LOCAL ENHANCED SERVICES

Stop Smoking Service
Provided by Community Pharmacy Services

April 2012
Guidelines for the Delivery of NHS Derby City Community Pharmacy Stop Smoking Service

April 2012
Introduction and Background

Smoking continues to represent a significant burden on the health of the UK population and remains the single most preventable cause of disease. The government continues to place emphasis on the critical position that smoking has in relation to heart disease, cancer and health inequalities. The Community Pharmacy stop smoking scheme is designed to target, support and increase the numbers of individuals stopping smoking.

It is apparent that many GP practices and community pharmacists undertake a range of activities which support stop smoking ranging from prescribing nicotine replacement therapy and offering advice, through referral to specialist services and providing space for specialist clinics within their own premises. In addition other health professionals already contribute to and have expressed a desire, to participate further in the delivery of stop smoking support.

The key elements of successful stop smoking support include: -

- Actively promoting stop smoking
- Ensuring adequate training for staff
- Ensuring the seamless provision of nicotine replacement therapy, or alternatives, where appropriate
- Providing adequate space and a suitable environment for support to occur
- Regular monitoring of activity, including validation of quitters
- An awareness and understanding of smoking targets

The Fresh Start service will continue to deliver stop smoking services in Derby City and support those involved in stop smoking. Fresh Start also continues to provide specialist support for stop smoking in certain groups e.g. smoking in pregnancy.

These guidelines will ensure that stop smoking delivered by community pharmacists will meet national recommendations with regard to stop smoking support. Smoking has such far-reaching health consequences that it is incumbent on all health professionals to, at the very least; promote the right messages and signpost to support.

The purpose of this document is to set out the criteria for stop smoking support in Community Pharmacies. Following the successful completion of Fresh Start training, funding will be available to community pharmacies to undertake this work.

Aims of Accreditation

- To extend the reach of the Stop smoking service in Derby City, acknowledging that community pharmacists are in a position to assist and support smokers to quit
- To ensure that this approach delivers services that meet all necessary quality and monitoring criteria
- To increase the number of smokers receiving stop smoking support, particularly in community settings
Training standards and competencies

Since 01 April 2010 the standards and competencies for stop smoking advisors have been set out in the NCSCT document *Learning Outcomes for training Stop Smoking Specialists*. Department of Health best practice guidance states that all stop smoking advisors working for NHS Local Stop Smoking Services should receive specific training to carry out their role which conforms to these standards.

Regular training to these standards has been and will continue to be available through the Fresh Start service. NHS Derby City envisage that many more healthcare professionals will wish to participate and it is important that as many as possible are trained to provide brief interventions with smokers and intensive one to one support.

Effective stop smoking interventions

**A. Promoting Stop smoking and brief interventions (basic level)**

The starting point for promotion is increasing awareness and recognition of the issues. A policy on smoking is a good starting point but the mainstay of promotion will be ensuring that opportunities for brief intervention are maximised and ensuring that all promotional material is in an appropriate format, accessible to all. This should be carried out routinely as part of day-to-day activity.

Brief interventions include:
- Opportunistic conversation raising smoking issues and the benefits of quitting
- Advice to stop
- The offer of support including information on availability of Nicotine Replacement Therapy, bupropion (Zyban) or varenicline (Champix) if appropriate
- Referral to specialist support for those who need and want it
- Prominent display of promotional material

**B. Intensive one to one support and advice (intermediate level)**

The established model for delivering specialist stop smoking services is by using advisors trained in the specialist skills needed to support those wishing to stop smoking. Training to achieve this level will require attendance on a 2-day training course delivered by Fresh Start staff, together with attendance at a minimum of 1 Advisor network event per year. Following attendance at training pharmacy staff will become Fresh Start Associate Advisors and be able to support clients to go smoke free on a 1-1 basis. Staff that have not achieved this level should not offer 1-1 stop smoking support.

**C. Group working (intermediate and above level)**

This type of support requires specific training, but can be delivered by experienced advisors or stop smoking specialists (experienced in stop smoking/tobacco control or qualified counsellors preferably with experience in addiction counselling).

Within this Local Enhanced Service it is expected that all accredited community pharmacies will offer brief intervention and 1-1 support. Trained staff at pharmacies that wish to deliver group support should contact Fresh Start on 01332 861174 prior to delivering groups.
Main Aim:
To provide a programme of stop smoking advice to smokers within an Associate Advisor’s role using Fresh Start protocols and evaluation methods. For this scheme, pharmacy staff will be acting as trained Associate Advisors:

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Support from Management</td>
<td>To negotiate and confirm with the Associate Advisor’s own management that time can be allocated to see clients on a regular basis. The amount of time or number of clients should be flexible depending on work commitments.</td>
</tr>
</tbody>
</table>
| Provide adequate space/suitable environment for stop smoking support to occur | Provision of support will require a quiet area as needed for a consultation, awareness should be apparent as to the confidential nature of discussions with smokers, e.g.:  
  - *The consultation area should be a designated area where both the patient/client and pharmacist can sit down together.*  
  - **The client and pharmacist should be able to talk at normal speaking volumes without being overheard by other visitors to the pharmacy, or by pharmacy staff undertaking their normal duties.**  
  - A large enough area if group sessions are to be conducted  
*The consultation area should be clearly designated as an area for confidential consultations, distinct from the general public areas of the pharmacy.*  
** Reference New Contractual Framework for Community Pharmacy |
| Activity promoting Stop Smoking         | The Pharmacy will display material on stopping smoking and the services they offer, in a format accessible for all. The Pharmacy will actively pursue brief intervention whenever possible and act as a link person for the Fresh Start service.                                             |
| Skills and competencies                 | Those involved in delivering “intermediate level” stop smoking support will have the necessary skills and competencies, through attendance at Fresh Start training courses and update sessions. A specialist advisor will be identified from the Fresh Start service to support associate advisors to deliver a high quality service. All associate advisors are required to attend at least one update training session every 12 months (see provider obligations section in this document for further guidance). |
| Service Delivery                        | During the initial consultation, the Associate Advisor assists the client in planning behavioural changes in preparation for their quit date. Contact is maintained with the client throughout a minimum 4-week quitting programme from their declared quit date. This could involve face-to-face meetings or a combination of meetings and telephone counselling, though it is recommended that the initial session and the 4-week outcome session are face-to-face meetings. Additional support may be offered and should be dependant upon the client’s on-going support requirements. All providers should return 4-week quit rates of between 35 - 70%, as detailed in the Department of Health's NHS Stop Smoking Services: Service and Monitoring Guidance 2011/12 publication. Any pharmacies that are outside of this range will be contacted by Fresh Start to obtain reasons for this. |
| Timely provision of pharmacological support | NRT, Champix or Zyban will be supplied in a timely manner. Reimbursement of NRT costs to the pharmacy will be through the NRT voucher scheme. Standard patient exemption criteria apply. A maximum of twelve vouchers for the twelve week period can be issued though eight weeks is the recommended time required for a successful quit. Fresh Start recommends vouchers are issued on a weekly basis. If a client wishes to use Zyban and Champix then they should receive this from their GP. However the associate advisor should continue to offer behavioural support. |
| Regular monitoring of activity, including validation of quitters | Data regarding smoking status must be collected four weeks post client’s quit date either by CO validation or self report*. The advisor must correctly complete the Initial Monitoring Form at each stage of the process and immediately forward the form to the Fresh Start Service at Coleman Health Centre, Coleman Street, Derby DE24 8NH to enable prompt data input. A copy of the IMF should be received by Fresh Start within 10 working days of the scheduled date of the 4-week follow-up session. The validation of quit status is a necessary component and equipment should be in place to do this. Validation meters (CO Monitors) will be made available to those providing these services. An 85% validation rate is required as recommended by the DOH Service & Monitoring Guidelines (2011/12) for Stop Smoking Services. |
| An Awareness and understanding of Smoking Targets | The government have set ambitious targets for stop smoking services, an understanding of what these are and how they are being met is important in the delivery of stop smoking services across Derby City. |
| Audit | In order to maintain high standards in the delivery of stop smoking services, pharmacists will be subjected to audit procedures as agreed by the PCT and Fresh Start service. |
| Communication with Local Fresh Start Service | The associate advisor will regularly communicate with the local PCT Fresh Start team to inform of progress and/or any difficulties, identifying training needs/concerns and to express any ideas that may further develop the service. |
| Complaints | All complaints received by the pharmacy in relation to this service should be dealt with in accordance to the pharmacy-based standard operating procedure for handling complaints. A summary of each complaint will be made available to those managing the service using the agreed complaints/incident reporting policy. These should be sent to: Primary Care Contracts Manager – NHS Derby City, Floor 3 North Point, Cardinal Square, 10 Nottingham Road, Derby, DE1 3QT |

*A client should be counted as having successfully quit smoking if he/she has not smoked at all since 2 weeks after the set quit day. Smoking status can be determined by CO validation or self-report no later than six weeks post the client’s quit date. Any client not followed up by 6 weeks must be counted as lost to follow up.*
Contractual Agreement

Prior to the delivery of a stop smoking service under the Accreditation scheme, pharmacies will be required to sign a Contract of Agreement.

Benefits of Accreditation

There are a number of benefits in becoming accredited to take part in the Community Pharmacy, stop smoking scheme, including:

- A per client fee as detailed below
- Free training and support for staff up to an agreed level
- An increase in the skills of staff
- A “close to home” service for clients within your community that wish to quit smoking
- A shorter waiting period between a smoker expressing the motivation to quit and support for that smoker commencing on a quit attempt
- Building relationships and loyalty between clients and patients who come to the pharmacy for this service
- Accreditation is awarded to individual associate advisor, not the pharmacy

Pharmacies will only be accredited if they are able to demonstrate they have effective systems and processes in place to facilitate delivery of the enhanced service.

Reimbursement

In order to reimburse pharmacies for delivering stop smoking services under this LES, payment will be made as outlined in Appendix 2.

Service Delivery

Weekly contact with the client is required for the four weeks running up to the smoking status validation visit. It is important that, face-to-face contact takes place on the first visit and also when the four-week validation is performed.

The following topics should be discussed in the initial assessment with the client:

- The client’s readiness to make a quit attempt
- The client’s willingness to be supported by the Associate Advisor
- The typical treatment programme, including aims, benefits, length, options available, benefits and commitment required from the client

The client should be encouraged to return the following week for an initial consultation which will include:

- A description of the main features of tobacco withdrawal
- Discussion of appropriate behavioural support and coping strategies
- A carbon monoxide test and explanation as to its function
- Identifying pharmacological options
- The monitoring requirements and consent procedures
• Setting a quit date
• Conclude with an agreement as to the preferred support pathway and treatment options

After four weeks contact should be more flexible, depending on the client’s ongoing support requirements. NRT supply is recommended for 8 weeks but may continue, if necessary, for a maximum of 12 weeks. This is at the discretion of the advisor where there may be a risk that the client will relapse if not provided with further supplies of NRT. Contact during this period should be maintained. Dual therapy (a patch plus an oral product) can only be provided on a maximum of four vouchers, please contact the Fresh Start office for further guidance if required.

The initial consultation should take approximately 20-30 minutes.

Follow up interventions need not be face to face, although a CO reading is required to be attempted to confirm quit status.

Initial Monitoring Forms should be returned to Fresh Start, Coleman Health Centre, Coleman Street, Alvaston, Derby DE24 8NH within 10 working days of a client’s scheduled 4-week outcome visit. NRT vouchers should be returned to Fresh Start on a monthly basis.

**Previous Users**

Clients that are not successful at becoming smoke-free at four weeks, but who exhibit motivation to quit can re-access the service immediately, however clients should not exceed two quit attempts per quarter.

**Termination of Service**

To formally end this service, three months’ notice must be given in writing by either party

**Contact Details**

Should you have any questions or concerns in respect of the Derby City Community Pharmacy Stop Smoking Scheme please contact the Primary Care Contracts Manager – NHS Derby City PCT, Floor 3 North Point, Cardinal Square, 10 Nottingham Road, Derby, DE1 3QT 01332 868757

For more information relating to Fresh Start please contact Fresh Start on 01332 861174.
Appendix 1

Pharmacological support

Nicotine Replacement Therapy

- **Those exempt from prescription charges** will receive free NRT on production of proof of exemption for up to eight consecutive weeks, or a maximum of 12 weeks in exceptional circumstances. Pharmacies will send in a voucher each week to be reimbursed at Drug Tariff prices.

- **Those not exempt from prescription charges** will pay the standard current prescription charge.

- **Combination therapy / Dual therapy.** Two products may be used where necessary with clients who have previous unsuccessful quit attempts or have a higher dependence on nicotine. The products supplied must be a patch and an oral / nasal product (Gum, lozenge, inhalator and nasal spray). Dual therapy must not exceed four vouchers.

- **A quit date should be established early in the treatment programme (ideally in the first two weeks)** and re-assessed if necessary the following week.

- **Motivation** should be re-assessed if the client has not quit within two weeks and NRT discontinued. If the client is using Champix or Zyban then the GP must be informed.

- **The Name and Address of the client’s GP must be written on every voucher.**

- **The week number** should be written on the voucher to indicate how many vouchers a client has had. (i.e. week 1-8)

- **At present any NRT product can be issued on a Fresh Start voucher.** Certain client groups, for example pregnant smokers and those with CHD problems may be given certain NRT be products with caution. These clients should be clinically assessed for suitability to use NRT. Pregnant women may be referred to the Fresh Start Specialist Advisor.

- **Vouchers cannot be used for under 12’s,** and these children should be referred to Fresh Start.

**Champix (Varenicline) and Zyban (Bupropion)**

- Fresh Start Associate Advisors will support a client’s quit attempt regardless of whether they decide to use NRT, Champix or Zyban or try to give up using willpower alone.
Associate Advisors should inform a client about their options and give information regarding Champix or Zyban, **but are not able to prescribe this drug, nor can the vouchers be exchanged for it.** It is the responsibility of the client’s GP to make the clinical decision as to their suitability for Champix or Zyban.

- Pharmacists can assess a client’s motivation to stop smoking at their first appointment, and give them a letter to take to their GP asking them to assess the client’s suitability for Champix or Zyban (see Appendix 3-5).

- A letter (Appendix 4-6) should be sent to the GP informing them when a client who is taking Champix or Zyban has failed to attend for their appointments at the pharmacy.

- **Champix and Zyban are not suitable for certain groups.** As with all medicines, Champix and Zyban can cause side effects in some people, and should not be combined with certain other medication. These have to be carefully weighed up against the health benefits of stopping smoking. **For this reason it is important that the client discusses the issue with their GP who will have knowledge of their full medical history.**

- Once a client has been prescribed Champix or Zyban **any adverse or unexpected side effects should be reviewed by the client’s GP** as soon as possible.
Appendix 2

Payment Structure April 2012

In return for delivering the service, Accredited Pharmacies will receive:

- A payment of £60 will be paid where a client is CO verified as still abstinent 4 weeks after the quit date (a minimum of 85% of all quits should be CO verified). A payment of £45 will be paid where a client has not been CO verified but has reported that they are still abstinent at 4 weeks. In both these cases the pharmacy, having recorded that the client has quit on the IMF, should return the white copy of the IMF to stop smoking service. Pharmacies should return all client paperwork as soon as the client has stopped attending the pharmacy for support.
- Pharmacies will be paid monthly and the payments will be paid on timely receipt of the IMF Forms at Fresh Start, Coleman Health Centre
- Pharmacies will receive a full breakdown of the payments made on a monthly basis for this support LES.
- Payments in relation to the NRT voucher scheme are separate to this LES and not dependent on delivery of the smoking cessation service described within this LES.

Enhanced payment arrangements

Pharmacies will be entitled to a one off payment of £100 for each block of ten quitters at the end of the financial year, if they achieve at least four of the following key performance indicators:

- An increase on the previous year's number of quits
- A CO validation level in excess of 80%
- Demonstrate a quit rate of between 35% - 70% of clients setting quit dates
- At least 10 four week quits in a year
- Support for 30 or more clients setting a quit date during the financial year
- Demonstrable commitment to promoting smoking cessation amongst clients including participation in any campaigns, and attendance at a minimum of one Re-Fresh training event every 12 months.

Consumables

A CO monitor will be loaned to an accredited Community Pharmacy for use, together with an initial supply of single-use disposable mouthpieces. Pharmacies will be responsible for the maintenance and calibration of the CO monitor and will be required to purchase additional supplies of single-use disposable mouthpieces for use with the monitors. Calibration and servicing can be arranged with the Fresh Start advisors. Calibration should occur every 6 months.

Fresh Start will supply all NRT vouchers and IMF pads and these should be requested from Fresh Start as needed in a timely fashion. Pharmacies should not share their stock with other pharmacies and should not stockpile resources.
Appendix 3

Letter to client’s GP, referring client who is requesting Champix as their choice of pharmacological support (Community Pharmacy Advisors will ask clients to take this letter to arrange an appointment with their GP.)

Dear Doctor

Re: Name: ______________________ Date of Birth: _______________
Address: __________________________________________

The above named patient has commenced the ‘Fresh Start’ Smoking Cessation programme. The patient has selected Champix as the preferred method of support, in their quit attempt.

To ensure that Champix is suitable for this patient, we have already checked the following:

**Motivated to quit**
Has the client demonstrated motivation to quit smoking? (Circle as appropriate) YES / NO

**Contradictions**
Is the patient hypersensitive to varenicline tartrate or to any of its excipients? *GP to check patient records*

**Warning/precautions**
Is the patient under 18 years old? YES / NO
Does the patient have end-stage renal disease? YES / NO
Is the patient pregnant? YES / NO
Is the patient breast feeding? YES / NO
Does the patient have epilepsy? YES / NO
Does the patient have history of psychiatric illness? *(If yes, GP to make clinical decision about the use of Champix)* YES / NO

The patient must be seen by a doctor before Champix is prescribed.

If, following your assessment of the patient you feel that Champix is clinically appropriate, a suggested prescribing schedule is:

1st request (weeks 1-2) – 0.5mg – 1mg starter pack, 2 week supply
2nd request (weeks 3 - 4) – 2 week supply, 28 tablets
3rd request (weeks 5 – 8) – 4 week supply, 56 tablets
4th request (weeks 9 -12) – 4 week supply 56 tablets

Days 1-3 - 0.5mg once daily (morning)
Days 4-7 - 0.5mg twice daily (morning & afternoon)
Day 8 onwards - 1mg twice daily (morning and afternoon)

Treatment is for a maximum of 12 weeks

The above prescribing schedule will reduce wastage from patients who do not complete the duration of the course.
We suggest that repeat prescriptions be issued when the client has demonstrated attendance at the smoking cessation service. Smoking advisors will ask clients to take their appointment card to the surgery in order to redeem their repeat prescription.

Your patient will be advised to report any perceived adverse drug reaction to Champix, to yourself in the first instance or to the dispensing pharmacist.

Many thanks for your assistance.

Yours sincerely

Fresh Start Stop Smoking Advisor
Appendix 4

Letter to GP relating to Champix client’s non-attendance

Dear Doctor

RE: NAME:  
DOB:  
ADDRESS:  
DATE LAST ATTENDED:  

The above-named patient attended a Fresh Start Stop Smoking Appointment and was issued with a letter requesting you to prescribe **Champix**, if you felt this was clinically appropriate.

Unfortunately the patient has failed to attend their follow up appointments; therefore their progress has not been monitored.

Yours sincerely

Fresh Start Stop Smoking Advisor
Dear Doctor,

Re: Mr/Mrs/Miss ____________________________

Date of Birth: ____________________________

The above named patient has commenced the Pharmacy Stop Smoking Programme. The patient has expressed a preference for using Zyban, as the method of support for their quit attempt.

**A doctor must see the patient before Zyban is prescribed.**

If, following your assessment of the patient you feel that Zyban is clinically appropriate, a suggested prescribing schedule may be:

- Weeks 1-2  30 tablets
- Weeks 2-4  30 tablets
- Weeks 4-8  30 tablets. This completes the course of treatment.

The above schedule will reduce wastage from patients who do not complete the duration of the course.

We suggest that repeat prescriptions be issued for the client as per the above schedule, totalling three visits to the pharmacy with each prescription. The patient will be advised to report any perceived adverse drug reaction to Zyban, to you in the first instance or the Community pharmacist advisor they are signed up to.

Many thanks for your assistance.

Yours sincerely,
Fresh Start Stop Smoking Advisor
Dear Doctor,

Re Patient…Mr/Mrs/Miss

Date……………………..

We wish to inform you that your patient named above has failed to attend subsequent appointments arranged with the Pharmacy Stop Smoking Service.

The patient attended a first appointment and is using Zyban to support their quit attempt.

Please note that this patient has not attended further appointments and consequently we are unable to monitor and support the client through the pharmacy stop smoking service.

Yours sincerely,

Fresh Start Stop Smoking Advisor
Appendix 7
SERVICE SPECIFICATION FOR SUPPLYING NICOTINE REPLACEMENT THERAPIES (NRT) THROUGH PHARMACY

*Please note that for the purposes of this scheme length of treatment with NRT will be for eight weeks, reference to treatment in the table below refers to BNF recommendations

<table>
<thead>
<tr>
<th>Name of authorising NHS body</th>
<th>Derby City PCT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Service specification comes into effect</td>
<td>01.04.2012</td>
</tr>
<tr>
<td>Service Specification to be reviewed</td>
<td>31.03.2013</td>
</tr>
<tr>
<td>Supply and legal classification</td>
<td>NRT may be supplied in the following forms:</td>
</tr>
<tr>
<td>P – Pharmacy</td>
<td>Gum</td>
</tr>
<tr>
<td>GSL – General Sales List</td>
<td>2mg (GSL); 4mg (GSL)</td>
</tr>
<tr>
<td></td>
<td>Patch</td>
</tr>
<tr>
<td></td>
<td>5mg /16 hrs (GSL); 7mg /24 hrs (GSL); 10mg /16 hrs (GSL); 14mg /24hrs (GSL); 15mg /16 hrs (GSL); 21mg /24 hrs (GSL), 25mg / 16hrs (GSL)</td>
</tr>
<tr>
<td></td>
<td>Sublingual tablet</td>
</tr>
<tr>
<td></td>
<td>2mg (GSL)</td>
</tr>
<tr>
<td></td>
<td>Lozenge</td>
</tr>
<tr>
<td></td>
<td>1mg (GSL); 2mg (GSL); 4mg (GSL)</td>
</tr>
<tr>
<td></td>
<td>Mini Lozenge</td>
</tr>
<tr>
<td></td>
<td>1.5mg (GSL); 4mg (GSL)</td>
</tr>
<tr>
<td></td>
<td>Inhalator</td>
</tr>
<tr>
<td></td>
<td>10mg / cartridge (GSL)</td>
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<tr>
<td></td>
<td>15 mg / cartridge (GSL)</td>
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<tr>
<td></td>
<td>Nasal spray</td>
</tr>
<tr>
<td></td>
<td>500 micrograms / metered spray (GSL)</td>
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<tr>
<td></td>
<td>Mouth spray</td>
</tr>
<tr>
<td></td>
<td>1mg / metered spray (GSL)</td>
</tr>
<tr>
<td></td>
<td>All supplies:</td>
</tr>
<tr>
<td></td>
<td>Maximum length of treatment under SPS is eight weeks (up to 12 weeks in exceptional circumstances)</td>
</tr>
</tbody>
</table>

Class of health professional who supply and distribute: Community Pharmacists and Pharmacy staff
| **Clinical situations for which the medicine is to be used** | **As an aid to treating tobacco dependence in:**  
| | • Clients receiving specialist advice and support from the NHS stop smoking services  
| | • Clients receiving specialist advice and support from accredited professionals in other settings, e.g. pharmacies or practice nurse clinics  
| | • Clients who can be supplied NRT for use within its product specifications  
| **Criteria for inclusion** | • Tobacco users identified as sufficiently motivated to quit  
| **Criteria for exclusion** (to be referred to GP) | • Clients who are under 12 years old  
| | • Clients with severe cardiovascular disease (including severe arrhythmia or immediate post-myocardial infarction period)  
| | • Clients with a history of recent (within four weeks) cerebrovascular disease (including transient ischaemic attacks)  
| | • Pregnant or breastfeeding women, may also be referred to the Fresh Start Specialist Advisor  
| | **OR when:**  
| | • Continuing supplies are required beyond the specified maximum length of treatment, clients may elect to purchase extra supplies  
| | • Clients with previous serious reaction to NRT or any of the other ingredients contained in the products, e.g. glue in patch  
| | • *Patches only* – clients with chronic generalised skin disease such as psoriasis, chronic dermatitis and urticaria; clients who have had a previous reaction to transdermal patches; occasional smokers  
| | • *Nasal spray only* – clients with chronic nasal disorders such as polyposis, vasomotor rhinitis and perennial rhinitis  


## Criteria for referral

When NRT may be appropriate, but supply through pharmacy on the NHS is not authorised, then the client should be referred to a GP. (see also ‘Criteria for exclusion’ above)

Clients to be referred include those with the following conditions:

- Hyperthyroidism
- Diabetes mellitus
- Severe renal or hepatic impairment
- Peptic ulcer
- **Severe** cardiovascular disease
- A history of *recent* cerebrovascular disease
- Clients taking theophylline (see 'Drug Interactions' below)
- Where intervention with Varenicline or Bupropion might be appropriate

## Dosage and method of administration

<table>
<thead>
<tr>
<th>Dosage and method of administration</th>
<th>See pages 38 - 44 for individual product details</th>
</tr>
</thead>
</table>

- **Period of administration**

  Supply is made weekly from week 1 to 4, and then maybe fortnightly from week 4 to 8. A further 4 weeks supply may be given where clients require this but should not be encouraged as a matter of course. The offer of support is given at all visits.

  **The client must prove that smoking has ceased by validation with a CO monitor at each visit to the pharmacy.**

  - If the smoker is not smoke-free at 4 weeks, treatment should be discontinued. Client’s readiness to quit should be reassessed and support provided again if appropriate.

  - If the smoker is successful in abstaining at 6 to 12 weeks then no further treatment need be provided unless the client is at risk of relapse.

## Drug interactions

Theophylline - as tobacco smoking increases the metabolism of theophylline stopping smoking can cause theophylline plasma levels to rise. Clients taking theophylline should be advised and supplied with NRT as appropriate but the
A pharmacist should inform their GP of their attempt to stop smoking.

Stopping smoking may also cause alterations in the circulating drug levels of the following (but not normally enough to cause therapeutic problems):

- Insulin
- Adrenergic agonists and antagonists
- Fluvoxamine
- Clozapine
- Clomipramine
- Imipramine
- Olanzapine
- Flecainide
- Tacrine
- Pentazocine

Clients who are taking NRT together with any of the above medicines should be advised to inform their GP that they are trying to stop smoking.

**Side effects**

These are usually transient but may include: nausea, dizziness, headaches, cold and flu-like symptoms, palpitations, dyspepsia and other gastro-intestinal disturbances, hiccups, insomnia, vivid dreams, myalgia, chest pain, blood pressure changes, anxiety and irritability, somnolence and impaired concentration, dysmenorrhoea.

Product-specific side effects are detailed in pages 23-29.

**Advice to client**

Advice to clients should include specific product advice plus the following general advice on:

- withdrawal symptoms
- possible changes in the body on stopping smoking, e.g. weight gain
- the effects of smoking tobacco whilst using NRT
- written information on products supplied, self-help leaflets and where to obtain more information. Clients wanting more information can be referred to:

  The NHS Smokefree Helpline: **0800 169 0 169**
  Fresh Start **01332 861174**
  • Follow-up and obtaining further supplies of NRT

**Client Consent**

The client should be informed that information relating to the supply of NRT under this SLA may have to be passed to other health service organisations - in particular their GP and the NHS stop smoking service (if appropriate).

The client’s informed consent must be obtained.
| Details of record keeping | Records of the consultation must be kept for at least two years including the following documents in particular:

- One copy of the voucher should be retained with the client’s record
- Details of the product(s) supplied, invoices and prescription charges collected should be recorded as required for audit purposes
- Audit forms should be completed and returned as required |
### A) GUM

| Dose and method of administration | Oral administration (as resin).
<table>
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<tr>
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<tbody>
<tr>
<td><strong>Nicotinell – 2mg gum</strong></td>
<td>For individuals smoking 20 cigarettes or less daily – one 2mg piece chewed slowly for 30 minutes on urge to smoke.</td>
</tr>
<tr>
<td>Maximum of 25 pieces daily.</td>
<td></td>
</tr>
<tr>
<td><strong>Nicotinell – 4mg gum</strong></td>
<td>For individuals smoking more than 20 cigarettes a day or if they have failed to quit previously using NRT.</td>
</tr>
<tr>
<td>Maximum of 15 pieces daily</td>
<td></td>
</tr>
<tr>
<td><strong>Note:</strong> For this scheme treatment will only be offered for 2 months unless client needs extra support up to 12 weeks</td>
<td>Withdraw gradually by switching to lower strength gum and / or reducing number of pieces chewed each</td>
</tr>
<tr>
<td><strong>Nicorette – 2mg gum</strong></td>
<td>For individuals smoking 20 cigarettes or less daily – one 2mg piece chewed slowly for 30 minutes on urge to smoke.</td>
</tr>
<tr>
<td>Individuals needing more than 15 pieces of 2mg gum a day should consider the 4mg gum instead.</td>
<td></td>
</tr>
<tr>
<td><strong>Nicorette – 4mg gum</strong></td>
<td>For individuals smoking more than 20 cigarettes a day – one 4mg piece chewed slowly for 30 minutes on urge to smoke.</td>
</tr>
<tr>
<td>Maximum number of pieces a day: 15 pieces of 4mg gum.</td>
<td></td>
</tr>
<tr>
<td>Treatment should be continued for at least 2 months</td>
<td><strong>Niquitin CQ – 2mg gum</strong> For individuals smoking 20 cigarettes or less daily – one 2mg piece chewed slowly for 30 minutes on urge to smoke.</td>
</tr>
<tr>
<td>Individuals needing more than 15 pieces of 2mg gum a day should consider the 4mg gum instead.</td>
<td></td>
</tr>
<tr>
<td><strong>Niquitin CQ- 4mg gum</strong></td>
<td>For individuals smoking more than 20 cigarettes a day or those who have their first cigarette within 30 minutes of waking – one 4mg piece chewed slowly for 30 minutes on urge to smoke.</td>
</tr>
<tr>
<td>Maximum number of pieces a day: 15 pieces of 4mg gum.</td>
<td>Withdraw gradually by switching to lower strength gum and / or reducing number of pieces chewed each day</td>
</tr>
<tr>
<td>Specific side effects</td>
<td>Throat irritation, increased salivation, hiccups.</td>
</tr>
</tbody>
</table>
Specific advice to client | Gum should be chewed until the taste becomes strong and then ‘parked’ between the gum and cheek until the taste fades. Recomence chewing once the taste has faded. This ‘chew-rest-chew’ technique should be applied for 30 minutes.

---

### B) INHALATOR

| Dose and method of administration | Oral administration (nicotine-impregnated plug in mouthpiece). Inhale when urge to smoke occurs.  

**Note:** For this scheme treatment will only be offered for 2 months unless client needs extra support up to 12 weeks  
Advise using 6-12 cartridges (10mg / cartridge) daily for up to 8 weeks THEN  
Reducing the dose to 3 – 6 cartridges over the next 2 weeks THEN Reduce to 0 over next 2 weeks.  

Advise using 3-6 cartridges (15mg / cartridge) daily for up to 8 weeks THEN  
Reducing the dose to 0-3 cartridges over the next 2 weeks THEN Reduce to 0 over next 2 weeks  

Review treatment if abstinence not achieved in 2 months. |
| Specific side effects | Throat irritation, cough, rhinitis, pharyngitis, stomatitis, dry mouth headache, dyspepsia |
| Specific advice to client | Air should be drawn into the mouth through the mouthpiece. Clients should be warned that the inhalator requires more effort to inhale than a cigarette and that less nicotine is delivered per inhalation. Therefore the client may need to inhale for longer than with a cigarette.  
The inhalator is best used at room temperatures as nicotine delivery is affected by temperature.  
Used cartridges will contain residual nicotine and should be dispose of safely. |
| Dose and method of administration | Oral administration (nicotine as bitartrate).  
**Nicotinell – 1mg lozenge**  
Initially one lozenge (1mg) every 1-2 hours on urge to smoke.  
Maximum dosage: 25 lozenges per day.  
Withdraw treatment gradually within 3 months.  
**Note:** For this scheme treatment will only be offered for 2 months unless client needs extra support up to 12 weeks  
**NiQuitin CQ – 2mg and 4mg lozenges**  
Use **2mg lozenges** for smokers who have their first cigarette of the day more than 30 minutes after waking.  
Use **4mg lozenges** for smokers who have their first cigarette of the day within 30 minutes of waking up.  
**Weeks 1- 6:** 1 lozenge every 1-2 hours.  
Users should take AT LEAST 9 lozenges per day, but should not exceed 15 lozenges a day  
**Weeks 7 – 9:** 1 lozenge every 2-4 hours  
**Weeks 10 – 12:** 1 lozenge every 4-8 hours  
**NiQuitin - Mini lozenge – 1.5mg / 4mg**  
One lozenge should be placed in mouth and allowed to dissolve. Periodically the lozenge should be moved from one side of the mouth to the other, this should be repeated until the lozenge has dissolved (approx 10mins).  
Use up to a maximum of 15 per day. After 6 weeks begin a gradual reduction in daily use.  
Individuals smoking more than 20 cigarettes per day – 4mg minis mint are suitable  
Individuals smoking less than 20 cigarettes per day – 1.5mg minis mint are suitable  
Specific side effects | Throat irritation, increased salivation, hiccups.  
Specific advice to client | **Nicotinell Lozenge:**  
Lozenge should be sucked until the taste is strong and then ‘parked’ between the gum and the cheek until the taste fades. Once faded then sucking should recommence.  
Simultaneous use of coffee, acid drinks and soft drinks may decrease absorption of nicotine and should be avoided for 15 minutes prior to sucking lozenge.  
**NiQuitin Lozenge:** |
One lozenge should be placed in the mouth and allowed to dissolve. Periodically, the lozenge should be moved from one side of the mouth to the other, and repeated, until the lozenge is completely dissolved (approximately 20 –30 minutes). The lozenge should not be chewed or swallowed whole. Users should not eat or drink while a lozenge is in the mouth.

NiQuitin Mini lozenge
Users should not eat or drink whilst the lozenge is in the mouth.

D) NASAL SPRAY

| Dose and method of administration | Nasal administration (500 micrograms / metered spray).
|                                  | Apply one spray into each nostril as required up to a maximum of twice per hour, over a 16 hour period (= maximum of 64 sprays daily) for a period of 8 weeks THEN |
|                                  | Reduce dosage gradually over next 4 weeks achieving half the dose reduction required in the first 2 weeks THEN |
|                                  | Continue to reduce dosage to 0 over next 2 weeks. |
|                                  | Maximum period of treatment: 3 months |

**Note:** For this scheme treatment will only be offered for 2 months unless client requires support up to 12 weeks

| Specific side effects | Nose and throat irritation, nosebleeds, watering eyes, ear sensations, dyspepsia |
| Specific advice to client | Advise on correct use of spray. |
|                         | Warn of possible local effects but also that these tend to lessen within a few days. |
|                         | CAUTION – the nasal spray should not be used whilst driving or operating machinery as side effects could cause an accident. |

E) MOUTH SPRAY

| Dose and method of administration | Oral administration (1mg / metered spray).
|                                  | 1 or 2 sprays into mouth (not exceeding 2 sprays per dosing episode) as required up to a maximum of 4 sprays per hour, no more than 64 sprays in any 24-hour period. |
|                                  | Individuals should aim to reduce the number of sprays used when able to, until they have stopped completely. |

**Note:** For this scheme treatment will only be offered for 2 months unless client requires support up to 12 weeks
### Specific side effects

Dysgeusia, headache, hiccups, nausea and vomiting symptoms, dyspepsia, oral soft tissue pain and paraesthesia, stomatitis, salivary hypersecretion, burning lips, dry mouth.

### Specific advice to client

**Before first use or if the spray hasn’t been used for two days:** Prime spray by safely pointing away from self and others (including pets) and pressing the top of the QuickMist with the index finger three times until a fine spray appears.

Point the spray nozzle as close to the open mouth as possible. Press the top of the dispenser to release one spray into the mouth, taking care to avoid the lips. Do not inhale while spraying to avoid getting spray down throat. For best results, avoid swallowing for a few seconds after spraying.

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### E) PATCHES

<table>
<thead>
<tr>
<th>Dose and method of administration</th>
<th>Transdermal administration.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Apply on waking to dry, non-hairy skin on hip, chest or upper arm. Remove after time specified. New patch should be placed on a different area, avoiding ‘used’ sites for several days afterwards.</td>
</tr>
</tbody>
</table>

**Note:** For this scheme - treatment will be offered for up to 8 weeks unless client requires support for up to 12 weeks

If successful then gradually reduce dosage with time as discussed with client.

**Nicorette – 16 hour patch**

- 25mg patch for 16 hours daily for 8 weeks THEN
- 15mg patch for 16 hours daily for 2 weeks THEN

The 5mg patch is rarely used and should only be used as the weaning patch where the client originally started on the 15mg patch Maximum period of treatment: three months

**Nicotinell – ‘10’ patch**

For individuals smoking 10 cigarettes or less per day – one patch (7mg) daily.

**Nicotinell – ‘20’ patch**

For individuals smoking 20 cigarettes or less per day – one patch (14mg) daily.

**Nicotinell – ‘30’ patch**

For individuals smoking more than 20 cigarettes per day – one patch (21mg) daily.

Withdraw treatment gradually reducing the dose every 3-4 weeks. Maximum period of treatment: three months
**NiQuitin CQ**

For individuals smoking 10 or more cigarettes daily:
21mg patch daily for 6 weeks THEN
14mg “ “ “ 2 “ THEN
7mg “ “ “ 2 “ THEN review treatment

Individuals who experience persistent side effects with the 21mg patch should switch to the 14mg for the remainder of the 6 weeks followed by the 7mg patch for 2 weeks as above.

**Maximum period of treatment: ten weeks**

**NiQuitin CQ**

For individuals smoking less than 10 cigarettes per day:
14mg patch daily for 6 weeks THEN
7mg “ “ “ 2 “ THEN review treatment

<table>
<thead>
<tr>
<th>Specific side effects</th>
<th>Skin reactions. Discontinue use if severe.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Specific advice to client</td>
<td>Exercise may increase absorption of nicotine and therefore side effects. The patch should be applied once a day, normally in the morning, to a clean, dry, non-hairy area of skin on the hip, trunk or upper arm. Allow several days before replacing the patch on a previously 'used' area. Place the patch in the palm of the hand and hold onto the skin for 10-20 seconds. Patches should not be applied to broken or inflamed skin. Clients should not try to alter the dose of the patch by cutting it up.</td>
</tr>
</tbody>
</table>

**F) SUBLINGUAL TABLET**

<table>
<thead>
<tr>
<th>Dose and method of administration</th>
<th>Oral administration (sublingual) – 2mg.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>For individuals smoking 20 cigarettes or less daily – 2mg per hour.</td>
</tr>
<tr>
<td></td>
<td>For patients who fail to stop smoking or have significant withdrawal symptoms consider increasing to 4mg per hour sublingually.</td>
</tr>
<tr>
<td></td>
<td>For individuals smoking more than 20 cigarettes a day – 4mg per hour (2 x 2mg).</td>
</tr>
<tr>
<td></td>
<td>Maximum dose: 80mg per day (40 tablets)</td>
</tr>
</tbody>
</table>

**Note: For this scheme treatment will only be offered for 2 months unless client requires further support for up to 12 weeks**

Treatment should be continued for at least 3 months up to a maximum of 6 months. Dosage should be gradually reduced after 3 months.
<table>
<thead>
<tr>
<th>Specific side effects</th>
<th>Throat irritation, unpleasant taste, headache, dyspepsia</th>
</tr>
</thead>
<tbody>
<tr>
<td>Specific advice to client</td>
<td>Tablets should be placed under the tongue and allowed to dissolve slowly.</td>
</tr>
</tbody>
</table>
STOP SMOKING SERVICE 2012/13

AGREEMENT: I agree to adhere to the above criteria and confirm that I am able to comply with all requirements, in order to provide the Community Pharmacy Stop Smoking Service. I acknowledge that if I cannot fulfil the criteria I am not accredited to provide the service.

Pharmacist Signature……………………………………

PRINT name………………………………..Date…………………

(Where applicable) My line manager is aware and has granted permission for me to become, an Associate Advisor delivering the Pharmacy Stop Smoking Service.

Staff Signature…………………………………….. (Associate Advisor)

PRINT name………………………………….. Date………………

Staff Signature…………………………………….. (Associate Advisor)

PRINT name………………………………….. Date………………

(Please add additional staff signatures overleaf)

Manager’s Signature……………………………………

PRINT name………………………………….. Date………………

Pharmacy Stamp/ Pharmacy PPD Code:

Approved by Keith Mann, Head of Primary Care Contracts for NHS Derby City

Signature Date 11 July 2012

Please send this Agreement to: Jay Grindey, Primary Care Contracts, NHS Derby City, Floor 3 North Point, Cardinal Square, 10 Nottingham Road, Derby, DE1 3QT
CONTRACTUAL AGREEMENT FOR THE PROVISION OF COMMUNITY PHARMACY STOP SMOKING SERVICES (SSS) in DERBY CITY 2012/13

This Contract is dated 1 April 2012

BETWEEN:

(i) Derby City PCT

And

(ii) The Contracting Pharmacy:

For and on behalf of CONTRACTING PHARMACY

PHARMACY PPD CODE:.................................................................

SIGNATURE:..................................................................................

PRINT NAME:.............................................................................

POSITION:....................................................................................

DATE: ..........................................................................................

For and on behalf of PRIMARY CARE TRUST:

SIGNED BY KEITH MANN, HEAD OF PRIMARY CARE CONTRACTS:

DATE: 11 July 2012

Please sign this page and send to: Jay Grindey, Primary Care Contracts, NHS Derby City, Floor 3 North Point, Cardinal Square, 10 Nottingham Road, Derby, DE1 3QT
1. CONTRACT PERIOD

The Contract will commence from the 1st April 2012 to the 31st March 2013, renewable subject to continued availability of funding and satisfactory performance.

2. PURPOSE OF THE CONTRACT

The PCT wishes to engage the services of the Provider in supplying a community pharmacy based intermediate level stop smoking service for the population of Derby City PCT.

It is agreed as follows:

3. DEFINITIONS

In the Contract, where the context admits:

“Client” means a person referred to the SSS or who requests support from the Provider unprompted.

“Client File” means a Client’s case monitoring documentation including the Required Information for all counselling held, and in an PCT approved format.

“Premises” means a community pharmacy base specified by the PCT where the Support Services are provided to the Client by the Provider;

“Required Information” means all interventions and advice given to the Client, and progress made by that client;

“Review” means a review of the Provider’s performance conducted at the discretion of the PCT or Fresh Start.

“SSS” means the Derby City Fresh Start Stop Smoking Service.

“Support Services” means the stop smoking services supplied by the Provider to the Client following the Derby City PCT approved guidelines;

“Unauthorised Third Party” means any person who has not attended and passed a Fresh Start approved training programme and has not been registered with the SSS.

“IMF” means Initial Monitoring Form.

“Provider” accredited person who has completed a course approved by the PCT for the purpose of the Stop Smoking.
Service and has satisfied the PCT that he / she is competent to provide the service on behalf of the Contractor

“Contractor” the person conducting the retail pharmacy business whose name is included on the pharmaceutical list and with whom Derby City PCT has entered into this agreement for the provision of stop smoking services.

4. DURATION

4.1 This Contract will commence on 1\textsuperscript{st} April 2012 and unless terminated by either party in accordance with clause 8 or otherwise in accordance with this Contract, will continue until 31\textsuperscript{st} March 2013.

4.2 The PCT may conduct a review and following such review require such changes to the Contract, as it reasonably considers appropriate.

5. PROVIDER OBLIGATIONS

5.1 Prior to commencement of the Support Services the persons providing the service on behalf of the contractor agrees to:

(a) Attend and complete, to the satisfaction of the PCT, Fresh Start approved training programme; or
(b) Demonstrate competency in providing advice on stop smoking in accordance with the Fresh Start accredited training programme; and
(c) Register with the SSS as a Support Services Provider

5.2 For the duration of the Support Services, the Provider agrees to:

(a) Where necessary be assessed by specialist staff from the SSS, at an appropriate and agreed time including being observed offering client interventions, and regular phone contact.
(b) Attend refresher sessions as required at least once a year and provided for by Fresh Start; failure to attend could result in termination of this Contract.
(c) Work regularly (four out of five days, Mon-Fri and Sat am) at the Premises, and be readily available to clients, who wish to give up smoking as part of the SSS
(d) Ensure that appropriate space is available at the Premises for the confidential counselling of clients;
(e) Offer each Client, sessions in accordance with the Service Specification (for pharmacies), (Appendix 1) and established Guidelines (see separate document)
(f) To ensure that, when providing the full counselling service, a pre-quit carbon monoxide reading is taken and again when client is four week post quit, and also as appropriate throughout the treatment period.
(g) Record all required Information for the client as soon as is reasonably possible during a counselling session, and submit copies of the Individual Monitoring Form to the SSS at the end of the treatment period. Patient records will continue to be the property of the PCT;
(h) IMF’s must be returned within 10 working days of the treatment outcome being known, failure to comply could result in a delayed payment
(i) Complete the provision of the Support Services independently, and not to involve any Unauthorised Third Party
(j) Return to Fresh Start all IMF’s, other documentation and equipment related to the provision of the Support Services upon the termination, early or otherwise of this Contract.
(k) Agree to seek advice from the Fresh Start SSS if needing any clarification of processes or clinical advice.
(l) Maintaining the CO Monitor, including calibration, as recommended by the manufacturer, will be provided by the PCT Fresh Start team. This should be arranged between the contractor and Fresh Start as and when any maintenance is due.
(m) Liability for damages, loss, breakages of monitors lies with the pharmacy, except if monitor needs replacing due to technical fault beyond the pharmacies control.

6. **PCT OBLIGATIONS**

6.1 For each Client completing a treatment session, and where an IMF has been submitted by the Contractor to Fresh Start in accordance with the timetable, the Contractor will be paid the fees detailed in Appendix 2.
6.2 Payment of fees will be made directly to the Contractor on submission of the IMF’s within six weeks of receiving the completed payment claim forms to Fresh Start in accordance with Clause 5.2(h).
6.3 To provide update training for all associate advisors.
6.4 To ensure that the SSS provides ongoing support to associate advisors for the duration of the Contract.

7. **KEY PERFORMANCE INDICATORS**

7.1 Community Pharmacy providers of this services must ensure they deliver on at least four of the following key areas in order to continue to be commissioned to deliver the service. These will ensure pharmacies are able to maintain competencies and capability to deliver quality smoking cessation services.

- An increase on the previous years number of quits
- A CO validation level in excess of 80%
- Demonstrate a quit rate of between 35% - 70% of clients setting quit dates
- At least 10 four week quits in a year
- Support for 30 or more clients setting a quit date during the financial year
- Demonstrable commitment to promoting smoking cessation amongst clients including participation in any campaigns, and attendance at a minimum of one Re-Fresh training event every 12 months.

Pharmacies delivering on at least four key performance indicators will continue to receive ongoing support from Fresh Start.
Pharmacies not delivering on at least four key performance indicators, will no longer have the service commissioned from them.
Pharmacies delivering on all six indicators will continue to be accredited and be eligible for any incentive scheme developed by the PCT.

8 INDEMNITY
8.1 The Contractor will be responsible for meeting all costs, claims, liabilities or obligations in the provision of the Support Services.
8.2 The Contractor will fully indemnify the PCT for any costs, claims, liabilities or obligations from the acts or omissions of the Contractor in the provision of the Support Services.
8.3 The Contractor warrants that he or she has appropriate personal professional indemnity insurance for all accredited persons providing the service on behalf of the contractor and will ensure this cover is maintained and will produce evidence of such cover on request by the PCT.

9. TERMINATION
9.1 Either party may elect to terminate this Contract early by giving 30 days written notice to the other.
9.2 In the event that this Contract is terminated in accordance with clause 9.1: The Contractor agrees to complete where appropriate all client treatment episodes or transfer their care pathway to the Fresh Start SSS.
9.3 Notwithstanding anything in the Contract the PCT may terminate this Contract or any part of it immediately upon written notice to the Contractor if:
   (a) The Contractor commits an irredeemable material breach of this Contract; and/or
   (b) The Contractor having committed a material breach of this Contract, shall neglect or otherwise fail to remedy such breach within such a reasonable time as shall be specified after being required in writing to do so by the PCT, or repeats such remedial breach within the time allowed to remedy the original breach; and/or
   (c) The Contractor commits persistent minor breaches of this Contract.
9.4 This Contract may be terminated immediately by the PCT by giving notice in writing where:
   (a) The Contractor being an individual or where the Contractor is a firm any partner in that firm shall at any time become bankrupt or shall have a receiving order, administration order or interim order made against him/her or shall make any composition or scheme of arrangements with or for the benefit of his/her creditors or shall make any conveyance or assignment for the benefit of his/her creditors or shall purport to do so; or
   (b) The Contractor being a company shall pass a resolution or the Court shall make an order that the company shall be wound up (except for the purpose of amalgamation or reconstruction) or if an administrative receiver on behalf of a creditor shall be appointed or if the Court shall make an administrative order or if circumstances shall arise which entitle the Court or a creditor to appoint an administrative receiver or which entitle the Court to make a winding up or administration order or shall make any arrangement for the benefit of such creditors.
      Provided always that such a termination shall not prejudice or affect any right of the action or remedy, which shall have accrued or shall accrue thereafter to either party.
9.5 The Contract will not be terminated in the event of any change in the legal or statutory status of the PCT. Where such changes in status occur the rights,
obligations and liabilities of the PCT will be deemed to have reverted to any body, created by the Secretary of State for Health to replace the PCT. 9.6 Clauses 7,10,14,15 and 18 shall survive the termination of this Contract.

10 STATUTORY AND OTHER REGULATIONS

The Contractor will comply with the PCT’s policies attached hereto and will operate in accordance with all acts of Parliament, statutory regulations or such other laws, recommendations, guidance, practices as may affect the provision of the Support Services.

11 CONFIDENTIALITY

11.1 The Contractor shall not, and the Contractor shall ensure that its staff do not, disclose to any other person other than a person authorised by the PCT any information of a confidential nature received or acquired by them in connection with the PCT or this Contract without prejudice to the generality of the foregoing: (Please provide clarification for 11.1)

(a) Financial or other confidential information about or relating to the PCT;
(b) The identity of any patient at any of the PCT’s establishments; or
(c) The medical condition of or the treatment received by any patient.

11.2 The Contractor agrees to comply with NHS guidance on patient confidentiality and medical records.

12 DATA PROTECTION

The Contractor shall at all times store and retain (and shall only make any disclosure of or allow access to) all personal data held under this contract (as defined in the Data Protection Act 1998) in accordance with such Act and the Provider shall take appropriate technical and organisational measures against unauthorised or unlawful processing of personal data and against accidental loss or destruction of, or damage to personal data. For the avoidance of doubt the PCT may take such steps, as it deems necessary to ensure that the Contractor takes such measures and the Contractor shall not do anything in relation to any personal data without the prior consent of the PCT.

13 BREACHES

13.1 If the Contractor does not carry out the Services in accordance with this Contract the PCT may:
(a) Require the Contractor to remedy the default within such time as the PCT may reasonably specify by providing or providing again (as the case may be) without further charge to the PCT such part of the Services required to the Contract standards; and/or
(b) Itself provide or procure the provision of Services or any part of the Services until the PCT shall be satisfied that the Contractor is again able to carry out the Services in accordance with this Contract. If the cost to the PCT of executing or providing such Services exceeds the amount which would have been payable to the Contractor for carrying out the Support Services, the excess shall be paid by
the Contractor to the PCT in addition to any other sums payable by the Contractor to the PCT in respect of breach of Contract; and/or

(c) Without determining the whole of the Contract, determine the Contract in respect of part of the SSS only and thereafter provide and procure the provision of such part of the SSS itself.

13.2 The remedies of the PCT under this clause may be exercised concurrently in respect of any default by the Contractor.

14 VARIATION OF SERVICES

14.1 The PCT may give notice to the Contractor and LPC of proposed variations to this Contract.

14.2 Following the notice the PCT and the Contractor in consultation with the LPC shall use best endeavours to agree the variation, the timing for its implementation and the amount of the adjustment to the Contract price as a result of the variation.

14.3 Such agreed variation shall be in writing and signed on behalf of both parties.

14.4 Should no agreement be reached on variations to the contract the PCT or Contractor may elect to terminate this contract by giving 30 days written notice to the other.

15 PUBLICITY

The Contractor will be supplied with appropriate advertising material by Fresh Start. The Contractor must not advertise or publicly announce that it is supplying Services to the PCT without prior written consent of the PCT.

16 AUDIT

16.1 The Contractor shall keep and maintain full and accurate records of all receipts and payments for the provision of the Services under this Contract for a period required by the PCT and will provide to the PCT such information as the PCT may reasonably require;

(a) In order to prepare its own accounts for external audit;

(b) To comply with any other legal obligation placed on the PCT

16.2 The Contractor shall provide the PCT with such information the PCT may reasonably require, to answer all reasonable enquiries raised by the PCT in relation to the provision of any of the Services covered by this Contract.

16.3 The Contractor shall participate with the PCT in undertaking audits of the Support Services provided by the Provider. Such audits will be agreed between the parties in advance of work commencing.

17 TRANSFER AND SUB-CONTRACTING

The Contractor must not assign sub-Contract or otherwise dispose of the whole or any part of this Contract or any rights or obligations under it without the PCT’s previous written consent.
18 CONTRACTS (RIGHTS OF THIRD PARTIES) ACT 1999

For the avoidance of doubt, no third party shall have any rights in respect of this Contract by virtue of the aforementioned Act and the parties shall not require the consent of any person to any variation of or amendment to this Contract.

19 APPLICABLE LAW

This Contract shall be governed by and construed according to the Law of England and Wales and shall be subject to the exclusive jurisdiction of the English Courts.