1. Population Needs

1.1 National/local context and evidence base

The National Drug Strategy (2010); and “Medication in Recovery: Re-orientating drug dependence Treatment” (2012) formalised a shift of emphasis from treatment interventions to an integrated, personalised approach better suited to promote positive impacts on service users. This now promotes focusing on a person’s potential for recovery and the progress that they make towards the goal of abstinence.

The drug and alcohol misuse agenda has also been impacted by changes in the wider economic, social and political environment. These include the National Treatment Agency being integrated into Public Health England in April 2013 and the administration of funding for drug and alcohol services becoming the responsibility of Public Health teams within local authorities.

Locally the responsibility for commissioning, contracting, monitoring and evaluating substance misuse provision has been transferred to the new Drug and Alcohol Action Team Board which replaced the Joint Commissioning Group in April 2013.

In order to ensure that strategic purchasing partnership plans meet the needs of the local population, and in fulfilment of statutory duty, it is necessary that all provision is clearly specified, costed and evaluated, to ensure it is providing relevant high quality services at value for money. Public Health England will take a leading role in the performance management of drug treatment at a local level and will monitor treatment spend in each area.

2. Aims and Objectives

2.1 Aims

The overall aim of pharmacy supervised consumption is to reduce relapse rates, decrease health risks to the user and others in the community and reduce the risk of medicines being diverted to the illicit market.

2.2. Objectives

Objectives of pharmacy supervised consumption

The specific objectives of pharmacy supervised consumption are to:

- Optimise the benefits Service Users obtain from prescribed methadone and buprenorphine (Subutex)
- Ensure methadone and buprenorphine (Subutex) is administered in accordance with the prescriber’s instructions
- Ensure, as far as possible, that methadone and buprenorphine (Subutex) prescribed is used only by the service user
- Ensure adequate blood levels of methadone and buprenorphine (Subutex)
are maintained, therefore reducing the need for other opiates
- Reduce the risk of accidental overdose
- Prevent the diversion of prescribed methadone and buprenorphine (Subutex)
- Provide greater professional support to the Service User through regular contact with a community pharmacist
- Improve communication with the prescriber

**General objectives**

- To offer user-friendly, non-judgemental, Service User-centred and confidential services
- To encourage the uptake of services by ex-offenders, hard to reach groups, and those not engaged in treatment services
- To encourage those not engaged in treatment to access specialist services
- To increase access to treatment for drug misusers in primary care
- To prevent the risk of drug-related harm, including drug-related death
- To promote health through the provision of harm reduction facilities
- To conform with the 1999 Department of Health ‘Drug Misuse and Dependence Guidelines on Clinical Management’
- To develop good levels of communication with partners organisations and adopt agreed working protocols on referrals and monitoring and reporting requirements

### 3. Scope

#### 3.1 Location(s) of Service Delivery

Pharmacy stipulated as Provider

#### 3.2 Population covered

Supervised consumption services will be made available to all adult injectors/opiate drug users who have significant connection with the Isle of Wight.

#### 3.3 Scope

**Service Outline**
The pharmacy should offer a user-friendly, non-judgmental, client-centred and confidential service.

In line with NICE guidance, the Pharmacy will provide support and advice to clients accessing the service, including information. Pharmacists will need to share relevant information with other health care professionals and agencies, (contact list) in line with locally determined confidentiality arrangements, including, where appropriate, the need for the permission of the client to share the information.

- Pharmacists will complete treatment forms on PharmOutcomes
- The Isle of Wight Council should arrange at least one contractor meeting per year to promote service development and update pharmacy staff with new developments, knowledge and evidence.
The Isle of Wight Council will provide up to date details of other services which pharmacy staff can use to refer service users who require further assistance, including the location, hours of opening and services provided by each service provider.

The supply and support will be made free of charge to the client, other than the collection of a prescription charge from patients that do not qualify for exemption.

The services to be commissioned by the Isle of Wight Council’s Public Health Department from the participating pharmacies are:

a) Supervised consumption

A community based supervised consumption service located at participating pharmacies and delivered by pharmacists for dispensing prescribed substitute medication for problem substance users, and supervising onsite consumption.

The participating pharmacies will work in partnership with other drug service providers in the catchment area within a tier-based structure of care delivery for treatment of drug misuse. The participating pharmacies shall respond to self-referrals and referrals, and shall prioritise any urgent needs that arise on a day-to-day basis.

The participating pharmacies will provide the following services:

**Supervised consumption Service:**

- Accept the supervision responsibilities for Service Users who have been referred as suitable for the service and are being prescribed by a specialist or GP medical doctor
- Agree and facilitate dispensing arrangements with Service User
- Supervise the consumption of the substitute medication (i.e. ensure the prescribed does has been swallowed by the Service User)
- Monitor attendance and report regular missed doses and any other concerns
- Work in partnership with the prescribing service (specialist or GP) and the Service User keyworker

It is expected that other local drug services and allied services shall build working links with the participating pharmacies in pursuit of seamless provision for service users, developing partnership protocols, sharing information as necessary and engaging in good practice. Key local partners shall include, but are not limited to:

- Island Recovery and Integrated Service (IRIS)
- GPs and Primary Care Services
- Criminal Justice Services
- Cranstoun
- Hospital Trusts (including Accident and Emergency)
- Community Mental Health Teams
- Antenatal services
- Local Authority Departments

**3.4 Eligibility to provide the service**

A pharmacy may be accepted for the provision of this service if it has a partner, employee or sub-contractor who has the necessary skills and experience to carry
APPROVED PROVIDER LIST FOR THE PROVISION OF SUPERVISED CONSUMPTION

out the contracted procedures.

The pharmacy contractor will ensure that pharmacists complete the CPPE Substance Use and misuse – delivering pharmacy services (e-assessment).

The pharmacy contractor has a duty to ensure that pharmacists and staff involved in the provision of the service have relevant knowledge and are appropriately trained in the operation of the service.

The pharmacy contractor has a duty to ensure that pharmacists and staff involved in the provision of the service are aware of and operate within local protocols.

The commissioner should be informed of new permanent pharmacists. Pharmacies should ensure that their locums are suitably qualified to provide this service.

Pharmacists and other members of the pharmacy will also be expected to participate in relevant periodic updates, meetings and refresher training as and when required.

Management of the services

The overall responsibility for the management of the services to be provided will lie with the principle pharmacist of each participating pharmacy. The day-to-day operational line management of pharmacy staff will be that of the principle pharmacist of each participating pharmacy who will:

- Provide day to day operational line management
- Provide appropriate professional supervision for staff

For supervised consumption, the drug treatment services, responsible for prescribing, will be responsible for deciding which service users are eligible for supervised consumption and for notifying the relevant pharmacist. The IOW Public Health Drug and Alcohol Commissioner will be responsible for the pharmaceutical aspects of the service, monitoring and authorising payments to community pharmacists and monitoring participating pharmacies for provision of the service in accordance with agreed standards and guidelines. Where necessary advice will be sought from the IOW Clinical Commissioning Group Pharmaceutical Adviser.

The Services will comply with any future specifications for treatment modalities introduced by Public Health England as advised by the local drug and alcohol commissioner.

Staffing

Pharmacists shall conform to their respective professional bodies conditions of employment and abide by their clinical and professional standards. They shall be employed at appropriate clinical and professional grades, and be suitably qualified, competent and experienced to meet the requirement and responsibilities of the service.

Supervised consumption

Participating pharmacists will be expected to have attended a training event on
managing patients on methadone programmes and to be aware of, and adhere to, the standards for instalment dispensing included in the Royal Pharmaceutical Society’s Standards of Good Professional Practice. Recommended training packages include the CPPE distance learning pack “Pharmaceutical aspects of Methadone prescribing” and the CPPE distance learning pack “Drug use and misuse.”

All staff must be given a structured induction into the service, receive regular supervision and ongoing management support. At no time should staff exceed their level of professional ability by performing tasks or part of the service for which they are not qualified or trained.

The pharmacists shall provide effective and appropriate cover arrangements where staff are absent or vacancies exist; ensuring that professional cover is provided by a suitable trained and competent pharmacist. This will ensure the continuity of service and safety of Service Users and others.

The pharmacists shall operate a Diversity Policy with regard to all aspects of staff employment i.e. recruitment, training, policies, procedures. The Pharmacists shall ensure, as far as is reasonable, that they have access to interpreters to communicate with those people who do not use English as a first language or for those needing ‘signing’.

The Rehabilitation of Offenders Act does not apply and therefore the provider shall ensure that all staff working in the service declare any previous convictions. All staff employed by the service provider shall have been subject to a Data Barring Service (DBS) check and details shall be available for inspection by the purchaser. If a member of staff declares or is found to have previous convictions, their participation in delivering the service must be agreed with the commissioner.

3.5 Interdependencies

The Service cannot work in isolation and those delivering the service are required to work with partners to address the needs of service users and increase the opportunity for service users to achieve optimum sexual health outcomes. The provider will maintain effective working relationships with allied services, agencies and stakeholders to enhance the quality of care delivered and ensure the holistic nature of the service.

4. Expected Outcomes

4.1 Public Health Outcomes Framework 2013-2016

The Department of Health Public Health Outcomes Framework 2013-2016 includes the indicator, 2.15 ‘Successful completion of drug treatment’. The service will support delivery against this Public Health Outcome measure.

4.2 Local Outcomes

The Service will also aim to achieve the following local outcomes:

- Increasing the numbers of Pharmacists and other members of staff trained
to deliver
- Supervised consumption
- Regular continuous professional development (CPD)
- Provision of all required data
- A satisfactory system of audit to be in place

Service delivery expectations:
- Excellent patient satisfaction
- High quality treatment and advice in line with recognised clinical standards and best practice
- Clinical outcomes at least as good as those achieved by comparable NHS Providers
- Provider participates in relevant National and Local audits.

4.3 Key Quality and Performance Indicators

Performance Indicators
- Number and type of episodes of supervised consumptions

Quality Indicators
- The pharmacy should have appropriate Health Promotion material available for the potential client group and promotes its uptake.
- The pharmacy should review its standard operating procedures and the referral pathways for the service on an annual basis.
- The pharmacy should be able to demonstrate that pharmacists and staff involved in the provision of the service have undertaken CPD relevant to this service.
- The pharmacy should co-operate with any Isle of Wight Council led assessment of service user experience.
- The pharmacy must provide a reliable, regular service and in the event of circumstance changing within the Pharmacy rendering them unable to deliver the service, must contact the Isle of Wight Council to allow changes to signposting.

5. Applicable Service Standards

5.1 Applicable national standards
- The National Drug Strategy (2010);
- Medication in Recovery: Re-orientating drug dependence Treatment (2012)
- Royal Pharmaceutical Society guidance on the operation of needle and syringe exchange schemes (1996)
- Quality in Alcohol and Drug Services (QUADS) (1998) Alcohol Concern/SCODA
- PH18 Needle and syringe programmes: NICE Guidance (2009)

5.2 Applicable local standards
The provider will agree that access to records and documents containing information relating to individual patients treated under the terms of this agreement will be restricted to authorised personnel and that information will not be disclosed to a third party. Both parties will comply with the Data Protection Act, Caldicott Guardian and any other legislation covering access to confidential patient information.

The provider must follow and work within the Isle of Wight Local Safeguarding Children Board (LSCB). Guidance and information which can be found on the following website: http://www.4lscb.org.uk/isleofwight/

Representatives of LSCB have the right to visit the pharmacy at any reasonable time, having regard for the provision of services and the patient’s right to privacy and dignity

The provider will be responsible for ensuring on-going training and registration or membership of appropriate professional bodies.

5.3 Supervised consumption

All community pharmacists are required under their terms of service to dispense prescription for methadone, in addition or the provision of a needle syringe exchange scheme to drug misusers. Methadone oral mixture has been the principal treatment for opiate addiction. Inappropriate individual usage has resulted in national substance misuse strategies recommending that patients who are prescribed methadone should be required to take their daily does under direct supervision, where clinically indicated. The use of buprenorphine (Subutex) is an alternative to methadone for treatment of opiate addiction, and has been included in the supervised consumption scheme since April 2003.

Methadone should only be dispensed under supervision if the Service User is being prescribed under an agreed care plan by a Tier 3 specialist prescribing service or a GP practice. The Drug treatment service will have carried out an assessment and recommend a dose of methadone and the basis on which it should be prescribed, e.g.: reducing / maintaining. The Drug treatment service will also have written into the Service User’s care plan dispensing details. e.g. frequency of pick-up and whether consumption should be supervised.

Referrals

Referrals for supervised consumption will be made by Tier 3 specialist treatment agencies. There will be no open access to supervised consumption. Referring agencies will have assessed the Service user’s needs as suitable for pharmacy supervised consumption. There will be no prescribing of tablets or injectables as part of this agreement. The drug treatment service will decide the dose of Methadone or other opiate substitute to be prescribed. and thereby takes full clinical prescribing responsibility.
The drug treatment service will have explained the operation of the supervised consumption service to the Service User. The service user will be asked to nominate their choice from the list of participating pharmacies. The drug treatment service will make the referral to the pharmacist to seek agreement with this, prior to the service user presenting to the pharmacy.

The Service user will see the assessing Doctor at agreed intervals and will normally receive a prescription for oral Methadone mixture or buprenorphine (Subutex) from them following clinical guidelines set out by the DoH (Orange Book). The prescriber will issue a prescription for daily instalments that complies with the legal requirements and which clearly states that administration is by supervised consumption. Arrangements for providing supplies to cover Sundays and Public Holidays shall be stated on the prescription.

Service Users will be regularly reviewed by treatment services (usually three monthly) to include:

- Physical and emotional assessment
- Review of past three months to assess if Service User is ready to move on to less supervised prescribing.
- Service User’s future goals

The pharmacist shall be supportive with an understanding attitude and shall try to maintain a friendly, but professional relationship with the Service user. At the first meeting between the pharmacist and the Service User, they will together draw up and sign an agreement which states:

- The most appropriate time for collection of Methadone or other opiate substitute
- The arrangement for weekend and bank holiday doses
- That the Service User must demonstrate that they have swallowed the dose. (For supervised administration)
- That unsuitable or offensive behaviour towards the Pharmacists or their staff will result in the termination of the agreement
- That Methadone will not be supplied or supervised if the patient is intoxicated by drug or alcohol
- That the treatment provider will be told of regularly missed doses
- That if three or more doses are missed, the treatment provider will review the prescription before supply is considered
- That missed doses will not be supplied on a later date
- What to do if the Service User cannot attend

The pharmacy shall have in place a written operation protocol for all staff, including locums. The protocol shall include the following guidelines for dispensing and supervising oral consumption:

- Maintenance of records, including patient medication records
- The daily dose should be dispensed and labelled appropriately before the Service User arrives (when a prescription is current).
- The Service User’s identity should be checked before the dose is administered.
- The supervision procedure should be discreet and efficient to be mindful of the Service User’s dignity and the Pharmacist’s time.
Supervision should, ideally, not take place in the dispensary.
The Service User can check the name and quantity and dose on the label
before swallowing. The dose may be poured into a plastic cup.
The Pharmacists must be satisfied that the dose has been swallowed, either
by water being swallowed after the Methadone dose has been given,
conversing with the patient or other means of ensuring that the Methadone is
not retained in the mouth.
The disposal of waste
Sunday and bank holiday doses should be dispensed and labelled
appropriately for collection on the day before.
The Treatment Service and Pharmacists will agree on a suitable time to
discuss any issues which arise from treating a patient through this
agreement.
The Treatment Agency and Pharmacist will agree what information is to be
communicated.
Confidentiality

The daily dose should be measured into an opaque container, capped and labelled
so that when the service user arrives, the measured dose may be poured into a
disposable cup. The pharmacist shall be satisfied that the dose has been
swallowed either by water being swallowed after the dose, conversing with the
patient or other means, so as to ensure that the methadone is not retained in the
mouth.

The supervised consumption shall be undertaken in a designated area of the
pharmacy, which provides the Service user with adequate privacy. The procedure
shall be carried out in a discreet and timely manner.

Doses that are intended to be taken on Sundays or Public Holidays should be
dispensed in a container with a child resistant closure and appropriately labelled.
The pharmacist shall take every opportunity to emphasise the need for safe storage
of all medicines in the home, especially methadone.

If the pharmacist considers the service user’s behaviour is unacceptable of the
service user appears to be grossly intoxicated or unwell, the drug treatment service
shall be contacted and the dose withheld.

Waste should be disposed of safely and steps taken to minimise possible risks of
infection through meticulous hygiene and immunisation of staff where appropriate.
Service user identifiable labels should be removed from containers prior to disposal
(to safeguard confidentiality).

Pharmacists shall maintain a complete service user medication record in respect of
each service user for whom methadone is dispensed.

Compliance with legal requirement for the supply of controlled drugs is essential.

The Pharmacist will report to the treatment service if:-

- Regularly missed doses or whole doses are not consumed under
  supervision
- Service User is attempting to or wishes to avoid supervised consumption
- Three or more consecutive doses are missed
- The Service User displays unacceptable behaviour
- The Service User is Intoxicated
• There is deterioration in health and other health concerns
• There are problems concerning the prescription
• A Service User requests supervision

The pharmacies shall also conform to the Standards for Good Professional Practice for Pharmacists of the Royal Pharmaceutical Society for pharmacists who elect to become involved in schemes to exchange clean syringes and needles for contaminated equipment used by injecting substance and drug misusers and instalment dispensing.

6. Referral, Access and Acceptance Criteria

6.1 Referral route

Service Users will have been assessed through IRIS. On occasions, referrals will have been made by other treatment services such as General Practice.

6.2 Any acceptance and exclusion criteria and thresholds

Eligibility for supervised consumption service will be by agreement with prescribing services for those Service Users who have been assessed, and whose drug using needs can be met through the support of supervised consumption, in conjunction with either specialist prescribing services (e.g. IRIS or a prescribing GP).

Exclusions for supervised consumption

Supervised consumption will not be available for those Service Users who have complex needs and need to be supported by a Tier 3 specialist prescribing service for further stabilisation.

Service Users shall be resident in, or have a significant connection with the catchment area. Significant connection will be based on the local authority definition of ‘ordinarily resident’. The catchment area is the IOW Safer Communities area. Service Users may be excluded as a result of a professional risk assessment and if they pose a serious risk to staff, other service users and members of the public. The Provider has the right to refuse service provision to the users:

• who are unsuitable for treatment/care under the service on clinical grounds;
• who are temporarily unsuitable for treatment under the service on clinical grounds for as long as such unsuitability remains;
• who have not validly consented and were able to do so, or had consent validly given on their behalf where it could have been, to the treatment provided under the service;
• whose behaviour is unacceptable to the provider because it is unreasonable, notwithstanding that the judgments in those cases must take into account the mental health of such patients.

7. Monitoring
Pharmacies are required to input activity immediately onto the PharmOutcomes system once the consultation has taken place. Information provided will provide the basis of the remuneration for pharmacies.

8. Self-Care and Patient and Carer Information

Providers must provide appropriate patient and carer information as relevant for the patient's condition / complaint. Where appropriate, and to ensure ease of use and understanding by patients and carers, this information shall be provided in languages other than English and in formats other than written documentation.

9. Prices & Costs

9.1 Price

Payment for supervised consumption and needle exchange will be made monthly, in arrears, once activity has been recorded on the PharmOutcomes system.

<table>
<thead>
<tr>
<th>Basis of Contract</th>
<th>Unit of Measurement</th>
<th>Price (excluding std VAT)</th>
<th>Thresholds</th>
<th>Expected Annual Contract Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>PbR</td>
<td>Per recorded observation of methadone solution</td>
<td>£2.00</td>
<td></td>
<td></td>
</tr>
<tr>
<td>PbR</td>
<td>Per recorded observation of Buprenorphine</td>
<td>£4.00</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>