme is to be agreed between Humankind (local operational contract management supported by Director of Pharmacy) and relevant Local Pharmaceutical Committee(s) (LPC) (Community Pharmacy South Yorkshire) to represent the Pharmacy.
  2. Claims for payment via PharmOutcomes as outlined in the local PharmOutcomes licence agreement.

**Payment:**

* **£50 per pharmacy set up fee to cover training and preparation**
* **£4.00 per PharmOutcomes entry\***

This payment covers:

* + 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.
  + Active participation in Quality Assurance visits and achieving required Quality Standards (where applicable)

(\* It should be noted that the event payment is not associated with the process of naloxone (Nyxoid® intranasal spray) administration for the purpose of saving a life but rather for the governance, monitoring and recording activities undertaken within the pharmacy.)

* 1. Humankind will make provision for pharmacies to order stock from a third-party supplier. Details will be provided to the pharmacies after signed SLAs are received and at least one member of pharmacy staff at a minimum attended the training.
  2. Pharmacies will be selected to provide the Service dependent upon identified local needs.
  3. The Pharmacy should usually keep a minimum stock level of two kits of Nyxoid® intranasal spray at any given time, replenishing the stock as required.
  4. Any changes to the terms of the contract (including reduced funding) will be made with at least 60 days’ notice in order to cause the least disruption for people who need the service. The Pharmacy may choose to cease providing the Service at the end of this notice period without incurring a penalty. Humankind also has the option to terminate funding should the Pharmacy enter receivership or become insolvent.
  5. To enable payment, the Responsible Pharmacist assigned to the Pharmacy must complete the relevant PharmOutcomes sign up module. The Pharmacy is responsible for subsequently ensuring that Humankind are provided with the correct Pharmacy bank details to complete the enrolment process.
  6. Humankind will make payment to the Pharmacy within 30 days in arrears upon receipt of an invoice received via PharmOutcomes.
  7. No payment will be made if the invoice covers activity that was undertaken more than 3 months prior to the date of the invoice being submitted.
  8. Humankind will examine the data submitted and may seek to verify the fees claimed.
  9. Payments will only be made where Humankind is satisfied that the Service has been provided in accordance with the terms of this Agreement. Humankind shall be entitled to suspend payment and/or vary the amount of the payment if it considers the Pharmacy has committed a serious breach of the Agreement and shall forthwith notify the Pharmacy in writing accordingly. Once all relevant investigations are complete and if deemed appropriate, within 30 days Humankind will pay any sums to the Pharmacy that were suspended or varied.
  10. Humankind may from time to time, require reasonable changes to the terms of this Agreement, and where reasonably practicable, up to 14 days' notice will be given. Once agreed, Pharmacy shall use its reasonable endeavours to implement this change on the understanding that such change will not materially affect the nature of the Service or the Pharmacy’s ability to provide the Service.
  11. The Service must be offered every day that the Pharmacy is open. If the Pharmacy put in an application to reduce their opening days or times, then Humankind should be informed at the time of application and must be promptly told if it is subsequently granted.
  12. Notices must be given in writing via email (with acknowledged receipt) or by recorded delivery post to the details provided for that purpose. A notice given by post will be deemed to have been served the first working day after it was posted.
  13. This Agreement will be reviewed and subject to agreement, renewed on an annual basis. However, it may be ended earlier, either on dissolution of the Pharmacy or where at least 60 days’ notice is given by either Party of their intention to terminate the Agreement.
  14. Nothing in this Agreement confers or purports to confer on any third party any benefit or any right to enforce any term of this Agreement.

# Competency and Training

* 1. This Service may only be undertaken by competent Pharmacy staff and under the supervision of the Responsible Pharmacist registered with the GPhC.
  2. Pharmacy staff must be trained and assessed using [*Appendix A ‘Pharmacy Staff Naloxone Competency Assessment and Supply Form’*](#_Appendix_A:_Pharmacy), which must then be filed locally and kept readily accessible for audit and inspection purposes. This form may also be used to record supplies given to Pharmacy Staff for their personal issue.
  3. The assessor must ensure that the trainee has met all of the listed criteria and fully understands all requirements before signing to confirm their competence.
  4. Training may be provided either individually or in groups.
  5. Training may be provided remotely, and information conveyed e.g. in writing/via remote consultation via any suitable medium, so long as the trainer has been provided with assurances that the person can demonstrate the required competencies.
  6. Only placebo packs may be used for the purposes of training. They can be sourced direct from the manufacturer.
  7. Additional resources for training include:
* Nyxoid®:
  + <https://www.medicines.org.uk/emc/product/9292/video>
  + <https://www.medicines.org.uk/emc/product/9292/rmms>
  + [Nyxoid | HCP | About](https://www.nyxoid.com/uk/hcp/about)

* 1. It is the responsibility of the Pharmacy to ensure that the staff undertaking the Service have received appropriate training, including completion of relevant competencies/accreditation and relevant health and safety training.
  2. Mandatory training in the delivery of the ENAP is provided by Humankind which may be delivered virtually and the Pharmacy must retain a training record for each member of staff.
  3. The Responsible Pharmacist must have completed Safeguarding training to Level 2 and be DBS-checked in line with current guidance, which must be rechecked/updated in response to any legislative/best practice guidance changes. The Responsible Pharmacist must ensure the suitability of any Pharmacy staff who are in one-to-one situations with vulnerable service users.
  4. Where locums or part time staff predominantly operate a Pharmacy, the Superintendent Pharmacist or delegated deputy must nominate a lead person to act as a contact. This must be communicated to Humankind promptly.
  5. Humankind will seek to provide at least one training event per year (face-to-face or online) which will usually be available for access by the wider Pharmacy Team (including locum staff), to support broader development of competency and confidence in the management of substance misuse. The Pharmacy must be represented by at least one member of staff at a minimum of one Humankind training event relating to substance misuse service provision per year.
  6. The Responsible Pharmacist on duty at any time will retain professional responsibility and the Pharmacy shall retain liability for the Service.

# Emergency Naloxone Administration Programme (ENAP) - process

* 1. Pharmacies must have processes in place which cover the storage, monitoring, and disposal arrangements for the entire ENAP and the information contained in this **document where relevant.**
  2. The Pharmacy is responsible for ensuring that the medication is stored in line with manufacturers requirements.
  3. In addition to ENAP the Pharmacy team must:
  + Provide support and advice about drug overdose/harm reduction to people accessing the service.
  + Offer a user-friendly, non-judgmental, person-centred, and confidential service.
  + Link into existing networks for harm reduction services to enable rapid referrals.
  1. The individual administering the naloxone must be competent and have completed the relevant training and competency assessment.
  2. PharmOutcomes entry must be completed contemporaneously or as soon as possible after the incident, when overdose was suspected and Nyxoid® intranasal spray used, for each ENAP episode.
  3. The Pharmacy must maintain appropriate records to ensure effective ongoing service delivery and audit.
  4. An ambulance should be called before every administration or those activities to be run simultaneously (Nyxoid® intranasal spray administration while calling an ambulance) when overdose is suspected. While it is accepted the person who has had the naloxone administered may leave the scene, pharmacy staff should discuss the importance of further assessment and encourage the person to go with the ambulance crew for further assessment
  5. Individuals should be signposted to the local Humankind service for further information and referral for those currently not engaged in treatment.
  6. The Pharmacy must have sufficient staffing levels to ensure safe and effective service provision. Pharmacy staff delivering the Service must not lone work.
  7. Locum Pharmacy staff must be made aware of this Service and the procedures when providing locum cover, as the presence of a locum is not a valid reason for the Service not to be appropriately implemented.
  8. It is essential that communication channels (e.g. via PharmOutcomes/emails) are regularly checked and promptly actioned, otherwise the safety/quality of Service provision may be impacted and payment to the Pharmacy may be impacted.
  9. Every supply must be recorded using PharmOutcomes using the ENAP template. No entries are required to be added to the Patient Medication Record (PMR) system as supplies are usually anonymised.
  10. If the pharmacy also delivers a Take Home Naloxone (THN) service then the person should be encouraged to take a supply with them (either injectable or nasal naloxone). Both these community pharmacy services are separate so payment for recording the ENAP episode and supply of THN will be reimbursable.
  11. Basic Life Support (BLS) training is not delivered through the Humankind training programme for this SLA. However, basic information is provided during the Humankind training programme and pharmacy staff are encouraged to seek further information and training through local groups or via the following BLS sites
* [Adult basic life support Guidelines | Resuscitation Council UK](https://www.resus.org.uk/library/2021-resuscitation-guidelines/adult-basic-life-support-guidelines)
* [How to do CPR on an adult | St John Ambulance (sja.org.uk)](https://www.sja.org.uk/get-advice/first-aid-advice/unresponsive-casualty/how-to-do-cpr-on-an-adult/)

# Quality Standards

* 1. The Pharmacy must display health promotion material supplied by Humankind and make this available for the potential service user group and promote its uptake.
  2. All Pharmacy staff involved with ENAP must have signed all associated Standard Operating Procedures.
  3. All Pharmacy staff involved with ENAP must have completed the mandatory Humankind training and be signed off as competent to administer naloxone in an emergency/supply naloxone/train others as appropriate.
  4. The Pharmacy should usually keep a minimum stock level of two kits of Nyxoid® intranasal spray at any given time, replenishing the stock as required.
  5. Humankind may ask Pharmacy staff to demonstrate competency in providing this service.
  6. The Pharmacy must participate in audit of service provision, including any locally agreed assessment of service user experience.
  7. Outcomes will be monitored via PharmOutcomes and local service ENAP outcomes data.

# Appendix A:

# Community Pharmacy Nyxoid Administration Competency Assessment Form

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| --- | --- | --- | --- |
| **Name** |  | **Position** |  |

|  |  |
| --- | --- |
| **Assessment Criteria** | **Check** |
| **Understands what naloxone does** (temporarily reverses the effects of opioids for about 20mins, buys time for ambulance to arrive, not a ‘safety net’, overdose may return, especially if using again, used to help save lives, does not reverse other drugs e.g. alcohol or benzos) |  |
| **Identifies symptoms of opioid overdose** (e.g. pinpoint pupils, colour changes, unconscious, unresponsive to noise/touch, breathing problems/‘snoring’, blue tinge to lips/nose/fingertips) |  |
| **Identifies causes of drug overdose** (e.g. polypharmacy, lack of tolerance including post prison release/detox/hospital discharge, using alone/too much, injecting, changes in purity, poor health) |  |
| **Outlines actions to take if witnessing a suspected opioid overdose**   1. Keep self/others safe 2. Identify symptoms of possible opioid overdose. Place into recovery position if breathing 3. Dial 999 for an ambulance 4. Administer naloxone (first dose) 5. If not breathing administer basic life support (BLS)/cardio-pulmonary resuscitation (CPR) 6. Monitor and give further dose(s) if no response after every 2 mins and continue with BLS/CPR 7. Do not leave the person. Inform ambulance service about action taken 8. Dispose of used naloxone pack(s) correctly (Nyxoid® in clinical waste bin) |  |
| **Demonstrates how to use Nyxoid® nasal spray** (1.8mg; 1 spray from single use container, immediately into the nostril, repeat every 2 minutes if needed, alternating nostrils) |  |
| **Knows how to open the pack and knows not to do so except for emergency use** |  |
| **Aware of safe storage requirements** (out of sight and reach of children/pets, informing competent others of where supply is located) |  |
| **Knows to dispose of unwanted/expired packs of naloxone** (in pharmaceutical waste bin) |  |
| **Knows to dispose of used packs of naloxone** (Nyxoid® in clinical waste bin, Prenoxad® in the original container then a sharps bin: can be given to paramedics/local needle syringe provision) |  |
| **Knows about reminders for expiry dates/getting replacement packs** (checking dates, returning to service before expiry, should return with old pack) |  |
| **Can access information leaflets/training resources**   * <https://www.smmgp-elearning.org.uk/> * <https://www.nyxoid.com/uk> |  |
| **Demonstrates how to record a naloxone administration** on PharmOutcomes |  |

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| --- | --- | --- | --- |
| **Competency**  *[complete as appropriate]* | **Nyxoid®** | | |
| Administer | Supply | Train Others |
| **Date Achieved** |  |  |  |
| **Assessor’s Name** |  |  |  |