SERVICE SPECIFICATION

To provide safe and effective supervised consumption of prescribed opioid substitution therapy (OST) medications in accordance with the client's prescription

Service	**Supervised Consumption Scheme (methadone, espranor & buprenorphine) – Devon & Torbay**
Authority Lead	**Devon and Torbay**
Period	**1 October 2021 – 30 September 2023**
Date of Review	**October 2022**

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1. BACKGROUND AND EVIDENCE

1.1 The effectiveness of well-delivered, evidence-based treatment for drug misuse is well established. UK and international evidence consistently show that drug treatment – covering different types of drug problems, using different treatment interventions, and in different treatment settings – impacts positively on levels of drug use, offending, overdose risk and the spread of blood-borne viruses. For a significant proportion of those entering treatment, drug treatment results in long-term sustained abstinence. (Drug Misuse and Dependence – UK Guidelines on Clinical Management – DH 2017).

1.2 Opioid substitution therapy (OST) is "the frontline NICE recommended community-setting pharmacological therapy for people with heroin or other non-medical opioid dependence. An appropriate dose of opioid medication is able to maintain the patient's tolerance for opioids and prevent the onset of withdrawal symptoms for approximately 24 hours. In this way, treatment stabilises and manages physiological dependence on opioids and craving for heroin may be suppressed. Importantly, OST establishes a platform for people to receive psychosocial interventions, other medical care and social support." (An evidence review of the outcomes that can be expected of drug misuse treatment in England. PHE 2017. P44). Following the introduction of supervised consumption in England and Scotland, methadone-related deaths reduced fourfold (Strange et al 2010).

2. AIMS, OBJECTIVES AND EVIDENCE

2.1 Aim

2.1.1 The aim of this specification is to enable pharmacies in Devon and Torbay to provide a safe and effective supervised consumption of prescribed medications in accordance with the client's opioid substitution therapy (OST) prescription. The service will ensure clients remain stable on their prescribed medication and therefore do not need to use illicit drugs in addition.

2.2 Objectives

2.2.1 Pharmacy Supervised Consumption service must offer a user-friendly, non-judgmental, client-centred, confidential service where individuals are treated equitably and with respect at all times.

2.2.2 Stabilise and maintain engagement in prescribing regime. As part of a comprehensive treatment package, the daily supervision of OST can ensure that therapeutic plasma levels are maintained and help ensure that the client's opiate dependency is stabilised, which reduces the need for illicit opiates. The successful stabilisation of illicit drug use can reduce the risk of blood-borne virus transmission and opioid overdose, and impact positively on public and individual health.

2.2.3 Reduce diversion of medication – leakage. Opioid medication is highly sought after on the illicit drugs market and attracts a high street value. Supervised consumption assists in ensuring that opioids are taken in accordance with prescribers' instructions and reduces the likelihood of diversion onto the illicit drugs market - 'leakage', which may have a significant effect in reducing overdose deaths attributed to illicit consumption.

2.2.4 Support effective communications whilst a person becomes established in their treatment regime. Pharmacy staff have daily contact with individuals receiving treatment via supervised

consumption. As such, community pharmacies play a valuable role, both in supporting individuals and monitoring their day to day progress in drug treatment. The Supervised Consumption Scheme also enables the community pharmacy, prescriber and/or the treatment provider's keyworker to communicate effectively any relevant comments or concerns regarding the individual's progress or wellbeing.

3. SERVICE REQUIREMENTS

3.1 Standard Operating Procedures and contingency plans

3.1.1 All Pharmacies participating in the Supervised Consumption Scheme must develop Standard Operating Procedures and contingency plans which underpin the health and safety of both staff and clients and the service in general. Operating Procedures should reflect available national advice and locally produced operating guidelines in **Schedule 1**. A contingency plan must also be put in place which reflects the principles of **Schedule 2**.

3.1.2 The Standard Operating Procedures must have clearly stated objectives and stipulate whose responsibility it is to implement them. The process for monitoring, review and development must also be clearly defined. The Standard Operating Procedures should include the following areas (this list is not exhaustive):

- Dispensing and supervision of methadone/buprenorphine/espranor and other OST medication
- Client confidentiality and data protection
- Incident monitoring and reporting process
- Risk assessment and risk management
- Process for missed collection – to include where an individual has missed 3 consecutive days collection, the Pharmacy must notify the specialist community drug treatment provider before service close on day 3 and no later than midday on day 4. This triggers a welfare check and could potentially save someone's life. The day 4 medication must not be dispensed by the pharmacist following the day 3 notification until the Pharmacy have received confirmation from the specialist community drug and alcohol treatment service that it is safe to do so.

3.1.3 The Pharmacy should review its Standard Operating Procedures, contingency plans and the referral pathways for the Scheme in accordance with its organisational polices. Where there are none, this should be on an annual basis.

3.2 Availability of the Service

3.2.1 The Pharmacy must provide a supervised consumption service Monday to Saturday unless the pharmacy is contracted to be open 7 days a week, in which case the service should also be available on a Sunday. The only exception to the 6 day rule is where rurality is a factor, where a 5-day opening (Monday-Friday) may be acceptable. The decision to accredit pharmacies which are open only 5 days a week will be at the discretion of the Commissioner. Pharmacies wishing to amend their hours of availability should apply in writing to the Commissioner, providing a clear rationale.

3.2.2 The need for additional Pharmacy capacity will be agreed jointly with the Community Drug and Alcohol Treatment service. In this instance, the commissioner will discuss capacity requirements with the pharmacy provider(s) to explore a solution.

3.3 Governance and training

3.3.1 The Lead Pharmacist will oversee and be responsible for the operation of supervised consumption within the Pharmacy. There should always be a Pharmacist accountable for supervision in a position to intervene immediately when necessary.

3.3.2 The Lead Pharmacist will ensure that all dispensing is in accordance with all legal requirements and published pharmaceutical guidance for pharmacists providing instalment dispensing services to drug misusers, as well as the Supervised Consumption Scheme Operational Guidelines (**see Schedule 1**) and the Pharmacy's Standard Operating Procedure for the service (**see 3.1.1 above**).

3.3.3 The Lead Pharmacist should monitor their capacity for methadone/buprenorphine/espranor supervision to ensure that activity does not exceed a safe and manageable number of clients for supervision at the pharmacy (at any one time).

3.3.4 The Lead Pharmacist must ensure any staff member involved in supervised consumption is over 18 years of age and has completed medicine counter assistant training.

3.3.5 Lead pharmacists may delegate the responsibility for supervision of methadone or buprenorphine to appropriately trained staff. However, the Lead Pharmacist retains overall responsibility for ensuring staff have the appropriate level of competency and training.

3.3.6 There should always be a Pharmacist accountable for supervision in a position to intervene immediately when necessary.

3.3.7 Lead Pharmacists who delegate the supervision of methadone must ensure that any Deputy or Locum is qualified and competent to provide the service in advance of their providing cover. They must ensure delegated staff are aware of all written protocols and procedures which are in place for this service.

3.3.8 Locum Pharmacists may not assume the role of a Lead Pharmacist for the Scheme unless they are nominated to do so. Where Locum Pharmacists are nominated as leads for the scheme both the substance misuse treatment provider and the relevant Public Health commissioners must be notified.

3.3.9 Regular Locum and Deputy Pharmacists must have completed CPPE training for substance use and misuse and should also be encouraged to attend local harm reduction training.

3.3.10 It remains the Lead Pharmacist's overall responsibility to ensure that all staff, including Pharmacists, are fully trained and competent to deliver the Supervised Consumption service.

3.4 Premises

3.4.1 The Pharmacy **must** provide an appropriate quiet area so that supervision protects the privacy and dignity of all clients. Supervision will never take place in the Dispensary.

3.4.2 It is essential that Pharmacies providing supervised consumption have available at all times:

- Adequate visual/communication systems for the Pharmacist to monitor and control supervised consumptions carried out by delegated staff within the Pharmacy
- Appropriate storage conditions for the supply of Controlled Drugs

- Adequate privacy and dignity for clients being supervised
- A client's medication records system
- Separate consulting room/area for engagement with clients' supervision (ie supervision will never take place in the dispensary)

4.0 SERVICE DESCRIPTION

4.1 Assessment by Specialist Treatment Provider.

The Specialist Drug Treatment Provider (or GP prescribing in the Shared Care Scheme) will ensure that all clients undergo a comprehensive assessment as to their suitability for drug treatment via daily supervised consumption which is in accordance with Department of Health guidelines on Clinical Management of Drug Misuse (2017).

4.2 Comprehensive assessment will include a risk assessment to establish whether the client poses a significant identifiable risk to pharmacy staff or other customers. Any identified concerns must be discussed with the Lead Pharmacist in advance of dispensing being started. Likewise, any emerging concerns relating to an individual already in treatment will also be referred to the Lead Pharmacist for discussion.

4.3 **New clients.** The Pharmacy is advised to explain conduct rules to new clients on their first visit, based on the 3-way agreement/prescribing agreement between the Pharmacy, the client and the Specialist Drug Treatment Provider

4.4 Prior to supervision, the Pharmacist must:

- **Confirm the client's identity prior to issuing the daily dose**. All clients will have a photo provided as part of the 3 Way Agreement/prescribing agreement.
- **Note whether the client has recently missed a dose(s).** In the case of the client having missed 3 consecutive doses, please see Schedule 1 Operational Guidelines.
- **Observe that the client is not intoxicated** and confirm if there is any medical reason why they are unable to consume the prescribed dose. In cases of intoxication see Schedule 1 Operational Guidelines.
- **Before issuing any medication**, follow the Pharmacy's procedure to verbally confirm the dose and medication with the client.
- **Ensure that no drinks, other than water provided in the pharmacy** are being consumed by the client during supervision (this reduces the chances of medication, especially methadone, being diverted into a bottle/can etc).

4.5 In the event that the Pharmacist has concerns regarding the concordance of consumption by the client, the Keyworker should be notified immediately and the Pharmacy's *Incident Monitoring Procedures* followed (**see 2.1.2 above**).

4.6 The Pharmacist responsible for the service should be able to respond to requests from the Specialist Drug Treatment Provider or GP to discuss any clinical issues or queries within the same working day and at an interval of no later than 4 hours after the initial request.

4.7 The Pharmacist responsible for the service should relay to the Keyworker or Prescriber any appropriate concerns or comments they may have regarding a client's progress or conduct. Pharmacy staff will aim to do so in a manner which maintains a good client/pharmacy relationship and does not breach confidentiality.

4.8 Supervision of Doses.

All supervised consumption should take place in a consulting room or an appropriately dedicated "quiet area" within the pharmacy in order that the client is treated with dignity and respect. Consideration to confidentiality must be given if a "quiet area" is used as opposed to a dedicated consulting room or harm reduction suite; i.e. whether other customers could be in earshot if there is any discussion as to the client's medication or other personal matters.

4.9 Methadone supervision:

- The client may drink their methadone dose straight from the labelled bottle or from a disposable cup, which should be mutually agreed by the client and pharmacy. The dose must be measured and double-checked and must not be poured from a bulk supply straight into cups for presentation to the client. **All cups used in the pharmacy for supervision should be disposable and used once only. This is for infection control purposes.**
- Observe the client drinking the methadone, making reasonable steps to ensure that the dose is being swallowed and not diverted to a bottle or other receptacle
- Once the dose has been swallowed, offer a drink of water to the client to elicit conversation; this ensures that the dose has not been retained in the mouth. It also benefits the client's dental health as it serves to remove the methadone residue from the mouth and teeth.
- If the client declines a drink they must be engaged in conversation to ascertain that the dose has been swallowed.

4.10 Espranor Oral Lyophilisate supervision

- The 1st dose of Espranor should be taken at least 6 hours after the last opioid or when there are signs of withdrawal.
- The Espranor wafer dissolves within 1 minute, reducing the risk of diversion. It must be placed on the tongue not under the tongue.
- Espranor should not be consumed at the same time as food or drink.
- Individual's should not drive or operate machinery whilst taking Espranor.
- Make sure the person's hands are dry prior to consumption as Espranor is sensitive to moisture.

4.11 Buprenorphine supervision:

- If this is the client's first dose of buprenorphine, explain that they must have waited at least 8 (preferably 12) hours since last using heroin or at least 24 hours (preferably 36) since the last methadone dose. This is to minimise the risk of precipitated withdrawal (**see 2.5.12**).
- Explain that the tablet(s) must be dissolved under the tongue to absorb the active ingredient and that the client should avoid swallowing (both the tablet and their saliva whilst tablets are being dissolved).
- Offer the client a cup of water from a disposable cup prior to dosing. This enables saliva production and assists in absorption of medication.
- Pierce foil on blister pack and pop tablet(s) into a disposable cup/receptacle.

- Instruct client to place tablet (s) under tongue. If client is newly prescribed, explain the importance of sublingual absorption as opposed to swallowing tablets.
- Carefully observe the client's hand to mouth movement to ensure that tablets are not diverted into pockets etc. ('palmed').
- Observe the client closely for a minimum of THREE minutes, or until a chalky residue remains.
- If there is any doubt that the client is not complying with supervision, request that the client shows that the tablets are still under the tongue. Be aware that this is invasive and should not be employed routinely, though can be employed periodically to ensure compliance.
- Time for Sublingual Absorption of Buprenorphine. Information from the manufacturers indicates that it commonly takes 3-5 minutes for sublingual tablets to dissolve sublingually, although up to 8 minutes has been reported. The time required depends on a number of variables including the amount of moisture in the mouth and the dose administered. In practice, supervision of the client is most important for the first 2-3 minutes after administration, during which the tablets have begun to dissolve, and their value for re-sale and diversion generally diminishes. Once the tablets have dissolved under the tongue and only a chalky residue remains, the active ingredients have been fully absorbed and the client may leave.

4.12 After Supervision:

- Allow the client to leave the Pharmacy.
- Make the appropriate entry on paperwork.
- Dispose of waste to ensure that all cups etc. are used once only.
- All labels containing client information must be removed from dispensing packaging and disposed of as confidential waste (e.g. shredded).
- Promptly inform the Keyworker or Prescriber if the client does not consume their medication (including partial consumption of a dose) or if the client has not adhered to any of the other contractual obligations laid out within the 3 Way Agreement/prescribing agreement. Failure to consume medication should also be reported promptly via the Pharmacy's *Incident Monitoring Procedures*.

4.13 Identifying Signs of Opiate Withdrawal:

- Buprenorphine may cause opiate withdrawal if taken too soon after the client's last dose of heroin or methadone. The first dose of buprenorphine should ideally be taken at least 8 hours after the last heroin dose (or 24-36 hours after methadone), preferably when the client is experiencing mild withdrawal symptoms.
- Opiate withdrawal is caused by stopping or reducing taking opiates (e.g. heroin, methadone). Whilst very unpleasant, withdrawal does not come with medically serious risks (except in pregnancy).
- Heroin withdrawal often begins between 6 to 8 hours after the last dose, whereas methadone withdrawal often begins after 24 hours. Heroin withdrawal lasts from 5-7 days, methadone withdrawal lasts longer; approximately 2 weeks or more.

4.14 Intoxication

It is appreciated that clients who are still being stabilised on their medication are likely to use additional drugs, however 'significant intoxication' is demonstrated by the client's inability to function, such as:

- Has slurred or incoherent speech
- May appear sleepy or over-agitated
- Smell excessively of alcohol
- Their walking or standing is affected
- Their eyes show evidence of intoxication

All staff involved in supervised consumption must be aware that as many of the above symptoms could be attributed to other health problems, assumptions cannot always be made. If following interaction with the client, there remains any doubt, the matter should always be referred to the Pharmacist and, beyond that, the prescriber or keyworker.

5. PRESCRIPTIONS

5.1 The Specialist Treatment Provider will ensure that all prescriptions issued are compliant with legal requirements, stating that consumption will be under supervision and specify any weekend or Bank Holiday 'take home' doses.

5.2 All prescriptions will be delivered to the Pharmacy in sufficient time for the Pharmacist to dispense. Only unforeseen scenarios and exceptional circumstances, such as unprecedented changes to medication, should result in a prescription being presented to the pharmacy on the same day that it is to be dispensed.

5.3 The Specialist Treatment Provider will ensure that Pharmacy staff or other customers are not unnecessarily placed at risk by making changes to prescriptions, or by stopping an individual's medication without having made reasonable attempts to discuss such changes with the person beforehand.

5.4 In instances where the Specialist Treatment Provider has been unable to discuss impending changes to medication with the individual, the Pharmacy will be informed of the situation and of the intended changes so that any necessary risk management strategies can be put into place.

6. REFERRALS TO THE SERVICE

6.1 The Specialist Treatment Provider will check that the chosen Pharmacy for all referrals is accredited to provide a supervised consumption service and has sufficient capacity to deliver the service. If the Pharmacy is not accredited or does not have the capacity, an alternative must be found. If there is an exceptional reason why an individual cannot be supervised at the accredited Pharmacy and there is a Pharmacy willing to provide the service, the Specialist Drug Treatment Provider must ask the Commissioners to agree a temporary arrangement for this one client only, prior to the commencement of the prescription. The Commissioner will provide the Pharmacy with details of the temporary arrangement.

6.2 The Specialist Drug Treatment Provider will ensure that all new individuals (including those transferring from another Pharmacy) are discussed with the Pharmacist responsible for the service prior to treatment commencing and that ideally prescriptions are received at least with 3 working days' notice, but no less than 24 hours before the first dose is due. This is to

ensure that the Pharmacy is adequately prepared and has sufficient capacity to supervise an additional prescription for diversional opioids.

6.3 The Specialist Treatment Provider must provide the Pharmacy in advance with:

- Client's name and address
- Medication details (dosage and names of all medications to be dispensed)
- Start and expiry date of prescriptions
- 3-way agreement/prescribing agreement signed by the Specialist Drug Treatment Provider and the client themselves including photograph of client for identification purposes to ensure the individual understands their responsibilities and conditions before commencing treatment under supervision
- Contact details for the Keyworker (name, location and telephone number, (including work mobile number)

7. MONITORING AND AUDIT

7.1 The Lead Pharmacist will facilitate any audit process by allowing access to and inspection of relevant documentation and services within the premises.

7.2 The Lead Pharmacist is required to keep an accurate record of all methadone/buprenorphine supervision activity using the web-based data collection system - PharmOutcomes.

7.3 The Pharmacy should cooperate with any locally agreed Commissioner-led assessment of service user experience.

7.4 The Lead Pharmacist is required to complete an annual return to the Commissioner to confirm the safe capacity for their Pharmacy to deliver the service and the current number of supervised clients (methadone or buprenorphine).

7.5 The Commissioner will use the Supervised Consumption Scheme data supplied via PharmOutcomes to monitor the service delivered.

8. CLIENT CONSENT TO DATA SHARING

8.1 The client must give consent for their anonymised data to be shared with the Commissioner.

9. INFECTION CONTROL

9.1 All Pharmacy staff should take care to avoid exposure to any blood spills or other bodily fluids. It is unlikely that pharmacies which do not provide a needle and syringe service will be presented with used injecting equipment. However staff should be aware of what action to take in such an event and understand the first aid required in the event of a discarded sharps or needle stick injury. Advice regarding sharps safety is contained within the Needle & Syringe Provision service specification and can be made available on request.

9.2 Vaccination is not mandatory for pharmacy staff involved in supervised consumption only. Where a needle & syringe provision service is also in operation, the Pharmacist who is responsible for the service is legally obliged to conduct a risk assessment which will include the appropriateness of unvaccinated staff participating in needle exchange work. The Pharmacist who is responsible for the service must also consider the feasibility of the offering a comprehensive pharmacy needle exchange without the participation of all staff. (i.e. for a small local pharmacy running on limited staff members it may not be feasible for some staff members to opt out).

10. CONFIDENTIALITY

10.1 In accordance with harm reduction and patient confidentiality, Pharmacy staff will not inform the prescribing service in instances of a client using a needle and syringe provision service as well as collecting medication which is prescribed as treatment for drug dependence, unless there is a specific risk e.g. a child protection case where the pharmacist has formally agreed to notifying the Treatment Provider as part of the Child Protection Action Plan. Pharmacists may, however relay appropriate general concerns regarding the progress of clients in treatment which do not compromise client confidentiality (i.e. do not disclose that the client is accessing the needle and syringe provision service).

11. COMMISSIONER REQUIREMENTS

11.1The Commissioner will provide the following support to pharmacies to ensure that they can provide a high quality, accessible and effective Supervised Consumption Scheme.

12. TRAINING

12.1 Devon and Torbay commissioners will co-ordinate training with the Specialist Substance Misuse treatment service and other relevant providers to deliver formalised supervised consumption and harm reduction training, to promote service development and update the knowledge of pharmacy staff. These update training sessions will be provided on an annual basis as a minimum. For a pharmacy which is new to the Scheme, the commissioners will arrange training at the pharmacy. The Commissioner will ensure that all pharmacies and their staff are informed of training availability, new evidence, and information on clinical effectiveness. Invitations/booking to training/updates will be advertised via the LPC's training calendar and via PharmOutcomes.

13. POPULATION COVER AND ELIGIBILITY

13.1 This specification covers the provision of Supervised Consumption of methadone or buprenorphine prescribed for treating illicit drug dependence in adults (aged 18 and over) living or working in the Devon County Council's geographical area and Torbay Council's geographical area.

13.2 In this context, Torbay and Devon pharmacies should only dispense prescriptions from the services within the local authority area listed below:

Torbay services:

- Torbay Drug and Alcohol Service (Walnut Lodge)
- Shrublands Drug and Alcohol Services

Devon services:

- Together Drug & Alcohol Service (Specialist Treatment Provider)
- GPs accredited to the Devon Shared Care Scheme (to provide primary care prescribing services for drug misuse problems)

13.3 Pharmacies are advised to refer to **Schedule 1, Section 3** should they receive a prescription from a service not listed above.

13.4 The Scheme applies only to Pharmacies that have been accredited by the Commissioners.

13.5 The Pharmacy will make reasonable efforts to accommodate all new supervised consumption clients who are referred by the Specialist Drug Treatment Provider. Pharmacies

will not decline new referrals for supervised consumption unless they have reached a safe capacity for this work or there is a valid and non-discriminatory reason for refusal (i.e. the client is already banned from the premises or there is an identifiable reason why it would be inappropriate for the client to be supervised at the Pharmacy).

13.6 The Pharmacy will not differentiate between accepting prescriptions for supervised methadone or buprenorphine.

14. EXCLUSION CRITERIA

14.1 Unacceptable conduct

14.1.1 **Anti-social behaviour by clients**. Pharmacies should respond to any such acts by means of the appropriate channels, if they are unable to resolve the matter appropriately within the pharmacy or for repeated incidents. Action to be taken in such instances may include banning a client for an indefinite time span from their premises and denying them a dispensing service. For matters involving a criminal offence, the Pharmacist or their staff reserve the right to involve the Police for advice/law enforcement. In such instances, the Pharmacist must inform the Treatment Provider and comply with the Pharmacy's Incident Monitoring and Reporting procedures.

14.1.2 **Client intoxication**. If Pharmacy staff have any concerns that a client is intoxicated due to drug or alcohol use, they must not dispense medication to the client and must always refer the matter to the Pharmacist who will be responsible for making a judgement as to the client's suitability for their medication. Further guidance on this is found in **Schedule 1**.

15. 'OUT OF AREA' PRESCRIBERS

15.1 The supervision of methadone or buprenorphine prescribed by a Treatment Provider or GP other than those listed at **4.2** is not supported by this specification and Pharmacies are not eligible for payments under the Public Health contract. Further guidance on 'out of area' prescribers can be found at **Schedule 1, Section 3**.

16. INTERDEPENDENCIES WITH OTHER SERVICES

16.1 Drug and alcohol treatment providers

Devon	Specialist drug & alcohol treatment provider:	Single point of contact:
	Together Drug & Alcohol Service. The three main hubs are:	0800 233 5444
	Bideford & North Devon (option 3) Exeter, East & Mid Devon (option 1) Newton Abbot & South (option 4)	When prompted, select the area you require and then ask for prescribing support
Torbay	Specialist drug & alcohol treatment providers:	
	Shrublands Drug & Alcohol Service	01803 291129
	Torbay Drug & Alcohol Service (Walnut Lodge)	07825 027845 or 01803 604330 Ask for the access to treatment co-ordinator
Devon	Young Persons specialist substance misuse service:	
	Y-Smart	0800 121 4751
Torbay	Young Peoples specialist service:	
	Checkpoint	01803 200100

17. ASSESSMENT BY SPECIALIST TREATMENT PROVIDER

17.1 The Specialist Drug Treatment Provider (or GP prescribing in the Shared Care Scheme) will ensure that all clients undergo a comprehensive assessment as to their suitability for drug treatment via daily supervised consumption which is in accordance with Department of Health guidelines on Clinical Management of Drug Misuse (2017).

17.2 Comprehensive assessment will include a risk assessment to establish whether the client poses a significant identifiable risk to pharmacy staff or other customers. Any identified concerns must be discussed with the Lead Pharmacist in advance of dispensing being started. Likewise, any emerging concerns relating to an individual already in treatment will also be referred to the Lead Pharmacist for discussion.

18. THE 3-WAY AGREEMENT/PRESCRIBING AGREEMENT

18.1 The 3 Way Agreement/prescribing agreement is a contractual agreement between the prescriber, pharmacy and client. A 3-Way Agreement/prescribing agreement between the prescriber, pharmacy and client is an important aspect of clinical governance. It is also a requirement of the Supervised Consumption contract and is a mandatory part of drug treatment. A template 3-way agreement is available from the prescribing services if required.

19. REVIEW BY SPECIALIST TREATMENT PROVIDER

19.1 The clinical need for supervised consumption should be reviewed regularly by the prescriber. Although, ultimately, the responsibility for the level of supervision for any prescription lies with the prescriber, decisions on when to relax or increase the requirement for supervised consumption should include consultation with the multidisciplinary team, the patient and liaison with the dispensing pharmacist. For example, long-term, daily supervised consumption would probably not be appropriate for a patient in regular, full-time work or education where supervision would be a clear barrier to retention in treatment and recovery (DH guidelines - Clinical Management of Drug Misuse 2017)

19.2 Keyworker assigned by Specialist Treatment Provider - The Specialist Treatment Provider will ensure that every individual receiving treatment under supervised consumption is assigned a Keyworker who may be either the Prescriber or another Substance misuse professional. The Specialist Treatment Service will inform the Pharmacist who the Keyworker is.

19.3. Specialist Treatment Provider Response times

19.3.1 The Keyworker or a nominated deputy will normally respond to a request from the Pharmacy to discuss any clinical issues or untoward incidents within the same working day and at an interval no later than 4 hours after the initial request.

20. NATIONAL AND LOCAL STANDARDS

20.1 The following national guidance and service delivery standards are as follows:

- Department of Health. Drug Misuse and Dependence – UK Guidelines on Clinical Management (2017)
- NICE Public Health Guidance 52: Needle and syringe programmes (2014)

- CPPE open learning programme for pharmacists and pharmacy technicians: Substance use and misuse (2nd edition, revised May 2012

SCHEDULE 1 – OPERATIONAL GUIDELINES

OPIATE WITHDRAWAL SYNDROME		
Time after last heroin use	Signs and symptoms	Terms for opiate withdrawal
8-12 HOURS Initial symptoms will include:	Runny nose/watering eyes Yawning Sweating/Hot and cold flushes Nausea Agitation/irritability Loss of appetite	Cold turkey Turkeying/turkey Clucking/cluck Rattling/rattle Jonesing Hanging Strung out (This list is not exhaustive and there are many regional variations)
12-48 HOURS Subsequent symptoms will include:	Increased restlessness Dilated (widened) pupils Goosebumps/hairs standing on end (piloerection) Musculoskeletal symptoms e.g. back pain, leg cramp, muscle twitching/tremor Abdominal cramps Diarrhoea/nausea/vomiting	

48-72 HOURS Peak withdrawal symptoms will include (as well as intensification of above symptoms):	Insomnia More pronounced lack of appetite Severe runny nose/watering eyes Violent yawning/sneezing Inflammation of nasal mucous membranes Abdominal cramps Insomnia Goosebumps/hairs standing on end	Signs of heroin intoxication Itching/scratching Pinpoint pupils ('pinned') Impaired functioning/co-ordination Sedation/unconsciousness (if severe) Low blood pressure Pale/blueish complexion (cyanosis) Respiratory depression (slow/shallow breathing)
HEROIN WITHDRAWAL SYMPTOMS WILL DISSIPATE OVER 7-10 DAYS		
METHADONE WITHDRAWAL: Symptoms will follow a similar pattern but are likely to appear 24-36 hours after the last dose due to the longer half life of methadone. Withdrawal symptoms are also likely to continue for around 14 days.		

This information is based upon model contained in "Building bridges", information folder produced by Schering-Plough (June 2004).

1. Intoxication

Medication should not be dispensed in instances when the pharmacist considers the client to be significantly intoxicated due to drug or alcohol use. In all instances of a client presenting as significantly intoxicated, the pharmacist should telephone the prescribing service to seek advice from the care co-ordinator or their nominated deputy before medication is dispensed. In instances of possible intoxication where supervision is not undertaken by the pharmacist, and there are concerns that the client is intoxicated due to drug or alcohol use, the staff member responsible for supervision must never proceed with supervision, and in all instances refer the matter to the pharmacist who is responsible for making a judgement as to the client's suitability for their medication.

In instances when the client presents as significantly intoxicated and the prescribing agency is closed, the following course of action will be taken:

End of a working day

If the client presents as significantly intoxicated at the end of a working day after the prescribing agency is closed, the pharmacist must withhold the client's daily dose and ensure that the matter is discussed with the prescribing agency the following working morning. (Pharmacists handing over to locums/other pharmacists must ensure that the matter is communicated and that the pharmacist is able to deal with the matter on their behalf.) The client should be given an explanation as to why their dose is being withheld and if possible, advice given regarding the risks of overdose.

Weekends and/or Bank Holidays

If the client presents as significantly intoxicated on a Saturday or a long bank holiday period when the prescribing agency is closed, the pharmacist should decline to dispense the client's medication and ask them to return for their medication later in the day when the client's suitability to have their medication can be re-assessed. The pharmacist should explain to the client that if they are still intoxicated when they return, both their daily dose, and any take home/Sunday dose will be withheld and if possible, give advice regarding the risks of overdose. Regardless of the outcome, the pharmacist must ensure that the prescribing agency is contacted and informed at the beginning of the next working day.

Notes on 'significant intoxication'

It is appreciated that clients who are still being stabilised on their medication are likely to use additional drugs, however "significant intoxication" is demonstrated by the client's inability to function e. has slurred or incoherent speech, they may appear sleepy or over-agitated, smell excessively of alcohol, their walking or standing is affected, their eyes show evidence of intoxication). Pharmacy staff should be aware that as many of the above symptoms could be attributed to other health problems, assumptions cannot always be made. In any doubt, the matter should always be referred to the pharmacist.

In all instances where medication is withheld due to a client being significantly intoxicated, the pharmacist must ensure that they inform the prescribing agency at the earliest opportunity.

2. Missed doses

Should a client fail to attend for their methadone/buprenorphine or if a dose is withheld due significant intoxication, the Pharmacist **must** indicate on the prescription 'not dispensed' next to the relevant date. This should also be indicated on the data collection forms.

All missed doses should be reported to the client's Keyworker the following working day.

Medication must not be dispensed to any client who has missed three consecutive doses. This is due to reduced opiate levels within the body and an increased risk of overdose. In all instances of a client attending for their medication after missing three consecutive doses, the pharmacist must withhold the client's daily dose and refer the client back to their key worker or prescriber before any further dispensing occurs. The Pharmacist should also inform the key worker that a dose has been withheld and must not issue any further medication unless a specific instruction to endorse this has been given by the key worker/prescriber or their nominated deputy at the prescribing agency.

In instances where a client disengages from treatment and stops attending for their medication, the pharmacist will return any prescriptions which have not been dispensed to the prescribing agency and should void them by indicating "not dispensed" across the prescription.

All emerging patterns of regular failures to attend for methadone supervision should be brought to the key worker's attention for investigation.

3.Supervised consumption of prescriptions from non-Torbay or -Devon prescribers

- Supervised consumption is available and limited to clients receiving methadone or buprenorphine treatment for the illicit drug dependence via the appropriate prescribing service in your area (**see section 3.6.1**). Pharmacies should ensure that prescriptions presented for supervision are by accredited prescribers before commencing this work. All prescriptions presented for supervision should be accompanied with a 3 Way Agreement/prescribing agreement.

The supervision of any medication prescribed by a prescriber who is not described in **3.6.1** of the service specification, including Drug Treatment Services outside of your local authority boundary ('out of area'), is not supported by this contract and pharmacies are not eligible for payments for such work under the Scheme. In the event of such prescriptions being presented to pharmacies for supervision, the pharmacy is advised to refer to the following guidance:

- Any Controlled Drug prescription from an 'out of area' prescriber (whether supervised or not) should be carefully scrutinized to ensure that it is genuine and has not been altered. (The normal reporting arrangements for reporting fraudulent/stolen prescriptions would apply.)
- Wherever possible, the pharmacist should contact the prescriber/drug clinic to confirm that the prescription is genuine and to ascertain if there is a process for reimbursement by the local authority of residence. This should be considered prior to accepting any prescriptions that are not from accredited services as you may not be able to claim any accrued costs for providing this service.
- The pharmacist should consider the potential risks associated with supervising a prescription from an out of area prescriber as this activity is not covered by the Devon or Torbay contractual agreement.
- Any additional queries regarding 'out of area' prescriptions should be directed to your local Public Health Team.

4. General guidance on working with drug users

Drug users can be challenging and rewarding people to work with, and it should not be presumed that all drug users are by their nature problematic to interact with. Clients are likely to sense any fear or hostility from pharmacy staff and will usually respond to staff in the same manner with which they have

been treated. Likewise clients are likely to respond kindly to a courteous and genuinely empathetic approach.

Pharmacy staff may often be the only members of the shared care team who see clients that are in treatment on a daily basis. As such, staff can play a valuable role in both supporting individual clients and monitoring their day to day progress in drug treatment. For many clients, appropriately chosen words of encouragement can be a valuable source of support. However it is also wise that staff are mindful of when to refer clients to discuss complex or ongoing matters with their key workers and not to get over-involved in a client's 'story' or problems. Some clients may have complex needs or may have experienced a number of problems which require specialist help.

Clients who are still stabilising on their medication may still be chaotic in their drug use. At times clients may present for supervision whilst they are experiencing opiate withdrawal symptoms ("rattling", "clucking" or "turkeying") and may be feeling physically unwell. What may seem like a reasonable wait to pharmacy staff may feel unbearable to the client and may explain hostility or discourteousness.

It is important that clients have clear and consistent boundaries and are treated equally by all staff members within the pharmacy, regardless of whether they are a long term customer or new to the Supervised Consumption Scheme. Clients often socialise with others who are also in treatment and will quickly hear if someone else receives what may be perceived to be "preferential treatment".

Drug use can result in unforeseen behaviour changes and a client who normally presents as stable and amenable may unexpectedly present in a challenging manner. Therefore pharmacy staff are advised to develop a working rapport with all clients which carefully tempers a friendly professional approach with a degree of caution that never assumes a client will not have a bad day or present in an unforeseen manner.

SCHEDULE 2 – CONTINGENCY PLANNING

1. Purpose

1.1 The purpose of the Contingency Plan should be to provide documentation of instructional and reference information for emergency response, back-up operations, and post-disaster recovery for the ongoing delivery of the supervised consumption service. The aim is to minimise disruption to the provision for clients in the event of the usual service being interrupted. This is important as the potential impact of a catastrophic event would be hazardous to the client and may have significant implications for the individual's family, friends and wider community if their treatment was disrupted in such a way.

1.2 The supervised consumption service scheme delivered by the Pharmacy is an essential component in the provision of effective harm reduction for clients. The possibility for critical events, either natural or man-made, damaging or disabling the delivery of this service is ever present.

A robust contingency plan should:

- Identified the critical risk areas and devised responses to address these risks in the event that they are realised
- Have the full approval and backing of the Pharmacy's senior management
- Have a system for testing the plan recommendations through exercises
- Be kept current

1.3 A functional Contingency Plan is able to identify, access and mobilise the relevant resources that will be required in the event that the pharmacy's usual structures and/or systems are affected- either partially or totally – as a result of a calamitous event.

2. Scope

2.1 When developing strategies for the Contingency Plan, it is helpful to consider the entire range of probable and possible threats that present a risk to delivery of the supervised consumption service. From that range of threats, likely scenarios can be developed and appropriate strategies applied. A disaster recovery plan should be designed to be flexible enough to respond to extended business interruptions, as well as major disasters.

2.2 The scope of the Contingency Plan must include, but not be limited by the following crises:

- A damaged or destroyed building. For example, in the event of fire or flooding
- Key pharmacy staff, such as the pharmacist, being unexpectedly absent
- The disruption of supplies and safe storage and dispensing of medications by the supervised consumption service

2.3 The Plan must encompass, and specifically address, each critical system that is either owned or under the control of the Pharmacy. It should accomplish the following:

- Minimise the number of decisions that must be made during a crisis
- Identify actions that will be undertaken by pre-designated individuals or teams
- Identify the resources that are needed to execute the actions defined by the plan
- Identify which critical functions and processes will be prioritised during the recovery phase
- Define the process for testing and maintaining the Plan as well as training for staff in regard to the Contingency Plan, including the frequency and scale of these activities

2.4 In addition, the Contingency Plan must also include:

- Any assumptions that the Contingency Plan is based upon
- The authorising signature of the relevant senior manager or pharmacist
- The names and titles of those who have contributed to the Contingency Plan

- Details of where the Contingency Plan is held and who has access to it, in the event that it needs to be implemented

3. Contingency Process

3.1 In the event of a disaster or other circumstances which bring about the need for contingency operations, the normal organisation of the Pharmacy will shift into that of the 'contingency organisation'. The focus will, therefore shift from the usual structure and function of the pharmacy, to one that is working towards the resumption of normal service as quickly and smoothly as possible.

3.2 The contingency process consists of two main phases – responding to the event and recovering from the event. The Contingency Plan, therefore, is expected to cover both these aspects.

4. Responding to the event:

1. Identification of the staff member(s) responsible for responding to the incident in the first instance, i.e. at the point of occurrence. This should include the assessment of the immediate impact of the incident and the level of disruption to service that this poses.
2. Specifying the immediate actions will be taken according to the disruption that will be experienced.
3. Identification of the staff member(s) or management team that will oversee and coordinate the initial response to minimise the disruption of supervised consumption provision for clients.
4. Defining the actions that will be taken to mobilise and activate any alternative delivery mechanisms. For example, using alternative dispensing arrangements to ensure ongoing delivery of the supervised consumption service.
5. Specifying who will appraisal and notification of staff, managers and other internal individuals in the pharmacy organisational structure so that they can fulfil their responsibilities as defined in the contingency plan. It must be clear how this will be achieved.
6. Defining the notification procedures to make clients aware of the situation and how they will be able to access the medication as prescribed.
7. Alerting and notifying individuals and organisations that are external to the pharmacy. This must include information about what remedial action is being taken to minimise disruption of provision to clients. External individuals/organisations that must be immediately notified include prescribers and the Public Health Team.

5. Recovery from the critical incident:

1. Identification of the manager, pharmacist or staff member(s) responsible for coordinating and implementing the recovery plan so that 'normal service' can be resumed.
2. Specifying the actions that will be taken, in addition to the time-frame that these will be completed in, so that the pharmacy is able to resume the delivery of the supervised consumption service.
3. Defining the communication plan that will be implemented so that all parties have the appropriate information at key points in the recovery process.