



CGL Kirklees

Integrated Substance Misuse Service

**Service Level Agreement for Supervised Self
Administration of Methadone and Buprenorphine
(including Espranor)**

**Including guidelines for Pharmacists
and Pharmacy Technicians**

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Introduction

This Service Level Agreement and guidelines outline the background to and the administrative processes for the Supervised Self Administration Scheme for Methadone and Buprenorphine (including Espranor). This document also contains an application for those interested in joining the scheme.

Pharmacy services for drug users qualify as locally Enhanced Services under 'The Contractual Framework for Community Pharmacy' and as such participation by community pharmacists in this service remains voluntary and guided by localised need. However, those who join the scheme will have a contractual obligation to adhere to these guidelines and to input as appropriate into the 'shared care' of substance users.

Pharmacists participating in this service will be expected to take on the number of clients that they feel appropriate for their pharmacy within the parameters of good practice taking into account all of their community responsibilities.

Models of Care, introduced by the National Treatment Agency in 2002 outlines a four tier system of service provision based on the principles of National Service Frameworks. The aim is to provide treatment through integrated care pathways across these four tiers. Pharmacists are regarded as a tier one service in Kirklees, a non-substance misuse specific service, but which offers advice and support to substance users. The Care pathway developed for Supervised Self Administration of Methadone and Buprenorphine (including Espranor) is shown in Appendix 1.

One key element of drug treatment for opiate users is the prescribing of Methadone or Buprenorphine (including Espranor). Studies have shown that Methadone Maintenance Treatment reduces levels of injecting drug use and associated health problems, acquisitive crime and drug related death among those in treatment. Thus the Clinical Guidelines believe it to be 'an important part of drug misuse services' (DoH, 1999:45). Prescribing substitute medications allows time for individuals to implement personal or social changes that can reduce the impact of their illicit drug use and is a key element to increase the opportunities of individuals to achieve their goals.

Across Kirklees, opiate substitution treatment services are managed by the Public Health Commissioned local Substance Misuse Services (SMS).

The Role of Community Pharmacy and the need for a Supervised Methadone and Buprenorphine (including Espranor) Self-Administration Programme

Pharmacists play a key and unique role in the care of the substance users by:

- Being instrumental in supporting drug users in complying with their prescribing regime, therefore reducing incidents of accidental death through overdose.
- Keeping to a minimum the misdirection of controlled drugs, which may help to reduce drug related deaths in the community.
- The daily contact that they have with their service users, and their ability to monitor and offer advice on the service user's general health and wellbeing.
- Integrating the pharmacists into the 'shared-care' service their gateway role can be developed to maximise the positive impact treatment has for service users.

An important consideration however is that adhering to daily supervision regimes reduces opportunities for individuals to integrate back into society through employment, education, holidays etc. It is important that once the service user is stabilised and feeling confident, that the opportunity to increase their take home doses is fully considered. In line with the 'Drug Misuse and Dependence – Guidelines on Clinical Management' take home doses are unlikely to be provided for the first three months. At times of crisis or relapse, supervision may need to be temporarily reinstated. It should be noted that re-instatement dose may not be the same as the most recent dose. This should not be seen as a failure, as making changes to drug use and habitual behaviours can be a lengthy process with 'lapsing' a common feature.

It is therefore important that the service user attends the same pharmacy with each new prescription and that the pharmacist is supportive with an understanding and professional attitude.

The supervised consumption of opiate substitution treatments can:

- Prevent sale on the black market.
- Provide an opportunity for the pharmacist to build a rapport with the service user, which is to the service user's benefit and may well result in more orderly behaviour within the pharmacy.
- Provide an opportunity for the pharmacist to make a daily assessment of compliance with the programme and of the general health and wellbeing of the service user and advise accordingly.

Whilst supervision is desirable when service users enter the programme, it should also be noted that supervision itself may create a secondary dependence. It is important that once the service user is stabilised that they are trusted to accept a degree of responsibility, by extending treatment to the introduction of 'take home' doses. For example, from daily to twice weekly down to once weekly.

Methadone Substitution

Methadone is a long acting agonist for opioid receptors. One oral dose per day can eliminate the need for opiates but there may still be a craving for opiates and for injecting. Methadone is most frequently prescribed as methadone mixture 1mg/ml, which is unlikely to be injected. The half-life of methadone is approximately 1-2 days. This makes it particularly suitable for once daily dosing.

Methadone maintenance treatment has been shown to have a protective effect, reducing overdose among those in treatment. It is also linked to reductions in crime, IV use and injecting related harm. Service users stabilised on methadone should be alert and coherent.

Methadone is a schedule 2 drug subject to full controlled drug requirements relating to prescriptions, safe custody, the need to keep registers etc.

Although Methadone Mixture has a relatively low street value, there may be a temptation for the service user to sell the daily dose to help pay for a more euphoric alternative. In most cases it is preferable that self-administration of the daily dose of methadone is supervised by a pharmacist at the initiation into treatment. Through daily observation the pharmacist can monitor that adequate blood and tissue levels of methadone are maintained, therefore reducing the need for additional opiates.

Supervising the self-administration of methadone to service users on a daily basis has emerged as a key component of methadone programmes. Supervised consumption is recommended by the Clinical Guidelines for a minimum of 3 months or until service user compliance with treatment is achieved. This has the additional benefit of reducing the overdose risk during induction into treatment and reducing the diversion of methadone which also contributes to drug related mortality among those not in treatment both nationally and locally.

Methadone has a narrow safety window and small amounts can be lethal for those not used to it, which makes diversion a particular concern. Moreover, tolerance can drop quickly such that missed doses resulting in reduced opiate tolerance increase the risk of accidental overdose.

Buprenorphine Substitution

Buprenorphine is available in 0.4mg, 2mg and 8mg sublingual tablets. The tablets are administered sublingually because it has poor oral bioavailability – inactivated by gastric acid and a high first pass metabolism.

High doses of buprenorphine produce milder, less euphoric and less sedating effects than high doses of other opioids. Clients locally have also reported that it has less sedating effects and a less euphoric high leaving them clearer headed.

Buprenorphine is a mixed agonist/antagonist. It partially activates the mu opioid receptors whilst exerting sufficient opiate effects to prevent or alleviate withdrawal. It has a high affinity for the mu receptors and binds more tightly than methadone or heroin. It also binds strongly to the kappa opioid receptors where it acts as an opioid antagonist. In doing so it reduces the effects of using opiates on top of buprenorphine.

Buprenorphine is relatively safe during pregnancy and breastfeeding with less frequent, severe and shorter neonatal withdrawal than with methadone.² It may be better suited to those wishing to cease heroin use.³

The RCGP (2004:2) recognises that:

- There is a growing body of evidence that treatment for opioid dependence can be effective. Buprenorphine is an effective, safe medication for use in the treatment of opioid dependence and is a valuable addition to the formulary of medications for treating opioid dependence.
- Buprenorphine is also reported to have lower overdose potential, although caution should still be exercised when prescribing to service users using other CNS depressants such as alcohol, benzodiazepines, barbiturates, neuroleptics and tricyclic anti-depressants.
- Buprenorphine is a schedule 3 drug subject to special prescription requirements and must be kept in a CD cabinet, but there is no requirement to keep registers – although invoices must be retained for 2 years.

Currently Buprenorphine is associated less with abuse although evidence suggests it is traded on the black market for oral consumption. However, in the late 1980s in Glasgow there was widespread abuse of Buprenorphine where, due to its ready solubility, it was prepared and injected. Similar health problems and injecting related complications have been found in France where monthly dispensing resulted in approximately a half of clients injecting their own buprenorphine. A study of treatment centres in France reported 52% experiencing medical complications from injecting the drug with 33% experiencing hospitalisation as a result.⁴ Reports suggest buprenorphine injection is associated with acute hepatitis in service users with Hep C.⁵

There has been much debate regarding crushing buprenorphine tablets as part of supervised consumption programmes. Crushing buprenorphine tablets is not included in the product licence. However, doing so can significantly promote service user compliance through on-premises consumption given the practical difficulties of effectively supervising consumption of whole tablets which can take 5-10 minutes to dissolve under the tongue and possibly longer depending on the dose. Ineffective supervised consumption is associated with the development of a market for partially

consumed buprenorphine tablets, referred to as ‘fuzzies’ by users in some parts of the country.⁶ In Australia it is mandatory in certain states, including Victoria, to crush the buprenorphine tablets unless a prescriber specifically requires otherwise.⁷

This debate culminated in:

- The Royal Pharmaceutical Society of Great Britain (RPSGB) releasing guidance to members advising that crushing can take place where the pharmacist and service user agree to this course of action, the pharmacist is confident that this is in the best interests of the service user, and it does not compromise the efficacy of the treatment.
- The National Pharmaceutical Association (NPA) advising members that they will indemnify members crushing buprenorphine, against the licence, as long as they comply with a defined protocol for doing so. Note: this covers NPA members only.

There are some key principles of the NPA and RPSGB guidance:

- There must be collaboration between pharmacist, prescriber and service user to ensure that everyone understands:
 - the objectives behind a supervised scheme
 - the reasons for the crushing
 - that crushing is without the manufacturer’s marketing authorisation
 - there is clear understanding of the clinical and logistical implications of crushing.
- Pharmacists crushing buprenorphine need to be satisfied that crushing is in the service user’s best interest; crushing must be for the benefit of the service user rather than the convenience of the pharmacist. Pharmacists need to be satisfied that there is a true clinical need for crushing. They also need to consider the potential for distortion of the bioavailability profile as a result of crushing.

Clinicians in Kirklees use uncrushed buprenorphine routinely. Crushed buprenorphine is only used in a few clients. To aid pharmacies who need to crush buprenorphine in these instances please see an example consumption protocol (appendix 2) for crushed buprenorphine.

With regard to bio-availability there are a number of precautions pharmacists should take to ensure maximum bioavailability of buprenorphine when crushed:

- Bio-availability is seriously reduced if taken orally – studies suggest ½ bioavailability of oral compared to sublingual administration.⁸ Therefore even crushed it should be deposited under the tongue to dissolve. The manufacturers suggest that the active ingredients should be gone by 2-3 minutes.⁹

Some pharmacists are also concerned about reduced availability due to wastage in crushing. Even breaking the tablet along the score line will speed up dissolution and reduce value on the black market as the saliva will have begun to dissolve the matrix.¹⁰ In Australia advice is not to crush to a fine powder but to granules so that less of the medication clings to the crusher.¹¹ Loss due to crushing appears to be highest with low dose pills and negligible with higher dose pills.¹²

A trial in Australia showed that crushing to granules led to no apparent change in bioavailability.¹³

Espranor substitution.

Espranor oral lyophilisate is a freeze-dried wafer which dissolves rapidly on the tongue in around 15 seconds. This rapid dissolution greatly reduces the risk of diversion. Espranor is available in 2mg and 8mg wafer doses. Espranor is taken **by placing ON the tongue**, not under the tongue as buprenorphine tablets are. This route of administration is the only effective and safe route for this medicinal product. Patients should not swallow or consume food or drink until the lyophilisate is completely dissolved. Removal of Espranor from the mouth following supervised administration is virtually impossible.

Instructions for use:

Espranor is sensitive to moisture. Make sure hands are dry before handling the wafer.

1. Tear a square off the blister pack along the perforated lines.
2. The foil is easy to peel. Do not force the wafer through the foil as it is fragile and can easily break. Instead, fold back the foil and then peel it off.
3. Remove the wafer carefully from the foil and take out from the packaging immediately.
4. Place the wafer on the tongue and close mouth. Allow it to remain there for a few seconds until it has dissolved. Try to avoid swallowing during the first 2 minutes. Do not eat or drink for at least 5 minutes.

Espranor is **not directly interchangeable** with other buprenorphine products.

Espranor is used in adults and adolescent over 15 years of age, as part of a medical, social and psychological treatment programme for addiction. Espranor contains buprenorphine, an opioid (narcotic) analgesic. When it is used for the treatment of patients addicted to opiate (narcotic) drugs, such as morphine or heroin, it acts as a substitute for these drugs and therefore aids the patient in withdrawing from them over a period of time. If treatment is stopped abruptly, withdrawal symptoms can occur.

Aims and objectives of the service

To ensure compliance with the agreed treatment plan by:

- Dispensing prescribed medication in specified instalments
- Ensuring each supervised dose is correctly administered to the service user for whom it was intended (doses may be dispensed for the service user to take away to cover days when the pharmacy is closed)
- Liaising 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)
- Monitoring 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 with holding treatment if this is in the interest of service user safety, liaising with the prescriber or named key worker as appropriate
- Improving retention in drug treatment
- Improving drug treatment delivery and completion

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 dispensed medicines

Operational Procedures

Outlined below are the Operational Procedures for delivering substitution therapy with supervised consumption via pharmacies. All staff, including locums, should be aware of the following procedures. It is these procedures, along with the key principles outlined immediately above, which constitute a robust protocol.

Accepting new clients into Supervised Consumption

- The prescriber, usually the Substance Misuse Service will ask the service user which pharmacy participating in the supervised self-administration programme, would be most convenient for daily visits and at what times.
- The prescriber will contact that pharmacist before issuing the first prescription to ensure the pharmacist has the capacity to accept the service user at that time.
- Clients will be briefed by the prescriber on the date of commencement of supervised administration. The prescriber should inform the service user fully of what is expected when commencing supervised administration. In doing so the prescriber will inform the service user that the pharmacy will enter into a

contractual arrangement with the service user which the service user will be expected to adhere to.

- The service user will attend the pharmacy with their prescription for supervised methadone or buprenorphine (including Espranor) administration as agreed with the prescriber or keyworker. The Service user must provide identification which must accompany the prescription.
- For clients in receipt of crushed buprenorphine a signed agreement should be sought from both the prescriber and service user as confirmation that they understand the implications associated with supervised supply of crushed buprenorphine and that they agree to participation on this basis.

Service user contracts

- Clients may have a written contract with the SMS, part of which covers behaviour in the pharmacy. However, it is important that pharmacists use the Service user/ Pharmacy agreement (see resource section) outlining in greater detail the procedure for daily supervision.
- The aim of the agreement is to reduce the potential of misunderstandings and bad feeling to arise between service user and pharmacist.
- Clients should be informed in advance of what arrangements you make 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.

Identification of clients

- The clients' identity must be checked to ensure the prescription is dispensed to the correct person.
- The Service user Identification Form aims to assist this process.
- If there is any uncertainty with the identity of the service user the prescriber must be contacted and the dose withheld until the individuals identity is ascertained.

Controlled drugs prescriptions

- Controlled Drug prescriptions are subject to additional regulation and therefore must be checked for legality before medication is dispensed.
- The Pharmacist must be aware of and ensure all legislation requirements around controlled drugs
- If the starting date for dispensing is other than the date of writing the prescription, this must be clearly stated. Start dates should always be clear to

prevent the possibility of obtaining two doses at the end of one prescription and the beginning of another.

- The prescription should provide clear dispensing instructions. The amount of the instalments and the intervals to be observed must be specified. Prescriptions ordering 'repeats' on the same form are not permitted.
- The prescription must specify clearly that supervision is required.
- The prescription should also state if the buprenorphine tablets are to be crushed.
- The prescription should not be in any way tampered with, or in a condition where the instructions are no longer clear – e.g. water damaged, torn etc.
- The Home Office has confirmed that prescriptions can be worded as follows 'Instalment prescriptions covering more than one day should be collected on the specified day; if this collection is missed the remainder of the instalment (i.e., the instalment less the amount prescribed for the day(s) missed) may be supplied'¹⁴ This provision should be used in exceptional cases only, and the prescriber must alert the pharmacist that this instruction is to be made. The pharmacist should also notify the prescriber when this occurs.
- Emergency supply of methadone mixture and buprenorphine – The Misuse of Drugs Act does not allow for the 'emergency supply' of Schedule 2 or 3 Controlled Drugs (exemption – phenobarbitone or phenobarbitone sodium for epilepsy). Doses should never be given in advance of receipt of a valid prescription at the pharmacy. Phoned or faxed prescriptions for controlled drugs are also illegal.
- Pharmacists must satisfy themselves of the legality of the prescription, and its clinical appropriateness. If you have any doubts about the validity of the prescription – contact the prescriber.
- If a service user's prescriber changes, the clinic or service should inform the pharmacist of this change.
- If a Pharmacy is unusually closed for any reason the Pharmacy Manager or Head Office must inform the substance misuse service provider immediately so that alternative arrangements for supply can be made. If a script has not been dispensed it can be taken to an alternative pharmacy. If however the script has been partially dispensed, it cannot be transferred to a new location and a new script will be needed from the GP. This function should be incorporated into the pharmacy SOP and business continuity plan for the instances of sudden closures.
- Any concerns, incidents or discrepancies, within the service or use of the drugs, should be reported to the local NHS England Accountable Officer for controlled drugs (AOCD)

Preparation of medication

- It is important that the dose is ready for the service user's arrival. The whole operation should be as discreet and efficient as possible, maintaining the service user's dignity and saving the pharmacist's time.
- Doses that are collected to be taken on Sundays or bank holidays must be dispensed in a container with a child resistant closure. Clients must also be advised to store their medication out of the reach of children.

Methadone - The daily amount should be measured, placed into a container, capped and labelled. When the service user arrives, ideally the measured dose may be poured into a disposable cup. Please note drinking medicines directly from the bottle can set a bad example to children in the pharmacy.

The General Pharmaceutical Council (GPhC) issued guidance in May 2014 around the extemporaneous preparation of unlicensed medications. Pharmacists considering extemporaneous preparation of methadone should be aware of this new guidance.¹⁶

Buprenorphine – The prescribed tablets should be removed from the foil and placed in an appropriate container. If they are to be crushed they should be crushed into granules rather than a fine powder, in the service user's presence. This way the service user can confirm their dose before the medication is crushed. An appropriate crushing device should be used that minimises any loss of dose and has the confidence of clients.

Espranor - Espranor is sensitive to moisture. Make sure hands are dry before handling the wafer. Tear a square off the blister pack along the perforated lines.

The foil is easy to peel. Do not force the wafer through the foil as it is fragile and can easily break. Instead, fold back the foil and then peel it off.

Remove the wafer carefully from the foil and take out from the packaging immediately. Place the wafer on the tongue and close mouth. Allow it to remain there for a few seconds until it has dissolved. Try to avoid swallowing during the first 2 minutes. Do not eat or drink for at least 5 minutes.

Supervision of self-administration

- There should be discreet and efficient supervision by pharmacist or registered pharmacy technician
- Administration should take place in a discreet area and/or at times when the pharmacy is not likely to be busy, as agreed with the pharmacist. This will be discussed with pharmacies as part of the application process.
- Methadone - The pharmacist or pharmacy technician, see additional requirements below, must be satisfied that 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. 'Spit Methadone' has a street value and some clients may be under a great deal of pressure to hand over their dose to others.

- Buprenorphine – the tablet or crushed granules must be tipped directly under the tongue without handling and the service user supervised by the pharmacist or pharmacy technician until the tablets have dissolved – this can take 3-7 minutes depending on the dose, the service user and whether the tablets have been crushed. Providing or advising the service user to bring a drink of water with them for consumption before administering their medication, will help speed up the process. Clients should be advised that increased or excessive saliva production may reduce the effectiveness of the drug and is not desirable, and that saliva should be kept in the mouth rather than swallowed during dissolution. You may also wish to inform them that the medication has a bitter taste.
- Espranor – the wafer should be dissolved within around 15 seconds. Clients should be advised to try to avoid swallowing during the first two minutes. They should also be advised not to eat or drink for at least 5 minutes after taking this medication.

Supervision by a registered pharmacy technician

The accredited pharmacist providing this service may delegate the role of supervising the self-administration of Methadone and/or Buprenorphine (including Espranor) to a registered pharmacy technician, provided that clients using the service for the first time, or re-commencing treatment following relapse, are supervised by the accredited pharmacist for the first 4 weeks of treatment. Thereafter the pharmacy technician may be delegated this role. However overall responsibility and accountability will remain with the pharmacist.

Please note this service cannot be initiated or provided solely by an accredited pharmacy technician. At all times, including during supervision by the accredited pharmacy technician an accredited pharmacist must be present and accountable, except for annual leave and sick leave.

Pharmacist and Pharmacy Technician Accreditation, Training & Declaration of Competence

Commissioners, education providers and local pharmacy representatives have worked together in the North region over a number of years to harmonise the accreditation requirements for provision of locally commissioned services (the Harmonisation of Accreditation Group – HAG). Over the last few months this foundation has been built upon with the development of the Declaration of Competence (DoC) framework. The DoC framework has been designed to support

community pharmacy professionals (pharmacists and pharmacy technicians) in assuring their competence in delivering consistent and quality public health services.

CGL have adopted the DoC framework as the local process for accreditation; they wish to access the evidence that pharmacy professionals have taken the appropriate steps to reflect on their competence to deliver this service. Therefore, a DoC and a signed self-declaration of competence certificate for Supervised consumption of prescribed medicines will be required as the proof of accreditation. This DoC will ensure that pharmacy professionals have a knowledge and understanding of the legal and professional issues, clinical management and common practice situations relating to substance use and misuse services provided in pharmacies. Allowing them to deal confidently with clients that use the service. Completed assessments and certificates should be sent to andrew.craig@cgl.org.uk

Pharmacy professionals currently providing the service should provide their DoC within 6 months of 1st April 2019. All other Pharmacy professionals who wish to provide the service should provide their DoC on application. A new DoC must be provided at least once every three years.

The learning materials and DoC can be accessed via the Centre for Pharmacy Postgraduate Education (CPPE) website at: <https://www.cppe.ac.uk/> The LCC particularly recommends the completion of the material 'Substance use and misuse (2nd edition, May 2012) and the e-assessment 'Substance use and misuse – delivering pharmacy services (2014) in this programme. The Royal College of General Practitioners (RCGP) Certificate in the management of Drug Misuse is also recognised as being a valuable learning source. This RCGP course has been made available to Pharmacists and includes two online modules which take approx 2 hours each and one locally organised face-to-face training session. A total of nine accredited learning hours are available; further information can be obtained from www.rcgp.org.uk

The Substance Misuse in General Practice website is also a useful source of information and guidance and contains discussion groups to support those working with substance users. This can be found at www.smmgp.co.uk

Local training will also be provided by Substance Misuse Service in Kirklees at the commencement of the scheme and updates if there are significant changes to clinical practice.

Pharmacists and pharmacy technicians participating in the service must:-

1. Have completed or working towards completing a Declaration of Competence for providing a service for supervised consumption of prescribed medicines via the CPPE website. Certificates should be sent to andrew.craig@cgl.org.uk
2. Ensure compliance with all legal and professional requirements.
3. Ensure they have appropriate insurance cover.

4. Have a Standard Operating Procedure (SOP) for all personnel operating the scheme. If a pharmacy technician is to provide this service, the SOP must make specific reference to their role and responsibilities, highlighting steps in the procedure where referral to the pharmacist is necessary.
5. Supervise the daily consumption of methadone mixture (1 mg per ml), buprenorphine 0.4mg, 2mg or 8mg sublingual tablets or Espranor 2mg or 8mg wafers in accordance with the prescribers wishes.
6. Follow the procedures recommended in local guidelines.
7. Respect service user confidentiality at all times.
8. Ensure an accredited pharmacist or an accredited pharmacy technician, provided the first 4 weeks treatment is supervised by an accredited pharmacist, provides this service at all times. This excludes locums covering holidays or sick leave, however regular locums require accreditation (see point 10).
9. Inform CGL if there is an interruption to the delivery of this service for longer than 2 weeks duration by an accredited pharmacist. See resource section for the form 'Changes in the provision of Supervised Self Administration of Methadone or Buprenorphine by Accredited Pharmacist'.
10. Ensure new staff or locums are fully aware of the SOP and are able to enact this agreement appropriately. Regular locums should undergo accredited training.
11. Allow CGL to undertake an audit of service provision as required.

Liaison

Pharmacists should develop and maintain close links with prescribers and drugs services.

The pharmacist may be contacted by the prescriber/keyworker:

- For feedback after the first week of treatment
- After three months to feed into the review of the care plan/treatment package
- As required, to update on treatment goals or any significant issues regarding the management of the clients treatment package.

At all other times all steps should be taken to maintain the service user's confidentiality, with all staff protecting the privileged information they are party to by not divulging anything about the clients outside of the pharmacy.

Daily contact with the service user may allow the pharmacist to provide health promotion support and monitor service user compliance, suspected alcohol/drug intake, physical appearance and family support. People who are dependent on substances often have difficulty in accessing help and other social care.

As you get to know the service user you may be in a position to notice deterioration in their health.

The LPC supports the pharmacist developing a more formal role in monitoring and review.

Premises

Pharmacies, which offer the Supervised Methadone and Buprenorphine (including Espranor) Self Administration Service, shall have the following facilities:

- A service user medical records system.
- A secure internet connection to Neo and the local SMS Provider.
- Appropriate storage conditions for the increased supply of methadone/buprenorphine (including Espranor).
- A consultation area that is fit for purpose for administering methadone/buprenorphine to clients under supervision. The prescriber should discuss this with the service user when selecting a pharmacy. In agreement with the pharmacist the service user may choose not to consume their supervised medication in the consultation area but in another area of the pharmacy that is fit for purpose. In all circumstances the pharmacy must have a fit for purpose consultation area.
- An area for display of relevant health promotion leaflets including advice on the safe and secure storage of medicines.

Disposal of waste

Labels should be removed from containers and the container rinsed and immediately discarded.

Waste should be disposed of safely and steps taken to minimise risks of infection through meticulous hygiene and vaccination of staff if required.

Recording of information

Pharmacists may delegate but ultimately are responsible for maintenance of each service user's Service user Medication Record. This should include if buprenorphine tablets have been crushed. You should be able to record daily attendance, missed doses and other concerns that you may need to report back to the prescribers on Neo or via telephone contact. Thus the Service user Medication Record on Neo should note any additional services (e.g. general medical information) or advice provided to clients, referrals made on their behalf and liaison with the prescriber.

The Record of Medication Administered must also be completed and submitted via Neo. Recordings on this system will be used to calculate remuneration and serve as a record.

Controlled Drugs Register must be completed for methadone in line with legislation. Invoices, requisitions or orders must also be kept for the required number of years.

When to contact the prescriber

You should contact the substance misuse service immediately in the following circumstances:

- The service user does not consume the whole dose under supervision.
- The service user appears to be ill.
- The service user tries to avoid supervision or the process for proper administration.
- The service user appears to be intoxicated - Clients stabilised on methadone or buprenorphine should be clear-headed and coherent. If the pharmacist considers the service user is grossly intoxicated, the prescriber should be contacted and the dose withheld.

Methadone taken on top of other opiates, alcohol or benzodiazepines may increase the sedative effects leading to respiratory depression and potential overdose.

Buprenorphine is a partial opiate antagonist and, in isolation is less likely to cause overdose in opiate naive individuals, although it is still a risk. The risk with buprenorphine, and for Espranor, is also increased when taken in combination with alcohol and benzodiazepines.

- The service user misses doses
 - Missed doses may result in a drop in opiate tolerance with an increased risk of accidental overdose.
 - If a service user comes in after having missed three consecutive doses, their dose should be withheld and they must be referred back to the prescriber.
 - If clients regularly miss a single days dose, for example 3 doses in a 7-day period, the prescribing doctor must be informed.
 - Missed doses should not be replaced or issued at a later date.
- There are problems with the prescription – e.g. uncertainty about dates, validity, has been tampered with etc.
- The behaviour of the service user is unacceptable and contrary to the service user/pharmacy agreement - ultimately only you can decide what behaviour is 'unacceptable'. In circumstances where a dose is not administered, or you wish to cease future administrations, both the service user and prescriber must be made aware of this decision.
- There has been a change in dose that causes concern ie more than a 50% increase in dose as per NPSA rapid response alert of July 2008, on reducing dosing errors with opioids.

Appendix 3 further outlines circumstances in which the pharmacist should contact the prescriber. The decision is a professional one that should be made after considering the risk to the service user of non-disclosure and the damage that may be done to the supportive relationship between the pharmacist and the service user. Service user confidentiality should be respected at all times.

Contact with the prescriber should be swift following any reason for concern and especially where doses are missed or further administration has been withdrawn. Preferred method of communication is via telephone

Payments

Payments will be made per supervision at a rate of:

- Methadone £1.00 per dose supervised
- Buprenorphine £2.40 per dose supervised, crushed or non-crushed.
- Espranor £2.40 per dose supervised

Pharmacies will not be limited to numbers of clients that they provide a service for at any one time as long as they can fulfil their obligations to providing a full and high quality service to clients.

Payments will be made quarterly in arrears following the submission via Neo.

Payments can only be made to pharmacies that have signed up to this scheme and have agreed to provide the service outlined above. Payments are Pharmacy not pharmacist based.

Applying to join the scheme

Pharmacies wishing to join the scheme should complete both the self-assessment and Declaration of Competence and the application form on page 35. These documents should be sent to andrew.craig@cgl.org.uk

Leaving the scheme

If pharmacists wish to leave the scheme, or cease providing any aspect of the service at any point they should inform the CGL in writing of this intention 6 months in advance. This will enable prescribers to make alternative arrangements allocating clients to alternative scheme providers.

Contact Details:

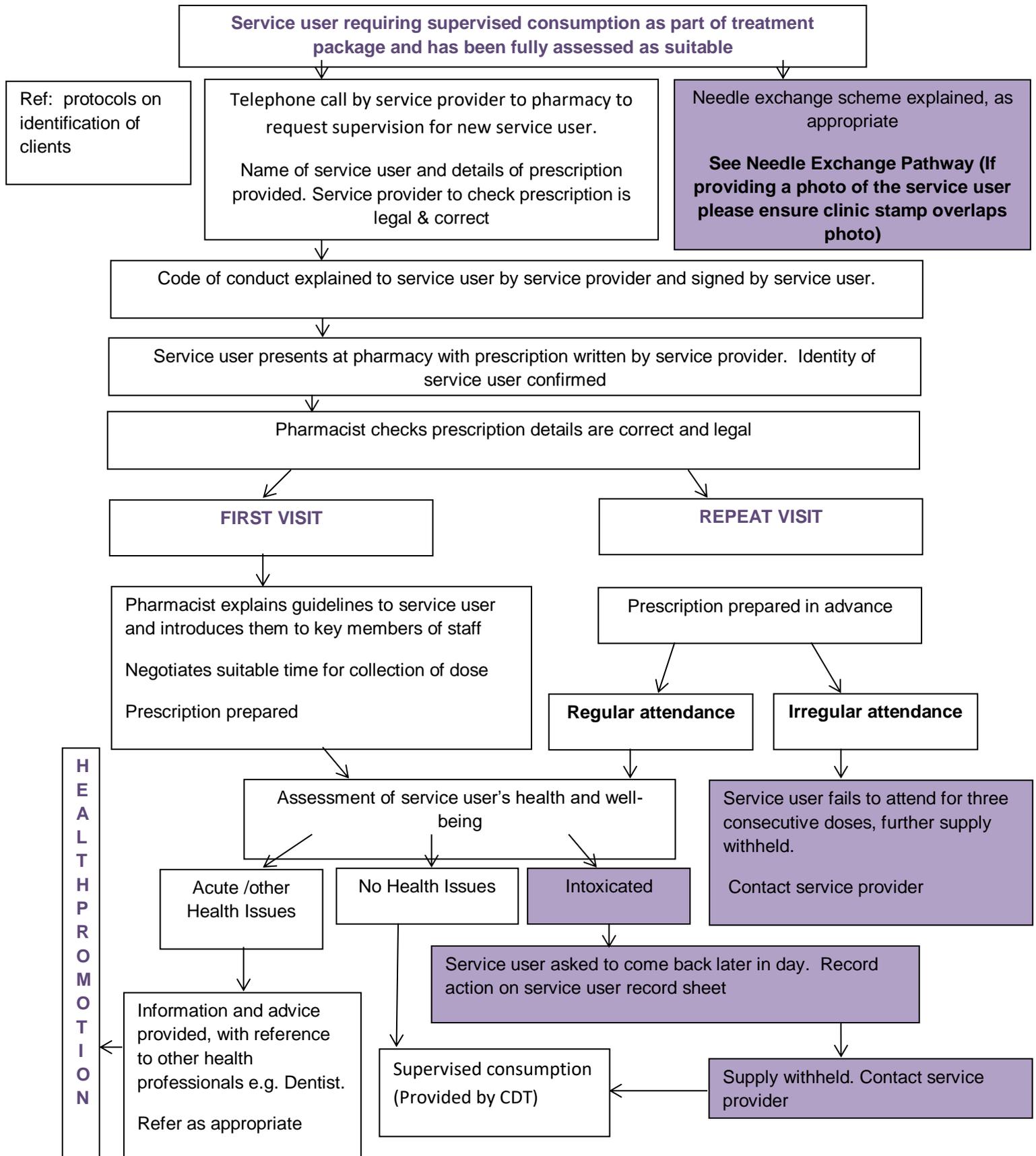
If you have any concerns in relation to your contract, please contact Andrew Craig at andrew.craig@cgl.org.uk.

If you need to contact the service regarding a service user, please ask to speak to the case coordinator referring to the service user by name by contacting 01484 353333 (Huddersfield) or 01924 438383 (Dewsbury)

References

1. See RCGP (2004) 'Guidance for the use of buprenorphine for the treatment of opioid dependence in Primary Care', for further details. Copy to be found in references section of this guidance.
2. de Wet et al (2005) 'The rise of buprenorphine prescribing in England: analysis of NHS regional data, 2001-03', in *Addiction*, 100:495-499, and, RCGP (2004) 'Guidance for the use of buprenorphine for the treatment of opioid dependence in primary care'.
3. RCGP (2004) 'Guidance for the use of buprenorphine for the treatment of opioid dependence in primary care'.
4. Jenkinson et.al. (2005) 'Buprenorphine diversion and injection in Melbourne', in *Addiction*, 100:197-205.
5. Ibid.
6. Posting to SMMGP discussion group.
7. NPA Guidance 'Supervised Subutex Supply – Professional Indemnity'
8. Jenkinson et al. (2005) 'Buprenorphine diversion and injection in Melbourne, Australia: an emerging issue?', in *Addiction*, 100:197-205.
9. Posting to SMMGP discussion group 19/04/05
10. Posting to SMMGP discussion group 01/4/04 from Community Pharmacist.
11. Posting to SMMGP discussion group 01/4/04
12. Posting to SMMGP discussion group 02/04/04, Shared Care Substance Misuse Manager based on local London trial prior to commencement of crushing scheme.
13. Posting to SMMGP discussion group 12/3/04
14. <http://www.pharmj.com/Editorial/20050430/society/ethics.html>
15. See new regulation 24a which has been added to the 2001 regulations.
16. General Pharmaceutical Council. Guidance for registered pharmacies preparing unlicensed medicines. May 2014

Appendix 1: Pharmacy Pathway for the Observed Consumption of Methadone and Administration of Buprenorphine (including Espranor)



Appendix 2 - Supervised Consumption of Buprenorphine – Model protocol

The following requirements are over and above the general legal and ethical requirements associated with the running of a pharmacy business and the specific requirements relating to the provision of controlled drugs and services to drug misusers.

- Pharmacies crushing Buprenorphine need to be satisfied that crushing is in the service user's best interest; crushing must be for the benefit of the service user rather than the convenience of the pharmacist. Pharmacies need to be satisfied that there is a true clinical need for crushing. They also need to consider the potential for distortion of the bioavailability profile of Buprenorphine as a result of crushing.
- Pharmacies must have a standard operating procedure to cover all the processes involved in the scheme which is readily available to and understood by all staff (and locum pharmacists) involved with the scheme
- There must be collaboration between pharmacist, prescriber and service user to ensure that:
 - everyone understands the objectives behind a supervised scheme
 - the reasons for the crushing of Buprenorphine,
 - that crushing is outwith the manufacturer's marketing authorisation
 - there is clear understanding of the clinical and logistical implications of crushing.
- A signed agreement should be sought from both the prescriber and service user as confirmation that they understand the implications associated with supervised supply of crushed Buprenorphine and that they agree to participation on this basis.
- A model service user information/consent form is included as an Annex.
- Prescriptions must clearly indicate that the consumption is to be supervised. Ideally the prescription should also state that the Buprenorphine tablets are to be crushed. Alternatively a signed agreement between the prescriber and pharmacist could specify circumstances in which it is appropriate to crush tablets – for example where diversion is suspected, where prescribed doses exceed 8mg or for all clients.
- Pharmacists must satisfy themselves of the legality of the prescription, and its clinical appropriateness.
- Pharmacists should refuse to supply, and contact the prescriber if:
 - There are any queries with the prescription
 - There is any uncertainty with the identity of the service user
 - The service user misses the number doses prescribed in local treatment agreements
 - The service user avoids, or attempts to avoid, supervision

- The service user does not consume the full dose, or attempts to avoid the process for proper administration
- The service user appears to be ill, under the influence of alcohol or other drugs to the extent that in the pharmacist's judgement this may impair treatment
- The service user displays threatening, violent or abusive behaviour toward staff
- Pharmacists must keep adequate records of supply preferably on the PMR clearly indicating that a crushed supply has been made.

Resources

This section of this guidance document contains blank copies of the forms required for the administration of the Supervised Self Administration of Methadone and Buprenorphine (including Espranor) scheme, including:

- Application to join the scheme
- Service user Identification Form
- Service user leaflet for buprenorphine
- Service user/pharmacy agreement
- Pharmacist - Prescriber Contact Form
- Pharmacy Record Form
- Notification of changes in the delivery of the scheme form

Application to Join the Supervised Self Administration Scheme for Kirklees

AGREEMENT

I apply to be paid for the supervision of methadone and buprenorphine self-administration by drug misusers in the premises named below in line with the Scheme Conditions and Guidance and to submit daily activity by the close of business each day via Neo.

The pharmacy will provide supervised self-administration of:

- 1. Methadone and**
- 2. Buprenorphine (including Espranor) per dose supervised**

The pharmacy is open for (5) (6) (7) days a week. (Circle correct figure)

I will claim the fees appropriate to this number of days opening following supervision of methadone and buprenorphine self-administration.

Signed: Contractor

Pharmacy Name:

Pharmacy Address:

.....

Tel No:

Date:

Relevant Training Courses attended by Supervising Pharmacists who work routinely in the premises and registered pharmacy technicians.

Pharmacist	Date of Course	Organiser	Title
And Pharmacy Technician			

Pharmacies wishing to join the scheme should complete this application and return it to:

andrew.craig@cgl.org.uk

To be completed with provider as part of the induction into treatment process

Service User Identification Form

Service user Information

Service user Name: _____

Address: _____

DoB: _____ Gender: _____

Signed (service user): _____ Date: _____

Medical Service Details

Doctor: _____ Keyworker: _____

Clinic address: _____

Telephone: _____

Signed (Doctor/Keyworker): _____ Date: _____

Clinic Stamp (if providing a photo of service user please ensure clinic stamp partly over stamps the photo)	O V E R L A P	Photograph of Service user (Provided by CDT) Please Affix Here (if providing a photo of service user please ensure clinic stamp partly over stamps the photo)
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For the Pharmacist

The service user should present a form of ID, which contains either, a photograph and name or name and address, which match that given above.

Acceptable forms of ID include:

- Photo ID
Driving licence, passport, proof of age card e.g. prove it, photo student ID,
- Name and address ID – no older than 3 months
bank statement, credit card statement, utility bill (not mobile phone bill), benefits correspondence, Council tax bill or payment book.

Form of ID Shown: _____

Date: _____

Service user Leaflet for Supervised Buprenorphine

Your doctor has prescribed buprenorphine and stated that this is to be “supervised consumption”. This means the following must happen.

- You come into the pharmacy on your own.
- You hand in your medication card
- We positively identify you
- You remove any chewing gum or sweets from your mouth and dispose of them in a waste bin.
- You will be provided with a drink of water as this speeds up the time it takes for the tablets to dissolve.
- The dispensed tablet is taken from the container with your name on and squeezed out of the foil and into a plastic medicine measure
- If the prescriber specifies “crushed” then the tablet(s) will be broken into smaller granular pieces. This will have been explained to you by your prescriber as crushing is off-licence
- You are expected to tip the tablet(s) or granules under your tongue without touching them and hand back the measure.
- **You must then sit down and allow these to dissolve - this usually takes between 3 and 5 minutes** for tablets - significantly less time for granules.
- Once the tablets have dissolved you should report to the pharmacist and will be provided with a drink of water, which you should drink.
- You will then be given back your medication card and may leave.

Important

- Failure to follow the points above will result in the prescription being suspended and you being referred back to your doctor.
- Missing 3 consecutive doses will also mean that you have to contact your clinic/doctor.

Name of GP/Prescriber: (please print).....

Prescribers signature:..... Date:.....

Clients Name: (please print).....

Clients signature:..... Date.....

Service user/Pharmacy Agreement

We are pleased to welcome you to the Kirklees Supervised Consumption Scheme and wish you all the best with your treatment. We aim to offer you a discreet and efficient service that supports you in achieving your treatment goals.

This 'agreement' sets out the arrangements for the service and a brief explanation as to why these arrangements are necessary. The pharmacist will go through each of the points with you and explain any that you are unsure about.

When you have completed the Agreement, the pharmacist will introduce you to the staff so that they know who you are and can help you should you require it.

We hope that the scheme proves helpful to you

The Arrangements

Why they are necessary

<p>We are available to supply your medication between: From.....To..... From.....To.....</p>	<p>We want to give you your medicine as quickly as possible. We prepare your medicine first thing in the morning and write up our records before the shop closes. When the pharmacy is busy, we must take all customers in turn, which may leave you standing around.</p>
<p>You will need to collect your take home doses on..... for weekends and Bank Holidays</p>	<p>The pharmacy is closed onday andday and on Bank Holidays. Opening times are:</p>
<p>We will need some way of identifying you. Our pharmacist will explain how this is done.</p>	<p>We want to ensure that we don't give your supply to anyone else</p>
<p>If you have missed three days collections in a row, we cannot supply your medication without speaking to your prescriber.</p>	<p>Your tolerance to the drug quickly drops and to take the full dose may risk your health</p>
<p>We must supervise you taking your medicine because this has been stipulated on your prescription</p>	<p>This is done to support you achieving your treatment goals and to reduce the risk of overdose</p>
<p>We cannot let anyone else collect your medication for you.</p>	<p>Again, we want to make sure you get your medicine and not anyone else</p>
<p>When you collect your medication we need time to up date our records. Please be patient.</p>	<p>By law, we have to make detailed records on each collection. We cannot do this in advance.</p>
<p>If you lose your prescription, we cannot supply the medication to you no matter how well we know you</p>	<p>Again, by law, we can only supply medications with a legally written prescription. If you have lost one you will need to contact your prescriber.</p>
<p>We cannot give you 'missed doses' that you have not picked up</p>	<p>The supply of your medication has to be made on the day and date specified on the prescription</p>
<p>Please bring your new prescription promptly before, or just after your current one finishes</p>	<p>There is sometimes a waiting list for places. If you do not show we may have to give your slot to someone else</p>
<p>We would like you to come alone and to behave in a reasonable manner in the pharmacy and in the area outside the pharmacy.</p>	<p>We want our pharmacy to be a welcoming place to you and all our customers and expect all our service users/customers to behave in a reasonable manner. Failure to do so will force a withdrawal of services</p>
<p>Please feel free to ask about other health related issues that maybe worrying you.</p>	<p>We offer information and advice on health related matters to all members of our</p>

	communities. You are a customer of ours and we value your custom.
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Confidentiality: We respect your right to keep matters relating to your health private and confidential and shall endeavour to provide a confidential service for you. However we may talk to your GP/Prescriber or drug therapist about your health care or medicines.

Name of Pharmacist:

Pharmacy Stamp:

Phone number of Pharmacy:

Name and contact details of GP/Prescriber:

Name and contact details of therapist:

Service users signature:..... Date.....

Print Name.....

Pharmacists signature:..... Date.....

Complaints procedure

If you are not satisfied with the service that you have received, please speak with your pharmacist therapist or drugs worker.

Your complaint will be investigated and you will be kept informed of the process and the outcome. A complaints procedure will be made available to you on request

Notes or Comments

We value your custom and will endeavour to do all we can to meet your health needs.

Pharmacist - Prescriber Contact Form

Service user: _____

Doctor: _____

Keyworker: _____

Supervised self administration of prescribed medications has been **withdrawn** because the service user above has:

- Missed three doses
(please append a copy of the service user record form)
- Exhibited unacceptable behaviour
Including : _____
- Refused to consume the whole dose under supervision
- Tried to avoid supervision
- Appeared intoxicated when attending the pharmacy
Please give details:
- Been admitted to hospital

Further information

Signature of Pharmacist: _____

Date: _____

Changes in the provision of Supervised Self Administration of Methadone or Buprenorphine (including Espranor) by Accredited Pharmacists/Registered Pharmacy Technicians

Pharmacy name: _____

Pharmacy address: _____

Please complete the relevant section:

Section A – newly accredited pharmacist

_____ has now _____ completed _____

(Pharmacist's name)

(date)

(Course name and provider)

Section B – change in accredited pharmacist

The Supervised Self Administration of Methadone and Buprenorphine (including Espranor) Scheme at :

_____ will henceforth _____ be administered by _____

(Pharmacy name)

(date)

(name)

who has completed _____

(Course name, provider and date of completion)

Section C – newly accredited registered pharmacy technician

_____ has now _____ completed _____

(Technician's name)

(date)

(Course name and provider)

Section D - temporary / interim arrangements longer than 2 weeks duration

This pharmacist must be aware of the Standard Operating Procedures for the scheme.

Between _____ and _____ the Supervised Self Administration of Methadone and Buprenorphine (including Espranor) Scheme will be provided by _____

This pharmacist has/has not completed an accredited course. (delete as appropriate)

Complete if appropriate _____

(Course name, provider and date of completion)

Section E – to be completed for any other changes to the scheme.

Please explain any other changes to the implementation of the scheme by trained pharmacists.

Please send to: andrew.craig@cgl.org.uk