SCHEDULE 1 –SERVICE SPECIFICATION

Service	**Supervised Consumption of Prescribed Medicines for Substance Misusers**
Authority Lead	**John Bolloten – Needle Exchange Co-ordinator, Public Health**
Period	**1st April 2018 – 31st March 20**

1 Population Needs

1.1 National/Local Context and Evidence Base

As of 1st April 2013 Public Health England (PHE) incorporated the National Treatment Agency for Substance Misuse (NTA) which was a special health authority within the NHS, established by Government in 2001 to improve the availability, capacity and effectiveness of treatment for drug misuse in England. PHE provide evidence based national guidance on the commissioning and delivery of treatment for adult drug misusers.

There are approximately 306,000 heroin and/or crack cocaine users in England of which around 200,000 are in treatment in any one year. Offenders who use heroin, cocaine or crack cocaine are estimated to commit between a third and a half of all acquisitive crime.

Approximately 400,000 benefit claimants (around 8% of all working age benefit claimants) in England are dependent on drugs or alcohol and generate benefit expenditure costs of approximately £1.6 billion per year.

The National Drug Strategy (2017) sets out a more coordinated approach to preventing drug use in our communities, and in supporting recovery from drug and alcohol dependence. The strategy has recovery at its heart and aims to:

- offer people with a drug dependence problem the best chance of recovery through support at every stage of their life
- prevent people, particularly young people, from becoming drug users in the first place
- target those criminals seeking to profit from others' misery and restricting the availability of drugs
- lead and drive action on a global scale
- form effective partnership working between health and social care, the criminal justice system, housing and employment support to deliver the strategy's aims

The National Institute for Health and Clinical Excellence (NICE) Guidelines make clear that the opiate substitutes methadone or buprenorphine should be offered as the front-line treatment for heroin dependency. Clinicians advise this is the best way to stabilise problem drug users in the short-term while their dependency is treated. Methadone reduces the cravings that addiction causes, enabling individuals to stop taking illegal drugs and start to rebuild their lives. Currently about 131,000 users in treatment (two thirds of all adults in treatment) are prescribed opiate substitutes by their doctors. Some are maintained on high doses to prevent withdrawal, but many are prescribed reducing doses as a step towards recovery. Once heroin addicts are stabilised, treatment offers a full range of options, including detoxification for those who wish to be abstinent.

"Methadone and buprenorphine (oral formulations), using flexible dosing regimens, are recommended as options for maintenance therapy in the management of opioid dependence. The decision about which drug to use should be made on a case by case basis, taking into account a number of factors, including the person's history of opioid dependence, their commitment to a particular long-term management strategy and an estimate of the risks and benefits of each

treatment made by the responsible clinician in consultation with the person. If both drugs are equally suitable, methadone should be prescribed as the first choice. Methadone and buprenorphine should be administered daily, under supervision, for at least the first 3 months. Supervision should be relaxed only when the patient's compliance is assured. Both drugs should be given as part of a programme of supportive care."
Methadone and buprenorphine for the management of opioid dependence January 2007
http://www.nice.org.uk/TA114

1.2 General Overview

The Bradford Metropolitan District is diverse and covers both rural and urban areas, city, towns (Shipley, Bingley, Keighley and Ilkley) and villages. It has a population of 524,600 and covers some 142 square miles making Bradford the 4th largest metropolitan district in England, and 5th largest in the UK. The inner city has high levels of deprivation and unemployment as ranked by the Index of Multiple Deprivation (IMD).

the Council's overall Corporate Priorities are:

- Improving educational attainment
- Supporting the District's economy, jobs and skills and city centre regeneration
- Supporting the most vulnerable adults, children and families
- Reducing Health Inequalities
- Securing an adequate supply of decent and affordable homes
- Safe, clean and welcoming neighbourhoods

1.3 Local Strategic Context

The Bradford District Community Safety Partnership (BCSP) considers tackling drug and alcohol misuse a major priority for the district and, to this end, has detailed a number of key aims in the local drug treatment strategy and Alcohol Harm Reduction Strategy designed to positively impact across the district as a whole. These aims are to:

- Reduce illicit and other harmful drug use
- Increase the numbers of individuals recovering from their drug or alcohol dependence
- Build recovery capital in communities
- Ensure the best possible outcomes for drug users, their families and the wider public
- Reduce the impact of drug misuse on communities
- Reduce re-offending

The number of Opiate and/or Crack users in treatment at the end of the financial year, 31st March 2017 was 2460.
) The Council'lead on the commissioning of substance misuse services on behalf of the Bradford Community Safety Partnership and aim to commission the very best services for local people that are based around the needs of the population served.

2 Key Service Outcomes

2.1 Expected Outcomes including improving prevention

The work conducted by the service will contribute towards the following outcomes:

- Reduce mortality and morbidity risks among high risk drug users
- To protect health and reduce the rate of blood –borne infections and drug related deaths among Service Users

- Providing and reinforcing harm reduction messages
- To help Service Users access treatment by offering referral to specialist drug and alcohol treatment centres and health and social care professionals where appropriate
- To help Service Users access other health and social care and to act as a gateway to other services (e.g. key working, prescribing, hepatitis B immunisation, hepatitis and HIV screening, primary care services etc)
- Increase the proportion of Problematic Drug Users (PDU`s) in effective treatment
- Increase the number of Service Users completing and exiting treatment in a positive way
- Reducing the proportion of drug users re-offending
- To improve their quality of life for substance misusers, their families and communities

3 Scope

3.1 Service Description

3.1.1 This Service requires an appropriately trained member of staff to supervise the consumption of prescribed medication used in the management of opiate dependence at the point of dispensing, if requested to do so by the prescriber.

3.1.2 The Pharmacy must be able to demonstrate that any staff delivering this service is suitable and competent to provide the service.

3.1.3 Pharmacies will offer a user friendly, non-judgmental, Client centred and confidential service.

3.1.4 The Pharmacy will provide support and advice to the Client, including referral to primary care or specialist centres where appropriate.

3.1.5 Service to be delivered by the pharmacist or any designated trained member of the pharmacy team working under the supervision of the pharmacist.

3.2 Aims and intended service outcomes

3.2.1 To ensure compliance with the agreed treatment plan by dispensing in specified instalments (doses may be dispensed for the Client to take away to cover days when the Pharmacy is closed in line with the instructions of the prescriber), ensuring each supervised dose is correctly consumed for whom it was intended.

3.2.2 To reduce the risk to local communities of over usage or under usage of medicines; diversion of prescribed medicines onto the illicit drugs market; and accidental exposure to the prescribed medicines.

3.2.3 To increase feedback to the prescriber to improve monitoring of Service User non-compliance, in line with the terms of agreement (see 3.3 &3.4 below).

3.2.4 To provide Service Users with regular contact with health care professionals and to help them access further advice or assistance. The Service User will be referred to specialist treatment centres or other health and social care professionals where appropriate.

3.2.5 To contribute to minimising the number of drug methadone related deaths.

3.3 Service Outline

3.3.1 The Pharmacy will give consideration to the part of the premises used for provision of the service, which should provide a sufficient level of privacy and safety for patients accessing the service.

3.3.2 If a consultation room is available then the Pharmacy can consider offering the Client the option of the consultation taking place within the consultation room.

3.3.3 The supervision must only take place on the Pharmacy premises and must not, under any circumstances, be delivered to the patient or supervised on any other premises.

3.3.4 The Pharmacy will present the medicine to the Service User in a suitable receptacle and will offer the Service User water (in a disposable cup) to facilitate administration.

3.3.5 The Pharmacy will ensure the dose has been taken appropriately.

3.3.6 It is good practice to establish terms of agreement. This is likely to take the form of a contract between the Pharmacy and Client (a two-way agreement) to agree how the service will operate. This may contain information about collection times, what constitutes acceptable behaviour by the Client, and what action will be taken by the prescriber and pharmacist if the user does not comply with the agreement (see appendix 1).

3.3.7 The Pharmacy has a duty to ensure that pharmacists and staff involved in the provision of the service are competent to provide the service. The Pharmacy must ensure that Pharmacists and pharmacy technicians providing this service can demonstrate their competence to deliver this service by completion of the CPPE/Health Education North West Declaration of Competence for Supervision Service (www.cppe.ac.uk). The Pharmacy should ensure that in-date copies of the Declarations of Competence for each relevant member of staff are available in the Pharmacy where they can be used as evidence to demonstrate competency of staff to the commissioner. Declarations of competency should be completed every 3 years.

3.3.8 The Pharmacy will have Standard Operating Procedures in place for the supervision of prescribed medication used in the treatment of opiate misuse which includes preparation, accuracy checking, relevant entries into the CD register, supervision and confirmation of Client details.

3.3.9 The Pharmacy will maintain appropriate records to ensure effective on-going service delivery and audit, in addition to legally required records. The information will be entered onto PharmOutcomes and there is no expectation of additional paper records being kept.

The information entered onto PharmOutcomes includes:

- Prescription start date
- Initials of patients
- Prescriber details
- Medication being supervised
- Total number of doses prescribed
- Number of doses to be supervised
- Actual number supervised
- Number of doses not collected
- Notes section to be used to record any relevant information such as action taken when dose missed, contact with keyworker, dose collected by Police Officer (Patient identifiable information must NOT be included in the notes section)

3.3.10 The Pharmacy will share relevant information, where appropriate, with other health care professionals and agencies, in line with locally determined confidentiality arrangements.

3.3.11 It is the duty of the Pharmacy commissioned to provide this service to ensure that all individual pharmacists and staff delivering this service from their premises are:

- Fit to Practise
- Suitable to deliver the service

- Can demonstrate they are competent to deliver the service

3.3.12 Payment will be at the rate of £1.40 per methadone supervision and £2.85 per buprenorphine or morphine supervision.

3.3.13 For non-supervised, daily pick-up Clients only, a fee of £1.40 (equivalent to the fee for methadone supervision as above) may be claimed if the Client fails to collect either three consecutive days' doses or any four doses on one prescription AND the pharmacist notifies the prescriber of this. This claim may only be made once per prescription and recorded on PharmOutcomes.

3.3.14 If two different strengths of buprenorphine (including Suboxone), methadone or morphine are supplied to a Client but are supervised together this only qualifies for one supervision fee. To ensure that the claims are accurate and that claims are not duplicated only one prescription should be recorded on PharmOutcomes. This applies even if the different strengths are prescribed on separate scripts.

3.3.15 The Pharmacy will feedback relevant information to the prescriber if:

- The Client does not consume the whole dose under supervision
- The Client regularly tries to avoid supervision
- The Client appears to be intoxicated e.g. alcohol, other prescription and/or illicit drugs (Clients stabilised on methadone should be alert and coherent). In the case of chronic alcoholism the Client should not be excessively intoxicated.
- The Client appears ill
- There are problems concerning the prescription e.g. ambiguity of dates for dispensing , identity of Client in doubt, alterations to the prescription
- The behaviour of the Client is unacceptable e.g. shoplifting, verbal and/or physical abuse
- The Client misses more than three doses consecutively (missing doses may result in a drop in opiate tolerance with an increased risk of accidental overdose)
- At the request of the Client for an acknowledged clinically important matter

3.4 Clinic/Prescriber Responsibilities

3.4.1 These guidelines relate to the supervised consumption of daily doses of methadone and buprenorphine. All prescriptions requiring supervision should be clearly marked 'Supervised Consumption'

3.4.2 The prescriber must reach an understanding with the Client that the prescribed medication will be dispensed at an agreed community pharmacy, where administration and consumption of the medication will be supervised by the pharmacist or appropriately qualified member of staff under the supervision of a pharmacist. The prescriber must also explain to the Client that the Pharmacy will be required to inform the prescriber of breaches of the agreed procedure, such as failure to collect, refusal to accept supervision, bad behaviour. As part of the prescriber's contract with the Client, the prescriber must obtain the Client's informed, written consent to the fact that such information may from time to time be passed back.

3.4.3 The prescriber should discuss with the Client the most suitable/convenient pharmacy and should seek the agreement of the Pharmacyo accept this Client.

3.4.4 It is good practice, though not always practicable, for the Pharmacy to be contacted in advance by the GP or representative of the clinic to discuss the dispensing arrangements for the Client.

3.4.5 If the Pharmacy accepts the Client, the prescriber should inform the Pharmacy of the name and address of the Client, prescribed dose, start and expiry date of the prescription, and the name of the key worker.

3.4.6 Clients should be prescribed the medication in daily (or twice daily) instalments, with supervised dose on day of collection with a take home doses for remainder of instalment and chemist closed days.

3.5 Pharmacy Responsibilities

3.5.1 When the Client arrives the Pharmacy should check the details of the introductory letter and should register the Client on the Patient Medication Record (PMR) system. The Clients details should be checked e.g. DoB and address prior to collection or supervision of methadone/buprenorphine.

3.5.2 It is good practice for the Pharmacy to go through a Client contract with the Client, agree and sign it. The main issues to be covered are:

- Times between which supervision is convenient for both parties
- Minimum interval between supervised doses
- Missed doses cannot be dispensed at a later date

3.5.3 The prescriber will be notified of failures to collect, refusal to co-operate with supervision, anti-social behaviour, deterioration of general appearance or anything giving rise to indications of concern for the health of the individual etc.

3.5.4 The prescriber will be contacted, and the medication may not be dispensed, if the Client has missed three consecutive days' doses.

3.5.5 The Client should come alone or with his or her abstinence carer, e.g. parent or spouse, or where two Clients co-habit and attend together by agreement.

3.5.6 If appropriate, the Pharmacy should introduce the Client to key members of staff.

3.5.7 When a prescription is presented it should be checked to see if it is legal, and if the quantities and details are correct for that Client.

3.5.8 The medication should not be dispensed to Clients who are excessively intoxicated with drugs and/or alcohol. If the pharmacist suspects the Client is intoxicated, he/she should telephone the clinic to inform them, and to ask whether the Client is to be sent back to the clinic for assessment, if appropriate.

3.5.9 If a Client has failed to collect three or more consecutive days' doses, no further medication should be dispensed without the agreement of the prescriber.

3.5.10 Where a daily dose of medication has not been dispensed by the pharmacist, or the dispensing service has been terminated for a Client for whatever reason, the pharmacist should indicate this on the prescription as 'not dispensed' for any remaining days on the current prescription. The clinic should be notified of any prescriptions which have not been started. The Pharmacy should document this as an intervention and shred the prescription with a witness.

3.5.11 Supervision must never take place in the dispensary. Where possible, a designated area offering suitable privacy should be selected in each Pharmacy, and should be used for this purpose.

3.5.12 The doses of medication should be made up in advance each day (assuming that the pharmacist is in possession of a current prescription). All doses must be labelled in accordance with requirements of the Medicines Act. The correct date of dispensing, i.e. the date of supply to the Client, should be shown on the label. Methadone should be dispensed into an appropriate child resistant container

3.5.13 When the Client arrives, the pharmacist or appropriately trained staff must ensure that the Client is correctly identified, and receives his/her dose of medication.

3.5.14 The methadone should be consumed directly from the bottle or may be poured into a disposable cup, as agreed by the pharmacist and Client.

3.5.15 The pharmacist or appropriately trained staff should observe the consumption of the medication by the Client. After methadone supervision Clients should be offered a drink of water in a disposable cup and spoken to, to ensure the dose has been swallowed. Buprenorphine can take several minutes to dissolve especially if the mouth is dry, water should be offered to dampen the mouth before the tablet is put into the mouth, no water should be consumed until the tablet has dissolved and has had a chance to be absorbed sublingually. Care should be taken that the Client does not swallow the tablet.

3.5.16 Supervised doses of medication must not be given to any other person on the Client's behalf other than in circumstances where the Client is in Police custody and a Police surgeon has authorised, preferably in writing for a Police Officer is able to collect the supervised dose on behalf of the Client.

3.5.17 Non-supervised doses of medication must not be given to the Client's representative unless previously authorised by the Client him/herself or by a member of the clinic staff or GP, preferably in writing.

3.5.18 After each dispensing/supervision the pharmacist or appropriately trained staff should then make the appropriate entries in the CD register and on the prescription. Any notable incidents/events should be recorded on the Incident Report Form and returned to the clinic. If there is a need to contact the clinic urgently this should be done by telephone. A report form can then be sent soon afterwards.

3.5.19 Locum pharmacists should be made aware of this service and the procedures, in advance of them providing locum cover. It is essential that the service runs smoothly and all records are kept up to date.

3.5.20 A Pharmacy may wish to ensure that they have adequate insurance cover prior to commencing the service.

3.5.21 Pharmacy should discuss with their staff the desirability of Hepatitis B vaccinations.

3.6 Local Authority (Council) Responsibilities

3.6.1 The Council will provide a framework for the recording of relevant service information for the purposes of audit and the claiming of payment via the PharmOutcomes system.
3.6.2 The Council will provide details of relevant referral points which Pharmacy staff can use to signpost Service Users who require further assistance.

3.6.3 The Council will provide health promotion material to pharmacies which is relevant to the Service Users, where appropriate.

3.6.4 The Councily will arrange contractor meetings as necessary to promote service development and update the knowledge of Pharmacy staff.

3.7 Interdependencies with Other Services

- Public Health Substance Misuse Commissioning
- Specialist substance misuse treatment providers in and outside Bradford District as appropriate
- CBMDC – Access to Housing Service
- Housing providers
- Family and Carers services
- NHS e.g. Hospitals

- Physical Health Nurse Team for substance misuse

The above is not an exhaustive list and the provider is expected to link with any services which are in the best interest of their Service User's recovery.

4 Applicable Service Standards

4.1 Applicable National standards

This list is not exhaustive and it is expected that the provider will keep up-to-date with the latest documentation and guidance and incorporate into their practice.

- Public Health Strategic Plan (DoH 2016)
- Clinical Governance Requirements for Community Pharmacy PSNC & NHS Employers (March 2012).
- National Drug Strategy (2017)
- Models of Care for treatment of adult drug misusers: Part 2, 2002
- Models of care for treatment of adult drug misusers: update 2006
- Drug misuse and dependence: UK guidelines on clinical management, 2017
- All relevant NICE guidance
- Bradford Council Plan 2016-2020 (2016)

4.2 Suggested Quality Indicators

- The Pharmacy reviews its standard operating procedures and the referral pathways for the service on an annual basis
- The Pharmacy can demonstrate that pharmacists and staff involved in the provision of the service are competent to deliver this service
- The Pharmacy participates in an audit of service provision when requested by the Local Authority. This will be no more than annually
- The Pharmacy co-operates with any locally agreed Local Authority-led assessment of Service User experience. This will be no more frequent than annually

  The Pharmacy has appropriate Local Authority provided health promotion material available for the user group and promotes its uptake

5 Location of Provider Premises

The service will be delivered from Pharmacy premises located within Bradford District as outlined in Para 3.3.1

Days/Hours of operation

The times to be determined by the Pharmacy

Appendix 1
Supervised Administration of Methadone/Buprenorphine
In The Community Pharmacy

Client / Pharmacist Agreement Form

As the Pharmacist I agree to:

- Provide a service where you may collect your dose at any time between (specify) …. .. . & ……. in the morning and …….. & …….. in the afternoon/evening
- Provide a quiet area for your treatment supervision.
- Keep records of your attendance.
- Dispense your treatment in accordance with the prescription.
- Liaise, when necessary, with the clinic or your GP with regard to your treatment.
- Refer you back to the clinic or your GP and discontinue dispensing your prescription if you do not collect your dose from the Pharmacy for three days or more. If you attend intoxicated, your methadone/buprenorphine may not be dispensed for that day. If your behaviour causes any problems, you will also be referred back to the clinic or GP.
- Provide health promotion and education.

Date.....

Pharmacist..... Signature.....

As the Client I agree to:

- Treat the Pharmacy, its customers and its staff with respect.
- Attend the Pharmacy daily within agreed times, and with an agreed time limit between visits if my prescription is for twice daily supervised doses.
- Not attend whilst intoxicated with alcohol and/or drugs.
- Attend alone and leave pets outside, unless agreed otherwise.
- In exceptional circumstances, wait or return later if the Pharmacy is busy.
- Return to my doctor or the clinic for a re-assessment if I have not collected doses from the Pharmacy for three days or more.
- Not allow any other person to attend the Pharmacy on my behalf unless arranged previously.
- Raise any queries or problems in a calm and reasonable manner with pharmacist.

Date.....

Client Name..... Signature.....