



Response to Request for Information

Reference FOI 001285
Date 3 July 2017

Commissioned Services and Community Pharmacy

Request:

Could you please supply me with some information regarding commissioned services and community pharmacy. I would like to know:

1. What services are currently commissioned through community pharmacy.
[Needle Exchange](#)
[Supervised Consumption](#)
[Smoking Cessation](#)
[Nicotine Replacement Therapy](#)
2. Please send SLAs or service specifications for each commissioned service
[Please see attached specifications.](#)

and details of lead commissioner plus contact details.

Juliet.Grainger@wolverhampton.gov.uk

[Tel 01902 551028](tel:01902551028)

3. Date that each service ends.
[31 March 2018](#)
4. Do you commission any services through other providers and if so what services and who are the providers, please include contact details.
[Emergency Hormonal Contraception is sub contracted to community pharmacists via our main sexual health contract with the Royal Wolverhampton NHS Trust, New Cross Hospital, Wolverhampton, West Midlands, WV10 0QP.](#)

[Contact Laura Morris, Head of Contracting and Business Intelligence.](#)

[Tel: 01902 307999](tel:01902307999)

5. Are there any future services being looked at and if so what are these services.
[N/A](#)

SERVICE SPECIFICATION

Service Specification Number	Lot 4 - PP
Service	Intermediate Stop Smoking Services
Commissioner Lead	Michelle Smith
Period	1st April 2016 – 31st March 2018
Date of Review	Annual basis

1. Introduction

This service specification sets the requirements for the provision of a Public Health service for intermediate smoking cessation support.

The provision of high quality Stop Smoking Services is a priority for Wolverhampton City Council and seen as a key means of securing health improvement. Stop Smoking Services commissioned or provided by the NHS have already helped many people to stop smoking successfully and are a key part of tobacco control and health inequalities policies at both local and national levels.

1.1 National/local context and evidence base

Smoking remains the leading cause of death and illness in the UK. Although smoking prevalence is falling nationally it is estimated there are still approximately 43,000 smokers in Wolverhampton. Smoking can contribute towards the development of many diseases, but is most commonly linked with cancer, cardio-vascular disease and respiratory disease. For those who smoke, quitting is often the single most effective method of improving health and preventing illness.

Smoking is also a key driver of health inequalities. Smoking prevalence is highest in deprived communities however reductions in smoking prevalence have been slower in these communities than in other population groups. Reducing the prevalence of smoking in pregnant women, routine and manual workers, some minority ethnic groups and disadvantaged communities will help reduce health inequalities more than any other measure to improve the public's health. The Smoking Still Kills report has proposed new targets to:

- Reduce smoking in the adult population to 13% by 2020 and 9% by 2025
- Reduce smoking in the routine and manual socio-economic group to 21% by 2020 and 16% by 2025
- Reduce smoking among pregnant women to 8% by 2020 and 5% by 2025
- Reduce regular and occasional smoking among 15-year-olds to 9% per cent by 2020 and 2% by 2025.

Reducing the number of people that smoke is an important priority for us all because of the well-known benefits to the health of both individual smokers and those around them. Public

Health in the Local Authority is responsible for a programme of work to improve local stop smoking services. A range of local approaches is needed, particularly the provision of stop smoking services in community settings and targeting hard to reach and higher risk groups.

The support provided by local stop smoking services continues to offer some of the best opportunities to stop smoking, proving up to four times more effective than attempting a quit unassisted and twice as effective as the provision of a stop smoking medicine by a health care professional. PH45 Tobacco: harm reduction approaches to smoking issued in June 2013 also recommends that harm reduction approaches may be helpful for people who:

- May not be able (or do not want) to stop smoking in one step
- May want to stop smoking, without necessarily giving up nicotine
- May not be ready to stop smoking, but want to reduce the amount they smoke.

1.2 Social Value Considerations

Smoking Cessation and other public health services address diseases and lifestyle behaviours which disproportionately affect socially disadvantaged communities in Wolverhampton. These include prevention of cancers and cardiovascular disease and supporting citizens to make healthy lifestyle choices, such as stopping smoking.

Through the prevention of smoking related diseases in the longer-term, smoking cessation services improve the economic and social well-being of Wolverhampton residents by keeping them healthier for longer, thereby reducing illness- related absence from the workplace and consequently decreasing demand on social care.

2. Key Service Outcomes

2.1 Insert any locally agreed outcomes and quality requirements which are NOT Quality Outcomes Indicators which should be set out in Appendix C (*Quality Outcomes Indicators*)

The intermediate Stop Smoking Service shall help to increase choice and improve access to smoking cessation support, including monitoring and follow up in community based settings. The Service shall provide intensive support to smokers in Wolverhampton and will be run by advisors who have received training in line with the NHS Centre for Smoking Cessation and Training (NCSCT). The service shall refer to specialist services if necessary.

The service contributes to the following Public Health Outcomes Framework indicators:

- Smoking status at time of delivery (2.3)
- Smoking prevalence – 15 year olds (2.9)
- Smoking prevalence – adult (over 18s) (2.14)
- Low birth weight of term babies (2.1)
- Infant mortality (4.1)
- Mortality from causes considered preventable (4.3)
- Mortality from all cardiovascular diseases (including heart disease and stroke) (4.4)
- Mortality from cancer (4.5)
- Mortality from respiratory diseases (4.7)

3. Scope

3.1 Aims and Objectives of service

Aims

The aim of the Service is to improve access to and choice of stop smoking services in order to reduce smoking related illnesses and premature deaths.

This shall be achieved through:

- The provision of high quality, evidence based stop smoking support including access to pharmacological stop smoking aids
- Proactive identification and recording of smoking status of clients, including pregnant women who can be signposted to early bird antenatal clinics and Healthy Lifestyles Service (HLS).
- Communication of risk and offering smoking cessation advice to current smokers
- The setting of a quit date in agreement with smokers
- The recording of four week and twelve week quitters
- Recording validated quit status i.e. via a carbon monoxide (CO) reading
- Improving the health of the population by reducing exposure to second hand smoke.

3.2 Service description

3.2.1 Service outline

- The Service shall provide evidenced based smoking cessation interventions; monitoring and follow up in accordance with NICE, NCSCT and NHS guidance.
- Staff involved in the delivery of smoking cessation interventions (“Smoking Cessation Advisors”) shall be trained in accordance with the standards recommended by the NCSCT. Local training (Level 2) is provided by the Local Stop Smoking Specialist Service, within Wolverhampton Healthy Lifestyles Department.

Smoking Cessation Advisors shall provide services in accordance with national quality principals and guidelines. The role of the Smoking Cessation Advisor is to:

- Assess the person’s readiness to make a quit attempt
- Inform the service user of the structure and process of the intervention
- Assess nicotine dependence and Carbon monoxide levels and offer appropriate feedback
- Apply appropriate behavioural support strategies to help the service user quit
- Establish the patient medical history, previous use of pharmacotherapy, and any other current medication to ensure the supply is safe and appropriate
- Offer comprehensive advice about available and appropriate drug treatments (Nicotine Replacement Therapy (NRT), Bupropion Hydrochloride and Varenicline) and methods of access and assess the person’s willingness to use treatment
- Reinforce the motivation to quit and support and advise the client on setting a quit date NRT must not be supplied unless a quit date has been set
- Arrange for the supply of the choice of treatment as agreed with the client

- Build a repertoire of coping strategies
- Describe the effects of passive smoking on children and adults
- Monitor pharmacotherapy use, in collaboration with the service user's GP, as required
- Provide information on the nature of tobacco withdrawal and advice on the management of withdrawal symptoms and barriers.

Smoking cessation interventions should:

- Be conducted in a private consultation area
- Include multi-session interventions with total potential client contact time being a minimum of 1.5 hours (from pre-quit preparation and during the four week post quit) to ensure continued monitoring and client/patient compliance.
- Address client specific problems.
- Verify (and record) four and twelve week quit status with carbon monoxide (CO) validation.
- Take into account cost effectiveness when assisting clients with the most suitable therapy.

The provider will receive support from the Wolverhampton Healthy Lifestyles Service who will:

- Provide staff with smoking cessation training and accreditation in accordance with national training standards
- Provide posters to indicate that the service is available - the provider must display at least one marketing resource at any one time
- Provide the service with relevant stop smoking services materials and resources, including a carbon monoxide monitor.
- Provide training on the use of CO monitors, calibration of monitors and replacement of very old or faulty machines
- Provide support with annual update training sessions for all intermediate Smoking Cessation Advisors, and by providing telephone and online support
- Promote the service.

The provider shall:

- Ensure that the service is fully available to those who live, work or are registered with a GP in Wolverhampton aged 12 and over.
- Ensure that the service can be suitably provided to young people under the age of 16, ensuring that at least one advisor meets the requirements for providing the Service to young people. This will include consent from Young People to provide service in accordance Fraser guidelines and Gillick competency.
- Undertake a comprehensive initial assessment with every service user.
- Where possible this service should be available during evenings and weekends.
- Offer a continuous service during all days of opening.

Follow up Consultations

Staff shall:

- Undertake all follow up consultations in line with NICE and the NCSCT 12 week

treatment plan guidelines. All interventions should be weekly for the 1st 4 weeks and then every 2 weeks up to 12 weeks quit. This is part of the Standard treatment programme recommended by the NCSCT.

- Agree timescales for each follow up consultation with the service user.
- Undertake an assessment of smoking status based upon the service users' self-report followed by a CO test for validation at all 4-week and 12-week follow up consultations.
- Provide support to the service user via the provision of the service for up to 12 weeks.
- If service users wish to continue to use NRT after the 12 week period, they should be referred back to either the specialist service at the HLS or GP.
- Service users not wishing to initially engage with the service, or those who do not complete the programme, shall be offered appropriate health promotion literature and provided with the HLS telephone numbers.
- If service users are not able to access the service, (this may be because another setting or geographical area would be preferred) they should be given the local HLS contact telephone numbers.

3.2.2 Referral, Access and Acceptance Criteria

All smokers who live, work in or are registered with a GP in Wolverhampton are eligible for this service.

Service providers must have the capacity to offer an appointment within a week of referral.

3.2.3 Contradictions and exclusions

Staff shall not provide smoking interventions to pregnant customers unless advisors have completed the NCSCT Smoking in Pregnancy Module. If staff have not been trained customers shall be referred to the HLS Positive Pregnancy and Beyond service (Tel: 01902 444246).

The smoking advisor should check whether the customer has any co-morbidities or is on any other medication that might interact with NRT.

Providers shall not be or become a subsidiary of the Tobacco Industry.

3.2.4 Interdependencies with other services

Providers who choose to deliver against this specification are required to work closely with the Healthy Lifestyle Service (HLS) for guidance and the monitoring of all quit attempts. Community Pharmacies will be responsible for the exchange of vouchers for Nicotine Replacement Therapies.

- The provider shall refer consenting customers with unhealthy lifestyles to the HLS
- The HLS shall collate, quality assure and report data on smoking outcomes delivered by the Intermediate - Stop Smoking Advisor.

The Healthy Lifestyle Service shall provide quarterly reports: see Key Performance Indicators and Quality requirements on performance activity against this specification. Payments will be based on the data included in these reports.

3.2.6 Business Continuity

The provider is responsible for ensuring that adequate arrangements are in place for continuity of the service and will notify the commissioner in the event of staffing shortages, facilities and system failures appropriate to the service.

3.2.7 Equality and Diversity

Providers should ensure that their services are clearly understood and can be accessed by individuals from new communities who may not have English as a first language or be literate in their own language. Where a GP provides the service they will be required to demonstrate that interpreting services are in place for those who require them. A clear policy on the provision of interpreting must be demonstrated.

The National Health Services (Charges to overseas visitors) regulations 2015¹ introduced changes to the entitlement to free NHS treatment for several groups. These regulations do not affect primary medical services, dental or ophthalmic services. There are no restrictions on migrants or overseas visitors registering with a GP.

This service will be delivered in accordance with the following legislation:

- The Race Relations Act 1976 and Amendment Act 2000
- The Equality Act 2010
- The Human Rights Act 1998
- The Health and Safety at Work Act 1974

3.2.8 Minimum Activity Level

The provider shall aim to achieve a minimum of 5 four week quits per quarter. This is to ensure that staff providing the smoking interventions achieve enough activity to maintain their competences.

Delivering behavioural support for smoking cessation is a clinical activity that needs to be carried out regularly so that the quality of support is maintained and to ensure that it 'adds value' to a quit attempt. The NCSCT has therefore established the term 'active stop smoking practitioner', referring to someone who supports a minimum of 20 smokers to set a quit date each year. Any less than this and it will be difficult for a practitioner to maintain the knowledge and skills necessary to deliver evidence-based smoking cessation interventions.

¹ The NHS Charges to overseas visitors regulations 2011(Statutory instrument 2011 No. 1556 and 2012 No 1586)
<http://www.legislation.gov.uk/ukSI/2011/1556/contents/made>

3.3 Criteria for participation in the scheme

The provider must ensure that all staff delivering brief advice and smoking interventions are appropriately registered, trained and competent to deliver the service as specified in 3.3.1.

1. The service provider must ensure all members of staff are able to demonstrate their participation in relevant mandatory training; and that education and training needs of staff providing the service is supported.

3.3.1 Accreditation

Required training & Qualifications

The accountable person for the service is the lead pharmacist who has applied to provide the service however for the purposes of operational delivery the term pharmacy staff will be referred to.

1. Staff involved in the provision and/or accountability of this service must have completed the 'Stop Smoking – very brief advice' e-package (NCSCT version).

~~3.2.~~ All staff providing stop smoking intermediate interventions must be fully trained to NCSCT level 2 and be required to complete the Wolverhampton Healthy Lifestyle Service training programme in order to comply with local paperwork requirements and local context. All staff should participate in shadowing, co-facilitation and be signed off by the Healthy Lifestyles Service that they are competent to deliver the service unsupervised.

~~4.3.~~ All staff delivering intermediate stop smoking services shall attend annual update training with the Healthy Lifestyles service. These are held twice per annum in order to ensure that the service is continually improved and updated.

~~5.4.~~ Providers shall be responsible for identifying their own learning needs and recording their Continuing Professional Development (CPD).

~~6.5.~~ Making Every Contact Count online training, information and resources available at www.makingeverycontactcount.co.uk

3.3.2 Premises and Equipment

All resources equipment and maintenance for the delivery of the respective service remain the responsibility of the service provider.

The service will provide a private consultation room to conduct the smoking interventions.

4. Clinical Governance

Robust clinical governance arrangements will take account of the providers existing governance infrastructures with regards to risk management, quality assurance processes, Incident reporting and complaints management. Overarching governance arrangements will be finalised following award and with full co-operation of the provider.

4.1 Incident reporting

Incident reporting will reflect national and local reporting arrangements.²

Providers are required to report any of the following incidents in writing to phcommissioning@wolverhampton.gov.uk:

- any clinical incidents which may cause harm or directly affect a service user
- any events that may stop or disrupt the service from operating normally or safely
- any medicine or medical device adverse incidents via the [Medicines and Healthcare products Regulatory Agency \(MHRA\) Yellow Card Scheme](#)

Providers must Inform the commissioner within two working days of any incidents occurring and will investigate incidents; implement any action and recommendations following investigation and share lessons learned.

4.2 Responding to National Patient Safety Alerts

- Commissioners will require assurance that all safety alerts applicable to the provider will be responded to appropriately via the national Central Alert System (CAS)
- Providers are required to keep a record of what has been done to implement or comply with alerts
- Providers will inform commissioners, within the timeframe stipulated on the alert, of the response, actions and any risks to service users or service delivery

4.3 Risk Management

- Providers will ensure that any risks associated with the service are identified and managed.
- Providers will ensure that appropriate risk assessments are undertaken to account for access to premises in line with Equality Act 2010.

4.4 Information Governance

Providers are required to ensure that service user identifiable data is managed in accordance with the law.³

² [NHS England Serious Incident Framework \(updated 2015 \)](#)

Data breaches must be reported to commissioners within two working days of the incident occurring.

4.5 Complaints

Providers will ensure that they have adequate policies and procedures in place to respond to service user complaints.

Providers will inform commissioners in writing to phcommissioning@wolverhampton.gov.uk of any formal complaints relating to the service within two working days.

5. Applicable Service Standards

5.1 Applicable national standards

- NICE Smoking: Harm Reduction Quality Standard 92 issued July 2015
- NICE guidance (PH10) – Smoking cessation services in primary care, pharmacies, local authorities and workplaces, particularly for manual working groups, pregnant women and hard to reach communities.
- NCSCT Local Stop Smoking Services: Service and delivery guidance 2014
- NICE Brief interventions and referral for smoking cessation (PH1)
- NICE Workplace interventions to promote smoking cessation (PH5)
- NICE Preventing the uptake of smoking by children and young people (PH14)
- NICE Identifying and supporting people most at risk of dying prematurely (PH15)
- NICE School-based interventions to prevent smoking (PH23)
- NICE Quitting smoking in pregnancy and following childbirth (PH26)
- NICE Technology Appraisal Varenicline for smoking cessation (NICE 2007)
- NICE Smokeless tobacco cessation - South Asian communities (PH39)
- Healthy Lives, Healthy People: A Tobacco Control Plan for England (March 2011)
- Care Quality Commission Standards for Better Health <http://www.cqc.org.uk/>
- Department of Health Local Stop Smoking Services: key updates to the 2011/12 service delivery & monitoring guidance for 2011/12.
- NICE Guidance on the use of NRT and Bupropion
- NICE Guidance on the use of Varenicline
- All NICE Technological Appraisals for Smoking related Pharmacotherapy
- <http://www.ncsct.co.uk/usr/pub/assessing-smoking-cessation-performance-in-nhs-stop-smoking-services-the-russell-standard-clinical.pdf>

5.2 Applicable local standards

- Wolverhampton Healthy Lifestyles Service monitoring arrangements and protocol

6. Data requirements and monitoring

The provider will be expected to complete internal audits of clients on a regular basis, including progress around smoking quitters to aid service development and review outcomes. The Provider shall produce an implementation plan demonstrating how it will deliver, monitor and evaluate the service which will meet the requirements of this service specification. The Commissioner will review the service on a regular basis as well as responding to issues which may require a more urgent review.

The following section outlines requirements regarding data and information that shall be supplied to the Commissioner and the Healthy Lifestyles Team (Specialist Stop Smoking Service).

5.1 Data capture and information systems

If available the provider must utilise the web-based IT system stipulated by the Commissioner that will deliver a fully electronic client record. The system will also populate internal patient record systems where relevant. Validated tools must be used to collect data as agreed with the Commissioner and as per the Russell Standards.

<http://www.ncsct.co.uk/usr/pub/assessing-smoking-cessation-performance-in-nhs-stop-smoking-services-the-russell-standard-clinical.pdf>.

Furthermore, to fulfil reporting, contract monitoring and payment requirements, the Provider will also need to make certain data available to the Commissioner via the procured system, both datasets are specified below. The Provider will also need to demonstrate that the appropriate information governance requirements are met for all data collection and reporting, gaining patient consent for the data to be shared where required.

5.2 Contract monitoring and information submission requirements

Healthy Lifestyles Team (Specialist Stop Smoking Service)

All providers must complete the Wolverhampton Stop Smoking Service Monitoring Form for each client and send this data to the Healthy Lifestyles Service following a 4 week follow up.

Commissioner

Appendix 1 specifies a list of fields for a minimum dataset (MDS) extract that will need to be available to the Commissioner at a raw anonymised individual level for each client; the Commissioner will create a dashboard to present relevant indicators for regular contract monitoring and payment validation. In addition to the MDS, there are also quality measures that will need to be available to the Commissioner via an aggregated data report with a qualitative narrative where relevant.

From the MDS the Commissioner will calculate the following Key Performance Indicators (KPIs) for monitoring:

KPI	Frequency	Target
% of clients from a deprived LSOA	quarterly	To be determined

% clients who set a quit date	quarterly	85%
% of quits CO validated	quarterly	85%
% Achieving a 4 week quit rate (this will be broken down by interventions provided and provider)	quarterly	35-75% Local service aspirational target of 50%
% Achieving a 12 week quit rate (this will be broken down by interventions provided and provider)	quarterly	Local service aspirational target of 25%

Quality measures KPIs (provided separately via an aggregated report)

KPI	Frequency	Target
Total number of vouchers issued	quarterly	
% of sessions held on evenings or weekends out of all sessions	quarterly	For information
Proportion of DNAs	quarterly	For information
Client satisfaction-% of clients that are surveyed	annually	For information
Client satisfaction-% of clients that are satisfied with the service	annually	For information

7. Location of Service Provider Premises

7.1 The intention of the local authority is to ensure a good geographical spread of provision.

8. Payment Schedule

A fee of £70.00 will be paid to the provider for each 4 week quit
A fee of £45.00 will be paid to the provider for each 12 week quit
A fee of £10.00 will be paid to the provider for each 4 week relapse
A fee of £5.00 will be paid to the provider for each 4 week lot to follow up

Completed 4 week quits should be submitted to the Healthy Lifestyles Service within 6 weeks of the agreed quit date, allowing time for 4 week follow up to be completed and returned.

Completed 12 week quits should be submitted to the Healthy Lifestyles Service within 14 weeks of the agreed quit date, allowing time for 12 week follow up to be completed and returned.

Claims outside of this period will not be paid.

The data required to receive payments is fully specified in the data requirements and monitoring section.

Wolverhampton City Council will make payments on a quarterly basis.

The data recording and information requirements for this service may be subject to further changes in accordance with the development of a web based monitoring system the provider will be required to use (stipulated by the commissioner).

Appendix 1-Minimum dataset fields

Note, data to be submitted as on the monitoring form where fields match unless otherwise specified.

Field	Definition/options
Unique ID	A unique ID to be able to identify individuals
Readiness to quit	Yes/no
Date of first contact	DD/MM/YYYY
Ward Code	A look up is provided
Ward Name	A look up is provided
LSOA	A look up is provided
Mosaic category	Social marketing tool-A look up is provided
Referral source	i.e. Self, Family, GP, Healthy Lifestyles
Venue	
GP Practice Code	Mcode
Gender	
Age	
Ethnic Group	
Country of birth	
Main language	
Migrant/Asylum status	
Pregnant	
Occupation code	
Free prescriptions	

Co-morbidities	
Average cigarettes smoked per day	
Type of intervention delivered	
Agreed quit date	DD/MM/YYYY
1 week quit	Type of follow up: face to face, letter, telephone Quit: Yes-self reported, yes-CO validated, no, lost to follow up
4 week quit	Type of follow up: face to face, letter, telephone Quit: Yes-self reported, yes-CO validated, no, lost to follow up
Type of support used	
12 week quit	Type of follow up: face to face, letter, telephone Quit: Yes-self reported, yes-CO validated, no, lost to follow up
Type of support used	
Referral to other services	Yes (please state which), no

SERVICE SPECIFICATION

Service Specification Number	Lot 2 - PP
Service	Pharmacist Supervised Consumption of Prescribed Opiate Substitution Therapy (OST)
Commissioner Lead	Michelle Smith
Period	1st April 2016 – 31st March 2018
Date of Review	Annual basis

1. Introduction

This service specification sets the requirements for the provision of a Public Health service for the supervised consumption of prescribed opiate substitution therapy (OST) within a community pharmacy. The principal focus of the service is to provide supervision of the self-administration of methadone or buprenorphine by service users on a regular basis.

The provision of this service is commissioned via a targeted approach in line with the local drug and alcohol specialist treatment service and based upon locally defined needs.

The role of the pharmacist

Pharmacists play a key and unique role in the care of substance users through the supervision of consumption of methadone or buprenorphine, the pharmacist is instrumental in supporting drug users in complying with their prescribed regime, therefore reducing incidents of accidental deaths through overdose. Also through supervision, pharmacists are able to keep to a minimum the misdirection of controlled drugs, which may help to reduce drug related deaths in the community.

The daily contact that pharmacists have with their service users is a 'unique' role that enables pharmacists to monitor adherence and offer general health and well-being advice. Hence, by integrating pharmacists into the 'shared care' service this 'unique' role can be developed and therefore maximise the impact of the treatment service users receive.

1.1 National/local context and evidence base

Background

The National Institute for Health and Clinical Excellence (NICE) Clinical Guidelines recommend the use of opiate substitution therapy (OST) to treat individuals with addiction to opiates¹.

¹ TA114 - Methadone and buprenorphine for the management of opioid dependence, NICE, January 2007

Pharmacological treatments are broadly categorised as maintenance (also known as 'substitution' or 'harm-reduction' therapies), detoxification or abstinence. The aims of the maintenance approach are to provide stability by reducing craving and preventing withdrawal, eliminating the hazards of injecting and freeing the person from preoccupation with obtaining illicit opioids, and to enhance overall function. To achieve this, a substitution opioid regimen (a fixed or flexible dose of methadone or buprenorphine to reduce and stop illicit use) is prescribed at a dose higher than that required merely to prevent withdrawal symptoms. The aim is for people who are dependent on illicit opioids to progress from maintenance to detoxification and then abstinence (when a person has stopped taking opioids).

The introduction of supervised methadone dosing has resulted in substantial declines in deaths related to overdose of methadone².

Opiate substitutes such as methadone and buprenorphine should be administered daily, under supervision, for at least the first 3 months of treatment. Supervision should be relaxed only when the patient's compliance is assured. Both drugs should be given as part of a programme of supportive care¹.

In Wolverhampton we commission an integrated system of services to meet the needs of substance misusers, and the provision of OST dispensed with supervised consumption is a core component of the treatment and recovery pathway.

1.2 Social Value Considerations

The delivery of OST services, including supervised consumption, addresses priorities which disproportionately affect socially disadvantaged communities in the city. These include reduction of substance misuse and supporting individuals to make choices to reduce the harms caused to themselves, their families and the wider community. This includes a reduction or complete abstinence from the use of illicit drugs, reduction in the injection of drugs and associated injecting site wounds and abscesses, and a reduction in needle stick injuries in the general public resulting from discarded needles. It also reduces death from accidental overdose from illicit use, and the spread of blood borne viruses. The services also promote access to the specialist Recovery Service to support the service user in achieving abstinence. OST alongside supervised consumption reduces the risk to communities in a number of ways including overuse or underuse of medicines, diversion of prescribed medicines onto the illicit drugs market and accidental exposure to the dispensed medicines, therefore, the delivery of these Services improve the service users health in the longer-term, as well as improve the economic and social well-being of Wolverhampton by keeping service users healthier for longer and decreasing demand on health and social care services as well as criminal justice services.

² *BMJ*2010;341:c4851

2. Key Service Outcomes

The service contributes to the following Public Health outcomes:

2.15i Successful completion of treatment-opiate users

2.15ii Successful completion of treatment-non-opiate users

The government's Drug Strategy 2010 introduced the concept of recovery from drugs and alcohol dependence into policy with clear practice outcomes, namely:

- Freedom from dependence on drugs or alcohol
- Prevention of drug-related deaths and blood borne viruses
- A reduction in crime and re-offending
- Sustained employment
- The ability to access and sustain suitable accommodation
- Improvement in mental and physical health and wellbeing
- Improved relationships with family members, partners and friends
- The capacity to be a caring and effective parent

References: Medications in recovery: Re-orientating drug dependence treatment (NTA 2012)

Drug misuse and dependence – UK guidelines on clinical management (DH 2007- Orange Book)

3. Scope

3.1 Aims and Objectives of service

Aims

- The principle aim of supervised consumption in the clinical context is to provide a comprehensive service to drug users that will reduce drug-related harm and the potential for death.

Objectives

- To ensure compliance of the service user with the agreed drug treatment plan by:
 - Dispensing in specified instalments (doses may be dispensed for the patient to take away to cover days when the pharmacy is closed)
 - Calculation of any missed dose from the treatment start date NOT the dispensing date.
 - Ensuring each supervised dose is correctly consumed by the patient for whom it was intended.
- To reduce the risk to local communities of:
 - Overuse or underuse of medicines
 - Diversion of prescribed medicines onto the illicit drugs market
 - Accidental exposure to the supervised medicines
- To provide service users with regular contact with healthcare professionals, advice and support to assist them access further interventions. The service user will be referred to specialist treatment centres or other health and social care professionals where appropriate.
- This pharmacy service will assist the service user to remain healthy, reduce drug related harm, work towards recovery, provide service users with regular contact with a healthcare professional and help them access further advice or assistance.
- This service will require the Service Provider to provide a supervised consumption of prescribed opiate substitution therapy to Service Users living in Wolverhampton. This will involve the dispensing and supervised consumption of either methadone or buprenorphine.

3.2 Service description

3.2.1 Pathway

The pharmacist shall supervise and electronically record the consumption of methadone and buprenorphine at the point of dispensing in the pharmacy which can be for titration, reduction or maintenance (as prescribed by the specialist treatment service or shared care clinician only under the local shared care arrangements) ensuring that the dose has been administered appropriately to the service user.

The provider shall offer a user-friendly, non-judgemental, service user centred and confidential service. Service users shall be treated with the same degree of courtesy as would be afforded to any other service user group within the pharmacy.

The provider shall provide support and advice to the service user including signposting to primary care or specialist services where appropriate.

The service shall be provided in conjunction with either the local GP's and/or the specialist prescribing service as part of a programme to manage opiate dependency.

To be an effective member of the prescribing treatment team pharmacists participating in this service need to form close links with other members of the team. Effective communication between all parties is vital. The provider shall therefore ensure that they are aware of the contact details of the service users named key worker in addition to the prescriber.

A treatment agreement should be set up between the provider and service user prior to supervising any medications. This shall include how the service will operate, what constitutes acceptable behaviour by the service user and what action will be taken by the pharmacist if the service user does not comply with the treatment agreement.

Confidentiality issues and information sharing between team members shall be addressed in the treatment agreement, which service users agree to abide by when they engage with the prescribing services. The provider shall ensure that they are personally aware of the terms of the agreement used by their local prescribing service and that service users who attend their pharmacy are also aware and have a current treatment agreement in place.

Service users shall receive information about methadone and buprenorphine, risks of overdose, loss of tolerance following missed or uncollected doses, drug interactions, an explanation of supervised consumption, where and how it will occur and opening and closing times of the pharmacy.

Service users shall receive written and verbal information regarding the safe storage of medicines and instructions to reduce the incidence of accidental exposure to medicines. The provider will distribute a safe storage information leaflet to all service users. Two copies of the leaflet will need to be completed with one copy retained by the pharmacist and signed by the service user. This should be recorded as an intervention on the PMR. You will be required to submit a declaration each month with your normal monthly returns confirming that all existing and new service users have been given a leaflet.

Pharmacy staff should carry out this practice with all service users every six months in July and January. Please note if a service user drops off script and returns to the same pharmacy a new signature does not need to be obtained if within 6 month period. If a service user moves to another pharmacy they will obtain a signature through the new service user process.

The Service Provider will:

- Ensure compliance with an agreed care plan by dispensing prescribed medication in specified instalments.
- Methadone - the pharmacist must be satisfied the dose has actually been swallowed, for example, by water being swallowed after the dose or conversing with the service user to ensure that the methadone is not retained in the mouth.
- Buprenorphine – the service user must be supervised until the tablets have dissolved – this can take 3-7 minutes depending on the dose, brand of medication dispensed and the service user.
- Water (if required) will be provided by the pharmacy.
- Ensure each supervised dose is correctly administered to the patient for whom it was intended (doses may be dispensed for the patient to take away to cover days when the pharmacy is closed).
- Liaise with the prescriber, named key worker and others directly involved in the care of the service user (where the service user has given written permission).
- Monitor and electronically record the service user's response to prescribed treatment; for example if there are signs of overdose, especially at times when doses are changed, during titration of doses, if the service user appears intoxicated or when the service user has missed doses and if necessary withholding treatment if this is in the interest of service user safety, liaising with the prescriber as appropriate.
- Provide referral or signposting to other related services.

3.2.2 Accepting new service users into Supervised Consumption

- The prescriber/recovery worker will ask the service user which pharmacy participating in the supervised consumption programme would be most convenient for daily visits and at what times.
- The prescriber will contact the pharmacist before issuing the first prescription to ensure the pharmacy has the capacity to accept the service user at that time.
- The provider will be responsible for verifying the service user's identity but will not be under any obligation to provide the service if the service user's identity cannot be verified.
- All prescriptions will have the agreed dispensing pharmacy name printed on the prescription.
- The service user will attend the named pharmacy with their prescription for supervised methadone or buprenorphine consumption as agreed with the prescriber or recovery worker.
- Service users will be briefed by the prescriber on the date of commencement of supervised consumption. The prescriber should inform the service user fully of what is expected when commencing supervised consumption. In doing so the prescriber will inform the service user that the pharmacy will enter into an arrangement with the service user which the service user will be expected to adhere to.
- Service users should be informed in advance of what arrangements will be made for when the pharmacy is closed.

In addition the service user should be given a practice leaflet detailing additional professional services offered by the pharmacy. Health promotion is an important issue for

this group of service users and pharmacists should take every opportunity to provide advice on diet, exercise and oral hygiene.

3.2.4 Identification of service users

- The service users' identity must be checked to ensure the prescription is dispensed to the correct person.
- If there is any uncertainty with the identity of the service user the prescriber/recovery worker must be contacted and the dose withheld until the individual's identity is ascertained.

3.2.5 Missed doses

- To prevent service users from falling off script pharmacy staff must alert the keyworker after the second missed dose.
- Missed doses may result in a drop in opiate tolerance with an increased risk of accidental overdose.
- All missed doses should be communicated to the keyworker by 11am on the day following the second missed dose (call 0300 200 2400 or by emailing the secure email address rny_pharmacies.bsmhft@nhs.net), ensuring recovery workers are aware of service user adherence to the prescribing regime and can work with service users to improve adherence and reduce risks.
- Where three consecutive doses have been missed the service user will need to restart treatment arranged by the prescriber.

3.2.6 Business Continuity

The provider is responsible for ensuring that adequate arrangements are in place for continuity of the service in the event of staffing shortages, facilities and system failures appropriate to the service.

Adequate arrangements must be in place in order to ensure continuity of supply.

3.2.7 Contradictions and exclusions

Patients have the right to choose which pharmacy (providing the service) they have their prescription dispensed/receive supervised consumption from.

Dispensing supply and supervised consumption can be refused in certain circumstances, as defined by NHS terms of service:

- If the pharmacist believes the prescription is not genuine or for the person named on the prescription form
- If the pharmacist believes the prescriber has made a clinical error or that the prescription is clinically inappropriate
- If the patient or anyone with them behaves or threatens to behave violently, or commits or threatens to commit any criminal offence (in the pharmacy).

Patients may be excluded as a result of professional judgement – this can include patients who have, for example:

- Missed collecting their prescribed medicine for a specified number of instalments and their tolerance to the drug may have reduced, in accordance with the three day rule.
- Those appearing intoxicated or showing signs of overdose (patients must be informed prior to initiation of treatment what types of behaviour may result in exclusion). The pharmacist will inform the prescriber and/or key worker.

3.2.8 Interdependencies with other services

- Shared Care Prescribing for Drug Misuse
- The Specialist Substance Misuse Service

3.3 Criteria for participation in the scheme

3.3.1 Accreditation

The accountable person for the service is the lead pharmacist who has applied to provide the service however for the purposes of operational delivery the term pharmacist/registered technician (where the appropriate training specified below has been undertaken) will be referred to.

Providers must ensure that staff are managed and supported appropriately to be able to undertake their duties competently and efficiently.

The pharmacist/registered technician regularly involved in the provision of this service must have successfully completed or plan to complete within 3 months of registering to join the scheme and completed every 3 years thereafter:

- The open learning programme 'Substance Use and Misuse' (2nd edition, May 2012) – available from the Centre for Pharmacy Postgraduate Education CPPE and the CPPE e-assessment 'Substance Use and Misuse'-delivering pharmacy services (2009).
 - CPPE Safeguarding Children and Vulnerable Adults (Oct 2012)
 - CPPE Consultation Skills (Jan 2013)
- All can be accessed via www.cppe.man.ac.uk

If a pharmacist/registered technician has not completed the open learning programmes and e-assessments they must successfully complete them within 3 months of registering to be accepted onto the programme.

3.3.2 Pharmacists participating in this service must:

- Community pharmacies providing this service shall work with a number of service

users that is appropriate to the capacity of the pharmacy within the parameters of good practice.

- Ensure compliance with all legal and professional requirements.
- Ensure appropriate insurance cover is in place – the CPPE course outlines how you can check this.
- The pharmacy must have a standard operating procedure (SOP) for all personnel operating the scheme. Local pharmacy SOP's are intended to support pharmacists working in the community by setting out strategies for risk management and harm reduction that comply with clinical governance requirements.
- Ensure an accredited pharmacist/registered technician, as outlined in the accreditation section provides this service at all times.
- Ensure new staff or locums are fully aware of the local pharmacy SOP and are able to enact this agreement appropriately. The provider will be responsible for ensuring regular pharmacists are accredited to deliver the service.

3.3.3 Competences

The pharmacist will:

- Offer a supportive, friendly and professional service
- Respect service user confidentiality at all times
- Have the confidence to ensure and ascertain medication has been ingested
- Maintain appropriate standard operating procedures for the safer management of controlled drugs
- Provide advice on safe storage of methadone and buprenorphine at home
- Maintain sufficient staff in place to provide and/or support the service
- Provide a continuous service on all days of opening
- Provide safe disposal and destruction of clinical waste and items which may identify service users.

3.3.4 Premises and Equipment

The provider shall ensure the premises used for the provision of the service are sufficient to meet the reasonable needs of the service users.

Pharmacies which offer supervised consumption services shall have the following facilities:

- A service user medication record
- Appropriate storage conditions for increased supply of methadone/buprenorphine
- The service must be provided in pharmacy premises that meet the national standard for consultation areas i.e.
 - a. The service user and the pharmacist can sit down together
 - b. The service user and pharmacist can talk at normal speaking volumes without being overheard by staff or customers
 - c. The area is clearly signed as a private consultation area (a closed room is not necessary)
- An area for display of relevant health promotion leaflets including

advice on the safe and secure storage of medicines.

3.3.5 Equality and Diversity

Providers should take all reasonable efforts to ensure that their services are clearly understood and can be accessed by individuals from new communities who may not have English as a first language or be literate in their own language.

The National Health Services (Charges to overseas visitors) regulations 2015³ introduced changes to the entitlement to free NHS treatment for several groups. These regulations do not affect primary medical services, dental or ophthalmic services.

This service will be delivered in accordance with the following legislation:

- The Race Relations Act 1976 and Amendment Act 2000
- The Equality Act 2010
- The Human Rights Act 1998
- The Health and Safety at Work Act 1974

3.4 Population covered

Adults over the age of 18 registered with a Wolverhampton GP who are:

- Patients prescribed methadone or buprenorphine
- Patients prescribed by named GP's
- Patients prescribed by the specialist substance misuse treatment service

The supervised consumption of methadone and buprenorphine will only be undertaken for patients prescribed within the local 'shared care model' initiated through the specialist treatment provider and, or clinician within the scheme.

4.0 Clinical Governance

Clinical Governance requirements as part of the Community Pharmacy Contractual Framework (CPCF) must be implemented in conjunction with any regulatory standards and guidance such as:

- [General Pharmaceutical Council \(GPhC\) Standards for registered Pharmacies 2012](#)
- [GPhC Standards of Conduct ,ethics and performance 2012](#)
- [Information Governance Toolkit](#)
- [Pharmaceutical Services Negotiating Committee \(PSNC\) Clinical Governance Requirements for Community Pharmacy 2012.](#)

4.1. Incident reporting

Providers are required to report in writing to phcommissioning@wolverhampton.gov.uk:

- Any clinical incidents which may cause harm or directly affect a service user
- any events that may stop or disrupt the service from operating normally or safely

³ The NHS Charges to overseas visitors regulations 2011(Statutory instrument 2011 No. 1556 and 2012 No 1586)
<http://www.legislation.gov.uk/uksi/2011/1556/contents/made>

- any medicine or medical device adverse incidents via the Medicines and Healthcare products Regulatory Agency (MHRA) Yellow Card Scheme
- Inform the commissioner within two working days of any incidents occurring
- Providers should investigate any incidents; implement any action and recommendations following investigation and share lessons learned.

4.2 Responding to National Patient Safety Alerts

- Providers are required to respond appropriately to all relevant safety alerts issued via the national Central Alert System (CAS) and must keep a record of what has been done to implement or comply with any actions required.
- Providers will inform commissioners, within the timeframe stipulated on the alert, of the response, actions and any risks to service users or service delivery.

4.3 Risk Management

- Providers will ensure that any risks associated with the service are identified and managed.
- Providers will ensure that appropriate risk assessments are undertaken to account for access to premises in line with Equality Act 2010, which replaces the Disability Discrimination Act 1995.

4.4 Information Governance

- Providers are required to ensure that service user identifiable data is managed in accordance with the law.⁴
- Breaches, including prescription loss, should be reported to commissioners within two working days of the incident occurring.
- In the event of the pharmacy losing a prescription, the responsible pharmacist must report this to the relevant prescriber (or recovery worker if prescriber unavailable) immediately and discuss plans to ensure the service user's treatment is not interrupted.

4.5 Clinical Judgement Decisions

- Service users stabilised on methadone or buprenorphine should be clear headed and coherent.
- If the pharmacist considers the service user to be grossly intoxicated, the prescriber should be contacted and the dose withheld.

4.6 Complaints

- Providers will ensure that they have adequate policies and procedures in place to respond to customer complaints.

⁴ Data Protection Act 1998

- Providers will inform commissioners (in writing to phcommissioning@wolverhampton.gov.uk) of any formal complaints relating to the service within two working days.

5. Applicable Service Standards

5.1 Applicable national standards

Department of Health guidelines for the UK recommend that when a person starts maintenance opioid therapy, they should take each dose under the supervision of a nurse, doctor or community pharmacist for a minimum of 3 months, and this supervision should be relaxed only when their compliance is assured. However the need for supervised consumption should take into account social factors, such as whether the person has a job or childcare responsibilities. As the person progresses with their maintenance therapy, the need for supervision may change.

Pharmacy staff are expected to operate the scheme in line with the General Pharmaceutical Council's Standards of conduct, ethics and performance (July 2012).

Pharmacy contractors should also be familiar with the following guidelines:

- Drug Misuse and Dependence UK guidelines on clinical management (the Orange Guidelines) http://www.nta.nhs.uk/uploads/clinical_guidelines_2007.pdf
- Guidance for the use of methadone and buprenorphine for the treatment of opioid dependence in primary care can be downloaded from the smmgp website www.smmgp.org.uk

All Service Providers will adhere to NICE Clinical Guidelines and Quality Standards, relevant standards include but are not limited to QS23, CG51, CG52 and TA114.

5.2 Applicable local requirements

- The pharmacy is open for a minimum of 40 hours per week over a 5 day period Monday to Friday.
- The pharmacy has appropriate staffing levels to cover the service.
- The pharmacy has appropriate health promotion materials available for service users and promotes its uptake.
- The pharmacy has standard operating procedures for the service (SOP's) and reviews its SOP's on a bi-annual basis or following critical incident(s).
- Non-regular pharmacists must be made aware of the service and the operational procedures in order to provide cover for the pharmacist.
- The pharmacy will provide the service in such a way as to promote equality of access across all community groups regardless of ethnicity, gender, disability or sexuality.

6. Data requirements and monitoring

The provider will be expected to participate in internal audits to aid service development and review outcomes. The Commissioner will review the service on a regular basis as well as responding to issues which may require a more urgent review.

The following section outlines requirements regarding data and information that shall be made available to the Commissioner.

6.1 Data capture and information systems

The Provider must utilise the web-based IT system stipulated by the Commissioner that will deliver a fully electronic client record. Validated tools must be used to collect data as agreed with the Commissioner.

Furthermore, to fulfil reporting, contract monitoring and payment requirements, the Provider will also need to make certain data available to the Commissioner, specified below. The Provider will also need to demonstrate that the appropriate information governance requirements are met for all data collection and reporting, gaining patient consent for the data to be shared where required.

6.2 Contract monitoring and information submission requirements

The following data shall be supplied via secure mechanisms:

Client name/address/telephone number/ID number
Attendance records
Prescribing

Commissioner

Appendix 1 specifies a list of fields for a minimum dataset (MDS) extract that will need to be available to the Commissioner at a raw anonymised individual client level for each transaction; the Commissioner will create a dashboard to present relevant indicators for regular contract monitoring and payment validation.

In addition to the MDS, there are also quality measures that will need to be available to the Commissioner via an aggregated data report with a qualitative narrative where relevant.

From the MDS the commissioner will calculate the following Key Performance Indicators (KPIs) for monitoring:

KPI	Frequency	Target
% of supervised consumption out of all activity	quarterly	For information
Number of individuals using the service	quarterly	For information
% referrals-broken down by type i.e. sexual health,	quarterly	For information

mental health, smoking cessation

6.3 Quality Measures

1. Pharmacists must demonstrate they have undertaken appropriate training to deliver supervised consumption.
2. Pharmacists will demonstrate they have standard operating procedures and that these are reviewed annually for the supervised consumption service.
3. Pharmacists will remain up to date with the relevant CPPE packages in relation to the delivery of supervised consumption services.

KPI	Frequency	Target
Client satisfaction-% of clients that are surveyed	annually	To be determined
Client satisfaction-% of clients that are satisfied with the service	annually	To be determined

A qualitative narrative should be supplied to support quality measures and KPIs.

7. Location of Service Provider Premises

7.1 Provision of the service should cover a good geographical spread based on population need.

8. Payment Schedule and finance

A fee of £2.50 will be paid to the provider for each supervised dose of Methadone.

A fee of £3.00 will be paid to the provider for each supervised dose of Buprenorphine.

Claims for payment

Details of all activity must be entered on to the web based system provided by commissioners in a timely manner to meet claims deadlines. The data required to receive payments is fully specified below in the data requirements and monitoring section.

Wolverhampton City Council will make payments on a quarterly basis. The data requested must be submitted and available to the Commissioner a maximum of 7 working days following each quarter to ensure timely payments.

Payments will be made according to the number of transactions, and as such the data entered onto this system will determine the level of payment to each provider. Claims for activity more than three months old will not be paid.

The information required for each transaction may be developed to reflect the Council's monitoring requirements along with the development of newer monitoring systems.

Appendix 1-Minimum dataset fields

Field
Unique ID
Ward Code
Ward Name
LSOA
Pharmacy ID
GP Practice code
Gender
Age
Ethnic Category
Country of birth
Main language
Migrant/asylum status
Employment Status
Date
Medicine supplied
Status (supervised consumption, DNA, take out dose)
If take out dose, reason why
Sexual health referral
Mental health referral
Other referral (specify)

SERVICE SPECIFICATION

Service Specification Number	Lot 1 - PP
Service	Supply of Nicotine Replacement Therapy (NRT) by Community Pharmacists Using the Voucher Scheme
Commissioner Lead	Michelle Smith
Period	1st April 2016 – 31st March 2018
Date of Review	Annual basis

1. Introduction

This service specification sets the requirements for the provision of a Public Health service for the supply of Nicotine Replacement Therapy (NRT) by community pharmacists using the voucher scheme.

The provision of high quality Stop Smoking Services is a priority for Wolverhampton City and seen as a key means of securing health improvement. Stop Smoking Services commissioned or provided by the NHS have already helped many people to stop smoking successfully and are a key part of tobacco control and health inequalities policies at both local and national levels.

A core component of Stop Smoking Service provision is access to pharmacotherapy including NRT. There are a number of mechanisms by which contracted providers can make NRT available to service users, one of these being the voucher scheme. Under the scheme, contracted Stop Smoking Service providers issue an official voucher to the service user to be redeemed for NRT at a designated pharmacy.

1.1 National/local context and evidence base

Smoking is the leading cause of death and illness in the UK. It is estimated there are approximately 60,000 smokers in Wolverhampton. Smoking can contribute towards the development of many diseases, but is most commonly linked with coronary heart disease, stroke, lung cancer, asthma and chronic obstructive pulmonary disease. For those who smoke, quitting is often the single most effective method of improving health and preventing illness.

Smoking is also a key driver of health inequalities. Smoking prevalence is highest in deprived communities however reductions in smoking prevalence have been slower in these communities than in other population groups. Reducing the prevalence of smoking in routine and manual workers, some minority ethnic groups and disadvantaged communities will help reduce health inequalities more than any other measure to improve the public's health.

NRT aims to replace the nicotine in cigarettes with another form of delivery. It provides a background level of nicotine and alleviates the short-term difficulties smokers' experience

when trying to stop smoking by reducing craving and withdrawal symptoms.

Forms of NRT currently available are patch (16 hour and 24 hour), inhalator, nasal spray, mouth spray, mouth strips, sublingual tablet, gum and lozenge. Adults can use a single NRT product or a combination of a patch with an oral product if they are heavily dependent smokers. Young people aged over 12 years are limited to a single NRT product. Duration of treatment with NRT is usually 12 weeks for a cessation attempt.

2. Key Service Outcomes

The service contributes to the following Public Health Outcomes:

- Smoking status at time of delivery (2.03)
- Smoking prevalence at age 15 (2.09)
- Smoking prevalence – adult (over 18) (2.14)
- Mortality from causes considered preventable (4.3)
- Mortality from all cardiovascular diseases (including heart disease and stroke) (4.4)
- Mortality from cancer (4.5)
- Mortality from respiratory diseases (4.7)

3. Scope

3.1 Aims of service

Aims

The overall aims of the service are to:

- Enable clients attempting to quit smoking to easily access NRT when attending a Stop Smoking Service provider for support to quit.
- Enable accredited Stop Smoking Advisors and Stop Smoking Intermediate Advisors to arrange for NRT to be supplied to service users from a choice of accessible designated pharmacies, for the first 2 weeks of their quit attempt.

3.2 Service description

3.2.1 Service outline

Accredited Stop Smoking Advisors and intermediate advisors will provide service users making a quit attempt with a voucher for NRT. The voucher will specify what NRT product(s) should be provided.

On receipt of an official voucher from a service user pharmacy staff will check that Section A has been correctly completed by the advisor. Incomplete forms should not be accepted; the pharmacist should inform the smoking cessation advisor by telephone and refer the service user back to the advisor.

Where no contraindications are noted, the pharmacist will issue the proposed product or a suitable alternative to the service user and complete Section B of the voucher.

Immediately after the issue of NRT section 4 of the voucher should be fully completed and signed by the staff involved and stamped on behalf of the pharmacy.

The pharmacist will maintain a record of all products issued against vouchers, the following details will be recorded (criteria will be satisfied by keeping a copy of the voucher. Entering this information as a note on the PMR is considered good practice) and kept on file for a minimum of 6 months:

- Voucher Reference Number
- Date products issued
- Products issued
- Product cost (validated by HLS using NRT trade prices schedule)

The pharmacist will ensure adequate stock control to meet the demands of the service.

3.2.2 Referral, Access and Acceptance Criteria

NRT should be provided to any customer with a Healthy Lifestyle Service NRT voucher.

Vouchers may only be accepted from contracted Stop Smoking Service providers.

Service users must live, work or be registered with a GP in Wolverhampton.

Pharmacies must be designated by contractual agreement to Wolverhampton City Council to provide NRT for service users under this scheme.

The designated pharmacy must ensure that all consent processes comply with the Data Protection Act.

3.2.3 Interdependencies with other services

Pharmacies who choose to deliver against this specification shall work closely with the Healthy Lifestyle Service (HLS) 01902 444246. The HLS team will provide support to the pharmacy upon joining the scheme in relation to the monitoring processes and forms to be used.

Stop Smoking Advisors will give service users the voucher.
The pharmacy will return exchanged vouchers to the Healthy Lifestyle Service.

The Healthy Lifestyle Service shall provide quarterly reports on Pharmacy activity and payments to be made, (see section 6.2) against this specification. Payments will be based on the data included in these reports.

3.2.5 Business Continuity

The provider is responsible for ensuring that adequate arrangements are in place for continuity of the service in the event of staffing shortages, facilities and system failures appropriate to the service.

Adequate arrangements must be in place in order to ensure continuity of supply.

3.2.6 Contradictions and exclusions

Those not living, working in or registered with a GP in Wolverhampton.
The pharmacist should check whether the customer has any co-morbidities or is on any other medication that might interact with NRT.

3.2.7 Equality and Diversity

Providers should take reasonable steps to ensure that their services are clearly understood and can be accessed by individuals from new communities who may not have English as a first language or be literate in their own language.

The National Health Services (Charges to overseas visitors) regulations 2015¹ introduced changes to the entitlement to free NHS treatment for several groups. These regulations do not affect primary medical services, dental or ophthalmic services.

This service will be delivered in accordance with the following legislation:

- The Race Relations Act 1976 and Amendment Act 2000
- The Disability Discrimination Act 2005
- The Human Rights Act 1998
- The Health and Safety at Work Act 1974

3.3 Criteria for participation in the scheme

The provider must ensure that all staff are appropriately registered, trained and competent to deliver the service as specified.

The service provider must ensure all members of staff are able to demonstrate their participation in relevant mandatory training; and that education and training needs of staff providing the service is supported.

3.3.1 Accreditation

The accountable person for the service is the lead pharmacist who has applied to provide the service however for the purposes of operational delivery the term pharmacy staff will be referred to.

Dispensing/Pharmacy Assistants

Pharmacists have a professional obligation to ensure that dispensing/pharmacy assistants are competent in the areas in which they are working to a minimum standard equivalent to Medicines Counter Assistants, Pharmacy Service Skills NVQ level 2 (QCF) qualification or undertaking training towards this.

3.3.2 Premises and Equipment

All resources equipment and maintenance for the delivery of the respective service remain the responsibility of the service provider.

Ensure adequate stocks of the NRT products available on the voucher scheme are maintained within the pharmacy. Where suitable products are not in stock signpost to other participating pharmacies in accordance with approved list.

4.0 Clinical Governance

Clinical Governance

¹ The NHS Charges to overseas visitors regulations 2011(Statutory instrument 2011 No. 1556 and 2012 No 1586)
<http://www.legislation.gov.uk/uksi/2011/1556/contents/made>

Clinical Governance requirements as part of the Community Pharmacy Contractual Framework (CPCF) must be implemented in conjunction with any regulatory standards and guidance such as:

- [General Pharmaceutical Council \(GPhC\) Standards for registered Pharmacies 2012](#)
- [GPhC Standards of Conduct ,ethics and performance 2012](#)
- [Information Governance Toolkit](#)
- [Pharmaceutical Services Negotiating Committee \(PSNC\) Clinical Governance Requirements for Community Pharmacy 2012.](#)

4.1. Incident reporting

Providers are required to report in writing to phcommissioning@wolverhampton.gov.uk:

- any serious incidents which may cause harm or directly affect a service user
- any events that may stop or disrupt the service from operating normally or safely
- any medicine or medical device adverse incidents via the [Medicines and Healthcare products Regulatory Agency \(MHRA\) Yellow Card Scheme](#)
- Inform the commissioner within two working days of any incidents occurring
- Providers should investigate any incidents; implement any action and recommendations following investigation and share lessons learned.

4.2 Responding to National Patient Safety Alerts

- Providers are required to respond appropriately to all relevant safety alerts issued via the national Central Alert System (CAS) and must keep a record of what has been done to implement or comply with any actions required.
- Providers will inform commissioners, within the timeframe stipulated on the alert, of the response, actions and any risks to service users or service delivery.

4.3 Risk Management

- Providers will ensure that any risks associated with the service are identified and managed.
- Providers will ensure that appropriate risk assessments are undertaken to account for Access to premises in line with Equality Act 2010, which replaces the Disability Discrimination Act 1995

4.4 Information Governance

Providers are required to ensure that service user identifiable data is managed in accordance with the law.²

Data breaches should be reported to commissioners within two working days of the incident occurring.

² Data Protection Act 1998

4.5 Clinical Judgment Decisions

Using professional judgement, the provider must ensure that the product prescribed on the voucher is clinically suitable for the individual service user and liaise with the prescriber where necessary.

Providers may substitute prescribed products for a clinically equivalent brand where necessary in order to meet service user needs. Any substitution must be appropriately recorded and claimed accordingly.

4.6 Complaints

Providers will ensure that they have adequate policies and procedures in place to respond to customer complaints.

Providers will inform commissioners (in writing to phcommissioning@wolverhampton.gov.uk) of any formal complaints relating to the service within two working days.

5.0 Applicable Service Standards

5.1 Applicable national standards

- NICE guidance (PH10) – Smoking cessation services in primary care, pharmacies, local authorities and workplaces, particularly for manual working groups, pregnant women and hard to reach communities.
- Department of Health Local Stop Smoking Services: Service Delivery and Monitoring Guidance 2011/12.
- Department of Health Local Stop Smoking Services: key updates to the 2011/12 service delivery & monitoring guidance for 2011/12.
- NICE Guidance on the Use of NRT and Bupropion
- NICE Guidance on the use of Varenicline
- All NICE Technological Appraisals for Smoking related Pharmacotherapy

5.2 Applicable local requirements

- The pharmacy is open for a minimum of 40 hours per week over a 5 day period Monday to Friday.
- Provide a continuous service on all days of opening.
- The pharmacy has appropriate staffing levels to cover the service.
- The pharmacy has appropriate health promotion materials available for service users and promotes its uptake.
- The pharmacy has standard operating procedures for the service (SOP's) and reviews its SOP's on an annual basis.
- Non-regular pharmacists must be made aware of the service and the operational procedures in advance of providing local cover for the pharmacist.
- The pharmacy will provide the service in such a way as to promote equality of access across all community groups regardless of ethnicity, gender, disability or sexuality.

- Pharmacy staff are expected to operate the scheme in line with the General Pharmaceutical Council's Standards of conduct, ethics and performance (July 2012).

6. Data requirements and monitoring

The provider will be expected to participate in internal audits to aid service development and review outcomes. The Commissioner will review the service on a regular basis as well as responding to issues which may require a more urgent review.

The following section outlines requirements regarding data and information that shall be made available to the Commissioner and Healthy Lifestyles Service.

6.1 Data capture and information systems

If available the provider should utilise the web-based IT system stipulated by the Commissioner that will deliver a fully electronic client record.

In the absence of this system these records need to be shared with the Healthy Lifestyles Service on a quarterly basis for them to be able to validate payment information.

Furthermore, to fulfil reporting, contract monitoring and payment requirements, the Provider will also need to make the data specified in section 6.2 available to the Commissioner. The Provider will also need to demonstrate that the appropriate information governance requirements are met for all data collection and reporting, gaining patient consent for the data to be shared where required.

6.2 Contract monitoring and information submission requirements

Healthy lifestyles Service

The following data shall be supplied via secure mechanisms:

Client name/address/telephone number/ID number
Attendance records
Voucher number and voucher exchanges
NRT supplied
Cost of NRT product

The blue carbonated voucher copy should be returned to the Healthy Lifestyles Service either by hand or by recorded delivery (pharmacy to retain the yellow copy).

Commissioner

Appendix 1 specifies a list of fields for a minimum dataset (MDS) extract that will need to be available to the Commissioner at a raw anonymised individual client level for each transaction; the Commissioner will create a dashboard to present relevant indicators for regular contract monitoring and payment validation.

In addition to the MDS, there are also quality measures that will need to be available to the Commissioner via an aggregated data report with a qualitative narrative where relevant.

From the MDS the commissioner will calculate the following Key Performance Indicators (KPIs) for monitoring:

KPI	Frequency	Target
% of vouchers exchanged out of those supplied	quarterly	For information

6.3 Quality Measures

1. The pharmacy contractor has appropriate locally agreed health promotion material available for the stop smoking service and promotes its uptake.
2. The pharmacy contractor has a standard operating procedure (SOP) and reviews the implementation within their organisation on a bi-annual basis or following a critical incident.
3. The pharmacy contractor can demonstrate that all staff involved in the provision of the service has undertaken CPD relevant to this service.
4. The pharmacy contractor co-operates with any locally agreed council-led assessment of service user experience as a minimum reporting any complaints and compliments received by service users.

KPI	Frequency	Target
Client satisfaction-% of clients that are surveyed	annually	For information
Client satisfaction-% of clients that are satisfied with the service	annually	80%
% of clients that receive health promotional materials	As appropriate	For information

A qualitative narrative should be supplied to support quality measures and KPIs.

7. Location of Service Provider Premises

7.1 Provision of the service must cover a good geographical spread based on population need.

8. Payment Schedule

A handling fee of £2.50 will be paid to the provider for each voucher transaction.

Claims for payment

Providers will ensure all charges for NRT are in line with up to date Drug Tariff and accurate at time of issue.

On a monthly basis the pharmacist will complete a schedule outlining details of each individual NRT product dispensed and respective costs, in addition to the total amount owing to the pharmacy.

An invoice is raised for the total amount owing to Wolverhampton Stop Smoking Service.

The schedule, an original copy of each voucher accepted that month and the invoice for the total amount owing is sent promptly for reimbursement to:

Wolverhampton Healthy Lifestyle Service
West Park Hospital Site
10E Tettenhall Road
Wolverhampton
WV1 4SA

Wolverhampton City Council will make payments on a quarterly basis. Claims for activity more than three months old will not be paid.

The data reporting and claims for payment processes are subject to change throughout the lifetime of the contract in accordance with the development of a new web based monitoring system.

Appendix 1-Minimum dataset fields

Field	Definition/options
Unique ID	A unique ID to be able to identify individuals
Voucher ID	
Date of voucher exchange	DD/MM/YYYY
Product received	
Duration of product received	
Ward Code	A look up is provided
Ward Name	A look up is provided
LSOA	A look up is provided
Mosaic category	A social marketing tool-A look up is provided
GP Practice Code	Mcode
Gender	
Age	
Referral to HLS	
Referral to other services	

SERVICE SPECIFICATION

Service Specification Number	Lot 3 - PP
Service	Needle Exchange – Pick and Mix
Commissioner Lead	Michelle Smith
Period	1st April 2016 – 31st March 2018
Date of Review	Annual basis

1. Introduction

This service specification sets the requirements for the provision of a Public Health service for needle exchange ‘pick and mix’ services. The service will be provided by community pharmacies to injecting drug users who require sterile needles, syringes, injecting paraphernalia, harm reduction advice and signposting to relevant health and social agencies.

The provision of this service is commissioned via a targeted approach in line with the local drug and alcohol specialist treatment service and based upon locally defined needs.

The role of pharmacy staff

The significant role that pharmacy staff play in offering the needle exchange service is the daily contact that they have with injecting service users, and their ability to understand, monitor and offer advice on the service user’s general health and wellbeing.

1.1 National/local context and evidence base

Needle and syringe programmes (NSPs) supply needles and syringes, and often other equipment, used to prepare and take illicit drugs. NSPs reduce the transmission of blood-borne viruses (BBVs) and other infections caused by sharing injecting equipment. Many NSPs also aim to reduce the harm caused by injecting drugs through providing information and advice and acting as a gateway to other services, including drug treatment such as opioid substitution therapy (OST). NSPs may be the only contact that some people (for example, those who inject performance and image-enhancing drugs [PIEDs]) have with health services. NSPs in England are based across a range of services including specialist services, pharmacies, outreach/mobile services, police custody suites, walk-in centres and accident and emergency departments. However, over 70% of NSPs are provided by pharmacies.

The true extent of injecting drug use is difficult to determine. The latest estimates relate to people injecting heroin, other opiate drugs or crack cocaine and do not include people injecting PIEDs such as anabolic steroids. However, recent anecdotal reports from across the country suggest that the use of anabolic steroids is on the increase, particularly among

young men.

In the UK almost half of injecting drug users are infected with Hepatitis C and about 1 in 90 with HIV. The Advisory Council on the Misuse of Drugs 2009 report states that in England and Wales 120,000 to 300,000 people are infected with Hepatitis C. Approximately one in five people recover, with the rest becoming chronically infected. There is no vaccine to protect against Hepatitis C and chronic infection can lead to severe liver disease, liver cancer and death. Chronic Hepatitis C can be cleared successfully in at least half of treated patients.

Commissioners should ensure that NSP providers (community pharmacies and specialist NSPs) supply people who inject drugs with needles, syringes and other injecting equipment such as filters, mixing containers, sterile water and sharps bins.

NICE Public health guidance PH52 issued March 2014 recommends provision of a mix of services namely level 1 (universal), 2 (pick and mix) and 3 (specialist services).

2. Key Service Outcomes

The service contributes to the following Public Health outcomes:

2.15i Successful completion of treatment-opiate users

2.15ii Successful completion of treatment-non-opiate users

The local authority is committed to commissioning services that fulfil requirements of the national drug strategy whilst meeting local need. Key objectives are to:

- Ensure 100% coverage for all injecting drug users
- To reduce the rate of blood borne infections among drug users
- To reduce drug related deaths (immediate death through overdose and long term such as blood borne infections)
- To increase the safe disposal of used injecting equipment through the scheme
- Increase the safety of communities from drug related crime and needle litter.

3. Scope

3.1 Aims and Objectives of service

Aims

To provide injecting drug users with sterile equipment and access to advice and harm reduction information until they are ready, able and willing to cease injecting and ultimately achieve a drug free life with appropriate intervention and support.

To offer service users the choice to tailor the equipment they require and reduce the amount of unused needle litter found in local communities.

To protect health and reduce the rate of blood-borne infections and drug related deaths among service users:

- By reducing the rate of sharing and other high risk injecting behaviours
- By providing sterile injecting equipment and paraphernalia and other support by promoting safer injecting practices
- By providing and reinforcing harm reduction messages including safe sex advice and advice on overdose prevention (e.g. risks of poly-drug use and alcohol use)
- Signpost to specialist substance misuse service for BBV testing.

To improve the health of local communities by preventing the spread of blood-borne infections by ensuring the safe disposal of equipment.

To protect the well-being of local communities and reducing needle litter by continually emphasising the importance of the return of used injecting equipment to Pharmacy staff.

To help service users access treatment where appropriate by offering signposting and referral (where appropriate) to specialist treatment services and health and social care professionals where appropriate.

To operate a friendly, non-judgemental, non-discriminatory and equal access policy to service provision.

To maximise the access to services for service users, paying special care to the socially excluded.

To provide a confidential, convenient needle exchange service during all opening hours.

3.2 Service description

The accountable person for the service is the lead pharmacist who has applied to provide the service however for the purposes of operational delivery the term pharmacy staff will be referred to.

Pharmacy staff will provide a range of injecting equipment as deemed appropriate (either loose or in packs with written harm reduction information) by the commissioner.

Equipment listed below may change in accordance with national legislation and local policy.

Item
Foil
1ml 'One hit kit' (1 x 1ml 29g identifiable filter syringe, 1 x citric acid, 1 x pre injection swab, 1 x spoon with filter)
2ml Orange 'One hit kit' (1 x 2ml identifiable syringe barrel, 1 x Orange 25g 5/8" needle, 1 x pre injection swab, 1 x citric acid sachet, 1 x spoon with filter)
2ml Blue 'One hit kit' (1 x 2 ml identifiable syringe barrel, 1 x Blue 23g 1 1/4" needle, 1 x pre injection swab, 1 x citric acid sachet, 1 x spoon with filter)
0.2 litre lockable Sharpsafe containers
Citric acid or Vitamin C sachets
Condoms
A new Steroid pack (10 x 2 ml identifiable syringe barrels, 10 x green 21g 1 1/2" needles, 10 x Blue 23h 1 1/4" needles, 10 x pre injection swabs, 1 x 0.45 litre lockable Sharpsafe container, 2 x 1ml 29g identifiable syringes).
1x pictorial menu sheet showing the paraphernalia available
Harm reduction leaflet
Bags

Pharmacy staff will provide an introduction of the scheme and explain the rationale behind the needle exchange service to service users and will issue information leaflets regarding services on offer.

Pharmacy staff will facilitate the service users' access to information and advice on minimising harm, general health and health promotion.

Pharmacy staff will refer the service user to effective health and social care agencies where appropriate.

Pharmacy staff will record needle exchange activity using a web based system that the commissioners will provide and provide an explanation of the purpose of monitoring information and what it is used for.

Pharmacy staff will ensure adequate stock control procedures are in place to meet service user needs.

3.2.1 Process of supplying equipment

1. New clients – when a new client comes into the pharmacy for equipment, pharmacy staff or trained person should:

- (a) Show the client to a quiet and discreet area where they can talk without being overheard.
- (b) Introduce themselves and explain which members of staff are trained and involved in the scheme.
- (c) Explain how the Client order form works and how to fill it in. It is important to reassure the client that the monitoring information is for service development purposes only and cannot be used to identify individual clients. The service user may require additional assistance to complete the form which pharmacy staff shall accommodate where necessary.
- (d) Explain that any reasonable number of needles can be offered in one visit but that this number is reliant upon returns being made to the pharmacy.
- (e) Where no used equipment is returned service users will be restricted to a maximum of 5 needles/syringes and associated paraphernalia in any one transaction.
- (f) Returns should be made using the existing sharps bins provided by the clinical waste contractor.
- (g) Advise clients how they can make a direct referral into the specialist substance misuse treatment service.
- (h) Ensure there is a quiet and discreet area where needle exchange clients can go to fill in their client order form.
- (i) Provide equipment in the bags supplied, taking care to respect the client's right to privacy by being discreet.
- (j) At least one sharps container must be provided with every transaction (working on 1 container for up to 10 needles). Pharmacy staff to use their discretion on increasing numbers of needles provided, taking into consideration; bank holidays or special circumstances for the client and the clients willingness to return the used equipment.
- (k) Filters, citric acid etc. should be provided in the same quantities as the needles and syringes.
- (l) If the service user opts to use Vitamin C this should be provided in the same quantities as the needles and syringes.

3.2.2 Returns

Pharmacy staff will emphasise and encourage 100% returns and facilitate the safe disposal of used equipment. Pharmacy staff should explore with the service users where needle exchange equipment is being disposed.

Non-returns should not impact the provision of equipment unless the service user continues to make poor returns in which case the amount of equipment supplied should be restricted to a maximum of 5 needles.

The service user must place used injecting equipment in the sharps bins. Used injecting equipment must not be handled by any member of staff.

Returns in any form other than the sharps bins supplied (i.e. plastic bag) should not be refused. Pharmacy staff should provide the client with a sharps bin and request that the client place the used equipment in the sharps bin.

The pharmacy sharps clinical waste container should only be filled to the "full line" before being sealed for collection. Pharmacy staff will allocate a safe area to store equipment and returned injecting equipment for onward safe disposal.

Returned injecting equipment will be stored in the sharps containers provided by SCLR Waste Management and collected at a frequency agreed with the pharmacy.

3.2.3 Business Continuity

The provider is responsible for ensuring that adequate arrangements are in place for continuity of the service in the event of staffing shortages, facilities and system failures appropriate to the service.

Adequate arrangements must be in place in order to ensure continuity of supply.

3.2.4 Population covered

Adults over the age of 18 who inject illicit substances. These include opioids (for example heroin) and stimulants (for example cocaine) either separately or in combination.

3.2.5 Contradictions and exclusions

Pharmacy staff retain the right to refuse to serve a needle exchange service user. Service users may be excluded if they pose a serious risk to staff, other service users and members of the public.

Young people aged 17 and under who require needle exchange services shall access the young person's specialist substance misuse service.

3.2.6 Interdependencies with other services

Wolverhampton City Council procures and contract manages the supply of needle exchange equipment and commissions a clinical waste disposal service for each participating pharmacy.

3.2.7 Equality and Diversity

Providers should take reasonable steps to ensure that their services are clearly understood and can be accessed by individuals from new communities who may not have English as a first language or be literate in their own language.

The National Health Services (Charges to overseas visitors) regulations 2015¹ introduced changes to the entitlement to free NHS treatment for several groups. These regulations do not affect primary medical services, dental or ophthalmic services.

This service will be delivered in accordance with the following legislation:

¹ The NHS Charges to overseas visitors regulations 2011(Statutory instrument 2011 No. 1556 and 2012 No 1586)
<http://www.legislation.gov.uk/uksi/2011/1556/contents/made>

- The Race Relations Act 1976 and Amendment Act 2000
- The Equality Act 2010
- The Human Rights Act 1998
- The Health and Safety at Work Act 1974

3.3 Criteria for participation in the scheme

3.3.1 Accreditation

The accountable person for the service is the lead pharmacist who has applied to provide the service however for the purposes of operational delivery the term pharmacy staff will be referred to.

The pharmacist involved in the provision of this service must have successfully completed and complete every 3 years thereafter:

- The open learning programme 'Substance Use and Misuse' (2nd edition, May 2012) – available from the Centre for Pharmacy Postgraduate Education CPPE and the CPPE e-assessment 'Substance Use and Misuse'-delivering pharmacy services (2009).
 - CPPE Safeguarding Children and Vulnerable Adults (Oct 2012)
 - CPPE Consultation Skills (Jan 2013)
- All can be accessed via www.cppe.man.ac.uk

3.3.2 Pharmacy contractor roles and responsibilities

The contractor will ensure that:

- Pharmacists and staff involved in the provision of the service have relevant knowledge and are appropriately trained.
- Community pharmacies providing this service shall work with a number of service users that is appropriate to the capacity of pharmacy staff within the parameters of good practice.
- Staff are made aware of the risk associated with the handling of returned used equipment and will use the correct procedures to minimise those risks.
- Pharmacy staff will have in place standard Operating Procedures to deal with needlestick injuries of staff.
- The pharmacy clearly displays the national scheme logo or a local logo indicating participation in the service.
- Pharmacy staff clearly signpost service users to other available needle exchange services for when the pharmacy is closed.
- The contractor will ensure compliance with the Data Protection Act, Caldicott and other legislation covering access to confidential information.
- Pharmacists will only share information with other health care professionals and agencies in line with GPhC Standards of conduct, ethics and performance (July 2012).
- Pharmacists will promote Hep B vaccination amongst staff involved in needle exchange service as part of good practice.

3.3.3 Competences

Pharmacy staff will:

- Offer a supportive, friendly and professional service
- Provide information and advice in a manner appropriate to the needs of the service user
- Recognise and define actual or potential problems in the service users lifestyle or quality of life in relation to the service
- Respect service user confidentiality at all times
- Maintain sufficient staff in place to provide and/or support the service
- Provide a continuous service on all days of opening.

3.3.4 Premises and Equipment

The provider shall ensure the premises used for the provision of the service are sufficient to meet the reasonable needs of the service users.

4.0 Clinical Governance

Clinical Governance

Clinical Governance requirements as part of the Community Pharmacy Contractual Framework (CPCF) must be implemented in conjunction with any regulatory standards and guidance such as:

- General Pharmaceutical Council (GPhC) Standards for registered Pharmacies 2012
- GPhC Standards of Conduct, ethics and performance 2012
- Information Governance Toolkit
- Pharmaceutical Services Negotiating Committee (PSNC) Clinical Governance Requirements for Community Pharmacy 2012

4.1. Incident reporting

Providers are required to report incidents in writing to phcommissioning@wolverhampton.gov.uk:

- any clinical incidents which may cause harm or directly affect a service user
- any events that may stop or disrupt the service from operating normally or safely
- any medicine or medical device adverse incidents via the [Medicines and Healthcare products Regulatory Agency \(MHRA\) Yellow Card Scheme](#)
- Inform the commissioner within two working days of any clinical incidents occurring
- Providers should investigate any clinical incidents; implement any action and recommendations following investigation and share lessons learned where

appropriate.

4.2 Responding to National Patient Safety Alerts

- Providers are required respond appropriately to all relevant safety alerts issued via the national Central Alert System (CAS) and must keep a record of what has been done to implement or comply with any actions required.
- Providers will inform commissioners, within the timeframe stipulated on the alert, of the response, actions and any risks to service users or service delivery.

4.3 Risk Management

- Providers will ensure that any risks associated with the service are identified and managed.
- Providers will ensure that appropriate risk assessments are undertaken to account for Access to premises in line with Equality Act 2010, which replaces the Disability Discrimination Act 1995

4.4 Information Governance

- Providers are required to ensure that service user identifiable data is managed in accordance with the law.²
- Data breaches must be reported to commissioners within two working days of the incident occurring.

4.5 Complaints

- Providers will ensure that they have adequate policies and procedures in place to respond to customer complaints
- Providers will inform commissioners of any formal complaints relating to the service within two working days.

5. Applicable Service Standards

5.1 Applicable national standards e.g. NICE, GPhC

- NICE Public health guidance PH52 Needle and Syringe Programmes– issued March 2014 recommends provision of a mix of services namely level 1 (universal), 2 (pick and mix) and 3 (specialist).
- DEFRA Tackling drug related litter – Guidance and good practice (October 2005)
- Pharmacy staff are expected to operate the scheme in line with the General Pharmaceutical Council's Standards of conduct, ethics and performance (July 2012).

² Data Protection Act 1998

5.2 Applicable local requirements

- The pharmacy is open for a minimum of 40 hours per week over a 5 day period Monday to Friday.
- The pharmacy has appropriate staffing levels to cover the service.
- The pharmacy has appropriate health promotion materials available (obtained via Public Health England/Public Health Wolverhampton for service users and promotes its uptake.
- The pharmacy has standard operating procedures for the service (SOP's) and reviews its SOP's on a bi-annual basis or following critical incident(s).
- Non-regular pharmacists must be made aware of the service and the operational procedures in order to provide cover for the pharmacist.
- Pharmacy staff will provide the service in such a way as to promote equality of access across all community groups regardless of ethnicity, gender, disability or sexuality.

6. Data requirements and monitoring

The provider will be expected to participate in internal audits to aid service development and review outcomes. The Commissioner will review the service on a regular basis as well as responding to issues which may require a more urgent review.

The following section outlines requirements regarding data and information that shall be made available to the Commissioner.

6.1 Data capture and information systems

If available the provider should utilise the web-based IT system stipulated by the Commissioner that will deliver a fully electronic transaction record.

Furthermore, to fulfil reporting, contract monitoring and payment requirements, the Provider will also need to make certain data available to the Commissioner, specified below. The Provider will also need to demonstrate that the appropriate information governance requirements are met for all data collection and reporting, gaining patient consent for the data to be shared where required.

6.2 Contract monitoring and information submission requirements

Appendix 1 specifies a list of fields for a minimum dataset (MDS) extract that will need to be available to the Commissioner at a raw anonymised individual client level for each transaction; the Commissioner will create a dashboard to present relevant indicators for regular contract monitoring and payment validation.

In addition to the MDS, there are also quality measures that will need to be available to the Commissioner via an aggregated data report with a qualitative narrative where relevant.

From the MDS the commissioner will calculate the following Key Performance Indicators

(KPIs) for monitoring:

KPI	Frequency	Target
Number of needles/equipment supplied	quarterly	
Number of individuals using the service	quarterly	
Number of returned sharps bins		
% of returns as a % of equipment supplied		80%
% referrals-broken down by type i.e. sexual health, mental health, smoking cessation	quarterly	

6.3 Quality Measures

KPI	Frequency	Target
Client satisfaction-% of clients that are surveyed	annually	To be determined
Client satisfaction-% of clients that are satisfied with the service	annually	To be determined

A qualitative narrative should be supplied to support quality measures and KPIs.

7. Location of Service Provider Premises

7.1 The intention of the local authority is to ensure a good geographical spread of provision based on local needs.

8. Payment Schedule and finance

Payments to the contractor will be made in accordance with the tariff below.

Pharmacy payments will be quarterly and consist of:

- £25.00 per month retainer to cover administration and storage requirements.
- £0.20p for each needle and accompanying syringe (one hit kit) distributed as part of the pick and mix scheme.
- £1.00 per steroid pack distributed.
- 75p per sharps bin returned.

Claims for payment

Details of all activity must be entered on to the web based system provided by commissioners in a timely manner to meet claims deadlines. The data required to receive payments is fully specified below in the data requirements and monitoring section.

Wolverhampton City Council will make payments on a quarterly basis. The data requested must be submitted and available to the Commissioner a maximum of 7 working days following each quarter end to ensure timely payments.

Payments will be made according to the number of transactions, and as such the data entered onto this system will determine the level of payment to each provider. Where this information is not input onto the system within the required timescales this may result in payment for those service users not being able to be made to the Service Provider. Claims for activity more than three months old will not be paid.

The information required for each transaction may be developed to reflect the Council's monitoring requirements along with the development of newer monitoring systems.

Appendix 1-Minimum dataset fields

Field
Unique ID
Ward Code
Ward Name
LSOA
Pharmacy ID
Gender
Age
Ethnic Category
Country of birth
Main language
Migrant status
Date
Quantity of equipment supplied
Type of equipment supplied
Quantity of equipment returned
Substance misuse referral
Sexual health referral
Mental health referral

Other referral (specify)