**SERVICE SPECIFICATION**

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| **Service Specification No.**  | N/A |
| **Service** | Supervised Consumption |
| **Commissioner Lead** | Jayne Hardman |
| **Provider Lead** | Various |
| **Period** | 01.04.24 – 31.03.25 plus one |
| **Date of Review** | January 2026 |

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| **1. Population Needs** |
| **1.1 National context** The National Drugs Strategy 2021 contains two overarching aims to reduce illicit and other harmful drug use and increase the numbers recovering from their dependence through reducing demand, restricting supply and building recovery in communities.**1.2 Local context** Halton’s Drug Strategy sets out the local response to the National Drug Strategy through a system-wide approach which prioritises effective partnership-working and integration of servicesHalton has developed a one stop shop approach at where drug users are able to access a wide range of support services. This service (known as the Prescriber or Prescribing Agency) links into the supervised consumption service by providing a source of referrals and support for participating community pharmacies.Community pharmacists are ideally placed to link in with the specialist prescribing services in Halton to meet the need for supervised consumption of methadone or Buprenorphine within an agreed and structured protocol.A valuable supportive relationship often develops between the pharmacist and the patient. Daily contact allows the pharmacist to monitor patient compliance and offer advice and responses on apparent issues for concern. The pharmacist thus has an important role to play in monitoring treatment and as a result may contribute to the patient’s review by the prescribing service. The pharmacist should be aware that supervision might need to be reinstated at times of crisis, relapse or by client choice, as part of an evolving treatment plan. |
| **2. Outcomes** |
| This service will contribute to the aims contained within Halton’s Drug Strategy to reduce illicit and other harmful drug use and to restrict supply and tackle illegal activities in addition to contributing to the following objectives within the Public Health Outcomes Framework:* C19a – Successful completion of drug treatment: opiate users
* C19b - Successful completion of drug treatment: non opiate users
* C19d – Deaths from drug misuse
* C20 – Adults with substance misuse treatment need who successfully engage in community based structured treatment following release from prison
* E03 – Under 75 mortality rate from causes considered preventable
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| **3. Overview** |
| **3.1 Scope**This service specification relates to the supervised consumption of Methadone and Buprenorphine on pharmacy premises.**3.2 Aims and objectives of service** To ensure clients are compliant with their agreed treatment plan by:* Dispensing their medicines in specified instalments as instructed on the prescription.
* Supervising the consumption of the prescribed medicines at the point of dispensing to ensure that the prescribed dose has been correctly consumed by the client.

To reduce the risk of local communities of:* Diversion of prescribed medicines onto the illicit drugs market
* Accidental exposure to prescribed medicines.
* To provide clients with regular contact with healthcare professionals and to help them access further advice or assistance.

**3.3 Population covered**Halton residents (age 18 or over) who have been referred by a Drugs Service or Prescribing agency.**3.4 Any acceptance and exclusion criteria and thresholds**The service is only available to drug users who have been referred by a Prescribing agency, for example the Council’s commissioned drug support services. New clients who have been prescribed medication will be required to take their daily dose under direct observation. They will be referred into the service after full discussion with the client, named worker and community pharmacist.Clients may be re-referred to the scheme if:* Consumption is erratic
* There is failure to produce satisfactory urine tests
* There is concern that the prescribed drug is being diverted or used inappropriately.
* The patient shows a continued and unstable, or unauthorised, pattern of drug misuse.

Observation will normally be for a minimum of 3 months.**3.5 Interdependencies with other services**It is important that close links are maintained between the Prescriber and Pharmacy involved in the scheme. To avoid any confusion or ‘mixed messages’ each client will have a named contact whose role will include production of and ensuring delivery of prescriptions and informing pharmacists when a client will be entering the scheme. This will include any relevant background information on the client. The named contact will approach the pharmacist to confirm arrangement. Regular meetings with the pharmacist may provide information on drug or alcohol intake, physical appearance, and general health state. Failure of the named contact to communicate adequately with the pharmacy would entitle the pharmacy to suspend or refuse to commence the service for that client. **3.6 Any activity planning assumptions**The pharmacy (service provider) will have in place robust systems for the identification, mitigation, and management of clinical and non-clinical risk.Ideally, the service should be provided by pharmacies which are open for a minimum of six days per week but it is recognised that this may not be the case with service providers. |
| **4. Service Description** |
| This part of the specification outlines the procedures for carrying out the service and its administration. It has been separated into general requirements, Pharmacist and Prescriber responsibilities.**4.1.1 General requirements*** Supervised consumption is recommended for new prescriptions for a minimum of 3 months.
* The need for supervised consumption should take into account the client’s social factors, such as employment and childcare responsibilities.
* Supervision itself may create secondary dependence. Clients should not see this as a punishment and, once stabilised, clients should be trusted to take home their medication.
* Service providers will be supported from the Prescribing Agency through sharing of information and regular liaison.
* There must be a designated area in the pharmacy, suitable for supervised consumption taking into account both the clients’ dignity and that of other pharmacy customers.

**4.1.2 Prescriber responsibilities** * The Prescriber shall reach an agreement with the client that their prescriptions will be dispensed at a designated community pharmacy. The Prescribing Agency must negotiate the most suitable pharmacy that is part of the scheme, with the client.
* The Pharmacy shall be contacted in advance by the Prescriber or Prescribing Agency to ascertain if the Pharmacy has capacity to take the client. If the Pharmacy is able to take the client Prescriber or Prescribing Agency will discuss the dispensing arrangements for the client.
* If the Pharmacy accepts the client the Prescriber or Prescribing Agency must inform the Pharmacy of the name, address and description of the client, dosage, start and expiry date of the prescription and named worker contact name and contact number. The Prescriber or Prescribing Agency will complete the ‘Supervised Consumption Registration Form’, the blue copy will be presented to the Pharmacist by the client at first visit.
* On days when the pharmacy is closed a take home dose will be provided, the prescription should reflect this change.
* If the medication is dispensed for non-supervised consumption (e.g. Sundays, bank holidays) the client must be provided with information regarding the safe storage of the medication and reminded of the danger it presents to others.
* The Prescriber or Prescribing Agency should provide feedback to Pharmacists, when appropriate, on client issues flagged up by the Pharmacists.

**4.1.3 Pharmacist Responsibilities** When the client first attends, the Pharmacist must check that the client meets the description given by the named contact and register the client on the Patient Medical Record (PMR) system. The pharmacy will establish an appropriate system to aid client identification when collecting medication subsequently.The Pharmacist should discuss any relevant information with the client, including:* Opening hours for client to access services (this should be flexible where possible)
* The pharmacist’s right to contact the prescriber or named contact
* Missed doses cannot be dispensed at a later date
* Medication will not be dispensed if a client has missed three consecutive doses. They will be referred back to the prescriber.
* Medication will not be supplied if the pharmacist suspects that there is drug or alcohol intoxication (the client may be asked to return later or contact prescribing agency for assessment)
* Client should come in alone
* Acceptable behaviour.
* The pharmacist should introduce the client to key members of staff

For Buprenorphine, a time slot that is mutually agreeable to both the Pharmacist and client for supervision of dose may be agreed. If a time slot is made a written record should be made and held in the pharmacy and written copy given to the client. The client should be made aware that if they do not present during the agreed time slot for collection of their dose they may be asked to return at a more convenient time. Three or more missed dosesThe Pharmacist should contact the Prescriber or Prescribing Agency if the client fails to attend regularly to collect their medication. Where the Pharmacist has not dispensed a daily dose of medication entries should be made on the relevant data collection form(s).Where three consecutive doses have been missed, the pharmacist will not supply a further dose. Contact the prescriber to notify them that the client has missed three doses and refer the client to their drug service to be clinically re-assessed.Where the dispensing service has been terminated for a client for whatever reason, any prescriptions that have not yet been started should be returned to the Prescribing Agency crossed and marked “INVALID”. In the event of any ‘adverse incident’ or ‘near miss’ the pharmacist must complete the appropriate incident reporting form and demonstrate that the pharmacy has learnt from the incident.* + 1. **Dispensing and Supervision**

Pharmacists must follow good practice guidance as issued from time to time by the General Pharmaceutical Council (GPhC).Supervision should never take place in the dispensary. A suitably discreet area will be selected in each pharmacy and should be used for consumption (preferably a consultation area). The pharmacist must be satisfied that they have a suitable area where they can have a confidential consultation with the client.Doses of medication can be made up in advance each day (assuming the Pharmacist is in possession of a current prescription). Medication should be dispensed into an appropriate child resistant container labelled in accordance with the requirements of the Medicines Act,and must be stored in the Controlled Drugs (CD) cabinet until the client arrives at the pharmacy.When the client arrives, the Pharmacist must ensure that the client is correctly identified, interact with them to determine general health and suitability for collecting medication and receives his/her dose of medication.The Pharmacist should show the medication to the client and confirm strength and dose.Methadone Methadone may be consumed directly from the dispensing bottle or may be poured into a cup, as agreed by the client and Pharmacist. The Pharmacist shall observe the consumption of methadone by the client. The client should then be offered a drink of water to help prevent tooth decay and engage in conversation with the client. This is to ensure that the methadone has been swallowed.BuprenorphineA drink of water should be supplied to the client to moisten the mouth and aid dissolution of the tablet. The Pharmacist should place the tablet(s) into a pot and hand this to the client. The Pharmacist then observes the client placing the tablet(s) under the tongue to dissolve. The client should be observed until the tablet(s) have dissolved. Continued observation can be made by the Pharmacist or an appropriately trained Dispensing Technician.Once the tablet(s) have dissolved the client should be referred back to the Pharmacist to confirm supervision is complete. The client should open his / her mouth to confirm the tablet(s) has dissolved. NoteClients should not bring their own drinks into the pharmacy.All labels must be removed from the clients’ dispensed containers, or have the patient name obliterated indelibly, before throwing away, to maintain confidentiality.After each dispensing the Pharmacist must then complete the data collection form for that client in accordance with instructions as well as making the appropriate entries into the CD register and on the prescription. It is imperative that full details are recorded, including where there have been any issues causing concern. Any issues causing concern must be reported to Change, Grow, Live (CGL). If the client declines any medication, the Pharmacist should contact the prescribing agency for further advice.The pharmacy must protect personal data in accordance with the provisions and principles of the Data Protection Act. At all times the pharmacist will be mandated to preserve client confidentiality in accordance with GPhC standards for Pharmacy Professionals.**Practical Aspects**A written SOP will be in place in the Pharmacy and all staff, including locums, must be aware of the content. The supervised consumption of medication will always occur in discreet areas, (preferably consultation area).The Pharmacist should consider contacting the Prescriber / Prescribing Agency if:* The client appears ill.
* The client misses two consecutive doses.
* The client does not consume whole dose.
* The client tries to avoid supervision of the procedure.
* The client appears to be intoxicated with alcohol or illicit drugs.
* The behaviour of the client is unacceptable, e.g. shoplifting/verbal and/or physical abuse.
* There is any doubt whether it is safe to supply the dose.

*NOTE:*Missing doses may result in a drop in Opiate tolerance with increased risk of accidental overdose.Clients stable on medication should be alert and coherent.**The Supervised self-administration procedure**1. A written protocol must be in place within the Pharmacy and all staff including locums, must be aware of the contents. The protocol must include how staff deal with clients and what to do if a client fails to attend or is abusive etc., as well as the following points:
2. Close liaison between the Prescriber or Prescribing Agency and the pharmacist must be monitored
3. The Prescriber or Prescribing Agency will identify and allocate clients to Pharmacies. The Prescriber or Prescribing Agency will confirm with Pharmacist prior to issue of prescriptions, including collection times for medication.
4. The Prescriber or Prescribing Agency will make it clear to the client that the daily dose will be consumed in the Pharmacy, followed by a drink of water.
5. A contract between the pharmacist and the client must be developed and explained to the client at the outset. This will cover issues such as:
6. When and when not to attend
7. Missed doses cannot be dispensed
8. Weekend/Bank Holiday arrangements
9. Acceptable and unacceptable behaviour – within the Pharmacy
10. The daily dose will be measured into a container, capped and labelled so that when the client arrives they are handed the container; client consumes his medication followed by a drink of water. The pharmacist must be satisfied that the dose has actually been consumed.
11. It is important that the medication is ready for the client’s arrival. The whole operation should be as discreet and efficient as possible, maintaining the client’s dignity and saving the pharmacist’s time.
12. The patient’s identity must be checked and, if need be, verified by the Prescriber or Prescribing Agency.
13. Doses that are collected for Sunday/Bank Holidays must be dispensed in a container with a childproof lid.
14. If the pharmacist considers the client’s behaviour to be unacceptable, or the client is intoxicated, the Prescriber or Prescribing Agency must be informed and the dose withheld.
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| **5. Applicable Service Standards** |
| **5.1 Applicable national standards (e.g. NICE)**The service must comply with the following as appropriate:* NICE Guidelines CG52 – Drug Misuse - Opioid detoxification July 2007
* NICE Guidelines CG51 – Drug Misuse – Psychosocial interventions July 2007

NICE Guidelines NG64 – Drug misuse prevention: targeted interventions February 2017* NICE Technology appraisal TA114 – Methadone and buprenorphine for the management of opioid dependence January 2007
* NICE Quality Standards QS23 – Drug use disorders in adults November 2012
* Care Quality Commission’s Essential standards of quality and safety

The service provider must comply with Standards for registered pharmacies as set out by the General Pharmaceutical Council as well as qualities set out by NHS England.* 1. **Applicable local standards and terms of service**
		1. The service provider will operate and provide a service in accordance with this specification unless altered/changed by mutual agreement with the service commissioner.
		2. A contract agreement will be signed by the service provider (Head Office in the case of multiples) and will be subject to operational and performance review by Halton Borough Council. The service provider will be given advance written notice of quality assurance visits

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| **6. Obligations** |
| **6.1 Responsibilities of the service provider**The area of the pharmacy used for provision of the service must provide a sufficient level of privacy and safety and meet other locally agreed criteria.The service provider has a duty to ensure that staff involved in the provision of the service have relevant knowledge and are appropriately trained in the operation of the service.The service provider has a duty to ensure that staff involved in the provision of the service are aware of and operate within local protocols, subject to change authorised by Commissioner and mutually agreed with the service provider.The pharmacy will ensure that if the pharmacy has locum cover, that the locum pharmacist clearly understands the practices within the Halton footprint on supervised consumption and adheres to the particulars of this specification, subject to change authorised by Commissioner and mutually agreed with the service provider.The service provider should maintain appropriate records to ensure effective ongoing service delivery and audit.Appropriate protective equipment, including gloves, overalls and materials to deal with spillages, should be readily available close to the storage site.Pharmacists will share relevant information with other health care professionals and agencies, in line with locally determined confidentiality arrangements.The service provider will maintain a signposting file which contains contact details for relevant services and suppliers, referral forms, health promotion leaflets and other information relevant to the delivery of the service including advice on safer injecting and identification of injection site wounds etc.Service providers are encouraged to appoint a member of staff to act as a Substance Misuse champion who will take the lead for stock control, invoicing, managing waste, maintaining the signposting file, attending training courses and training and supporting new staff and locums in the delivery of the service.**6.1.1 Professional responsibility**All pharmacists and registered technicians involved in providing this service must adhere to their professional code of conduct and at no point does this service abrogate their professional responsibility, professional judgement must be used at all times.It is the professional’s responsibility to practice only within the bounds of their own competence.The responsible pharmacist on each given day has overall responsibility for ensuring the service is delivered in accordance with this service specification. **6.1.2 Standard Operating Procedures**The service provider will develop a Standard Operating Procedure (SOP) which specifically details the operational delivery of this service.The service provider must ensure that all staff including those other than pharmacists, involved in the provision of the service, have relevant knowledge, are appropriately trained and operate within the SOP, this includes sensitive client centred communication skills.The SOP will be reviewed at least every two years or before if circumstances dictate. Each review should be documented and the SOP/protocol subject to version control. Staff delivering the service must be trained in the SOP and a training record held by the provider. Changes to procedure must be highlighted within the SOP for special attention.The service contractor must ensure that there are systems in place to make locum pharmacists aware of the enhanced service. Locum pharmacists operate under the same procedures and protocols as permanent staff and must have completed the appropriate training to deliver this service. **6.2 Responsibilities of Halton Borough Council (HBC)** Provide a framework for the recording of relevant service information for the purposes of audit and the claiming of payment.Provide details of relevant referral points which pharmacy staff can use to signpost service users who require further assistance.Obtain health promotion material relevant to the service users and making this available to pharmacies in Halton.Distribute lists of participating pharmacies to Drug/HIV, sexual health agencies and to Hospital Accident and Emergency departments on an annual basis.**6.3 Service provision and continuity**It is the responsibility of the service provider to have a process in place which ensures that all new staff and locums are aware of all enhanced services provided by the pharmacy and commissioned by HBC and must maintain continuity of service during and after staff changes. |
| **7. Training and Competency**  |
| **7.1 Training and Competency**In order to deliver the service on behalf of Halton Borough Council the service provider must:Be registered with the General Pharmaceutical Council (GPhC) and be working in a pharmacy contracted to NHS England;Ensure, on a 3 yearly basis, that the lead/regular pharmacist providing the service has successfully completed:* CPPE Substance Use and Misuse (pharmacist version) and the associated Declaration of Competence
* CPPE e-learning module Safeguarding Children & Vulnerable Adults and the associated e-assessment.

All pharmacists will be required to complete the CPPE Self Declaration of Competence for Supervised Administration of prescribed medication. It is recommended that all registered pharmacy technicians complete the same declaration. Staff should not provide the service until trained. The declaration of training and reading and signing the SOP will need to be confirmed on PharmOutcomes via enrolment. There will be a three-month grace period from the start of the service; after this if not completed you will not be able to access the service;A staff training log must be available for inspection, by arrangement.**7.1.1 Locum Pharmacists** 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. The pharmacy has a duty to ensure that staff and other pharmacists (including locums) involved in the provision of the service have relevant knowledge and are appropriately trained in the operation of the service to ensure the smooth continuation of the service for clients.Where possible, the pharmacy should ensure it is staffed by a regular pharmacist/s. Should the pharmacy be in a position where the pharmacy will be run on different locum pharmacists for more than a month, the Contract Manager must be informed. |
| **8. Welfare and safeguarding concerns** |
| Where there are concerns about the welfare of any person aged 0 to 18 within the pharmacy setting and/or accessing the service appropriate immediate action must be taken to address those concerns by following the Safeguarding pathway.Additional information on Child Safeguarding procedures can be found at:<https://hcypsp.haltonsafeguarding.co.uk/><https://hcypsp.haltonsafeguarding.co.uk/procedures-guidance/> If there are concerns about the welfare of someone over the age of 18 pharmacists are required to contact Halton Borough Council on 0303 333 4300 (this will be picked up by the Emergency Duty Team if outside of normal office hours) or if there is an immediate threat to safety or wellbeing the pharmacist should contact the Police. |
| **9. Significant Event Reporting** |
| The service provider must have an adverse incident and near miss reporting system in place which includes maintaining a log of patient safety incidents. The service provider should be able to demonstrate that it has learnt from an event.Halton Borough Council reserves the right to undertake its own root cause analysis if it feels that the root cause is derived from the implementation of the service specification, protocol or PGD. Patient or staff safety incidents or near miss incidents related to this service must be reported to public.health@halton.gov.uk. |
| **10. Complaints** |
| The service provider must have a complaints procedure that complies with Local Authority Social Services and National Health Service complaints (England) Regulations 2009. The service provider should inform clients connected to this service of their right to complain to Halton Borough Council. Information shall be provided to the client in order for them to access the Council’s complaints procedure.Complaints directly linked to this service must be reported to Halton Borough Council. Any complaints must be sent to public.health@halton.gov.uk. The Council reserves the right to directly investigate complaints about the service. In such cases the pharmacy will co-operate with the investigating officer giving full access to all relevant documents, files and information and will allow them to interview any personnel in the pharmacy’s employment or agent in order to carry out their investigation effectively. This will be agreed prior to investigation by the pharmacy lead. |
| **11. Equality and Diversity** |
| The service provider must comply with the requirements of the Equality Act 2010, and will not treat one group of people less favourably than others because of their Age, disability, Gender reassignment, Marriage and civil partnership, Pregnancy and maternity, Religion and belief, Sex, Sexual orientation.  It is the responsibility of the service provider to make reasonable adjustments to meet the individual needs of their patients.   |
| **12. Health and Safety** |
| The service provider shall comply with the requirements of the Health and Safety at Work Act 1974, the management of health and safety at work regulations 1999 and any other acts, regulation, orders or rules of law pertaining to health and safety.  |
| **13. Freedom of Information** |
| The commissioner and the commissioned service provider recognize that this service specification and/or associated recorded information may be subject to Freedom of Information Requests (FOI). Each party shall comply with any such Freedom of Information requests received, in accordance with the Freedom of Information Act 2000 legal obligations. |
| **14. Required Insurances** |
| * Employers Liability - £10m minimum
* Public Liability - £5m minimum
* Professional Indemnity - £5m minimum
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| **15. Data Requirements and Record Keeping** |
| The service provider undertakes that they shall:(i) Keep all information concerning clients confidential.(ii) Keep safe at all times all papers and documents placed in their possession concerning clients.(iii) Provide a consultation area as defined in the community pharmacy contractual framework.(iv) Comply with the requirements of all legislation relevant to the service and in particular with the Data Protection Act 2018, Human Rights Act 1998 and Freedom of Information Act 2000.Halton Borough Council may require the pharmacist to supply it with any relevant information required to carry out monitoring and evaluation of the service. Any client information supplied can be anonymised where appropriate and will not be used for any purpose other than monitoring, evaluation and validation. |
| **16. Performance Monitoring** |
| * The service provider will have an NHS dispensing contract with NHS England and must fully comply with the National Pharmacy Contract regulations for delivery of Essential Services.
* Halton Borough Council retains the right to audit any part of the service provided by the service provider or the accredited pharmacist to ensure continued quality.
* Any audit/quality visit will be arranged in advance with the service provider.
* Halton Borough Council reserves the right to ask for evidence from the service provider that it is following the procedures outlined in this specification.
* The service provider will co-operate with any Halton Borough Council led assessment of client experience or audit of the service in order to evaluate service provision and identify areas for service improvement.
* Halton Borough Council reserves the right to evaluate other health professionals’ perception of the overall quality of the service.
* Changes to the level or quality of the service will not be introduced without prior agreement with Halton Borough Council. Changes will be authorised in writing.
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| **17. Fees for Providing the Service** |
| **17.1 Fees**Payment will be made to the Pharmacy on a monthly basis. The payment schedule is as follows:(i) Supervision of methadone £45.50 per month per client1. Supervision of Buprenorphine £75.00 per month per client

**17.1.2 Payment arrangements**In all cases payment will be made monthly in arrears from the data you will have entered on PharmOutcomes, PharmOutcomes is an online reporting mechanism. All claims are subject to the validation of data input and authorization from a certifying officer. **17.1.3 Terms of payment**The only sums payable to the Provider for the provision of the Services shall be the Contract Price. All other costs, charges, fees and expenses of whatever kind arising out of or in connection with the Agreement shall be the responsibility of the Provider. |