



TENDER DOCUMENTS

PART 2 – SPECIFICATION

Contract title	PHARMACY SUPERVISED CONSUMPTION SERVICE
Contract ID	DN339056

Specification Version 2 (1.6.2018) Amended:
Section 2.1.4 updated to include the supervision of Espranor (effective 1 January 2020)
Section 2.6 updated to confirm Data Controller Status (effective 1 January 2020)
Section 2.8 updated regarding the notice requirements and terms regarding transfer of ownership or other significant changes including location and opening hours (effective 1 July 2021)

This specification forms part of the Pharmacy Supervised Consumption Service Contract. A copy of the contract can be obtained by emailing SubstanceMisuse@leeds.gov.uk

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SECTION 1

1 PREAMBLE

1.1 INTRODUCTION

This Specification sets out the Council's requirements in respect of a Pharmacy Supervised Consumption Service. It must be read in conjunction with Chapter 4 (Pharmacological interventions) of the Department of Health's *Drug misuse and dependence (UK guidelines on clinical management)* 2017 document. <https://www.gov.uk/government/publications/drug-misuse-and-dependence-uk-guidelines-on-clinical-management>

It details the standards and outputs which the Contractor (the pharmacy) is required to achieve and how these will be measured.

It will form part of the contract with the Council.

1.2 GENERAL DESCRIPTION

The Council commissions a comprehensive and integrated drug and alcohol treatment service (Forward Leeds) which provides a full range of structured treatment and support interventions. This includes delivery of evidence based psycho-social interventions (individual, family and group work) and the delivery of a full range of pharmacological interventions including prescribing and clinical support for withdrawal, stabilisation, reduction and detoxification. A key element in the recovery journey of a significant number of service users is the prescription of opioid substitution medication i.e. replacing an addictive substance with a prescribed medication. The pharmacist will supervise the consumption of opiate substitution medication to service users who have had this prescribed as part of their package of treatment.

Supervised consumption (of methadone or buprenorphine) is an important service provided by pharmacies to target misuse of illicit substances, prevent withdrawal symptoms and reduce risk to service users. Prior to prescription, a full assessment of the service user will have been undertaken by a prescribing clinician. As with any other prescription received in the pharmacy, the pharmacist has a responsibility to undertake a clinical check for interactions and appropriateness.

Treatment for addiction that includes the use of medication along with counselling and other support is often the best choice for opioid addiction. For service users who are addicted, medication allows them to regain a normal state of mind, free of drug-induced highs and lows. It can reduce problems of withdrawal and craving. These changes can give service users the chance they need to focus on the lifestyle changes that lead back to healthy living. Used properly, the medication does not create a new addiction but helps manage addiction so that the benefits of recovery can be maintained.

Local pharmacies are well-placed to deliver this service. Not only are they widely based in all communities across the city, making it easier for service users to access the service, the pharmacists and support staff also have the relevant knowledge and training to deliver the service and provide additional support and advice.

Safety of service users is an integral part of the service. The person supervising the consumption will be the pharmacist or another appropriately trained pharmacy staff member. As well as administering the buprenorphine or methadone to a professional

standard, the pharmacist will also provide harm reduction advice and sign-post service users to relevant treatment or health services (e.g. One You).

1.3 VISION AND OUTCOMES

Leeds has a vision to be the best city in the UK: one that is compassionate with a strong economy that tackles poverty and reduces the inequalities that still exist. We want Leeds to be a city that is fair, sustainable, ambitious, fun and creative for all.

The Leeds Drug and Alcohol Strategy and Action Plan 2016-18 sets out the ambition:

“Leeds is a city that promotes a responsible attitude to alcohol and where individuals, families and communities affected by the use of drugs and alcohol can reach their potential and lead safer, healthier and happier lives”.

The provision of an efficient and effective supervised consumption service, working hand in hand with the package of support provided by the commissioned integrated drug and alcohol service, will contribute to this ambition by:

- helping service users to stabilise and / or reduce their drug usage and ultimately become drug free
- providing a free, accessible, effective and efficient service
- providing a professional, user-friendly, non-judgmental, person-centred and confidential service
- ensuring the safe and consistent consumption of prescribed substitute medication
- supporting service users to adhere to their treatment plan, thereby reducing the harm caused by illicit drug use
- helping service users to maintain and improve their level of health through the provision of support and advice on general health and wellbeing
- keeping to a minimum the misdirection of controlled drugs, thus contributing to a reduction in drug related deaths in the community
- promoting access and making referrals to other primary care agencies where appropriate
- accurately recording information relating to supervisions to inform service delivery and development

1.4 DRIVERS AND BENEFITS

The commissioning of this Pharmacy Supervised Consumption Service directly supports the delivery of key outcomes and priorities within a number of national and local strategies, policies and initiatives.

National

2017 Drug Strategy	Aims are to reduce all illicit and other harmful drug use, and increase the rate of individuals recovering from their dependence
The Department of Health publication: Drug misuse and dependence - UK guidelines on clinical	Guidelines intended primarily for clinicians (including pharmacists) providing drug treatment for people who misuse or are dependent on drugs. For the purposes of this specification, Chapter 4 – Pharmacological interventions – is of particular relevance

management (often referred to as the Orange Book)	
NICE Guidance (TA114)	Recommendations relating to the use of methadone and buprenorphine for the management of opioid dependence
Royal College of General Practitioners: Guidance for the use of substitute prescribing in the treatment of opioid dependence in primary care	Provides detailed guidance covering the use of substitute medication
General Pharmaceutical Council: Standards for pharmacy professionals	Clearly sets out the standards that pharmacy professionals must meet in order to deliver safe and effective care

Local

Strategy	Priorities	Indicators
Vision for Leeds 2011-30	<ul style="list-style-type: none"> • best city for communities • best city for health and wellbeing 	<ul style="list-style-type: none"> • people are safe and feel safe • people are active and involved in their communities • people live longer and healthier lives • people are supported by high quality services to live full, active and independent lives
Best Council Plan 2017-18	<ul style="list-style-type: none"> • better lives – giving people with care and support needs the right care and support at the right time • health and wellbeing- improving physical and mental health 	<ul style="list-style-type: none"> • reduced avoidable years of life lost
Health and Wellbeing Strategy 2016-21	<ul style="list-style-type: none"> • people will live longer and have healthier lives • people will live full, active independent lives • people's quality of life will be improved by access to quality services 	<ul style="list-style-type: none"> • avoidable years of life lost • people supported to manage their health condition
Leeds Drug and Alcohol Strategy 2016-2018	<ul style="list-style-type: none"> • early identification and support of people who want to change their alcohol and/or drug using behaviour • ensure good quality drug and alcohol treatment services that respond rapidly and effectively to changing patterns of drug and alcohol misuse • ensure that the harms caused to health by the use of drugs and alcohol are prevented and reduced to improve health outcomes 	<ul style="list-style-type: none"> • number of successful completions from drug and alcohol treatment

SECTION 2

2 STATEMENT OF REQUIREMENTS

2.1 Scope

2.1.1 Principles

There are certain elements of the service that are integral to its delivery and are emphasised here as they should be considered throughout the specification.

Person-centred

The service will play an important role in supporting individuals in their treatment journey. It is crucial the service user is at the heart of what is delivered and how. This means focusing on what is important to them, ensuring ease of access, understanding their context, any barriers, and providing opportunities for the service user voice to be heard throughout delivery. Within this however, it is important to note that reducing drug related deaths is the most important outcome of this service. Being on supervised consumption reduces risk and sometimes goes against service user wishes, but nevertheless is mandatory until risk to individual and the public is seen to be at an acceptable level. This restriction of choice needs to be handled with due sensitivity and a willingness to uphold unpopular boundaries.

Accessible and inclusive

Support around drug and alcohol use can be required by people from a range of different ethnicities, religions, class, age, sexual orientation, disability and lifestyle. It is essential therefore that the service recognises, understands and addresses the barriers that can prevent individuals from all communities in Leeds from fully engaging with support. Pharmacy staff need to make service users feel welcome and safe in the pharmacy building and be able to provide information and advice in an easy-to-understand and engaging manner.

Responsive

The service must be responsive to changes in a service users condition and follow up concerns regarding the health and wellbeing of service users in a timely manner. This will involve providing information and advice, contacting the prescriber / key worker and signposting to other services as appropriate.

Holistic approach

The service will ensure all staff are skilled at having 'better conversations', with service users to enable them to build positive relationships. This may enable them to identify additional needs, with a view to either addressing those needs or encouraging the service user to make links with other organisations. The client group is likely to have other health and wellbeing needs, e.g. housing-related support, care support, social isolation or mental ill health, and the service should be able to signpost appropriately, including to other Forward Leeds services, thereby making a more sustainable outcome for the service user more likely.

2.1.2 Scope of the Service and Eligibility

This specification relates to the provision of a supervised consumption service carried out on pharmacy premises only. All pharmacies must be located in Leeds.

The service is primarily for Forward Leeds service users.

Short-term arrangements for service users where the prescriber is not Forward Leeds are acceptable. The Council will monitor and review the number and level of these supervisions, in particular those from out of the Leeds area and reserves the right, in particular where such

arrangements appear long term or excessive and are not for the benefit of Leeds residents, to make it the pharmacy's responsibility to seek payment from the prescribing agency instead of from the Council.

Regarding Leeds residents where the prescriber is not Forward Leeds, work will be undertaken, in conjunction with Forward Leeds to support GPs/agencies in referring service users into Forward Leeds where they can benefit from the full range of recovery-focused, specialist services available. Where service users do not wish to transfer, these prescribers will be encouraged to ensure supervision is part of a longer-term plan with other wrap-around support provided and regular review of prescriptions.

Opiate addiction is relatively uncommon in under 18 year olds, but nevertheless does occur and then opiate substitute prescribing may be required. In these instances additional support for the service user will be required and the pharmacist will be expected to work very closely with the young person's key worker to ensure appropriate support is provided.

The Department of Health publication: Drug misuse and dependence - UK guidelines on clinical management (often referred to as the Orange Book) states that *the aims of a community pharmacy based supervised consumption service include:*

- *ensuring the patient receives the prescribed dose*
- *reducing diversion of prescribed doses*
- *providing an opportunity for the pharmacist to make a regular assessment of patient compliance with treatment and of their general health and wellbeing*
- *providing an opportunity for the pharmacist to build a therapeutic relationship with the patient that is beneficial to promote health and harm reduction*
- *reducing the risks of drug related overdose and deaths*
- *minimising the risk of accidental consumption by children*

2.1.3 Funding

The pharmacy will be paid per supervision and the unit price is:

- £1.45 per methadone supervision
- £2.85 per buprenorphine supervision

This payment is for the act of supervision only. There are separate arrangements in place for funding the cost of the methadone and buprenorphine.

If two different strengths of buprenorphine or methadone are supplied to a service user and are supervised together this only qualifies as one supervision fee. To ensure that claims are accurate and there are no duplications, only 1 prescription per service user per day should be recorded. If more than one supervision is claimed for a service user on any day, this will be viewed as a duplicate and appropriate action will be taken to rectify any over payment.

2.1.4 Core activities

Supervise the consumption of prescribed methadone or buprenorphine

In order to safely and effectively deliver the supervised consumption service, the pharmacist must:

- confirm the identity of the service user – the person receiving the dose of medication must be the person named on the prescription. If there are any concerns regarding a service user's identity the pharmacist must get in touch with the prescriber or key worker. The pharmacist should not supply the prescription until they have confirmed the service user's identity
- at the first visit a treatment agreement should be discussed; this will outline areas such as the role of the pharmacist and the service user, opening hours, missed dose procedures, unacceptable behaviour and under what circumstances the pharmacy would share data/information with other agencies etc; the treatment agreement should be signed by both the pharmacist and the service user and a copy kept by both; it is the responsibility of the pharmacy to develop a robust and appropriate treatment agreement
- undertake a full clinical check of the prescription and ensure that it is legally compliant
- dispense exactly what the prescription specifies, contacting the prescriber for clarification if the prescription is unclear or ambiguous
 - if possible, prepare daily doses in advance in order to avoid delays when the service user comes into the pharmacy
 - pack daily methadone doses in a standard dispensing bottle, label and store
 - pharmacies using automated dispensing systems may measure a daily dose for supervised consumption into a labelled cup
 - daily buprenorphine tablets should be placed in a labelled container; where there are suspicions that buprenorphine is being diverted in order to abuse, sell or swap, crushing tablets can be an option to support adherence to treatment (noting that tablets do not need to be ground to a powder but merely broken into a few small fragments); this course of action must only be undertaken with agreement from the prescriber

Crushing of buprenorphine tablets is permitted in the Orange Book:

“Some pharmacists have been crushing buprenorphine tablets before consumption to make the supervision process more straightforward. This practice, while technically off-licence, may sometimes be undertaken with appropriate clinical governance approval and protocols”

- all methadone and buprenorphine supplies must be kept in the pharmacy's Controlled Drugs cabinet
- offer a quiet, discreet and confidential area where consumption of substitute medications can take place
- ensure that each dose is fully supervised
- monitor the service user's response to the prescribed treatment
- provide general health advice, including service user safety and information on minimising harm

- offer access to appropriate health promotion materials and signpost to further advice and support
- promote safe practice to the service user, including advice on storage and handling of medication where appropriate, especially if living with children and/or other vulnerable adults

The right to request pharmacies to issue a receipt for prescriptions received is reserved and will be implemented where there is a history of lost/misplaced prescriptions. This procedure will be discussed with individual pharmacies on a case by case basis.

Supervise the consumption of prescribed Espranor

Espranor is a freeze dried wafer (oral lyophilisate) which contains buprenorphine (2mg or 8mg) and dissolves when placed on the tongue. It is licensed for substitution treatment for opioid drug dependence, within a framework of medical, social and psychological treatment for persons aged 16 and above.

To ensure effective supervision the oral lyophilisate should be removed from the blister pack with dry fingers – any contact with moisture will result in disintegration of the wafer. The oral lyophilisate must be placed whole on the tongue until dispersed. This is different to current buprenorphine tablets which are placed under the tongue. Although the wafer will disintegrate quickly, swallowing must be avoided for at least 2 minutes. Food and drink should not be consumed for 5 minutes after administration. Observation during this period is essential. If the oral lyophilisate or saliva containing buprenorphine is swallowed, the buprenorphine will be metabolised, excreted and have minimal effect.

Espranor results in similar clinical outcomes and can also have the same adverse effects as other buprenorphine products. Espranor is not directly interchangeable with other buprenorphine products. Unlike other oral forms of buprenorphine, Espranor contains gelatin. It also has a minty taste.

Prior to commencing the supervision of Espranor, pharmacies may be required to undertake training and / or demonstrate that staff are familiar with the requirements of Espranor supervision. Confirmation of stock and/or access to reliable supplies may also be requested.

When recording the supervision of Espranor on PharmOutcomes for payment purposes, Espranor should be selected from the drop down menu (not Buprenorphine). The unit price payable is £2.85 per supervision.

With the exception of the specific reference to the crushing of buprenorphine tablets, all other references to Buprenorphine and general terms within the Specification shall apply to the supervision of Espranor.

When to withhold dose and/or contract prescriber/key worker

The pharmacist must withhold the dose if the service user:

- has missed 3 doses; tolerance may be lost quickly and it is important that the prescriber has the opportunity to reassess the service user before treatment is continued
- appears intoxicated; it may be appropriate to ask the service user to return later in the day

The pharmacist must withhold the dose until the prescriber has been contacted when:

- the service user asks someone to collect a dose on their behalf e.g. in case of illness
- the prescription is ambiguous or incorrectly written

- the identity of the service user is in doubt
- a prescription is presented for a new service user and prior contact has not been made by the prescriber
- a prescription is presented that states the name and address of a different pharmacy

The pharmacist must contact the prescriber or key worker when the service user:

- has missed 2 consecutive doses
- misses single doses on a regular basis
- appears intoxicated
- tries to avoid supervision or does not consume the whole dose under supervision
- is abusive or threatening

A Standard Operating Procedure must be in place, clearly setting out the roles and responsibilities of both the pharmacy staff and the service user. It is the responsibility of the pharmacy to develop a robust and appropriate Standard Operating Procedure.

All of the above activities must be carried out within the context of a user-friendly, non-judgmental, person-centred and confidential service.

2.1.5 Access

It is important to have numerous pharmacies delivering the service across the city, as having a pharmacy that is easy to access (e.g. one that is close to home or work) reduces barriers for service users accessing the service. Any potential barrier to being able to access substitute medication might encourage service users to swap their substitute medication for illegal street drugs. As well as proximity being a factor in reducing barriers, having pharmacies with late night and weekend opening will also encourage better engagement with the service.

The pharmacy must make it clear to service users what days and hours the supervised consumption service is available. It is expected that the service will be available during the pharmacy's normal opening hours, unless there is strong justification for this not being the case.

If a pharmacy intends to change the days or hours during which it is open, or the hours during which the supervised consumption service is available where this is different to standard opening hours, three months notice must be given in writing to the Council of any intended change.

2.1.6 Partnership working with key agencies

The Orange Book states that:

As part of the service, there should be systems to ensure information about patients can be fed to and from the prescriber and keyworker, as well as agreement from the patient that confidential information can be shared between the pharmacist and named members of the multidisciplinary team.

The service is part of community treatment provision for drug users and as such is commissioned to work closely with other treatment service providers, especially Forward Leeds. For the service to operate effectively, it is essential that good working relationships are

developed and maintained with Forward Leeds and other prescribing and complementary services within Leeds. The pharmacy will be expected to develop its own working links with local health and social care agencies as appropriate.

The relationship with the prescriber and key worker is particularly important when there are concerns about the health of a service user and/or when they are missing pick-ups. In these instances it is important to have effective 2-way communication routes and a prompt response to telephone messages and emails is essential. Pharmacies should consider and may be requested to provide Forward Leeds with an alternative means of contacting the pharmacy in the event of difficulties using the main pharmacy telephone number.

In terms of service users missing pick-ups of medicines, the Orange Book states:

If a patient has not taken their regular prescribed dose of opioid, there is the possibility that their tolerance to the drug could have reduced, increasing risk of overdose if the usual dose of medication is then taken...It is good practice for the pharmacist and prescriber to communicate about a patient failing to collect methadone or buprenorphine doses as it may be an indicator of instability or increasing risk.

Judgement is required over how to respond to single or repeated missed pick-ups. However, failure to collect medication should prompt the dispensing pharmacist to consider contacting the prescribing clinician, especially during induction. If the medication is not collected for three consecutive days, then the pharmacist should obtain advice from the prescriber on what action to take. A pharmacist should not normally dispense the fourth day's dose unless they have confirmed with the prescriber that it is appropriate to do so. Depending on what the prescribing service knows about the circumstances of the patient, and on their assessment of risk, this will result in advice to the pharmacist either to continue to dispense or to ask the patient to attend the prescribing service for urgent clinical review.

2.1.7 Staffing

The pharmacy must have a named Accountable Officer who is responsible for ensuring the service is delivered effectively. This is likely to be the Lead Pharmacist or the Store Manager. The pharmacy must inform the Council of any changes to the named Accountable Officer and have in place a hand-over procedure for any new or replacement staff members who will be involved in delivering the service.

The pharmacy must employ sufficient numbers of suitably qualified staff to enable it to effectively carry out the service. The pharmacists and support staff involved must have relevant knowledge and be appropriately trained.

All staff involved in the delivery of the service must adhere to the standards for pharmacy professionals as set out by the General Pharmaceutical Council set out below:

Pharmacy professionals must:

- Standard 1: provide person-centred care
- Standard 2: work in partnership with others
- Standard 3: communicate effectively
- Standard 4: maintain, develop and use their professional knowledge and skills
- Standard 5: use their professional judgement
- Standard 6: behave in a professional manner
- Standard 7: respect and maintain a person's confidentiality
- Standard 8: speak up when they have concerns or when things go wrong
- Standard 9: demonstrate leadership

In addition to the above standards, it is important that staff have knowledge of drug and alcohol issues in order to:

- listen to, respect and reflect on the concerns of the service user with his/her drug use and use this to determine the most appropriate action for further information, advice or referral
- have a better understanding of the challenges faced by service users
- explain clearly the harm reduction messages associated with drug use and identify factors that might discourage service users from practicing harm reduction methods and seek to help with those factors by simple measures or suggestions

The CPPE (Centre for Pharmacy Postgraduate Education) offers a range of training relating to substance use and misuse and it is expected that pharmacy staff will complete this training. All staff involved in the delivery of this service must complete the CPPE Declaration of Competence (DoC) relating to supervised consumption. This must be recorded on PharmOutcomes.

2.2 KEY CONTRACT DATES

The contract will take effect from 1st July 2018 and expire automatically on 30th June 2021. The Council may extend the term of this contract (the extension period) up to a period of 36 months. If the Council wishes to extend this contract, it shall give the pharmacy at least 3 months' written notice of such intention before the expiry date.

The pharmacist should be aware that when reviewing whether to take up any contract extension provision which is at the sole discretion of the Council, the Council will, under its duty to obtain best value, consider a range of factors when deciding whether to extend or retender this contract. The most important factors will be contract performance, efficiency improvements and/or cost reductions in line with the potential savings the Council has reason to believe would be achievable by retendering the contract.

2.3 CLIENT DETAILS

See Section A "The Particulars", paragraph A.4

2.4 ORDERING OF SERVICES

NOT USED

2.5 COMMUNICATIONS STRATEGY

Communicating with service users

The pharmacy will ensure that information provided verbally and in written and other formats follows good practice guidance and recommendations, such as Plain English Crystal Mark.

The pharmacy will be required to respond appropriately to any differing communication needs, requirements and preferences of the community and to provide a service which addresses issues of language, literacy, hearing, visual, and / or cognitive impairment, and other forms of support in communication.

Service user involvement

The pharmacy will develop mechanisms to routinely collect feedback on service user satisfaction and respond to any issues raised. Feedback will be shared with the prescriber and the Council as appropriate.

Complaints

There will be a clear complaints procedure which will be made available to service users. All complaints will be logged and recorded and documents must be made available to the Council when requested. Where complaints cannot be resolved within the service, the Council reserves the right to investigate and take action where required and appropriate, including escalating concerns to NHS England, the Police and other agencies as appropriate.

2.6 INFORMATION GOVERNANCE

2.6.1 Contractor identified as Data Controller

In accordance with Data Protection Legislation, the Contractor has been identified as the Data Controller for all Personal Data which is being processed in relation to this contract.

As a Data Controller the Contractor determines both the purposes for which and the manner in which all Personal Data, which is being handled in relation to the performance of the contract, is to be processed. The Contractor is responsible for ensuring compliance by its sub-contractors with Data Protection Legislation.

As a Data Controller the Contractor is required to ensure that any processing of Personal Data, which is needed to fulfil the terms of the contract, is carried out in accordance with Data Protection Legislation, and any information security breaches or security incidents must be reported to the Council immediately after the Contractor becomes aware of the breach.

Further information about the principles of the General Data Protection Regulation and the Contractor obligations as Data Controller can be found on the Information Commissioner's website (<http://www.ico.org.uk>)

2.7 TRANSITION AND MOBILISATION

No mobilisation period is required but the pharmacy is expected to familiarise themselves with the new specification and make sure that the transition into the new contract period is managed smoothly.

2.8 EXIT PLAN

Notice Requirements

2.8.1 If a pharmacy wishes to stop delivering the Pharmacy Supervised Consumption Service at one or more pharmacy locations, or make significant changes to pharmacy provision that will impact on this service, either during or at the end of this contract, a minimum of 30 business days' notice must be given in writing. This applies, but is not necessarily limited, to the following circumstances:

- i. pharmacy closure
- ii. a transfer of pharmacy ownership including operation through a management agreement

- iii. relocation to new premises (whether or not a transfer of ownership is involved)
 - iv. a significant reduction in pharmacy opening hours - this is particularly important where it affects evening opening hours or the number of days a pharmacy is open
- 2.8.2 This notice period is required to allow appropriate contractual and operational arrangements to be put in place to ensure continuity of care for existing service users. The Pharmacy will also need to liaise direct with the Forward Leeds substance misuse service so that they have adequate time to review prescribing and support requirements prior to any change taking place. With a closure or transfer, Community Pharmacy West Yorkshire should also be contacted regarding payment.
- 2.8.3 Note that, for the purposes of this contract, a business day is Monday to Friday (excluding bank holidays); so, in practice, the notice requirement is a minimum of 6 calendar weeks.
- 2.8.4 Notice in writing can be given by email to SubstanceMisuse@leeds.gov.uk
- 2.8.5 Failure to give the correct notice may result in delays to the agreement and commencement of a new contract and / or variation to an existing contract leading to delays in payment.

Transfer of Pharmacy Ownership

- 2.8.6 Where a change of pharmacy ownership is involved, there is no automatic right for delivery of a Pharmacy Supervised Consumption Service under contract to Leeds City Council to be transferred to the new owner. If the business acquiring the pharmacy wishes to deliver the Pharmacy Supervised Consumption Service, prior agreement from Leeds City Council is needed. This must be requested at least 30 business days (i.e. 6 calendar weeks) in advance of the date the pharmacy wishes to commence delivery.
- 2.8.7 The above applies even when the business acquiring the pharmacy already has a contract with Leeds City Council to deliver the Pharmacy Supervised Consumption Service at other pharmacy locations. It also applies where delivery would be through a management agreement until transfer is completed.
- 2.8.8 Leeds City Council will take into account a number of factors when making a decision as to whether to enter into a new contract or agree to the variation of an existing contract. This includes, but is not restricted to, previous track record and experience in delivering supervised consumption and the need for the service in the area where the pharmacy is or will be located. This also applies where there is no change of ownership but the pharmacy is making significant changes to existing provision such as relocating to new premises or reducing its opening hours.

The Service Specification forms part of the aforementioned contract (as varied 1 January 2019). All other terms and conditions contained within the aforementioned contract shall remain unchanged excepting the amends mentioned above. Should you require a copy of the contract, please email SubstanceMisuse@leeds.gov.uk

2.9 EQUALITY

The pharmacy shall comply with all relevant Equality legislation as set out in Part 3 Terms and Conditions Clause.

The pharmacy must not discriminate between or against service users, on the grounds of age, disability, gender reassignment, marriage or civil partnership, pregnancy or maternity, race, religion or belief, sex, sexual orientation or any other non-medical characteristics except as permitted by the Law.

The pharmacy must provide appropriate assistance and make reasonable adjustments for service users who do not speak, read or write English or who have communication difficulties (including without limitation hearing, oral or learning impairments).

In performing this contract, the pharmacy must comply with the Equality Act 2010 and have due regard to the obligations contemplated by section 149 of the Equality Act 2010 to:

- eliminate discrimination, harassment, victimisation and any other conduct that is prohibited by the Equality Act 2010
- advance equality of opportunity between persons who share a relevant protected characteristic (as defined in the Equality Act 2010) and persons who do not share it
- foster good relations between persons who share a relevant protected characteristic (as defined in the Equality Act 2010) and persons who do not share it and for the avoidance of doubt this obligation shall apply whether or not the Contractor is a public authority for the purposes of section 149 of the Equality Act 2010

The pharmacy must provide to the Council as soon as reasonably practicable, any information that the Council reasonably requires to:

- monitor the equity of access to the services
- fulfil their obligations under the Law

All communication and branding must be accessible to a wide range of audiences and make it clear that the service is fully inclusive and available to all (subject to eligibility criteria).

The service will be accessible to all Leeds residents (subject to eligibility criteria).

2.10 ENVIRONMENT AND SUSTAINABILITY

The pharmacy shall in performing the service for this contract meet all Legislation, Guidance and Good Industry Practice in environmental management and meeting the objectives of the Councils sustainability policies.

The Council is committed to reducing both its direct and indirect carbon dioxide CO₂ emissions. Internally, many steps have been taken to address the impacts, including the implementation of relevant policies to embrace the sustainable procurement concept. A key focus of the drive is to reduce the impact of the transportation associated with the delivery of our services. As such,

there is an expectation from providers to implement initiatives to reduce and / or offset the travel emissions linked to commissioned contracts.

2.11 HEALTH AND SAFETY

The pharmacy must comply with all relevant health and safety legislation and requirements during this contract.

Controlled drug error reporting

Methadone dispensed in excess of that prescribed can lead to toxicity. The risk of overdose is particularly high during induction, therefore extreme caution is required in the early stages of treatment. If an amount greater than the prescribed dose is dispensed and given to the service user, either as supervised or 'take home', the pharmacist must:

- advise the service user of the mistake and explain the possible seriousness of consequences
- inform the service user of signs/symptoms of toxicity and advise they go to hospital if these symptoms develop
- advise the service user to remain in the company of others for the following few hours
- if the service user has left before the mistake is realised, every attempt must be made to contact them; if they cannot be contacted it may be appropriate to request the assistance of the local police in locating the person should this be deemed necessary to ensure the person's safety
- contact the prescriber and key worker immediately and update them on the situation
- if the prescriber decides that the service user needs to go to hospital it is important that they are accompanied to ensure accurate information is provided and to support service user safety. Examples of when hospitalisation would be advised are when:
 - service user has taken two doses of the prescribed daily dose on the same day
 - service user has taken more than the prescribed dose in addition to alcohol and/or other substances
- record the details of the incident and all action taken following the serious incident reporting procedure as outlined in Appendix 1

2.12 EMPLOYMENT SKILLS AND ENGAGEMENT PLAN

NOT USED

2.13 CORPORATE SOCIAL RESPONSIBILITY

NOT USED

2.14 INSURANCE AND LIMITATION OF LIABILITY

See Section C "Special Terms and Conditions", paragraph C3

2.15 QUALITY MANAGEMENT

The pharmacy will ensure that all provision is delivered safely and to a high standard of quality, working within the standards as described in 2.1.8. and 2.16. This will include:

- reviewing its Standard Operating Procedure on an annual basis

- demonstrating that all pharmacists and staff involved in the provision of the service have undertaken relevant training
- demonstrating that clear and accurate records are kept
- participating in any evaluation of the service as requested by the Council, including the assessment of service user experience.

2.16 STATUTORY GUIDANCE AND GOOD INDUSTRY PRACTICE REQUIREMENTS AND GUIDELINES

Pharmacy staff must be familiar with and compliant with:

- NHS Pharmaceutical Services Regulations (NHS Contractual Framework for Community Pharmacy)
- Department of Health: Drug misuse and dependence (UK guidelines on clinical management)
- General Pharmaceutical Council: Standards for pharmacy professionals
- NICE guidance: Methadone and buprenorphine for the management of opioid dependence

The pharmacy will provide and maintain a safe and suitable environment for service users and comply with all relevant statutory requirements, legislation, Department of Health Guidance and professional codes of practice and all health and safety regulations.

The pharmacy will ensure that all relevant consents and certification required by legislation, guidance or good industry / working practice are obtained and maintained.

Legislation - The pharmacy is expected to comply with all relevant legislation in so far as they are applicable to the service. Relevant legislation includes:

- The Equality Act 2010
- The Protection of Freedoms Act 2012
- General Data Protection Regulations 2018
- Disabled Person Act 1986
- Race Relations Amendment Act 2000
- Safeguarding Vulnerable Groups Act 2006

2.17 SAFEGUARDING

See Appendix F

2.18 LEEDS CITY COUNCIL POLICIES

The Council policies detailed below are relevant to the service described within this specification but not exhaustive:

- Vision for Leeds 2011 – 2030
- Leeds Drug and Alcohol Strategy 2016-18
- The City Priority Plans
- The Council Business Plan
- Clear Desk & Screen Policy
- Leeds Interagency Policy for Sharing Information (2009)

- Raising Concerns Policy
- LCC Whistle Blowing Policy
- Code of Conduct for Contractors, Service Contractors and Suppliers
- Equality and Diversity
- LCC Information Sharing Policy

SECTION 3

3.1 CONTRACT MONITORING, MEASUREMENT AND PERFORMANCE

Contracts will be managed by officers from the Council to ensure safe and effective delivery of the service. This will include ongoing performance monitoring, risk management and cost analysis which will be undertaken in conjunction with public health colleagues, Forward Leeds and Community Pharmacies West Yorkshire (CPWY) as appropriate to ensure the service continues to meet requirements including quality standards and value for money.

It is important that the pharmacy accurately records all activity taking place through this service. CPWY act as the service administrator for the Council for this contract. All pharmacies delivering the supervised consumption service must use PharmOutcomes - a web-based system designed to help pharmacies provide services more effectively and to make it easier for commissioners to audit and manage these services.

The process is:

- pharmacy receives prescription
- if the service user is new they are registered on the system with date of birth and initials – this will create a unique and anonymous identification number
- each prescription is then input onto the system, with the number of days / days that are supervised
- the system will notify the pharmacist when the prescription has ended to make sure that the record is up-to-date and complete
- each day of the prescription should be marked as one of the following, with only 'Supervised' generating a cost:

PharmOutcomes Entry	Description
Supervised	Medication supervised as per prescription
Take home dose	Not supervised as dose supplied on a previous day
Missed dose - did not attend	Script indicated supervision but service user did not attend pharmacy
Missed dose - refused supply	Script indicated supervision, service user attended pharmacy but was refused supply
New prescription issued	New script was issued to replace existing script
Prescription complete	Script was for less than 14 days. Mark all days not covered by the script with this option
Poured but not collected	Where methadone was measured and prepared for the service user but the service user did not attend to collect

The system will prevent multiple prescriptions being entered for a service user, e.g. where a drug is prescribed at different doses on separate prescriptions that run concurrently, only one supervision is recorded for payment.

The aggregated data provided by the individual pharmacies will be used to monitor the overall service, measure the demand for the service and help forecast future budget requirements.

The information stored on PharmOutcomes will be used to generate reports which include the following information:

- system created patient identification number
- age, initials and partial postcode of service user

- number of service users each month
- number of provision / prescriptions
- prescription start date
- details of prescriber
- drug details (methadone or buprenorphine)
- status of supervision on each given day of prescription (supervised, take home, missed etc.)

The Council will have quarterly meetings with CPWY. Due to the number of pharmacies delivering the service, CPWY is an effective channel for the Council to communicate with pharmacies via PharmOutcomes and newsletters. Any key messages or opportunities that the Council wishes to share with pharmacies can be delivered via CPWY.

3.2 GOVERNANCE

The provider must have a robust quality assurance procedure, which includes regular internal monitoring of the service (to ensure compliance with the contract and other regulations and good industry practice standards), gathering of information about service user satisfaction and analysis and action on findings.

3.3 PAYMENT TERMS AND INVOICING

Pharmacies are paid per supervision of either methadone (£1.45) or buprenorphine (£2.85) with CPWY administering payments on behalf of the Council through a separate contract.

Payments are made on a monthly basis, generated by the data input onto PharmOutcomes. All service activity should be entered promptly and the provider must ensure that all information recorded on PharmOutcomes is a fair and accurate recording of the activity it has undertaken. If supervisions are recorded after 4 weeks following the last supervision date they may not be paid.

3.4 INDEXATION

Indexation shall not be applicable to the agreed contract price.

3.5 VARIATIONS

See Section B “General Terms and Conditions”, paragraph B22

3.6 OPTIONAL ADDITIONAL FINANCIAL REQUIREMENTS

NOT USED

SECTION 4

DEFINITIONS AND BACKGROUND INFORMATION

4.1 DEFINITIONS AND INTERPRETATIONS

See Appendix O

4.2 PRESENT PROVISION

The service is currently available at 164 pharmacy outlets across Leeds through 64 separate contracts with a wide range of pharmacies from small independents to large national chains. This represents the majority of pharmacies in Leeds and provides city-wide coverage facilitating access to provision and service user choice. The service is currently used by an average of 1,700 service users per month. Service users select which pharmacy to use, basing their choice on factors such as proximity to home, transport routes and opening hours. The pharmacy is remunerated for each individual supervision at a rate of £1.45 per methadone supervision and £2.85 per buprenorphine supervision.

4.3 LEEDS CITY COUNCIL INFORMATION

The Service is to be delivered within the Leeds Metropolitan District. More information can be found at www.leeds.gov.uk.