

Northern Ireland Primary and Secondary Care Opioid Substitute Treatment Guidelines (2013)



**Health and
Social Care**

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FOREWORD

Since substitute prescribing services were established in Northern Ireland, many individuals have received treatment for addiction to opioids in both primary and secondary care. The effectiveness of well-delivered, evidence based treatment for drug misuse has been shown to reduce harm to individual drug misusers, their families and local communities.

Northern Ireland guidelines for substitute prescribing were first produced in 2004 to assist all clinicians who treat opioid addicted individuals. Since then there have been significant developments in the management of addiction and the Northern Ireland Primary and Secondary Care Opioid Substitute Treatment Guidelines (2013) reflect these changes and replace the 2004 document. These guidelines are based on current evidence and also reflect local consensus around the appropriate standards for care of opioid addicted patients. They were developed by a multidisciplinary team (see Appendix 4: Working Group for the development of Northern Ireland Primary and Secondary Care Opioid Substitute Treatment Guidelines) with representation from primary and secondary care.

The guidelines are intended for all those involved in providing support for drug misusers, especially those providing pharmacological interventions as a component of drug misuse treatment. This includes community addiction teams, GPs, prison staff and community pharmacists. Treatment should only be initiated by those with specialist training, expertise and experience.

These guidelines should be regarded as a framework for the treatment and support of opioid addicted individuals, and inform the setting of benchmarks for establishing and maintaining a minimum standard of care for this patient group. They do not override clinical responsibility for individual patients, which remains within the clinical team as per the shared care model, and ultimately with the prescriber. It is also the clinical responsibility of those working in a shared care model to discuss all decisions relating to care with the patient. The revised guidelines are intended to complement, not replace, other established references and should be read in conjunction with other relevant resources including:

- *Drug Misuse and Dependence, UK Guidelines on Clinical Management 2007*
- *NICE Appraisal TA114*
- *NICE Clinical Guideline CG52*
- *RCGP 'Guidance for the use of substitute prescribing in the treatment of opioid dependence'*

- *BAP 'Evidence-based guidelines for the pharmacological management of substance abuse, harmful use, addiction and comorbidity'*
- *NPC MeReC Bulletin 'The management of opioid dependence'*
- *DHSSPSNI 'Safer Management of Controlled Drugs' (covering legal issues)*

A Regional Substitute Prescribing Database has been developed to record and provide information on the Regional Substitute Prescribing Service. At key points and defined intervals in the patient's treatment, the Regional Substitute Prescribing Database should be updated by completing the relevant **Opioid Substitute Treatment (OST) form**.

The symbol to the left will be used throughout the guidelines to indicate a point in treatment when an OST form should be submitted.



See SECTION 14: Reporting to the Regional Substitute Prescribing Database for further details of the reporting requirements of the Regional Substitute Prescribing Database

Please note at time of publication these three forms are named "Substitute Prescribing" ("SP") forms. A change of name is due early in the lifetime of the guidelines to "Opioid Substitute Treatment" ("OST") forms. Therefore throughout the document they will be referred to as OST/SP forms.

It should be noted the guidance is not aimed at meeting the chronic pain needs of individuals with concurrent opioid misuse issues. The British Pain Society has produced a document entitled '*Pain and substance misuse: improving the patient experience*' (2007) and this may provide a useful information source when managing such individuals.

SECTION 1: Eligibility criteria

All providers should ensure patients meet the following criteria before commencing a substitute treatment programme:

- a. Opioids are being taken on a regular basis, usually daily
- b. There is convincing evidence of current dependence (including objective signs of withdrawal wherever possible)
- c. Patients are motivated to change at least some aspect of their drug misusing behaviour
- d. The assessment (including history, examination, toxicology, drug diary) clearly substantiates the need for substitute prescribing
- e. The clinician is satisfied that the patient has the capacity to comply with the substitute prescribing regimen
- f. The patient is not receiving a substitute prescription from another clinician
- g. The patient can provide evidence they are resident within the Trust geographical boundary (and are not being treated within other Trust areas). It is recognised that Trusts will liaise with each other when transfer of patients occurs across boundaries.
- h. The patient is registered with a GP or undertakes to register as soon as possible
- i. A community pharmacist has been identified as willing to dispense substitute treatment
- j. The patient agrees to sign the Service User and Provider Agreement (see Appendix 1)
- k. In exceptional circumstances, patients who have had an enforced detoxification e.g. in prison or acute hospital may be considered for treatment.

Caution should be exercised where:

- Severe physical or mental health problems co-exist
- Polydrug misuse co-exists, especially high dose benzodiazepine or severe alcohol dependence (consider inpatient treatment if available)
- There is a lack of reliable history or assessment
- History of drug use is less than one year

- Patient is under 18 years old. In the case of adolescents ensure appropriate liaison with CAMHS, children's services and child's parents/carers.

Before embarking on prescribing treatment, careful consideration should be given to the history and duration of drug-taking, and the potential prolonged nature of substitute prescribing discussed with the patient. The discussion of this with the patient should be documented.

SECTION 2: Assessment of suitability for opioid substitute treatment

According to ICD-10, dependence syndrome is 'a cluster of physiological, behavioural, and cognitive phenomena in which the use of a substance or a class of substances takes on a much higher priority for a given individual than other behaviours that once had greater value'. A definite diagnosis of dependence should be made only if at least three of the following have been present together in the past year:

- Compulsion to take substance
- Difficulties controlling substance-taking behaviour
- Physiological withdrawal state
- Evidence of tolerance
- Neglect of alternate interests
- Persistent use despite harm

Substance use disorders should generally be treated with a combination of psychosocial and pharmacological interventions.

From The Maudsley Prescribing Guidelines in Psychiatry David Taylor, Carol Paton Shitij Kapur . Eleventh Edition Wiley-Blackwell 2012 page 355

Assessment may need to be conducted over several sessions or consultations and should include:

- a. Detailed history of opioid use including type(s) used, frequency, level of use, duration of use, route of administration and reason for drug use e.g. pain or other physical conditions. If possible a collateral history and /or a detailed report from a previous treatment provider, family member or significant other should also be obtained.
- b. Review of prescribed and non-prescribed substance use, in particular use of alcohol and benzodiazepines. See **UK Guidelines on Clinical Management 2007** for specific advice on managing benzodiazepines (pages 60-61) and alcohol (pages 72-73).
- c. Particular emphasis on signs of physical dependence including tolerance and signs of withdrawal. Consider use of a validated

assessment tool for physical dependence e.g. The Clinical Opiate Withdrawal Scale (COWs)¹.

- d. A minimum of two face-to-face contacts before prescribing commences. This is generally required to carry out a comprehensive assessment (unless previously known to service).
- e. Assessment that patient is motivated to change at least some aspects of their drug misusing behaviour and is agreeable to comply with both the prescribing regimen and other aspects of the care plan including psychosocial therapies
- f. Physical examination, including assessment of injection sites
- g. Assessment of mental and physical health including blood borne virus status. Ensure patients are offered testing for HIV, Hepatitis B and C and offered immunisations against Hepatitis A and B.
- h. Assessment of need for ECG monitoring for patients being considered for methadone maintenance if they:
 - have a history of cardiac or liver disease
 - have had unexplained episode(s) of collapse or seizure
 - are on other medicines which also affect the QTc interval
 - have any other risk factors
- i. Risk assessment for each individual to establish specific risks that may need to be prioritised e.g. unsafe injecting practices, polydrug and alcohol misuse, history of overdose, risk of self-harm and risk of harm to others including children. A regional risk assessment tool is contained within the DHSSPSNI document ***'Promoting Quality Care- Good Practice Guidance on the Assessment and Management of Risk in Mental Health and Learning Disability Services'***.
- j. Review of current prescribed medication. This should be carried out prior to commencing treatment to identify any medicines that may potentially interact with oral substitution therapy (OST) (see Appendix 1 of current BNF).
- k. At least one, and preferably two, positive drug screens for opioids (one is acceptable if previously known to the service or imperative that treatment is commenced urgently). Saliva and near patient urine screening are acceptable, however, at least one test should ideally be laboratory based. Consideration should be given to whether detailed analysis / breakdown is required.

¹The Clinical Opiate Withdrawal Scale (COWS). DR Wesson, W Ling - Journal Of Psychoactive Drugs, 2003

- I. Baseline Liver Function Tests (LFTs). This is good practice especially where there are concerns about liver function, or where clinically appropriate, either before or as soon as possible after treatment commences. It is particularly important in the following cases:
 - Previous history of alcohol misuse
 - History of blood-borne virus exposure
 - Suspected paracetamol hepatotoxicity e.g. combined analgesic misuse
 - Considering treatment with buprenorphine
 - Any other risk factors for hepatic impairment
- m. Assessment of social issues including childcare, housing, employment status, funding of drug use, driving status
- n. Assess the risk of overdose and management. See boxed text below regarding 'Take-Home Naloxone'



Once the client has been assessed and considered eligible for opioid substitute treatment, an **OST1/SP1 Form** must be completed for submission to the Regional Substitute Prescribing Database.

See Section 14 for full details.

The Northern Ireland 'Take Home Naloxone programme' allows naloxone kits to be provided to anyone at risk of opioid overdose in the community. Initial assessment provides an opportunity to provide information on the scheme, encourage participation and arrange supply of a naloxone kit, regardless of whether the patient eventually undergoes substitute treatment or not.

For more information contact Public Health Agency on 02890311611.

For further information on assessment for suitability for opioid substitute treatment, see ***UK Guidelines on Clinical Management 2007 pages 25-34 and page 47.***

SECTION 3: Factors influencing type of therapy (maintenance or detoxification)

Choosing between maintenance and detoxification for a patient can occur at any point during treatment, starting at the first assessment and then being reviewed at various points along the treatment journey. The patient should be involved in the decision making and allowed to make an informed choice by being presented with the evidence and made aware of the treatment options. This should be supplemented with written patient information. However, the decisions made must also be clinically justified and safe.

While a few patients can achieve abstinence rapidly (*detoxification*), it has been shown that patients who detox as a process of being excluded from treatment, fall out of treatment or undergo premature detoxification have particularly poor outcomes. Therefore, most patients will require at least a period of maintenance to ensure stability before embarking on detoxification. For some patients, maintenance may need to continue for many years.

Evaluation of previous episodes and outcomes may guide the decision making process. Choosing between detoxification and maintenance treatment is complex; there are many factors to consider and patients may move between these two aspects of treatment. Thorough preparation for detoxification is essential and patient safety must be paramount.

Maintenance is suitable for people who want to stop using illicit opioids but are not yet able to achieve abstinence from all opioids. Patients should be fully involved in the development of their care or treatment plans, in setting appropriate treatment goals and reviewing their progress in treatment. The goals can include harm reduction and stabilisation of lifestyle. The achievement of these goals should be monitored on an ongoing basis.

Work should always continue on other drug use, alcohol use, psychological interventions and any health and social needs. There is a strong evidence base for maintenance and it is often an important step towards detoxification and abstinence.

Detoxification is suitable for people who are ready to become drug-free. This can occur either in the community or with the person being treated as an inpatient. The speed of reduction is governed by the patient and their clinical response. The person needs to be given the evidence about success rates and informed that detoxification is part of the process of becoming abstinent and not a stand-alone treatment. It is also important to assess whether the patient's circumstances are conducive to maintaining abstinence and to advise on the timing accordingly.

It is crucial to warn of the potential loss of tolerance after detoxification; relapsing to heroin or other opioid use after a period of abstinence may be fatal.

Pregnancy

It is not usually appropriate to carry out detoxification during pregnancy, however, if there are exceptional reasons to do so, it should generally occur during the second trimester and links should be firmly established with the Maternity and Neonatal Services before commencing treatment.

For further information on factors influencing type of therapy see **UK Guidelines on Clinical Management 2007 page 54-59** and **NICE Clinical Guidance 52 Drug misuse: opioid detoxification.**

(A summary is included in the Table overleaf)

Table 1**Factors to consider when deciding on Maintenance/ Detoxification**

Maintenance	Detoxification
Longer period of opioid use	Shorter history of opioid use
Higher levels of dependence and/or opioid use	Lower levels of dependency and/or low tolerance to opioids
Poly-substance misuse	Predominantly single opioid use or stable on maintenance therapy
Injecting	Non-injecting
Chaotic lifestyle e.g contact with criminal justice, housing problems, unemployment, living with other drug users	In a stable and supportive social situation or able to go into one following detox. Plans for continuing support are in place.
Significant risk factors identified on assessment of physical, psychological and social needs	Assessment of physical, psychological and social needs indicates a lower risk individual
Active blood borne virus	Blood borne virus status either clear or controlled
Pregnancy	Generally inappropriate in pregnancy, (see section 3)
Patient not prepared to or cannot commit to detox at this stage and the associated high risk of relapse	The patient is fully committed to, prepared for and informed about process of detox. They accept and understand the high risk of relapse and associated risks.

SECTION 4: Drug choice in maintenance

The licensed drugs for substitute treatment are methadone and buprenorphine. Both drugs have a good evidence base and both should be available to patients for substitute treatment. Clinical factors, including drug interactions and patient choice should be considered when making a choice between the two drugs (see Table 2). If both are considered equally suitable after a full assessment, methadone should be prescribed as first line treatment (as recommended by **NICE TA114, Jan 2007**).

Patients may need to move from one drug to another depending on personal preferences, treatment outcomes, side-effects and/or supervision issues. For advice on switching from methadone to buprenorphine treatment, a useful source of information is the RCGP '**Guidance for the use of substitute prescribing in the treatment of opioid dependence in primary care**' (2011, p14).

The patient view is important when choosing a drug for maintenance and they must be presented with the evidence and made aware of the treatment options supplemented with written patient information. However, the decisions made must also be clinically justified and safe.

Dihydrocodeine

Dihydrocodeine should only be prescribed by clinicians with appropriate specialist competencies in very exceptional circumstances. Dihydrocodeine is not licensed for this indication and patients should be made aware of this before commencing therapy.

Dihydrocodeine may in exceptional circumstances be prescribed for some patients for whom methadone and buprenorphine are unsuitable. In Northern Ireland some patients are on this treatment historically. There is a small evidence base that dihydrocodeine can be used effectively for maintenance although it has not been shown to be superior to other opioid medicines. Dihydrocodeine is short acting and needs frequent dosing; it is therefore difficult to supervise.

For further information on Drug Choice in maintenance see **UK Guidelines on Clinical Management 2007** page 45-48, and page 55.

Table 2
Factors to consider when choosing Buprenorphine or Methadone as treatment

	METHADONE	BUPRENORPHINE
Induction risks	See dedicated information in section 5 “Induction Risks”	See dedicated information in section 5 “Induction Risks”
Opioid usage	High usage and/or extensive injecting history	Lower level usage (including OTC and POM) and/or shorter history of abuse
Previous treatments	Consider if previous poor treatment response to buprenorphine	Consider if previous poor treatment response to methadone or side effects e.g. weight gain, sweating, sexual dysfunction
Treatment duration	Long-term maintenance	More likely to move to abstinence in short-term
Differences in side effect profiles	Patients may require additional monitoring e.g. methadone may be associated with QTc prolongation and torsades de pointes, therefore ECG monitoring may be required (depending on dose and/or other risk factors)	Often described as less sedating than methadone QTc prolongation is not an issue Should not normally be used in patients with liver dysfunction
Concurrent chronic pain	Patients with chronic pain conditions that require additional opioid analgesia may have difficulties being treated with buprenorphine because of the “blockade” effect. Methadone is the preferred treatment.	Appears to provide greater “blockade” effects than doses of methadone <60mg . This may be considered an advantage or disadvantage by patients

	METHADONE	BUPRENORPHINE
Combining with other medications	<p>Consider drug-drug interactions (BNF appendix 1) Methadone levels may alter with drugs that inhibit/induce CYP3AA, e.g. erythromycin, several SSRIs, ribavirin and some anticonvulsants. This may make dose assessment difficult, if a person is not consistent in their use of these CYP3AA-inhibiting drugs.</p>	<p>Consider drug-drug interactions (BNF appendix 1)</p>
Pregnancy	<p>Suitable for women who are pregnant or planning a pregnancy and is drug of choice</p>	<p>Off licence. Should not be initiated due to risk of buprenorphine-precipitated withdrawal but may be continued following patient discussion.</p> <p>NOTE- Suboxone® (naloxone combination product) is contra-indicated in pregnancy; the patient should be switched to methadone or single drug buprenorphine preparation</p>
Diversion	<p>Suitable for patients at greater risk of diversion of medication (e.g. past history of diversion, treatment in a prison setting)</p>	<p>Sublingual buprenorphine tablets can be easily diverted (with the risk of tablets then being injected). Available in combination with naloxone (<i>Suboxone®</i>) which makes injection or snorting counterproductive and may be considered where a greater number of take home doses are required.</p>

SECTION 5: Induction risks

There is an increased risk of death during the induction period for both methadone and buprenorphine and consideration should be given to the associated risk factors listed in Section 4. Although partial and full agonists offer a relatively safer option than continued drug misuse for some patients, it should be remembered both methadone and buprenorphine are dangerous drugs. Methadone presents a particularly high risk. This can never be eliminated completely but can be reduced with proper supervision and by incorporating other safety factors. Treatment should only be initiated by those with specialist training, expertise and experience.

Induction risks for both drugs:

- Low opioid tolerance
- Too high an initial dose
- Concurrent use of CNS depressant drugs, including other sedatives and/or alcohol
- Excessively rapid dose increases
- Impaired hepatic, respiratory, cardiac or renal function

Induction risks with methadone:

- Concurrent use of drugs which can increase methadone levels such as erythromycin or cimetidine (see table 2, current BNF and individual drug datasheets)
- Slow methadone clearance

Induction risks with buprenorphine:

There is a risk of precipitating withdrawal which is increased if insufficient time is left before administering buprenorphine in patients who have:

- Recently used heroin, particularly at higher doses
- Recently consumed long-acting opioids such as methadone

When initiating buprenorphine at least eight hours should have elapsed since last heroin use, or wait until experiencing withdrawal symptoms. If switching from methadone the methadone should be reduced to 30ml or less and an interval of at least 24 hours left between the last dose of methadone and the first dose of buprenorphine. If the patient wishes to switch from a higher dose they should be adequately prepared and consented.

SECTION 6: Criteria for inpatient treatment



An **OST2/SP2 Form** should be completed to inform the Regional SP Database if prescribing responsibility changes.

See Section 14 for further details.

Community treatment / initiation of oral substitution therapy is the mainstay of treatment in Northern Ireland but inpatient treatment may be considered for those who have failed to progress or who are deemed inappropriate for community treatment e.g.:

- Patients who require additional assistance with withdrawal or maintenance initiation e.g. co-existing chaotic alcohol and polydrug use, other opioid dependence, high dose benzodiazepine use, cocaine or other stimulant use
- Patients with a lack of social support or chaotic social circumstances
- Patients who experience significant difficulty in travelling to access services in a community setting
- Patients with complex needs e.g. co-existing mental health or physical health problems
- Patients where tolerance to buprenorphine or methadone is uncertain
- Restabilisation of patients receiving maintenance treatment if there are significant difficulties or risks associated with community stabilisation
- Stabilisation of pregnant patients

SECTION 7: Initiation of treatment



Once the client has been assessed and considered eligible for opioid substitute treatment, an **OST1/SP2 Form** must be completed for submission to the Regional Substitute Prescribing Database.

See Section 14 for full details.

Once assessment indicates that prescribing is a suitable option, prescribed treatment should generally be commenced within 3-4 weeks from the date of initial referral, although complex assessments may take longer. Priority should be given to the following groups:

- Pregnant women
- HIV / Hepatitis B / Hepatitis C positive patients
- Patients being transferred from another treatment provider e.g. another Trust/region or prison
- High risk patients e.g. severe physical or mental health issues, high risk injecting practice
- Parents with children at potential risk

A written care plan should be developed and arrangements put in place to ensure on-going working arrangements and communication between all relevant parties. A patient agreement should be drawn up with the patient and signed by all parties (see appendix 1 for a sample version).

All treatment providers should be aware of the community pharmacies in their area that provide a supervised consumption service and details are available from **local HSCB offices**. Options for pharmacy location should be discussed with the patient. A prescriber or a member of the Community Addictions Team care team must contact the pharmacist to get agreement to provide the service and inform them that a new patient will be presenting at the pharmacy. The following information must be supplied:

- Patient Name, address, date of birth
- Prescription details i.e. drug name, daily dose, start date, supervision arrangements
- Patient description
- Any previous difficulties encountered with other pharmacies

An agreement should be reached on the date and time that the new patient will present at the pharmacy.

It should be noted that under **NHS (General Medical Service Contracts) Regulations 2004; Part 3 Regulation 39 (4)**, with regard to prescribing methadone or buprenorphine for the treatment of addiction by instalment dispensing, GPs are directed to “order only such quantity of the drug as will provide treatment for a period not exceeding 14 days.”

The latter sections of these guidelines (Section 15 onwards) deal with the processes and procedures required within community pharmacies, however it is important that all service providers have knowledge of how supervised consumption takes place in practice within a pharmacy. Of particular relevance are the sections:

SECTION 17: Prescription validity contains the legal requirements a prescription for methadone or buprenorphine must meet before a pharmacist may proceed with dispensing

SECTION 21: Communication between pharmacists, prescribers and keyworkers describes when the pharmacy should make contact with other members of the team

Appendix 2: Home Office approved wording on collection of doses contains Home Office approved wording for substitute prescriptions.

SECTION 8: Supervision vs. Take Home supply

The supervised self-administration of medication by pharmacists optimises compliance and minimises leakage of the prescribed medication into the illicit market. However, safety must be balanced against the need to provide a patient-centred approach when considering requests for increased take-home doses.

Ideally new patients should be started on a supervision regime of at least 6 days per week for a minimum of three months. When patients are transferred from another service, consideration may be given to varying this period of supervision, being mindful of the effect the change of situation may have on a patient.

After 3 months of supervised consumption an assessment of the patient's stability should be undertaken. This requires a holistic review of drug use, the patient's attitude and motivation to treatment and their social and personal circumstances. In addition, the following factors should be considered:

- a. Patient attendance at pharmacy and clinical review appointments
- b. Patient's attitude to treatment including commitment to controlling or abstaining from drug use including alcohol
- c. Drug screening results
- d. Change in patient's general health, wellbeing and social circumstances e.g. working arrangements
- e. Continued use of illicit drugs or misuse of prescribed drugs whilst on substitute medication and reasons for this
- f. Assessment of risk of overdosing including past history
- g. Patient's and clinician's perception of stability on current dose of treatment i.e. patient's dose is not still being titrated upwards
- h. Concerns about diversion

If appropriate, patients can move to reduced supervision arrangements to allow a greater number of take home doses and the following points apply:

- i. number of supervised doses should normally be reduced in a step wise manner
- j. There should be discussion with the patient about the importance of safe storage particularly if there are any concerns such as children at home

- k. The **maximum** number of take home doses is normally 6 days at any one time, with one supervised consumption per week
- l. The maximum volume of methadone for take home should not normally exceed 600mls. If this volume is exceeded then the healthcare team should be involved in the decision on an individual case basis.
- m. Take home doses should remain under regular review. Patients should be advised that the frequency of supervision can increase as well as decrease. An increase in frequency of collection or supervision may be required for some patients but should be seen as an effort to increase the level of support rather than a punishment.

For further information on Supervision vs. Take Home see ***UK Guidelines on Clinical Management 2007*** pages 50-52.

SECTION 9: Management of patients across specialist services and primary care



An **OST2/SP2 Form** should be completed to inform the Regional SP Database when prescribing responsibility changes.

See Section 14 for further details.

Transferring stable patients to primary care

Whilst generally patients commence treatment in secondary care, many patients once stable can be managed successfully under a shared care arrangement between Community Addiction Teams (CAT) and General Practice.

All GPs providing the service should be suitably trained and operating under a Local Enhanced Service (LES). The GP involved in provision of service may be either the patient's own GP or another provider in the area. When transfer to primary care takes place there should be a clear indication of the receiving GP's responsibility to provide the CAT with any relevant clinical or other information as part of a two-way process.

The following steps should be taken when transferring a patient from secondary to primary care:

- Patient should be assessed by keyworker and secondary care prescriber for suitability of transfer of care
- CAT should discuss transfer with patient
- CAT should identify Shared Care GP within patient's locality and discuss transfer with this GP
- CAT should communicate intention to transfer patient with patient's own GP (if not the Prescribing / Shared Care GP)
- CAT should provide GP with a summary of the comprehensive assessment and recent care plan
- Keyworker should inform community pharmacist of transfer
- Start date should be communicated to all involved
- A new service user and provider agreement should be drawn up

Managing a patient's care normally requires a multidisciplinary approach; this should be provided in collaboration with others such as other primary care practitioners, keyworkers, practice nurses, community pharmacists, practitioners with a special interest and addiction specialists. GPs may, for historic reasons, have managed patients outside a shared care model. This is not the recommended model of treatment and it may be appropriate to review any such arrangements. If management outside a shared care arrangement continues, all review and reporting requirements outlined elsewhere within the guidelines still apply.



GPs who manage patients outside a shared care arrangement (this is NOT recommended) must ensure **all relevant OST/SP forms** are completed and submitted in line with the schedule outlined in Section 14.

Transfer from primary care to specialist service

If a GP concludes that the shared care model is no longer appropriate and that the patient requires to be transferred to the specialist service, prompt transfer should be arranged so that the new specialist service clinic prescription will follow on seamlessly from the existing primary care prescription. Discussion should take place directly between the GP and specialist service clinician. The GP should contact the community pharmacy and advise of the transfer and the need to cancel remainder of prescription if appropriate.

SECTION 10: Ongoing review and monitoring of stable patients

Complete an **OST2/SP2 form** (Treatment Progress Form) at the point when the patient is stabilised on treatment.



If stabilisation does not occur within first 3 months then an **OST2/SP2 form** should be completed every 3 months until the patient is stabilised.

Once stabilised **OST2/SP2 forms** should continue to be completed on a six monthly basis. See Section 14 for further details

Good practice points

- a. Case reviews should be carried out every 3 months. They should involve all appropriate members of the team and include feedback from the designated community pharmacist.
- b. Face-to-face review should be carried out by a clinician or keyworker at least once every month
- c. Face-to-face medical review should be carried out by a prescriber at least once every three months
- d. A local Did Not Attend (DNA) policy should be in operation
- e. A written care plan should be developed across primary and secondary care and arrangements put in place to ensure ongoing joint working arrangements and communication between all relevant parties.
- f. A patient agreement should be drawn up with the patient and signed by all parties (see appendix 1 for a sample version).
- g. There should be systems in place to ensure two-way communication (either directly or via keyworker) where substitute prescribing services are provided by a GP other than the patient's own GP. Shared Care GPs who provide a substitute prescribing service to patients who are registered with another GP must provide the patient's own GP with regular updates about substitute prescribing treatment.
- h. Drug screens should be carried out to determine if the patient is taking the substitute medication as prescribed as well as any unprescribed drugs. Frequency of ongoing drug screens will depend

on clinical need with a recommended minimum of four per year. As part of the written care plan, it should be clear who is responsible for carrying out drug screens.

- i. Ongoing LFTs should be carried out as clinically indicated and considered annually. It is particularly important in the following cases:
 - History of alcohol misuse
 - History of blood-borne virus exposure
 - Suspected paracetamol hepatotoxicity e.g. combined analgesic misuse
 - Substitute treatment with buprenorphine
 - Any other risk factors for hepatic impairment
- j. ECG monitoring should be carried out every 12 months for methadone patients taking more than 100mg daily.
- k. ECG monitoring should be considered more frequently for all methadone patients who have:
 - History of liver disease
 - History of heart disease (such as ischaemic heart disease, long QT syndrome, myocarditis, left ventricular hypertrophy)
 - Experienced unexplained episode(s) of collapse or seizure
 - taken medicines that inhibit cytochrome P450 CYP 3A4 (refer to **BNF**)
 - Continued use of stimulants
 - Experienced bradycardia
 - History of congenital QT prolongation in the family
 - Any relevant medical factors, such as hypothyroidism, liver disease, malnourishment, HIV infection, anorexia nervosa and alcohol dependence
 - Used drugs known to prolong QT Interval (for more detailed information consult **BNF, SPC of individual drug** or the most recent edition of South London and Maudsley NHS Trust Prescribing guidelines, not currently available online although an app is available to purchase for some smartphones). These include:
 - class IA and III antiarrhythmics (e.g., amiodarone, dronedarone, quinidine)
 - antipsychotics (e.g., phenothiazine derivatives, pimozide, haloperidol)

- tricyclic antidepressants
 - some antimicrobial agents (e.g. moxifloxacin, erythromycin, clarithromycin)
 - some antihistamines (astemizole, mizolastine)
 - some antiretrovirals (e.g. ritonavir, saquinavir, lopinavir)
 - An extensive list of medications which may cause QTc prolongation can be found at, <http://www.azcert.org/medical-pros/drug-lists/drug-lists.cfm>
- Patients who continue to engage in risk behaviour (or have done so since last blood borne virus test) should be offered testing for HIV, Hepatitis B and C on an annual basis. Hepatitis A and B vaccination status should be confirmed and vaccination offered if required.

For more information on ongoing review and monitoring of stable patients **UK Guidelines on Clinical Management 2007** pages 25-33, and an explanation of ECG irregularities is provided on pages 100-101.

SECTION 11: Missed doses

The action to be taken by the community pharmacist will depend on the number of consecutive missed doses as follows:

- a. Missed 1-2 doses: situation should be reviewed by pharmacist and discussed with patient. The patient may be maintained on their current prescription. If deemed appropriate, the pharmacist should consider discussing this further with prescriber or keyworker before dispensing medication, e.g. if happening frequently.
- b. Missed 3 or more doses: prescription is held until patient has been reviewed by keyworker and prescriber to identify how the patient has managed without medication and to consider recommencing at a lower dose. If the patient's dispensing regime is less than daily dosing, the prescriber should consider increasing the level of supervision.

For more information on missed doses see **UK Guidelines on Clinical Management** 2007 pages 52-53.

SECTION 12: Lost prescriptions or medication

Practitioners should be familiar with the **HSCB Prescription Security Policy** (available on HSC Intranet or on request from local **HSCB Office**). The action required to be taken will depend on the circumstance of each case involving a lost or stolen prescription, but practitioners should consider the following:

- a. The patient should be advised that they must report the loss to the police and obtain an incident number if they were responsible for the prescription / medication at the time of loss
- b. Service providers should report lost/stolen prescriptions to the Counter Fraud Unit (08000 963396)
- c. When a prescription is reported as being lost prior to being dispensed the prescriber may consider issuing a replacement if it is established that there is little risk of “double prescribing”. Contact should be made with the designated community pharmacy and any duplicate script should have “DUPLICATE SCRIPT” transcribed across the top to reduce the possibility of a second dispensing.
- d. The consequence of not continuing treatment needs to be weighed against the risk of relapse and overdose
- e. Where medications have been lost, risk to others including children should be considered and discussed with patient or others as appropriate

SECTION 13: Travelling abroad

Patients travelling abroad can be considered for take home doses of normally up to 14 days. In some circumstances arrangements can be made to have OST dispensed from a local pharmacy or drug service at their destination while the patient is away if their stay exceeds 14 days, or if the patient is not stable. In exceptional circumstances only, up to 30 days of medication can be supplied. The decision about the most appropriate arrangement needs to be made on an individual basis.

Further points for consideration

- a. Patients should provide documentary evidence of travel and should provide reasonable notice
- b. For travel within the UK, a reciprocal agreement exists whereby both HS21 prescriptions and SP1/SP2 prescriptions can be dispensed by community pharmacies in England, Scotland or Wales. Contact with a local pharmacy should be made in advance of travel by the prescriber to facilitate the patient receiving supplies of their medication.
- c. If travelling abroad “Release” should be contacted to provide guidance on import/export of controlled drugs. The patient should be encouraged to do this themselves (Telephone number: 08454500215, www.release.org.uk).
- d. It is the patient’s responsibility to check legal issues regarding import/export of any medications supplied with the destination country
- e. Methadone tablets may be considered more appropriate for supply when travelling rather than large quantities of syrup. Due consideration should be given to the risk of injection of crushed tablets and an increased risk of diversion.
- f. The patient should be given a letter by the prescriber confirming treatment, dose and length of stay and advised to carry this with them whilst travelling
- g. The patient’s home community pharmacist should be advised of the travel arrangements

SECTION 14: Reporting to the Regional Substitute Prescribing Database

Please note: At time of publication the reporting forms outlined below are known as “Substitute Prescribing” (“SP”) forms. A change of name is due early in the lifetime of the guidelines to “Opioid Substitute Treatment” (“OST”) forms. Therefore term/abbreviation that has been used throughout this document is OST/SP form.

An SP1 form is equivalent to an OST1 form, an SP2 form equivalent to an OST2 form and an SP3 form to an OST3 form.

A Regional Substitute Prescribing Database has been developed to record and provide information on the Regional Substitute Prescribing Service. At key points and defined intervals in the patient’s treatment the Regional Substitute Prescribing Database should be updated by completing the relevant Opioid Substitute Treatment (OST) form.

The Regional Substitute Prescribing Database does not hold personal identifiable information on the client but holds a history of referrals to the service, review history, drug use and treatment, substitute medication, testing for HIV and Hepatitis and information on the clients’ residential, employment and legal status.

Each client will have a unique reference number in respect of each specialist addiction service. This is the **“SP Reference Number”**, pre-printed on the patient’s original OST1/SP1 form. This number should be used on all subsequent forms relating to the same client to enable proper linking of information at various stages to take place. This will guarantee the anonymity of the central database whilst allowing appropriate linking of client information.

The text below provides a brief overview of the circumstances when each of the OST/SP forms should be completed; please refer to the separate guidance notes on OST/SP Forms for full details. The guidance notes have been made available to each of the Community Addictions Teams and can also be obtained from the Regional Substitute Prescribing Database Office by contacting 02825311097. Some forms can also be made available in electronic format through this office. The forms are not included in this document.

OST1/SP1 Treatment Initiation Form

An **OST1/SP1 form** should be completed by specialist addiction services for all clients presenting for treatment who are likely to be considered for substitute prescribing. Forms should be completed for all clients beginning new episodes of substitute prescribing, irrespective of when previous maintenance therapy finished.

A separate DMD form ('Drug Misuse Database' form) is not required for clients commencing SP treatment as the **OST1/SP1** form is used to notify these clients to the DMD as well as the Regional Substitute Prescribing Database (provided the client provides consent for the information to be used in this manner).

It should be noted that the Substitute Prescribing Database and the DMD are entirely separate databases.

OST2/SP2 Treatment Progress Form

An **OST2/SP2 form** should be completed by specialist addiction services for all patients once stabilised on methadone or buprenorphine, and then again periodically as described below.

The first **OST2/SP2** form should be submitted once the patient achieves stabilisation, and thereafter on a six monthly basis to update on progress. It is recognised that a small number of clients will not follow the swift stabilisation route. If a client is not stabilised at the three month point of treatment, an **OST2/SP2** form should be completed, indicating that stabilisation has not occurred. This should be repeated every three months until patient has been stabilised. At this point an **OST2/SP2** should be submitted indicating stabilisation has occurred, and thereafter every six months as above.

An **OST2/SP2** form should also be submitted when prescribing responsibility changes e.g. to a GP from secondary care or from one GP practice to another GP practice.

It is possible that clients will be treated with drugs other than methadone and buprenorphine. Although not covered by the guidelines and protocols, services wishing to notify such clients to the substitute prescribing database should do so using the **OST2/SP2** form. Clinical judgment will be exercised as to when stabilisation has taken place.

OST3/SP3 Treatment Discontinuation Form

An **OST3/SP3 form** should be completed for all patients who have discontinued treatment, either in a planned or unplanned manner. Details should be completed to the best of your knowledge if discontinuation occurs in an unplanned manner. This form should also be completed if a patient changes substitute prescribing provider and moves to another specialist addiction team or into the prison service.

SECTION 15: Sharing care with pharmacy

The guidance from Section 15 onwards focuses on provision of care within the community pharmacy and the interaction between pharmacists and the other shared care providers.

The guidance includes a summary of some of the legal and professional requirements particularly relevant to the storage, supply and destruction of substitute treatments in community pharmacy. For more comprehensive direction consult the following two documents:

- *DHSSPSNI document Safer Management of Controlled Drugs: A guide to good practice in primary care*
- *Pharmaceutical Society of Northern Ireland document Medicines for Human Use (pt 2): Controlled Drugs*

The pharmacist must ensure that the supervised consumption of treatments for substitution therapy is carried out in an appropriate manner, they have a good understanding of the addictions service and provide a quality service to patients.

Pharmacist responsibilities

- a. The pharmacist must have the necessary training to provide this service
- b. They must ensure there are appropriate Standard Operating Procedures (SOPs) in place within the pharmacy. Protocols should be followed for the receipt and dispensing of the prescription, and supervising the consumption of methadone or buprenorphine.
- c. The pharmacy layout and staffing should be appropriate and adequate to allow provision of this service
- d. Each patient should be introduced to appropriate members of the pharmacy team to aid recognition when locums are working
- e. Methadone and buprenorphine should be stored, and disposed of according to the regulations
- f. All relevant documentation and records should be completed
- g. The pharmacist should liaise with the prescriber and other members of the shared care team if there are any queries or concerns

- h. The pharmacy team should ensure the dignity of the patient at all times and respect the patient's rights to privacy and confidentiality. Supervision of medicines should be conducted in a discreet manner that does not cause embarrassment to the patient.
- i. The pharmacist should advise the patient on medicine information including the safety and storage of take home doses. This should be reinforced as necessary throughout the treatment. General health information should also be provided.
- j. Patient identity checks are important to ensure continuity of care (see SECTION 16, boxed text on "Patient Identity")

SECTION 16: New patients

A prescriber or a member of the shared care team should contact the pharmacist to inform them that a new patient will be presenting at the pharmacy and the following information should be supplied/ requested:

- Patient name, address, date of birth
- Prescription details i.e. drug name, daily dose, start date, supervision arrangements
- Patient description
- Patient ID

An agreement should be reached on the date and time that the new patient will present at the pharmacy.

First Meeting

Patient Identity

Unlike most other dispensing situations there is virtually no time interval between supply and consumption; it is therefore important that robust systems are in place for identity confirmation to prevent potentially fatal errors. Particular care should be taken if there are language difficulties, if patients have similar names or when locum pharmacists are used.

It should be explained to the patient that identity checks are for their own safety. While many pharmacists will know their regular patients very well it is still good practice to confirm identity at every dispensing. This will ensure familiarity with the process when locums are providing cover.

Photographic identification (ID) is good practice. This can be by an agreement with the patient to produce photographic ID, such as a driving licence, on each occasion substitute medication is to be dispensed. Alternatively a labelled photograph held in the pharmacy may be useful however the patient must give permission for this. A patient medication record card may provide an alternative but be aware of the possibility of misuse by another individual.

Also it is good practice to ask for an additional patient identifier such as date of birth. The patient should be asked to supply the information using an open question (as opposed to the pharmacist supplying the information for a yes/no reply). Residential address may not be an appropriate check as patients will often tend to live in close proximity to each other.

The patient should present at the pharmacy at the agreed time and date and produce photographic ID which matches the patient description previously given. The pharmacist should introduce themselves and the pharmacy team to the patient.

The pharmacist and patient must discuss and agree a contract (preferably written). It may be incorporated into the multidisciplinary 'Service patient and provider agreement' (see appendix 1 for an example) or may be a pharmacy specific agreement. It should include the following:

- a. The method of checking the patient's identity prior to dispensing (see boxed text "Patient Identity")
- b. The patient will attend alone
- c. The most appropriate time for collection of doses
- d. Arrangements for weekend and Bank Holiday doses
- e. The patient must demonstrate that they have taken the dose appropriately i.e. methadone has been swallowed, buprenorphine has dissolved under the tongue
- f. Unsuitable or offensive behaviour towards pharmacists or their staff will result in the termination of the contract
- g. The pharmacist will exercise their professional judgement and doses will not be supplied or supervised if the patient appears intoxicated by drugs or alcohol
- h. The prescriber/keyworker will be told if there are more than two consecutive missed doses or if there is any other pattern of repeated missed doses e.g. every Monday failure to attend. In such circumstances the prescriber will review the prescription before reinstatement of supply is considered (see Section 11 Missed Doses).
- i. Missed doses will not be supplied at a later date
- j. The prescriber/ keyworker will be told if there are any concerns about the patient's general health
- k. The pharmacist is unable to supply the dose to a representative
- l. If the patient cannot attend the pharmacy due to medical reasons and wishes to make alternative arrangements he/she must contact the prescriber or keyworker who must contact the pharmacist. It is not appropriate for the patient to contact the out-of-hours GP service in relation to this.

If the contract is a written one, then a copy should be given to the patient.

SECTION 17: Prescription validity

The prescription can be a secondary care issued SP1/SP2 or a GP issued HS21.

The pharmacist must ensure the prescription is valid and written appropriately to comply with the requirements of the Misuse of Drugs Regulations (Northern Ireland) 2002 in that:

- a. It is written so as to be indelible (i.e. handwritten or printed from clinical system), be dated and be signed by the person giving it with their usual signature
- b. It specifies the address of the person issuing it
- c. It specifies the name and address of the person for whose treatment it is issued
- d. It specifies the name of drug e.g. methadone or buprenorphine
- e. It specifies the dose to be taken e.g. 50mg daily, 4mg daily
- f. It specifies the form e.g. mixture, mixture SF, tablets
- g. It specifies either the total quantity (in both words and figures) of the preparation or the number (in both words and figures) of dosage units to be supplied e.g. 50mls(fifty mls) or 10 (ten) tablets
- h. In the case of a prescription for a total quantity intended to be dispensed by instalments, contains a direction specifying the amount of the instalments that may be dispensed and the intervals to be observed when dispensing

In addition for substitute prescribing the prescription must indicate:

- i. The start date i.e. the date the first dose is to be dispensed (this is in addition to the date of issue)
- j. Whether supervision is required
- k. Arrangements for weekends or Bank Holidays should be explicitly stated on the prescription and not require interpretation e.g. 'Dispense on Saturday for Sunday'
- l. The pharmacy name

Methadone or buprenorphine must not be supplied:

- m. unless the pharmacist is either acquainted with the prescriber's signature and has no reason to suppose that it is not genuine, or has taken reasonably sufficient steps to satisfy himself/herself that it is genuine

- n. before the appropriate date specified on the prescription
- o. later than 28 days after the appropriate date on the prescription
- p. in the case of an instalment prescription, unless the first instalment is dispensed within 28 days of the issue date with the remaining instalments dispensed in accordance with the instructions.

It should be noted that under **NHS (General Medical Service Contracts) Regulations 2004; Part 3 Regulation 39 (4)**, with regard to prescribing methadone or buprenorphine for the treatment of addiction by instalment dispensing, GPs are directed to “order only such quantity of the drug as will provide treatment for a period not exceeding 14 days.”

See Appendix 2: Home Office approved wording on collection of doses for Home Office approved wording for prescriptions and *UK Guidelines on Clinical Management 2007 pages 106-107* for a more extensive list of possible prescribing/dispensing/supervision situations.

SECTION 18: Dispensing medications

The daily dose should be dispensed and labelled appropriately before the patient arrives. Prepared daily doses must be locked in the CD cupboard (see storage requirements).

The following should be adhered to when dispensing:

- a. Two members of staff should, where possible, check the volume and strength of methadone or the strength and quantity of buprenorphine dispensed. Self-checking is not recommended other than in exceptional circumstances when it is in the patient's best interests to do so and procedures are followed to ensure patient safety such as leaving a suitable time gap to provide a mental break between dispensing and checking the prescription.
- b. Use the smallest reasonably sized plastic or glass bottle for dispensing methadone. Doses must not be dispensed directly into a disposable plastic cup.
- c. The label must include:
 - Patient's name
 - Methadone/buprenorphine strength, form, quantity and dose
 - Whether supervised or take home
 - Date of dispensing
 - Name and address of the pharmacy
 - 'Last dose' when appropriate
- d. Take home doses of methadone must be dispensed in separate bottles for each day with clic-loc caps
- e. There is no requirement for take home doses of identical strength buprenorphine tablets to be dispensed in separate containers for each day as the tablets are easily counted by the patient
- f. If a mixture of strengths is involved, these must be dispensed and labelled separately in accordance with standard 'best practice' procedures

SECTION 19: Supervision

For both methadone and buprenorphine

- a. The patient's identity should be checked before the dose is administered
- b. The supervision procedure should be discreet and efficient, to be mindful of the patient's dignity and the pharmacist's time
- c. Supervision should not take place in the dispensary but rather should occur in a quiet area
- d. The patient should be informed in advance of the last dose on the current prescription to allow timely supply of next prescription
- e. In cases where disposable plastic cups are used, provision must be made for safe disposal to ensure no cross infection is possible.
- f. Patients should not be allowed to bring opened containers of drinks into the pharmacy.

For methadone

- g. The pharmacist should provide the opportunity for the patient to check the name of the medicine, quantity and dose on the label before dose is taken
- h. The dose should be poured into a new plastic disposable cup and given to the patient
- i. The pharmacist must be satisfied that the dose has been swallowed, either by water being swallowed after the methadone dose has been given, by conversing with the patient or other means of ensuring that the methadone is not retained in the mouth
- j. The patient should not use their own drink (bottle or can) after consuming methadone as this could be used to conceal the dose rather than swallowing

For buprenorphine

- k. The pharmacist should provide the opportunity for the patient to check the name of the medicine, quantity and dose on the label before dose is taken
- l. Ideally, the patient should have a drink of water before dispensing to moisten the mouth
- m. The pharmacist should pop the tablets out of the blister pack, either into the patient's hand or into a small disposable cup

- n. The tablet(s) should be placed under the tongue and left to dissolve. The active ingredient passes through the buccal mucosa and produces its effect
- o. The tablet should not be swallowed, as it is virtually ineffective if taken this way due to first pass metabolism
- p. The patient should be observed for five minutes or until the pharmacist is satisfied (either by conversing with the patient, water being swallowed or other means) that the medication has not been concealed in the mouth and is fully dissolved. Once dissolved, what remains is a chalky residue that can be swallowed.
- q. When the total daily dose of buprenorphine requires three or more individual tablets to be taken, the advice of the manufacturer is that no more than two tablets of any strength should be placed in the mouth and allowed to dissolve at one time. The patient should be encouraged to comply with this and be supervised appropriately; it is accepted in practice this may be difficult to achieve with some individuals.

Crushing buprenorphine tablets

This is an off-licence means of dispensing buprenorphine which was devised to make supervision simpler. It is generally not recommended and should not be routinely carried out unless explicitly requested by the prescriber. Both prescriber and pharmacist should be aware of the liability issues with using unlicensed methods and be prepared to accept responsibility for any adverse events which may result.

Crushing will affect the rate of dissolution of the drug and may result in a variable dosage being absorbed as any drug swallowed will be lost to first-pass metabolism. In the first instance any issues with supervision should be discussed with the prescriber as a switch to methadone may be more appropriate. Any change from crushed tablets back to whole tablets should also be discussed with the prescriber.

SECTION 20: Storage and disposal of methadone and buprenorphine

- a. All stocks of controlled drugs must be stored in accordance with the Safe Custody Regulations. The DHSSPS has advised that storage in the approved CD time delay safe would fulfil the requirements of the Regulations.
- b. Disposable plastic cups must be discarded after single use
- c. Labels must be removed from all bottles including stock bottles prior to disposal
- d. Patient names should be removed from dispensing labels prior to disposal to maintain patient confidentiality
- e. For take-home doses the safe storage message should be reinforced to the patient:
 - It should ideally be kept in a locked cupboard
 - It should never be accessible to children
 - It should not be kept in a refrigerator for both safety and stability reasons (the colouring may precipitate in some brands)

SECTION 21: Communication between pharmacists, prescribers and keyworkers

A current list of contact names and telephone numbers for prescribers and local addiction teams should be kept in the pharmacy.

The pharmacist must inform the prescriber or keyworker, where appropriate, of the following:

- A new patient who does not present as agreed
- More than two consecutive missed doses or if there is any other pattern of repeated missed doses e.g. every Monday failure to attend
- A patient attempting to avoid supervised consumption
- Unacceptable behaviour e.g. shoplifting, verbal or physical abuse of pharmacy staff, deviation from the contract
- Intoxication
- Deterioration in health and other health concerns
- Problems concerning the prescription
- A new patient presenting without prior contact from the prescriber
- Any concerns regarding the patient's social circumstances including child protection issues

Addictions Unit or GP practice staff may contact the pharmacist to advise if the patient is unable to collect a dose for medical reasons.

SECTION 22: Patient Medication Records

The following details should be entered into the Patient Medication Records:

- a. Name, address, DOB of patient
- b. Medical Conditions
- c. Prescriber details
- d. Medication details to include whether the dose is supervised or not
- e. Other relevant information such as keyworker contact details

SECTION 23: Controlled Drug Register

On supplying methadone to a patient, the Controlled Drug register must be completed within 24 hours. It should be remembered that completion of the register is an indication of a supply made to a patient, and not of the dispensing process, so in the case of an uncollected dose, no register entry should appear. Buprenorphine is a Schedule 3 controlled drug and while it must be stored in a complying CD safe, it does NOT require entry into the CD Register.

SECTION 24: Prescription processing

The prescription form must be completed with the prescription code endorsements and date of dispensing/supervision as appropriate. The original prescription should be kept until it expires or is completed. It is then submitted to BSO for payment in the usual way. Uncollected doses can be reused by the pharmacy. In order to claim a dispensing fee in this instance the prescription should be coded as normal but the quantity entered as '0'.

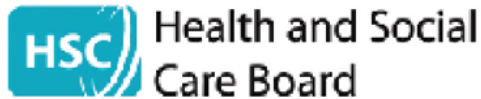
SECTION 25: Pharmacy Standard Operating Procedure (SOP)

Each pharmacy delivering this service should have a written SOP which is available for all staff including locums. This should be reviewed and updated regularly.

SECTION 26: Health information

Patients should be given a leaflet on the safety of take home doses. Health promotion leaflets and advice on medicines should also be provided.

Appendix 1: Service User and Provider Agreement



SERVICE USER AND PROVIDER AGREEMENT
Please take time to read all sections of this agreement before signing it

Service User _____ Keyworker _____

Service Users

I agree

- To treat with respect all people I have contact with in connection with my treatment
- To keep my appointments promptly and, unless absolutely necessary, **unaccompanied**
- To accept responsibility for my prescription and medication as replacements are normally not issued
- To store any medicine I am allowed to take home safely away from others (especially children)
- To my prescription being withheld if I am intoxicated or have missed more than two consecutive daily doses
- To provide samples for drugs of abuse screening
- To allow sharing of relevant information by all professionals involved in my treatment and to voluntarily disclose my treatment if I attend other providers such as A&E, Out of Hours or my own GP
- To participate in periodic reviews
- To inform the Driver and Vehicles Agency (DVA) if I intend to continue driving as required by law
- To discuss any holiday plans with the clinic well in advance of travel and provide documentary proof of same
- To supervised consumption of medicine in the pharmacy at mutually agreed times of day
- Not to engage in any antisocial or illegal behaviour in the clinic or pharmacy including theft/shoplifting and verbal/physical aggression
- Not to make any attempt to obtain medication by deception or to sell any medication provided
- Not to conceal or carry weapons

Service Providers

I agree

- To share relevant information with all professionals involved in the treatment
- To participate in periodic reviews as necessary
- To treat the above named service user with respect
- To ensure that the staff I work with treat the above service user with respect (Doctor/Pharmacist)
- To provide high quality health care, as for any other service user (Doctor)
- To provide adequate substitute drug treatment for the above named service user (Doctor)
- To provide a clear and legible prescription that meets legal requirements for controlled drugs (Doctor)
- To contact a community pharmacist and arrange dispensing (Doctor)
- To give the service user a regular therapeutic support sessions at the Shared Care Clinic (Keyworker)
- To provide a Personal Programme Plan to meet the needs of the service user (Keyworker)
- To facilitate access to other Health and Social Care as appropriate for the service user (Keyworker)
- To facilitate access to other external services as appropriate for the service user (Keyworker)
- To provide the service user with information about medications (Pharmacist)
- To ensure that supervised dispensing takes place in a private area of the pharmacy (Pharmacist)
- To explain protocols for missed doses (Pharmacist)
- To provide a pharmacy practice leaflet giving information about the service (Pharmacist)

Attention: If you fail to benefit from treatment a case review will be arranged to review your care

Service User:	Date:	Pharmacist:	Date:
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Keyworker:	Date:	Doctor:	Date:
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Warning: Methadone or buprenorphine can be dangerous, especially when taken with other opioids, benzodiazepines and/or alcohol or by anyone who has no tolerance to it.

(A Word version of this form is available on the HSCB internet site)

Appendix 2: Home Office approved wording on collection of doses

Where the prescription for a Controlled Drug contains a direction that specified instalments should be dispensed at specified intervals, supplies must not be made otherwise than in accordance with the directions unless the following text is on the prescription:

Supervised Consumption

“Supervised consumption of daily dose on specified days; the remainder of supply to take home. If an instalment prescription covers more than one day and is not collected on the specified day, the total amount prescribed less the amount prescribed for the day(s) missed may be supplied.”

Unsupervised Consumption

“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”. *

or;

“If an instalment prescription covers more than one day and is not collected on the specified day, the total amount prescribed less the amount prescribed for the missed days may be supplied.”

The Home Office approved wording to be used if the prescriber would like to ensure that the patient is not supplied with their dose if they have missed collecting their dose for three days is:

“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 total amount less the instalments for the days missed) may continue to be supplied in the specified instalments at the stated intervals, provided no more than three days are missed.”

Likewise, the following wording can be used to support the collection of Methadone when the pharmacy will be closed on the due date specified on the prescription:

“Instalments due on days when the pharmacy is closed should be dispensed on the day immediately prior to closure.”

*this wording is already printed by default on SP1 and SP2 forms

Appendix 3: References

(Web links last checked 31st May 2013)

AR Lingford-Hughes et al. (2012). BAP Updated Guidelines. Available: <http://jop.sagepub.com/content/26/7/899.full.pdf+html> . Last accessed 04th Aug 2012.

BAP evidence-based guidelines for the pharmacological management of substance abuse, harmful use, addiction and comorbidity http://www.bap.org.uk/pdfs/BAPaddictionEBG_2012.pdf

RCGP Guidance for the Use of Substitute Prescribing in the Treatment of Opioid Dependence in Primary Care. Available: <http://www.rcgp.org.uk/revalidation-and-cpd/~media/Files/SMAH/RCGP-Guidance-for-the-use-of-substitute-prescribing-in-the-treatment-of-opioid-dependence-in-primary-care-2011.ashx> . Last accessed 4th Aug 2012.

Department of Health England. (2007). Drug Misuse and Dependence, UK Guidelines on Clinical Management. Available: http://www.nta.nhs.uk/uploads/clinical_guidelines_2007.pdf . Last accessed 4th Aug 2012.

National Collaborating Centre for Mental Health. (2007). Drug Misuse - Opioid Detoxification. Available: <http://www.nice.org.uk/nicemedia/live/11813/35997/35997.pdf> . Last accessed 4th Aug 2012.

NHS. (Unknown). The Management of Opioid Dependence. Available: http://www.npc.nhs.uk/merec/cns/drug/resources/merec_bulletin_vol12_no4.pdf . Last accessed 04th Aug 2012.

Northern Ireland CNS formulary. <http://www.hscboard.hscni.net/NIFormulary/Chapter%20-%20Central%20Nervous%20System%20-%20PDF%201MB.pdf> . Last accessed 22nd Oct 2012.

Promoting Quality Care: Good Practice Guidance on the Assessment and Management of Risk in Mental Health and Learning Disability Services (as revised May 2010). <http://www.dhsspsni.gov.uk/mhld-good-practice-guidance-2010.pdf> Last accessed 30th Oct 2012.

Safer Management of Controlled Drugs: A guide to good practice in primary care (Northern Ireland) DHSSPS First published: August 2010 (Version 1) Updated: August 2012 <http://www.dhsspsni.gov.uk/pas-guidance>

The Clinical Opiate Withdrawal Scale (COWS). DR Wesson, W Ling - Journal Of Psychoactive Drugs, 2003

The National Health Service (General Medical Services Contracts) Regulations 2004 <http://www.legislation.gov.uk/uksi/2004/291/contents/made>

Unknown. (2007). Drug misuse - methadone and buprenorphine. Available: <http://publications.nice.org.uk/methadone-and-buprenorphine-for-the-management-of-opioid-dependence-ta114/guidance> . Last accessed 04th Aug 2012.

Unknown. (2012). Release Drugs, The Law & Human Rights. Available: <http://www.release.org.uk/> . Last accessed 4th Aug 2012.

Other useful resources not referenced in the main body of this document are listed below:

Addiction to medication: an investigation into the configuration and commissioning of treatment services to support those who develop problems with prescription-only or over the counter medication. National Treatment Agency for Substance Abuse 2012 <http://www.nta.nhs.uk/uploads/addictiontomedicinesmay2011a.pdf>

Delivering quality care for drug and alcohol users: the roles and competencies of doctors. A guide for commissioners, providers and clinicians College Report CR173 September 2012 Royal College of Psychiatrists and Royal College of General Practitioners London <http://www.smmgp.org.uk/download/guidance/guidance005.pdf>

Medications in recovery: Re-orientating drug dependence treatment National Treatment Agency for Substance Abuse 2012 <http://www.nta.nhs.uk/uploads/medications-in-recovery-main-report3.pdf> (accessed 22nd October 2012)
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