

. SPECIFICATION

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|----------------------|--|
| Service | Supervised Administration of Medicine – Methadone and Buprenorphine |
| Council Lead | Public Health Programme Lead – Substance Misuse |
| Provider Lead | Pharmacist |
| Period | 1st April 2024 – 31st March 2025 |

1. Purpose

Introduction

- 1.1 This Service covers the supervised consumption, at the point of dispensing in the pharmacy, of substitute medications to dependent drug users and others who have been assessed as requiring symptomatic treatment for drug related problems (Service Users). The Supervised Consumption and Wellbeing Check-in elements of the Specification only covers Service Users prescribed within the local treatment service (Gateshead Recovery Partnership including GP practices that prescribe as part of this partnership). The naloxone distribution element of the Specification covers any Gateshead resident who is at risk of opioid overdose or any member of their family or carers. The naloxone supply element of the specification is optional for pharmacies to deliver, if they choose to deliver the naloxone supply, then this service will be delivered to any individual who meets the inclusion criteria outlined in appendix 3.

National/local context and evidence base

- 1.2 For information and other resources to support provision of alcohol and drug interventions, please visit:

[Alcohol and Drug Misuse Prevention and Treatment Guidance](#)

[Gateshead Joint Strategic Needs Assessment](#)

[Gateshead Substance Misuse Strategy 2017 - 2022](#)

<https://www.makeeverycontactcount.co.uk/>

[Providing take-home naloxone for opioid overdose - GOV.UK \(www.gov.uk\)](#)

- 1.3 The Service is to support the delivery of national and local priorities and the statutory responsibilities of local partnerships. Priorities and objectives for services are articulated through the national Substance Misuse Strategy. [From harm to hope: A 10-year drugs plan to cut crime and save lives - GOV.UK \(www.gov.uk\)](#)

2. Key Service Outcomes

- 2.1 The Service is instrumental in supporting drug users in complying with their agreed drug treatment programme through the supervised consumption of prescribed substitute medication. In addition, through supervision, pharmacists are able to reduce the risk to Service Users and local communities from:
- Accidental poisoning, over-usage and/or under-usage of prescribed medicines.
 - Diversion of prescribed medicines onto the illicit drugs market.
 - Accidental exposure to medicines.
- 2.2 The vision for the Service is to provide an accessible, confidential, and safe environment for people with drug dependency to comply with their prescribing regime, thereby reducing incidents of drug related death through overdose and reducing harm to the wider community through preventing diversion of controlled drugs.
- 2.3 Through the delivery of the service, Providers will contribute to the following outcomes;
- A reduction in harm associated with drug misuse by increasing retention in specialist services.
 - A reduction in drug related deaths
 - The prevention of overdose
 - A reduction in the diversion of prescribed medicines onto the illicit drugs market

3. Scope

Aims and objectives of the Service.

- 3.1 The aim of this Service is to ensure that Service Users have access to supervision of methadone or buprenorphine consumption.

Training and Guidance Supervised Consumption

- 3.2 It is the duty of the provider to ensure that the Service is delivered by staff who have the necessary competence and training in this Service. A lead pharmacist or a lead registered technician should be assured that all staff (including support staff and locum pharmacists) are adequately trained to meet the requirements of the Service. (Schedule 1)
- Completion of CPPE Declaration of Competence every 2 years by a pharmacist and registered technician.
 - <https://www.cppe.ac.uk/services/declaration-of-competence>

Service description/pathway

- 3.3 The Provider is required to supervise the consumption of prescribed medicines at the point of dispensing in the pharmacy, ensuring that the correct dose has been administered to the Service User. This Service covers the supervised consumption of methadone and buprenorphine formulations used for the direct management of opiate dependence.

- 3.4 The Provider must:
- Ensure compliance with national guidance for supervision arrangements.
 - Be integrated and coordinated with the local treatment service (Gateshead Recovery Partnership).
 - Provide the necessary level of privacy to Service Users (e.g. availability of private area or consulting room).
 - Assist Service Users to access health advice and reduce drug-related harm.
 - Have effective links with the local treatment service (Gateshead Recovery Partnership including GP's that prescribe as part of this partnership) and liaise accordingly concerning specific Service Users and prescribing regimes, whilst having due regard for the Service Users' confidentiality.
 - Share relevant information with all professionals involved in the Service User's treatment, within the boundaries of pharmacists' professional confidentiality guidelines.

- 3.5 The Provider must:
- Dispense in specified instalments (although doses may be dispensed to the Service User to take away on days when the pharmacy is closed).
 - Ensure each supervised dose is correctly consumed by the Service User for whom it was intended.
 - Monitor the Service Users' response to prescribed treatment (e.g. if there are signs of overdose, especially at times when doses are changed; during titration of doses; if the Service User appears intoxicated or if the Service User has missed doses). If the Provider is unable to manage the Service Users response to prescribed treatment any concerns must be discussed with the local treatment service or the prescribing GP for advice and or guidance.

- 3.6 The Provider must ensure:
- There is close liaison between the Provider and prescriber of the above medications. Any problems or queries should be addressed by the Provider to the prescriber or Recovery Co-ordinator, in the local treatment service Gateshead Recovery Partnership (including GP's), as appropriate.
 - They have storage facilities for controlled drugs. As with all controlled drugs methadone or buprenorphine must be stored securely, i.e.in a controlled drugs cabinet awaiting collection.
 - A contract between the Provider and the Service User is signed and the conditions for participation in the Service explained to the Service User. (Appendix 1)
 - Medications for supervised consumption are prescribed using FP10MDA or FP10MDASS instalment prescriptions.

3.7 The Provider will present the medicine to the Service User in a suitable receptacle and will provide the Service User with water to facilitate administration and/or reduce the risk of doses being held in the mouth.

3.8 The Provider is to ensure that the part of the pharmacy used for provision of the Service provides a sufficient level of privacy and safety. Supervision must take place on the pharmacy premises; Service Users must not consume medicines outside of the pharmacy, The exception to this is, the doses that are dispensed to the Service User to take away on

the days when the pharmacy is closed. The take away doses are not subject to supervised consumption.

3.9 The Provider must:

- With regard to missed doses; The Provider should communicate with the local treatment service if two doses have been missed. If three doses are missed any subsequent medications should be withheld until guidance has been received from the Recovery Coordinator or prescriber from the local treatment service (Gateshead Recovery Partnership)
- Share any appropriate comments or concerns regarding the progress or conduct of Service Users, including any untoward incidents which occur in the pharmacy, with the Recovery Co-ordinator in the local treatment service (Gateshead Recovery Partnership). Pharmacy Staff must do so in a manner which maintains a good relationship with the Service User. Information sharing arrangements between the pharmacy, Gateshead Recovery Partnership community and the Service User must be clearly defined in the Service User contract, which will be signed by all parties prior to the Service commencing. (Appendix 1)

3.10 The Provider should offer opportunistic health advice, wherever possible to promote harm reduction, to include.

- Recognising Service Users with physical health problems or severe mental health problems and signposting/referring them onto appropriate services.
- Identification of immediate risks (such as injection site injuries) and provide appropriate advice, treatment, or referral.
- Actively encouraging Service Users to access hepatitis B immunisation from Gateshead Recovery Partnership or their GP, if not already immunised.
- Emphasise the risks of overdose and strategies to reduce those risks and to respond to overdose.
- Where there is a potential risk of overdose in relation to opioid/opiates, supply Naloxone take home kit to Service User.
- When supplying Naloxone take home kit to a Service User, deliver education / guidance on Naloxone take home kit and how to safely administer Naloxone in the event of an opioid/opiate overdose.
- Advise on safer sex, sexual health (see www.gatesheadsexualhealth.co.uk) HBV immunisation, HBV, HCV and HIV testing, also advise on condom and dual screening distribution.

3.11 Supervised consumption will take place during normal pharmacy opening hours. Opening times must be clearly displayed by the Provider and Service Users must be given clear information when there is any variation if the Service is not available during these times.

Wellbeing Check Ins

3.12 The Provider is to make available to Service Users health and wellbeing check ins at the point of dispensing **OR** supervision of substitute medications in the pharmacy, for dependent drug users and others who are open to treatment by the Gateshead Recovery Partnership (GRP) and require symptomatic treatment for drug related problems. **For**

clarity, this element is for all Gateshead Recovery Partnership Service Users, whether that treatment is made available through supervised consumption or a take-out amount of medication the consumption of which is not supervised.

3.13 Due to the nature of their regular contact Provider Staff are able to reduce the risk to Service Users and local communities by:

- Identifying health and wellbeing issues;
- Identifying vulnerabilities; and
- Encouraging and facilitating engagement in the Service.

3.14 The aim of the wellbeing check in is to provide an accessible, confidential and safe environment where people with drug dependency can be supported, issues can be identified and reported back to the treatment provider (GRP), thereby reducing incidents of drug related death through overdose, encouraging wellbeing conversations, building relationships, and strengthening communication to reduce drug related harm to service users and the community, which in turn will contribute to the following outcomes:

- A reduction in harm associated with drug misuse by increasing retention in specialist substance misuse treatment.
- A reduction in drug related deaths.
- The prevention of overdose; and
- Improved wellbeing of the local treatment service (Gateshead Recovery Partnership) Service Users.

3.15 This requirement for a wellbeing check in may be initiated by:

- The local treatment service (Gateshead Recovery Partnership) due to a specific concern that they will advise of;
- the request of the Service User; or
- due to a concern noted by The Provider.

3.16 The reason for a request from local treatment service (Gateshead Recovery Partnership) could include (but is not limited to): see Appendix 2

- encouragement to make contact/ concern about lack of contact.
- concerns about health and wellbeing; and/or
- to pass on information to the Service User.
- It is a new service user to the Provider.

During such contacts, the Provider will also confirm Service Users' contact details.

3.17 The Provider may initiate a wellbeing check in for reasons including (but not limited to):

- concerns about physical presentation;
- concerns about mental wellbeing; and/or
- changes in behaviour or new associates.

3.18 The Provider must:

- Provide the necessary level of privacy to Service Users (e.g. availability of private area or consulting room);
- Assist Service Users to access health advice and reduce drug-related harm.
- Have effective links with the local treatment service (Gateshead Recovery Partnership including GP's that prescribe as part of this Service) and liaise

accordingly concerning specific Service Users, whilst having due regard for the Service Users' confidentiality.

- Share relevant information with all professionals involved in the Service User's treatment, within the boundaries of pharmacists' professional confidentiality guidelines; and
- Share information via secure email to the local treatment service's secure email, but where the information relates to any safeguarding concern, also share information via a phone call direct to the prescriber or Recovery Co-ordinator, in the local treatment service Gateshead Recovery Partnership (including GP's), as appropriate.

3.19 The Provider should offer opportunistic health advice as noted in paragraph 3.10 wherever possible to promote harm reduction, to include:

3.20 The Service Users engagement with a wellbeing check in, is voluntary and Non-engagement will not impact on other Services provided by The Provider.

Naloxone Provision

3.21 What is Naloxone

Naloxone is an emergency antidote to opioid overdose. In the event of a suspected opioid overdose naloxone can temporarily reverse the life-threatening effects of an overdose of opioids such as depressed breathing, for 20-30 minutes. Naloxone itself has no psychoactive properties and so has no intoxicating effects or misuse potential. Only Prenoxad injection is licensed specifically for use in the community and comes in a pre-filled syringe containing 5 marked doses of 400 microgram. The recommended intramuscular dose is 400 micrograms initially, with further 400 microgram doses given incrementally every 2-3 minutes until an effect is noted or the ambulance arrives.

3.22 Naloxone Supply

With drug-related deaths continuing to increase, there continues to be a national focus on increasing the availability of naloxone. The 2021 RPS report Improving care, reducing harm, and preventing death in People Who Use Drugs: Pharmacy's role recommends that: Naloxone to be available from every community pharmacy for supply to people who use drugs. The aim of supplying naloxone (Prenoxad) is:

- A reduction in drug related deaths.
- Increased knowledge and understanding of naloxone (Prenoxad) in relation to prevention of opiate / opioid overdose.
- Increased provision of naloxone (Prenoxad) in the local community.

3.23 Once the pharmacy is ready to deliver the Service, the pharmacist / registered technician service lead should complete the service declaration on PharmOutcomes for 2024-25. (Schedule 3 and Appendix 4).

3.24 Training and Guidance Naloxone

It is the duty of the provider to ensure that the Service is delivered by staff who have the necessary competence and training in this Service. A lead pharmacist or a lead registered technician should be assured that all staff (including support staff and locum pharmacists) are adequately trained to meet the requirements of the Service.

3.25 Pharmacist and registered technician training Naloxone.

All initial supplies on naloxone (Prenoxad) distributed to adults, age 18 and over, who have never previously received naloxone (Prenoxad) must be distributed by a trained pharmacist or trained registered technician. The accredited pharmacist and registered technician must complete the e-learning module “Naloxone Saves Lives” or have attended a training and accreditation event organised by Gateshead Recovery Partnership before commencing the service. (Schedule 1 paragraph 3 Naloxone)

3.26 All repeat supplies of naloxone (Prenoxad) distributed to adults aged 18 and over, who have previously received naloxone (Prenoxad) can be distributed by any member of competently trained pharmacy staff. (Schedule 1 paragraph 3 Naloxone)

3.27 Naloxone (Prenoxad) supply, pharmacist or registered technician are required to complete PharmOutcomes declaration (See appendix 4.)

3.28 The Inclusion / Exclusion criteria for Naloxone (Prenoxad) supply is wider than for Supervised Consumption or Wellbeing Check In and may include any person at risk of opiate overdose and/or their family member/carer (See Appendix 3)

3.29 Pharmacy staff to complete and retain ‘Pharmacy to Service User Checklist’ form, to evidence the person supplied Naloxone understands the guidance delivered in relation to Naloxone (Appendix 5)

Quality and Safety

3.30 The Provider’s premises (the pharmacy) must have adequate storage facilities for controlled drugs and comply with all requirements of the Misuse of Drugs Act 1971

3.31 The Provider must comply with the General Pharmaceutical Council standards for Pharmacy Professionals

3.32 The Service must have in place a Standard Operating Procedure (SOP) for all personnel operating the Service.

3.33 The Provider will review their Standard Operating Procedures for the Service as per the Providers own internal procedures or every two years as a minimum.

3.34 The Provider has a duty to ensure that all Staff involved in the provision of the Service have relevant knowledge and are appropriately trained in the operation of the Service in accordance with Schedule 1

3.35 All Provider's Staff, where possible, should be vaccinated for Hepatitis B.

Population covered.

3.36 Service Users registered who are receiving treatment through the local treatment service (Gateshead Recovery Partnership). In relation to naloxone (Prenoxad) distribution, please refer to section 3.29 (see appendix 3)

Any acceptance and exclusion criteria

- 3.37 Supervised consumption (the Service) is available to all individuals in receipt of a valid NHS prescription who have drug related problems and are being prescribed methadone or buprenorphine as part of the local treatment service (Gateshead Recovery Partnership), such individuals being 'Service Users'.
- 3.38 Access to treatment in a pharmacy is voluntary. Service Users have the right to choose which pharmacy they have their prescription administered at. It is inappropriate for prescribers to direct Service Users to individual named pharmacies.
- 3.39 The local treatment provider (Gateshead Recovery Partnership) will ensure that Service Users have access to appropriate information about the supervised consumption Service Provider including information on opening hours.
- 3.40 The local treatment provider (Gateshead Recovery Partnership) will ensure that Service Users are aware of what constitutes unacceptable behaviour when accessing the supervised consumption Provider.
- 3.41 There are no exclusions to the Service based on gender, race, sexual orientation, physical and/or mental impairment, or any other protected characteristic, though the service provider may be able to exclude Service Users where:
- Acceptable behaviour is not upheld; or
 - If a Service Users behaviour indicates a serious risk to staff, other Service Users and/or members of the public.
- 3.42 The Service Provider will, for all cases where exclusion is made, inform the local treatment service (Gateshead Recovery Partnership), who are responsible for the supervised consumption prescription, as soon as possible and within 24 hours of the exclusion taking place.

Interdependencies with other services

- 3.43 The Provider must ensure that it has effective communication mechanisms in place with other healthcare professionals and agencies it may be required to link with, and in particular, Gateshead Recovery Partnership.
- 3.44 The Provider should attend the Local Pharmaceutical Committee (LPC) events where updates and information sharing opportunities with the local treatment provider (Gateshead Recovery Partnership) will be facilitated.

Claims process

- 3.45 The Provider must make claims for payment for Services delivered in accordance with Schedule 2 (claim framework).
- 3.46 Please note that the Council will only pay for one supervision for each controlled drug dispensed irrespective of dosage on a script e.g. 10 mg buprenorphine (8mg and 2mg) must only be claimed for one supervision cost.

4.1 The Provider in delivering the Service must adhere to all relevant guidance including but not limited to:

- General Pharmaceutical Council, Standards for pharmacy professionals 2017
- Medicines Act 1968
- The Misuse of Drugs Act 1971, The Misuse of Drugs Regulations 2001
- The Misuse of Drugs (Supply to Addicts) (Amendment) Regulations 2012
- Controlled Drugs (Supervision of Management and Use) Regulations 2013
- TA114 Methadone and buprenorphine for the management of opioid dependence (NICE, 2007)

4.2 The Provider is expected to adhere to all such relevant guidance, including any new publications in-year.

5. Location of Provider Premises

5.1 See Contract Particulars.

SCHEDULE 1

CONDITIONS PRECEDENT

1. GPhC

Upon request, provide the Council with the General Pharmaceutical Council Registration Number for the pharmacy premises along with details of a Pharmacy Superintendent and their GPhC Number.

2. Insurance

Upon request, provide the Council with a copy of the insurance policies to illustrate that the Required Insurances are in place, if demanded;

3. Training & Qualifications

The Contractor holder (Provider) will ensure that a suitable Standard Operating Procedure is in place, to ensure safety and consistency of service provision. The procedure will need to ensure practitioners are suitably trained and have the relevant competencies to operate the Service and must be available for viewing by the Council on request.

This must include:

- Training via Substance use and misuse: CPPE Making Every Contact Count (MECC)
- Completion of CPPE Declaration of Competence every 2 years by pharmacist and registered technician at
- <https://www.cppe.ac.uk/services/declaration-of-competence>.

Note: low volume pharmacies or registered pharmacy technicians could consider completing Unit 3 only of the CPPE Substance Use and Misuse training at <https://www.cppe.ac.uk/programmes//substance-e-02>

The Provider will also need to ensure staff are engaged locally through the LPC events with the treatment service provider to receive local updates. These will be arranged by the current commissioned substance misuse treatment provider (Gateshead Recovery Partnership).

Naloxone

[Addiction Professionals Educational Resources \(ap-elearning.org.uk\)](https://www.addictionprofessionals.org.uk)

This training can also be accessed via the CPPE website Substance Misuse([cppe.ac.uk](https://www.cppe.ac.uk))

Training will cover:

- Overdose risks: polydrug and alcohol use, getting older, post detox / rehab/ prison.
- What Naloxone can and cannot do: it only reverses opioid overdose. If someone has also taken too many other non-opioid drugs or too much alcohol, it will not reverse these effects.
- How to identify an opioid overdose: lack of consciousness, shallow breathing, 'snoring', and blueing of the lips and fingertips.
- How to use Naloxone.
- Steps to take in responding to an overdose.

Pharmacists / registered technicians intending to supply naloxone (prenoxad)

are required:

Read the brief information at:

- When and how to give Prenoxad injection (6 sections)
www.prenoxadinjection.com/drug/when_and_how.html

The above information is also available at:

<https://www.medicines.org.uk/emc/product/3054/rmms>

- Prenoxad Injection Issuers Guide
- Prenoxad Injection Client's Guide

Additional resources:

5 short videos (2-3 minutes each) demonstrating, how to respond:

- Someone is unconscious and unresponsive.
- Suspected opioid overdose.
- Put someone in the recovery position.
- Perform CPR
- Inject Prenoxad injection.

Complete the CPPE endorsed 'Naloxone saves lives' e-assessment at:

<https://www.ap-elearning.org.uk>

To demonstrate pharmacists and registered technicians

- Understand drug related deaths and risks and how to recognise the signs and symptoms of overdose.
- Know what to do and what not to do in the event of an overdose.
- Be aware of what naloxone is and how it can help.
- Be familiar with naloxone provision in the UK.
- Understand the importance of training people in the use of naloxone and what should be included in training.

On completion a Certificate of Completion is issued

4. Patient Group Directive

Not applicable

SCHEDULE 2

CLAIM FRAMEWORK

| Data collection | Method of collection |
|---|---|
| <p>Supervised Consumption Ensure that the following information is uploaded to PharmOutcomes on every occasion:</p> <ul style="list-style-type: none"> • Number of supervised consumptions per calendar month (methadone and buprenorphine) • Service Users Initials • Service Users Age • Therapy type • Day/date of attendance • Details of supervision • Reason for refusal (if appropriate) | <p>100% data upload required as per PharmOutcomes</p> |
| <p>Wellbeing Check-in Ensure that the following information is uploaded to PharmOutcomes upon completion of a wellbeing check in:</p> <ul style="list-style-type: none"> • Service Users Initials • Service Users Age • "Contact details checked Y/N?" completed. • Origin of wellbeing check in (GRP/Provider/SU) • Reasons for wellbeing check in (see Appendix 2) • Day/date of attendance • Reason for refusal (if appropriate) | <p>100% data upload required as per PharmOutcomes</p> |
| <p>Supply of Naloxone (Prenoxad) Ensure that the following information is uploaded to PharmOutcomes upon completion of a wellbeing check in:</p> <ul style="list-style-type: none"> • Service Users Initials • Service User D.O.B • Issued to: <ul style="list-style-type: none"> Person at risk Family member / carer Friend Other (if possible, specify) • Naloxone Kit issue date • Naloxone Kit batch number • Naloxone Kit expiry date • Naloxone Kit re-issued Y/N • Trained on use, overdose advice given. | <p>100% data upload required as per PharmOutcomes</p> |

Please note that the Council will only pay for one supervision for each controlled drug dispensed irrespective of dosage on a script e.g. 10 mg buprenorphine (8mg and 2mg) must only be claimed for one supervision cost.

A quality audit assessment can be arranged at any point within the Term of the Contract. To minimise the administrative burden, the Council would accept from Providers, (where applicable), existing quality audit information generated for the purposes of other principal stakeholders, for example NHS England (NHSE), Care Quality Commission (CQC).

The Council will endeavour to give the Provider 28 days' notice that it is carrying out the quality audit assessment, however if concerns or issues are raised regarding the Service, the Council can carry an unplanned audit assessment without any notice.

SCHEDULE 3

PRICING

In consideration of the Provider delivering the Service the Council will pay the Provider the following Price

| Element to be Delivered. | Amount | Claim |
|---|---|--|
| Supervised consumption of methadone | £2.16 per supervised consumption | To be claimed via the PharmOutcomes system |
| Supervised consumption of buprenorphine | £3.23 per supervised consumption | To be claimed via the PharmOutcomes system |
| Wellbeing Check in. | £15.00 per intervention | To be claimed via the PharmOutcomes system |
| Initial Setup Fee for Naloxone (Prenoxad) | £50 ex VAT plus the cost of two Prenoxad injections (Drug Tariff) | To be claimed via PharmOutcomes system |
| Supply of Naloxone (Prenoxad) | £8.00 per supply and intervention (in addition to restock cost (Drug Tariff)) | To be claimed via the PharmOutcomes system |

The claims are to be submitted to the Council on a Monthly basis via PharmOutcomes. The Council shall pay the Provider the Price within 30 days of submission of a valid claim form. There is a 3-month grace period for submission and payment of historical claims. For the avoidance of doubt, any claim made outside of the 3-month grace period (claims for activity undertaken more than 3 months previously) will not be paid by the Council.

The Price shall remain as set out during the financial year 2024/2025. If the Contract is extended in accordance with Clause 2.4 of the Terms and Conditions the Price shall continue at the same rate unless a variation is agreed with Council.

SCHEDULE 4 DATA SHARING FOR SUPERVISED CONSUMPTION SERVICE

DEFINITIONS

1. **Agreed Purposes:** The performance by each party of its obligations under this Contract and in order to deliver the Service under the provisions of the National Health Service Act 2006 with the Localism Act 2011 providing the incidental powers to share data in order to allow for payment to be made for the provision of the Service.
2. **Controller, data controller, processor, data processor, data subject, personal data, processing, and appropriate technical and organisational measures:** as set out in the Data Protection Legislation in force at the time.
3. **Data Protection Legislation:** (i) the Data Protection Act 1998, until the effective date of its repeal (ii) the General Data Protection Regulation ((EU) 2016/679) (**GDPR**) and any national implementing laws, regulations and secondary legislation, for so long as the GDPR is effective in the UK, and (iii) any successor legislation to the Data Protection Act 1998 and the GDPR, in particular the Data Protection Bill 2017-2019, once it becomes law.
4. **Permitted Recipients:** The parties to this agreement, the employees of each party, and the PharmOutcomes system.
5. **Shared Personal Data:** the personal data to be shared between the parties under clause 1.1 below. Shared Personal Data shall be confined to the following categories of information relevant to the following categories of data subject:
 - a. Unique identifier for Service User;
 - b. Age of Service User;
 - c. Initials of Service User
 - d. Type of substance supplied to Service User; and
 - e. Whether or not Service User took a supervised dose;
 - f. Up to date contact details
 - g. Origin of request for wellbeing check
 - h. Reason for wellbeing check
 - i. Information resulting from the wellbeing check.
 - j. Date of attendance

1. DATA PROTECTION

1. **Shared Personal Data.** This clause sets out the framework for the sharing of personal data between the parties as data controllers. Each party acknowledges that one party (the Data Discloser) will regularly disclose to the other party (the Data Recipient) Shared Personal Data collected by the Data Discloser for the Agreed Purposes and shared via the PharmOutcomes system.
2. **Effect of non-compliance with Data Protection Legislation.** Each party shall comply with all the obligations imposed on a controller under the Data Protection Legislation, and any material breach of the Data Protection Legislation by one party shall, if not remedied within 30 days of written notice from the other party, give grounds to the other party to terminate this agreement with immediate effect.

3. **Particular obligations relating to data sharing.** Each party shall:
- a. ensure that it has all necessary notices and consents in place to enable lawful transfer of the Shared Personal Data to the Permitted Recipients for the Agreed Purposes;
 - b. give full information to any data subject whose personal data may be processed under this agreement of the nature such processing. This includes giving notice that, on the termination of this agreement, personal data relating to them may be retained by or, as the case may be, transferred to one or more of the Permitted Recipients, their successors, and assignees;
 - c. process the Shared Personal Data only for the Agreed Purposes;
 - d. not disclose or allow access to the Shared Personal Data to anyone other than the Permitted Recipients;
 - e. ensure that all Permitted Recipients are subject to written contractual obligations concerning the Shared Personal Data (including obligations of confidentiality) which are no less onerous than those imposed by this agreement;
 - f. ensure that it has in place appropriate technical and organisational measures, reviewed and approved by the other party, to protect against unauthorised or unlawful processing of personal data and against accidental loss or destruction of, or damage to, personal data.
 - g. not transfer any personal data received from the Data Discloser outside the EEA unless the transferor:
 - i. complies with the provisions of Articles 26 of the GDPR (in the event the third party is a joint controller); and
 - ii. ensures that (i) the transfer is to a country approved by the European Commission as providing adequate protection pursuant to Article 45 GDPR; (ii) there are appropriate safeguards in place pursuant to Article 46 GDPR; or (iii) one of the derogations for specific situations in Article 49 GDPR applies to the transfer.
4. **Mutual assistance.** Each party shall assist the other in complying with all applicable requirements of the Data Protection Legislation. In particular, each party shall:
- a. consult with the other party about any notices given to data subjects in relation to the Shared Personal Data;
 - b. promptly inform the other party about the receipt of any data subject access request;
 - c. provide the other party with reasonable assistance in complying with any data subject access request;
 - d. not disclose or release any Shared Personal Data in response to a data subject access request without first consulting the other party wherever possible;
 - e. assist the other party, at the cost of the other party, in responding to any request from a data subject and in ensuring compliance with its obligations under the Data Protection Legislation with respect to security, breach notifications, impact assessments and consultations with supervisory authorities or regulators;
 - f. notify the other party without undue delay on becoming aware of any breach of the Data Protection Legislation;
 - g. at the written direction of the Data Discloser, delete or return and delete Shared Personal Data and copies thereof to the Data Discloser on termination of this agreement unless required by law to store the personal data;

- h. use compatible technology for the processing of Shared Personal Data to ensure that there is no lack of accuracy resulting from personal data transfers;
 - i. maintain complete and accurate records and information to demonstrate its compliance with this Schedule 4 and allow for audits by the other party or the other party's designated auditor; and
 - j. provide the other party with contact details of at least one employee as point of contact and responsible manager for all issues arising out of the Data Protection Legislation, including the joint training of relevant staff, the procedures to be followed in the event of a data security breach, and the regular review of the parties' compliance with the Data Protection Legislation.
5. **Indemnity.** Each party shall indemnify the other against all liabilities, costs, expenses, damages and losses (including but not limited to any direct, indirect or consequential losses, loss of profit, loss of reputation and all interest, penalties and legal costs (calculated on a full indemnity basis) and all other reasonable professional costs and expenses) suffered or incurred by the indemnified party arising out of or in connection with the breach of the Data Protection Legislation by the indemnifying party, its employees or agents, provided that the indemnified party gives to the indemnifier prompt notice of such claim, full information about the circumstances giving rise to it, reasonable assistance in dealing with the claim and sole authority to manage, defend and/or settle it. The liability of the indemnifying party under this clause shall be subject to the limits set out in 22 of the Terms and Conditions of this Contract.

Gateshead Recovery Partnership
47 Jackson Street, Gateshead
Tyne & Wear, NE8 1EE
T: (0191) 594 7821
F: (0191) 247 5844
W: change-grow-live.org



Gateshead Recovery Partnership
Integrated Drug & Alcohol Recovery Service

Private and Confidential

Date

Dear..... Pharmacist,

Re:

I wish to introduce the above-named client to you who has been assessed by our service on

The dispensing regime is (please complete as appropriate):

If you have any queries about a prescription, please contact us on the number provided. Our opening hours and contact details are listed below.

Yours sincerely

Recovery Coordinator
Gateshead Recovery Partnership

PTO

For discussion with the client



Change, grow, live (CGL) Registered Office: 3rd Floor, Tower Point, 44 North Road, Brighton BN1 1YR.
Registered Charity Number in England and Wales (1079327). Company Registration Number 3861209 (England and Wales).



I confirm I have been made aware of the following:

- The pharmacy opening hours and when I should attend.
- Arrangements for “take home dose(s)” when pharmacy is closed and safe storage of medication.
- The supervised consumption procedure and that the pharmacist must be satisfied that I have swallowed the dispensed medication before I leave the premises. (only for those on supervised consumption prescription)
- I have been told that if I miss 2 doses the pharmacy will contact the prescriber and that if I miss 3 consecutive pickups my prescription will be suspended until I have been seen by the prescriber.
- That it is expected that I behave in a respectful way towards the pharmacy staff and other customers.
- That if I attend the pharmacy under the influence of drugs and/or alcohol my prescription will be withheld, and prescriber will be contacted.
- The Confidentiality policy.

Signed:

Pharmacist.....

Date:.....

Gateshead Recovery Partnership Opening Hours

- Monday 09:00 - 19:00
- Tuesday 09:00 - 17:00
- Wednesday 09:00 - 17:00
- Thursday 09:00 - 19:00
- Friday 09:00 - 17:00

Contact Details

Gateshead Recovery Partnership
47 Jackson Street

Gateshead, NE8 1EE
T: 0191 5947821

Appendix 2

The following reasons may lead to a wellbeing check being initiated. This list is not exhaustive, as situations or concerns may present which fall outside of this list which would fall into the other category.

Difficulties highlighted in making contact with the Service User

Checking contact details are correct.

Encouraging engagement with treatment service

Concerns about health

Concerns about welfare

Harm reduction information or discussion

Medication issues

Storage/Disposal of methadone bottles

Other

In addition, during the first attendance with the Provide, the Wellbeing Check should be used to engage with the Service User to build relationships and clarify roles and expectations, opening times and the information detailed in Appendix 1.

Appendix 3

Inclusion Criteria, Naloxone (Prenoxad)

The person requesting naloxone (Prenoxad) resides in Gateshead, is aged 18 and over and is either:

- An individual currently, or with a history of using opioids.

Or

- A carer, family member, or friend liable to be on hand in case of overdose.

The SmPC of naloxone (Prenoxad) injection states that:

Prenoxad Injection may only be made available once the prescriber has assessed the suitability and competence of client or representative to administer naloxone in the appropriate circumstances, i.e. All those receiving a supply of naloxone (Prenoxad) should be able to demonstrate a basic awareness of opioid overdose, basic life-support, and naloxone use.

Under the Regulations, it is legal for a drug service to provide a family member / friend / carer of an opioid user with naloxone without the express permission of the individual who is using the opioid, if it is being supplied to save life in an emergency. Consider asking the family member / friend / carer if they intend informing the individual at risk of opioid overdose that they have a supply of naloxone injection. However, balance this against the fact that legally a 3rd party supply can be made to save a life in an emergency and that naloxone has a good safety profile when administered in the doses contained in the Prenoxad injection.

(i.e. Administering a relatively small dose of naloxone, then providing further small doses as needed in a graduated manner.)

Exclusion Criteria, Naloxone (Prenoxad)

- Persons under the age of 18 years of age.
- Persons unable to demonstrate a sufficient knowledge on the use of naloxone.
- Persons who have not consented to receiving a supply.
- Where the individual at risk has a known allergy to naloxone.

Appendix 4

PharmOutcomes Declaration

Naloxone (Prenoxad) Supply Service Declaration

The lead pharmacist / registered technician has confirmed that:

Training

- All pharmacists and registered technicians providing the service of naloxone (Prenoxad) supply have completed the training specified within the service specification before supplying any person with naloxone (Prenoxad).
- All pharmacy staff providing re-supplies have completed the training specified in the service specification before supplying any person with naloxone (Prenoxad).
- They will keep up to date with guidance / service changes (via information circulated on PharmOutcomes) and cascade this to other members of staff providing the service.

Supply

- The pharmacy stocks Prenoxad injection (minimum stock level of two)
- Trained pharmacists and registered technicians will supply naloxone (Prenoxad) injection to a person who has previously never received a supply, using the relevant customer materials and following completion of the customer supply record.
- Any trained member of staff may issue a re-supply of naloxone (Prenoxad) using the relevant customer materials and following completion of the customer (Prenoxad) re-supply record.

Supply of Naloxone - Pharmacy to Service User Checklist

| | | | |
|---|--|------------------|----------------------|
| New Supply | | Re-Supply | |
| Name | | DOB | |
| Address | | | |
| Telephone No. | | Email | |
| | | | Tick Relevant |
| Received 1-2-1 guidance/instruction from member of pharmacy staff. | | | |
| Signs and symptoms of suspected opioid overdose have been discussed | | | |
| Given printed guidance | | | |
| Aware of importance of calling an ambulance | | | |
| Aware of importance of staying with the person until arrival of ambulance | | | |
| Product given (remind about expiry date) | | | |
| Noted on PharmOutcomes (including expiry date) | | | |

- I have been given information of the dangers of opioid overdose, basic resuscitation, and the appropriate administration of naloxone.
- I am aware that the needle supplied is strictly for naloxone use only.
- I understand that naloxone is a treatment specific drug that reverses the effect of opiate/ opioid overdose and needs to be used solely for the purpose of saving lives.
- I agree that my information will be stored by the pharmacy for 6+1 years for audit purposes and in accordance with the Data Protection Act 2018. I acknowledge that anonymised data will be shared with the Public Health Team at Gateshead Council for payment and service evaluation.

| | | | |
|---|-------------------|------------------|----------------------------|
| Service user's name | | | |
| Signature | | | |
| Date | | | |
| Staff name | | | |
| Signature | | | |
| Date | | | |
| Drug: Naloxone HCL 2ml prefilled syringe | Issued by: | Date/Time | Batch No and Expiry |
| | | | |