SPECIFICATION

Service	**Supervised Administration of Medicine – Methadone and Buprenorphine**
Council Lead	**Joy Evans**
Provider Lead	**Pharmacist**
Period	**1ST April 2018 – 31st March 2019**

1. Population Needs

1.1 National/local context and evidence base

Best Practice Guidance for Commissioners and Providers of Pharmaceutical Services for Drug Users – National Treatment Agency February 2006 (currently being revised)

2017 Drug Strategy
https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/628148/Drug_strategy_2017.PDF

Drug misuse and dependence: UK guidelines on clinical management (2017)
https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/673978/clinical_guidelines_2017.pdf

An evidence review of the outcomes that can be expected of drug misuse treatment in England (Jan 2017)
https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/586111/PHE_Evidence_review_of_drug_treatment_outcomes.pdf

Healthy Lives, Healthy People: Improving Outcomes and Supporting Transparency – Public Health Outcomes Framework for England 2013 – 2016
https://www.gov.uk/government/publications/healthy-lives-healthy-people-improving-outcomes-and-supporting-transparency

Vision 2030 – Gateshead's Sustainable Community Strategy
http://www.gateshead.gov.uk/People%20and%20Living/communitystrategy/Vison2030.aspx

Planning to meet health, wellbeing and social care needs in Gateshead - Joint Strategic Needs Assessment 2011/12
http://www.gateshead.gov.uk/Care%20and%20Health/jsna.aspx

Gateshead Strategic Needs Assessment July 2012 to 2017
http://www.gateshead.gov.uk/DocumentLibrary/council/strategy/Gateshead-Strategic-Needs-Assessment-2012-17.pdf

Gateshead Substance Misuse Strategy 2017-2022. The Service will support the delivery of national and local priorities and the statutory responsibilities of local partnerships. Priorities and objectives for services are articulated through the new Substance Misuse Strategy.

2. Key Service Outcomes

2.1

The Service will:

- Support Service Users to successfully complete drug treatment programmes through the supervised consumption of prescribed substitute medication.

To reduce the risk to local communities of:

- Accidental poisoning, over-usage and/or under-usage of prescribed medicines
- Diversion of prescribed medicines onto the illicit drugs market
- Accidental exposure to the medicines

3. Scope

3.1 Aims and objectives of the Service

The aim of this Service is to ensure that Service Users have access to supervision of methadone or buprenorphine consumption in as convenient a location as possible.

3.2 Service description/pathway

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

The Service must:

- Ensure compliance with national guidance for supervision arrangements.
- Be integrated and coordinated with the local prescribing services and treatment systems
- Meet the demand of the local population and prescribing services
- Provide the necessary level of privacy to Service Users (e.g. availability of private area or consulting room)
- Offer user friendly, non-judgemental and confidential user centred services
- Assist Service Users to remain healthy and reduce drug-related harm
- Provide Service Users with regular contact with a healthcare professional, which can help access further advice or assistance. The Service User is to be referred to specialist treatment center or other health and social care professionals where appropriate
- Have effective links with prescribing services (Gateshead Evolve and GPs) and liaise accordingly concerning specific Service Users and prescribing regimes, whilst having due regard for the Service Users' confidentiality

- To provide performance management information as detailed in Schedule 2 in relation to the scheme to inform understanding of its effectiveness.
- The Provider will share relevant information with all professionals involved in the Service User's treatment, within the boundaries of pharmacists' professional confidentiality guidelines

The Provider is to ensure that all of the above elements of the Service are delivered.

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)

This Contract 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. The Specification only covers Service Users prescribed within the local shared care service or via the central prescribing service.

Services to be provided under this Contract are:

- Supervised consumption of specified medicines
- Provision of advice and information on drug treatment services available in Gateshead
- Provision of advice and support to the Service User on general health and social care issues, including referral
- Periodic participation in relevant health promotion campaigns

Supervision of medications in the categories below are covered by this Contract:

(i) Methadone

(ii) Buprenorphine

With regard to each of these categories the Provider should 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 cgl Gateshead Evolve case worker as appropriate.
- The Provider must 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.
- The Provider is to ensure that a contract between the Provider and the Service User is signed and the conditions for participation in the scheme explained to

the Service User. All Service Users must be treated with courtesy and respect by the Provider.
- Medications for supervised consumption must be prescribed using FP10MDA or FP10MDASS instalment prescriptions.

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.

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 Provider has a duty to ensure that pharmacists and staff involved in the provision of the Service have relevant knowledge and are appropriately trained in the operation of the Service. See Schedule 1 Conditions precedent - training and qualifications for the pharmacist.

The Provider should maintain appropriate records to ensure effective ongoing Service delivery and audit. This is a requirement of Essential Service 1 of the Community Pharmacy Contractual Framework. The Provider should also:

- Communicate information on missed and withheld doses with the treatment provider if 2 or more doses have been missed.
- 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 treatment service. Pharmacy staff will aim to do so in a manner which maintains a good relationship with the Service User. Information sharing arrangements between the pharmacy, community drug treatment provider and the Service User will be clearly defined in the Service User contract, which will be signed by all parties prior to the Service commencing.
- Participate in annual audit activity including site visits and share non-personalised data relating to the Service to support service review and development.
- Alert the community drug treatment provider to any observed deterioration in the Service User's wellbeing including but not limited to physical and mental health. In addition, they may be contacted by the treatment provider to seek feedback on the progress of Service Users.

The Provider will share relevant information with other healthcare professionals and agencies, in line with locally determined confidentiality arrangements.

The Provider should provide direct input as outlined below 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
- Emphasise the risks of overdose and strategies to reduce those risks and to respond to overdose.
- Advise on safer sex, sexual health, HBV immunisation, HBV, HCV and HIV testing.

Supervised consumption will take place during normal pharmacy opening hours. Opening times should 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.

Service Users should have access to services at as wide a range of times as possible.

It is important that all Provider's Staff involved with Service Users have a positive attitude to the Service. It is the responsibility of the Provider to ensure that any Staff they employ are fully advised of occupational health and safety procedures, especially with regard to risk of infection.

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.

The Provider must comply with the Royal Pharmaceutical Society of Great Britain (RPSGB) standards for the provision of dispensing and supervised consumption services.

All Provider's Staff where possible should be vaccinated for hepatitis B.

3.3 Population covered

Service Users registered with a Gateshead GP who are receiving drug treatment as part of the shared care scheme or through the central prescribing service.

3.4 Any acceptance and exclusion criteria

Supervised consumption is available to all individuals in receipt of an NHS prescription who have drug related problems and are being prescribed methadone or buprenorphine as part of the shared care scheme or through the central prescribing service.

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).

3.5 Interdependencies with other services

The Provider is to share relevant information with other healthcare professionals and agencies, i.e cgl Gateshead Evolve, in line with confidentiality arrangements. The Service User's Case Worker or GP must be informed by the Provider if two or more doses have been missed. The Provider should not supply medicines in these circumstances, and await further guidance from the Case Worker or GP

3.6 Any activity planning assumptions

Not applicable

4. Applicable Service Standards

4.1 Applicable national standards e.g. NICE

The Provider in delivering the service will adhere to all relevant guidance including but not limited to:

- Royal Pharmaceutical Society: Medicines ethics and practice - The professional guide for pharmacists
- 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
- Drug misuse and dependence – guidelines on clinical management (Department of Health, 2017)
- Models of care for adult substance misusers: updated 2006 (National Treatment Agency, 2006
- Medications in Recovery- Re-orientating Drug Dependence Treatment (National Treatment Agency, 2012)
- An evidence review of the outcomes that can be expected of drug misuse treatment in England (PHE, 2017)
- TA114 Methadone and buprenorphine for the management of opioid dependence (NICE, 2007)

The Provider is expected to adhere to all such relevant guidance, including any new publications in-year, and provide details of compliance where necessary.

4.2 Applicable local standards

Not applicable.

5. Location of Provider Premises

See Contract Particulars

SCHEDULE 1

CONDITIONS PRECEDENT

1. GPhC

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

2. Insurance

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 Provider must employ a pharmacist who is accredited. Accreditation is conditional on the following:

a) Proof of completion of the Centre for Pharmacy Postgraduate Education (CPPE) Open learning package either:
   i) Substance Use and Misuse
   ii) Opiate Treatment: supporting pharmacists for improved patient care

   A certificate of completion will be held by the Council.

b). The pharmacist 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.

c). Relevant, on-going, harm reduction training will be provided to Pharmacists and their Staff by the commissioned drug and alcohol treatment provider.

d). The pharmacy must demonstrate that service and monitoring guidelines are followed throughout the provision of this Service.

The pharmacist, not the premises is accredited. Should the pharmacist leave the employment of the Provider and not be replaced immediately by an accredited pharmacist, the Council must be informed by the Provider and this will be viewed by the Council as a Suspension Event resulting in the Council suspending the Provider from providing the Service. The prescriber must be notified immediately so that the Service User may be accommodated by another accredited pharmacy. The pharmacist may continue to participate in the scheme at other pharmacy premises in Gateshead providing the Council are informed.

4. Patient Group Directive

Not applicable

SCHEDULE 2

PERFORMANCE INDICATORS

Performance Indicators	Threshold	Method of Measurement	Consequence of breach
Ensure that the following information is uploaded on every occasion: • 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)	100% data upload required as per PharmOutcomes	As per PharmOutcomes report	Appropriate action under Clause 24 of the Terms and Conditions of the Contract (*defaults and suspension)*

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**	**Conditions**
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

The Provider shall submit to the Council on a monthly basis via the PharmOutcomes system. The Council shall pay the Provider the Price following verification of the claim form, within 30 days of submission of the claim form.

The Price shall remain as set out in this Schedule during the financial year 2018/2019.

In the event that the Contract is extended in accordance with Clause 2.4 the Price shall continue at the same rate, unless a variation is agreed with Council. Where appropriate, the Council shall pay the Price on a pro-rata basis in respect of any extension period.

SCHEDULE 4

DATA SHARING FOR SUPERVISED CONSUMPTION SERVICE

DEFINITIONS

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.

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.

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.

Permitted Recipients: The parties to this agreement, the employees of each party, and the PharmOutcomes system.

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 was took a supervised dose;

1. DATA PROTECTION

1.1 **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.

1.2 **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.

1.3 **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.

1.4 **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.

1.5 **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.