

**2020/21  
PUBLIC HEALTH SERVICES CONTRACT**

**SERVICE SPECIFICATIONS**

All subheadings for local determination and agreement.

<b>Service Specification No.</b>	3
<b>Service</b>	Community Pharmacy Stop Smoking Service – Standard Level
<b>Authority Lead</b>	
<b>Provider Lead</b>	Pharmacy
<b>Period</b>	1 <sup>st</sup> April 2020 – 31 <sup>st</sup> March 2021
<b>Date of Review</b>	

## **1. Population Needs**

### **1.1 National/local context and evidence base**

Smoking is the single most preventable cause of death and ill health in England. Half of all smokers will die prematurely as a result of smoking. Smoking disproportionately affects the poorest members of society, owing to differences in culture and lifestyle, and is therefore a primary cause of inequalities in health. The provision of high quality stop smoking services is a top priority in reducing health inequalities and improving health among local populations. Since stop smoking services began, they have supported more than 2.5 million people to stop smoking in the short-term and 625,000 people to stop smoking in the long term, saving over 70,000 lives.

Stop smoking services are a key part of tobacco control and health inequalities policies at local and national level. Evidence-based stop smoking support is highly cost effective both in relation to cost of the intervention and clinical outcomes and should be offered to all smokers.

By supporting local smokers who want to stop, stop smoking services can help reduce health inequalities and have a significant long-term impact on local and national smoking prevalence. In line with NICE best practice recommendations, service providers should aim to treat a minimum of 5% of their local smoking population per year.

Evidence suggests that around two-thirds of smokers want to stop smoking and three-quarters report having attempted to quit at some point in the past. Smokers attempting to stop smoking with pharmacotherapy alone can expect to have a success rate of 25% (for carbon monoxide (CO) validated quits) at four weeks; for self-reported quits the expected success rate would be around 35% at four weeks. To have an impact, stop smoking services must therefore achieve success rates in excess of these values. Evidence has shown that a combination of behavioural support from a stop smoking adviser plus pharmacotherapy can increase a smoker's chance of stopping by up to four times.

Reducing prevalence in the general population as well as among higher risk groups, such as smokers with a mental health disorder (mental illness, alcohol problems and substance misuse), pregnant smokers and young smokers (aged 12-16 years), was emphasised in the National Tobacco Control Plan for England (Department of Health, 2017) and the Public Health Outcomes Framework (Department of Health, 2013); updates to both of these documents are expected soon. These are therefore key priority groups in addition to smokers from the 'routine and manual workers' demographic group and those from specific black and minority ethnic (BME) communities; both groups demonstrate higher than average numbers of smokers per head of population.

Evidence-based guidelines for Stop Smoking Services (Department of Health, 2011) updated to reflect the new commissioning landscape (Public Health England and NCSCT, 2014) and NICE guidance should inform how services are delivered and the availability of smoking cessation aids. Commissioned stop smoking services have been provided by pharmacies in the Tees area for many years.

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The Stop Smoking+ model, developed by Prof. Robert West of University College London, recommends a three-tiered approach to the organisation of Stop Smoking Services from which smokers are able to choose their preferred quitting method. This evidence based model aims to maintain the delivery of cost effective support for quitting for all smokers; provided in a way that ensures priority groups are given the most intensive and effective interventions. Those who wish to have less intensive support can access brief face-to-face support and medication; while less effective than intensive support, evidence demonstrates this offer is more attractive to a larger number of smokers (thereby delivering a higher number of quitters more cost effectively).

This service specification describes an established pathway which is being refined and further developed to facilitate the safe extension to wider use of an NRT-voucher model and a varenicline PGD in the area.

## **2. Key Service Outcomes**

### **2.1 Locally agreed outcomes and quality requirements other than Quality Outcomes Indicators**

In each contracted pharmacy setting, key service outcomes are:

- Establishment of a safe and effective stop smoking service (standard level – Brief Support and medication) in a community pharmacy setting to support the wider provision of Stop Smoking services, commissioned and provided locally, for the resident population of Middlesbrough and Redcar and Cleveland local authority areas.
- **All pharmacies delivering this service will also be expected to be providing the Pharmacy Dispensing Only Stop Smoking Service (Introductory Level)**
- Evidence of systems and processes for active recruitment of patients and appointment or 'clinic' management, ideally showing whole staff involvement in the commitment to support provision of the service
- Evidence of seeking to achieve indicative activity levels by use of promotional materials and/ or brief advice/ brief intervention approach and reflective review of performance
- Indicative activity: pharmacy providers will be seeking to achieve minimum levels of activity as follows:
  - Recruiting to the service and completed Intermediate Assessments: a pharmacy should seek to recruit a minimum 8 clients per quarter
  - Client recruitment should reflect numbers of Intermediate Assessors that are trained in the pharmacy with the intent of maintaining competence through active service provision.

## **3. Scope**

### **3.1 Aims and objectives of service**

#### **3.1.1 Aims**

To deliver an evidence based Pharmacy Stop Smoking service to the resident populations (wishing to stop smoking) of Middlesbrough, and Redcar and Cleveland local authority areas.

All Stop Smoking Services are to be commissioned and provided in line with the Stop Smoking+ model and relevant NHS, Department of Health, Public Health England, NCSCCT and NICE guidance (see section 4.1 and any updates published after the date of this specification).

This service will contribute to the wider aims to;

- Contribute to the smoking quitter target for the respective locality of operation.
- Contribute to national tobacco control ambitions to:

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- motivate and assist smokers to quit, aspiring to reduce national smoking rates to 12% or less by the end of 2022;
- Reduce the rates of smoking throughout pregnancy to 6% or less by the end of 2022.

### **3.1.2 Objectives**

At local authority level, the Pharmacy Stop Smoking Service is commissioned

- To provide an accessible and evidence-based Stop Smoking Service in line with relevant NHS, Department of Health and NICE guidance (see section 4.1).
- To actively support opportunities for client choice across the delivery of Stop Smoking Services
- To optimise efficiencies within existing clinical, health and social care pathways such that opportunities for brief advice or intervention maximise opportunities for onward referral into locally commissioned stop smoking services.

For each pharmacy commissioned,

- To ensure that all pharmacy staff (including pharmacist locums) on any given day are fully aware of the commissioned service operating in the pharmacy and thereby able to promptly respond to each client presenting
- To ensure that each member of pharmacy staff involved in the service is suitably trained in accordance with their specific role in the provision of a stop smoking service in the pharmacy and that the required professional skills and competencies are kept up-to-date
- To collate and record accurate and timely client records electronically via QuitManager, ensuring all records meet the criteria outlined within local protocols and NHS Records Management policy and procedure. Such records will be used for generation of invoices and claims for remuneration from the local authority in accordance with the agreed scale of fees and payment schedule.
- To ensure necessary preparations are in place in the event of audit, including keeping detailed records of activities, NRT vouchers and Varenicline (Champix®) Recommendation Forms, available for inspection on request for a minimum of two years.
- To configure service in such a way to promote the successful achievement of the minimum levels of activity identified in section 2.1 of the specification
- To discuss the full range of pharmacological treatment options and respond appropriately according to protocols and pathways directed by the Specialist Stop Smoking Service and if appropriate following assessment
  - a) Offer appropriate NRT treatment from the pharmacy setting utilising NRT Pharmacy Voucher Pathway.
  - b) offer varenicline treatment utilising Champix® Recommendation Form Pathway (subject to individual client clinical assessment by a varenicline PGD accredited pharmacist for suitability for dispensed supply of varenicline)
- To supply NRT to clients that are engaged in an abstinence-contingent treatment, in which the smoker makes a commitment to stop smoking on or before a particular quit date (target quit date). Also ensuring advice, dispensing, governance and record-keeping practices are in line with protocols, NICE guidelines, product license terms for supply to any given individual without a prescription, the British National Formulary (BNF), any local formulary and pharmacy professional guidance
- To supply varenicline, subject to clinical assessment by a varenicline PGD accredited pharmacist to clients that are engaged in an abstinence-contingent treatment programme, as per varenicline Pharmacist PGD pathway.
- To have a pragmatic harm reduction approach to the use of e-cigarettes by those people who wish to use them as part of their quit attempt.
- To deliver a high efficacy service with a usual minimum success rate of 35% at 4 weeks validated by carbon monoxide monitoring.
- To actively reinforce the ethos of patient responsiveness and choice across the delivery of the service.
- To achieve high levels of service-user satisfaction ( i.e.>75% rating the service as good or above)
- To ensure services are effectively promoted, informed (where appropriate) by national, regional and local marketing resources including <https://campaignresources.phe.gov.uk>.

### **3.2 Service description/pathway**

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This agreement relates to provision of time-limited, quality interventions to support smokers to successfully and permanently quit smoking. The service should be delivered in the context of one (or a combination) of the service tiers outlined in section 3.2.2 ("*Service Model*"), subject to appropriate accreditation.

Community Pharmacy Stop Smoking – Standard level service should be delivered in-line with section 2.1. ("*Standard Treatment Programme*"), demonstrating clear alignment to the National and Local evidence-base and relevant NICE guidance, as amended from time to time (see section 4.1 "*Evidence Base*").

### **3.2.1 Standard Treatment Programme**

Services should be delivered in one or a combination of the following formats:

- drop-in one-to-one
- structured one-to-one
- open group
- closed group
- family/couple group

Service users should be offered the full range of treatment options including NRT treatments, varenicline and bupropion and be recruited or signposted accordingly.

Services are also encouraged to use proactive telephone outreach support (where appropriate) to increase service-user retention and motivation.

The service should provide each of the elements below in-line with the Department of Health's Intervention Quality Principles and NCSCCT Standard Treatment Plan (2014).

Service users will be offered an initial appointment with a minimum of 4 follow up appointments over a 12-week period.

#### Initial Assessment

- Assess service-users readiness and ability to quit;
- Assess the most appropriate level of support for the service user (incorporating the exclusion criteria).
- Assess service users suitability to be managed by level 2 intermediate Stop Smoking Adviser or if requires clinical input from nurse prescriber within specialist service
- Assess current smoking habits (heaviness of smoking index)
- Assess past quit attempts
- Ask the COPD screening questions and provide related advice
- Assess nicotine dependence (Fagerstrom)
- Discuss and agree a treatment programme with the service user
- Explain and conduct CO monitoring
- Discuss a range of pharmacological options available including NRT and varenicline, bupropion and NRT products and offer (where appropriate) pharmacological support or referral
- Set the Quit Date
- Provide behavioural support and coping mechanisms
- Complete Gold Standard Monitoring documentation, all data records must be inputted onto QuitManager contemporaneously alongside the consultation and be completed ideally within 45 minutes. In exceptional circumstances if there is a delay in the recording e.g. due to IT failure, then records should be updated within two working days
- Issue client with NRT Voucher or Champix® Recommendation Form to obtain their dispensed supply, subject to pharmacist clinical check\* (NRT) or varenicline clinical assessment by a PGD-accredited pharmacist. The Champix® Recommendation Form will indicate whether an initiation or continuation supply is recommended.
- The pharmacist will carry out a clinical check to ensure the NRT/product is suitable for the patient and that a supply is appropriate. The purpose of a clinical check by a pharmacist is to ensure that the medicine supplied is both safe and effective for use by a particular patient in relation to the risk and benefit to the patient:
  - a) Look at the client's assessment on QM for relevant medical history (e.g. renal patients should not use lozenges with high sodium content).

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- b) Review other concurrently prescribed medications which may require dose adjustment or closer monitoring on discontinuation of smoking (e.g. warfarin, cinacalcet, theophylline, olanzapine, chlorpromazine, erlotinib, riociguat and clozapine – see BNF and [sps.nhs.uk](http://sps.nhs.uk) for more information) and advise the patient to contact their GP practice for further advice and pharmacist also to ensure direct communication of planned quit attempt with usual prescriber. Please note patients taking clozapine are excluded from this service
- c) Note the client's smoking level (Fagerstrom score and number of cigarettes smoked per day) and ensure that product(s) and pack size(s)/dosage(s) is/are appropriate to client's needs.
- d) Check for contraindications or special precautions (e.g. age and suitability of product for pregnant women).

**Clinical responsibility for NRT or varenicline supplied will rest with the pharmacist in all cases.**

Following the issue of an NRT Voucher or Champix® Recommendation Form by the Pharmacy stop smoking adviser, the pharmacy will process the voucher or form to include:

For NRT -

- NRT treatment is issued via Pharmacy Initiated Vouchers. Standard treatment is 12 weeks in duration and is issued by Initial 5 week vouchers; dispensed as 1 week, 2 weeks and 2 weeks, and Continuation 8 week vouchers; dispensed as 4 weeks, 4 weeks.
- A maximum of two NRT product items is to be dispensed via voucher at any time.
- A PHARMACIST will complete a clinical check to determine which (if any) NRT product(s) will be supplied
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For Varenicline –

- A varenicline PGD-accredited PHARMACIST will complete a clinical assessment in line with the PGD

For both NRT and varenicline -

- NRT Vouchers and Champix® Recommendation Forms would normally be dispensed in two week supplies, however in exceptional circumstances the Pharmacy stop smoking adviser may dispense an extra two-week product voucher / form, e.g. to cover client holiday and in these circumstances, at the clinical discretion of the pharmacist a further two week supply may be made; the adviser must annotate form/voucher and Quitmanager in any circumstance of such a request being made.
- The NRT Voucher / Champix® Recommendation Form will be processed on Quitmanager including recording of the clinical check/assessment and by completing and signing the NRT Voucher or Champix® Recommendation Form.
- Products supplied will be labelled in accordance with routine dispensing practice and a copy of the labels will be attached to either the NRT Voucher or Champix® Recommendation Form for audit purposes.
- The client will be advised that their GP will be informed of medication issued within two working days; letters will be generated by Quitmanager as per current pathways.
- Ideally, the clients NRT voucher / Champix® Recommendation Form will be processed at the time that it is presented. However, given the unpredictable workload of a busy dispensary, and the need to be assured that all the information is available to complete a clinical check, if clinically necessary, a pharmacy can ask the client to return at a more suitable time. This should not be a routine occurrence.

Two week Post Quit appointment

- Assess progress
- Measure CO
- Discuss medication use and ensure that the client has a sufficient supply of medication, and where necessary issue the NRT Voucher / next Champix® Recommendation Form.
- Provide brief support and encouragement
- Advisor to complete Gold standard monitoring documentation on Quitmanager

Four Week Post-Quit appointment

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- Assess progress
- Measure CO
- Discuss medication use and ensure that the Discuss medication use. Ensuring that the client has a sufficient supply of medication, and where necessary issue the next NRT Voucher / Champix® Recommendation Form.
- Provide brief support and encouragement
- Advisor to complete Gold standard monitoring documentation on Quitmanager

Eight week Post Quit appointment

- Assess progress
- Measure CO
- Discuss medication use and ensure that the Discuss medication use. Ensuring that the client has a sufficient supply of medication, and where necessary issue the NRT Voucher / next Champix® Recommendation Form.
- Provide brief support and encouragement
- Complete session record on Quitmanager, all data must be inputted onto QuitManager within two working days

12 Week Post Quit appointment

- Assess progress
- Measure CO
- Provide advice about continued medication and use where appropriate
- Provide brief support and encouragement
- Complete Gold Standard Monitoring documentation (all data must be inputted onto QuitManager within two working days)

**3.2.2 Service Model**

This service operates within an Integrated Stop Smoking Service Framework, incorporating a Commissioned Specialist provider and support function and a service delivery arm that operates within a range of settings including those in the community, and in primary care and secondary care.

Stop smoking provision in community pharmacy is offered at 3 distinct levels:

**Table 1 - Service Outline.** Table 1 provides a description of the services provided by National community pharmacy contract only, introductory, standard and advanced level pharmacies. For details of accreditation requirements – see Section 4.2.1

<b>Accreditation Level</b>	<b>Outline Description of Service</b>
<b>National community pharmacy contract only</b>	Public health campaigns, brief Intervention and signposting only. (not a contracted service)
<b>Commissioned Introductory Level Pharmacy: 'Dispensing Only'</b>	<u>Dispensing-only</u> <ul style="list-style-type: none"> <li>• Supply NRT (following pharmacist clinical check) for clients who have been assessed by Stop Smoking Service accredited Advisors (external to the pharmacy) and including young people aged 12-16 and pregnant women. To process NRT vouchers and record via Quitmanager.</li> <li>• Supply varenicline subject to Clinical Assessment by a PGD-accredited pharmacist for clients who have been assessed by Stop Smoking Service accredited Advisors (external to the pharmacy) for patients over 18 years. To process Champix® Recommendation Forms and record via Quitmanager.</li> </ul>

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<b>Commissioned Standard Level Pharmacy Stop Smoking Service</b>	<ul style="list-style-type: none"><li>• Provision of Brief support and medication for all clients including young people aged 12-16, pregnant women and other specified cautionary groups.</li><li>• Supply NRT (following pharmacist clinical check) to clients including young people aged 12-16 and pregnant women. To process NRT vouchers and record via Quitmanager.</li><li>• Supply varenicline subject to Clinical Assessment by a PGD-accredited pharmacist to clients over 18 years. To process Champix® Recommendation Forms and record via Quitmanager.</li></ul> <p><b>NB Pharmacies offering the standard level service must also be commissioned to provide the Community Pharmacy Dispensing Only – Introductory Level service.</b></p>
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Pharmacies must only provide services that they are accredited to provide and where staff act within their competence and under adequate local (pharmacy-based) supervision as appropriate.

All pharmacies can assist in stimulating a referral to the stop smoking services through marketing of the wider service and appropriate brief opportunistic advice of harm reduction to customers identifying themselves as smokers; in accordance with NICE guidance (see section 3.4 for information regarding Brief Intervention training).

### 3.2.3 Commissioned Community Pharmacy Stop Smoking Service – Standard Level – specific requirements

- Pharmacies will provide an evidence based stop smoking service in accordance with the service standards and NCSCT Standard Treatment Plan (2014). The service will include NRT or varenicline treatment, on-going support, and appropriate monitoring and follow up. The pharmacy Stop Smoking Service is usually operated on an appointment basis. Appointments will be available at a variety of times throughout the normal opening hours of the pharmacy, including evenings and weekends.
- Suitable individuals are offered an appointment for the Intermediate Assessment at the soonest available opportunity, within one week of the first request. Clients will be advised in advance to allow approximately 20 minutes for the Initial Assessment process to be completed. Where the full service is unavailable in a pharmacy for any reason within the timescales above, clients should be signposted to the nearest available community pharmacy or alternative provider. The Specialist Stop Smoking Service should be informed at the soonest point, ideally within 24 working hours and a notification will be added to Quitmanager; when the service is able to resume the Specialist Service should be notified who will remove the block on Quitmanager.
- Pharmacies will have a minimum of two accredited Stop Smoking Advisors to ensure service continuity.
- Standard Level pharmacies are additionally accredited to offer assessment to smokers including young people of 12 years of age and over and pregnant women. With pharmacist input, they may also support those clients on specific drugs whose therapeutic levels are known to be affected by smoking status (warfarin, theophylline and olanzapine). **NRT products must only be supplied to Young People in accordance with their product license for GSL supply (or P if that were to be applicable)** N.B. Fraser Guidelines must be adhered to for smokers aged under 16 years.
- Pregnant women should ideally be offered an appointment within 2 working days of request, but within one week is acceptable. Where an appointment is unavailable within this timescale, clients must be referred to the nearest available alternative Commissioned Standard Level pharmacy or Specialist Stop Smoking Services.

NB. Some service-users may be referred into the Community Pharmacy Stop Smoking Service having received the Initial Assessment element via an alternative and accredited provider. It is the responsibility of the pharmacy to check the details of the service-users assessment (where instigated by an alternative provider) before proceeding with treatment.

### Discharge Criteria and Planning

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Treatment should ordinarily be completed 12-weeks post quit. Clients requesting varenicline further to the 12-week supply available via PGD should be referred to the Specialist Stop Smoking Service for Nurse prescriber consideration.

All treatment will stop if the client does not quit by day 14 post-quit date, or returns to smoking after this point.

**Self-Care and Patient and Carer Information**

Service users and their carers (where appropriate), should be supplied with appropriate and proportionate levels of advice and resource to enable a successful and sustainable quit attempt. All information supplied verbally and/or in writing, should be communicated in a way that is appropriate to the needs of the individual.

Where applicable, the service should work closely with other specialist substance misuse services to meet the needs of clients using both legal and illegal substances.

Where relevant providers should signpost clients to other relevant services such as NHS Health Check and the Lung Health Check.

**3.3 Population covered**

The Stop Smoking service should be offered to all smokers resident in the Middlesbrough and Redcar & Cleveland local authority areas who demonstrate a commitment and motivation to stop smoking.

Within this target population, the pharmacy is encouraged to ensure that services are configured and marketed appropriately as to appeal to key groups including:

- a) Routine and manual occupations
- b) Pregnant women
- c) Young people aged between 12-16
- d) People living in the top 20% most deprived ward
- e) Black and Minority Ethnic Population

**3.4 Any acceptance and exclusion criteria and thresholds**

Service-users may self-refer either directly (through contact with the pharmacy) and/or indirectly following advice from the local Stop Smoking Service. Service-users may also be referred into the service from other agencies.

Pharmacies can assist in stimulating a referral; through marketing of the service and appropriate brief opportunistic advice to customers identifying themselves as smokers (see section 3.4 for information regarding Brief Intervention training).

Referrals to alternative Stop Smoking Services (including Specialist Stop Smoking Nurse prescribers) should be offered in the following instances:

- service users who cannot be seen by the pharmacy within the maximum wait time,
- Service users meeting the exclusion criteria for NRT Voucher Pathway (see below for Exclusion criteria), or;
- Service users meeting the exclusion criteria for Varenicline Pharmacy PGD (see below for Exclusion criteria)
- service users who present with complex needs or clinical conditions that require more intensive or specialist intervention (e.g. immediate post MI or stroke),
- service-users who wish to use bupropion for their quit attempt.

Referrals may also be offered to service-users who explicitly request an alternative provider for ongoing treatment.

**NRT Voucher Pathway Exclusion Criteria:**



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- Young people under the age of 12 years are excluded from treatment in any pharmacy setting (Dispensing Only or Standard process). They should be referred to their GP practice for normal clinical care.
- Clients service explicitly requesting bupropion.
- Service users currently accessing, referred to and/or discharged from secondary care mental health services – inpatient, residential or long term care for severe mental illness in a hospital, psychiatric, specialist unit and/or secure hospital.
- Clients taking clozapine.
- Clients with severe cardiovascular disease. This is defined as patients with acute, unstable or poorly controlled disease i.e. more than 3 episodes of angina per week.
- Clients with history of an immediate cerebrovascular event.
- Clients with previous serious reaction to NRT or any other ingredients included in products.

**Varenicline Pharmacy Exclusion Criteria:**

Varenicline pharmacy exclusion criteria are defined in the varenicline PGD.

All service-users who meet any of the above exclusion criteria should be referred to the commissioned specialist Stop Smoking Service to manage the client either within the service or via onward referral. Young people under the age of 12 years may be referred to their GP practice.

### 3.5 Interdependencies with other services

Pharmacies will be required to work closely with:

- Middlesbrough, Redcar & Cleveland Stop Smoking Service and named Stop Smoking Advisers
- Public Health South Tees
- General Practices for communication regarding their patient commencing on a Quit attempt with supply of medication
- Bionical, Quitmanager helpdesk

NRT Vouchers and Champix® Recommendation forms will be issued by the local Specialist Stop Smoking Service under the authorisation of the commissioning borough council, as controlled stationary, to trained and accredited Stop Smoking Advisors (SSA) in the pharmacy.

All NRT Vouchers and Champix® Recommendation Forms must be retained by the Pharmacy for a period of 2 years for audit purposes.

### 3.6 Any activity planning assumptions

3.6.1 An annual activity threshold for Community Pharmacy Stop Smoking Services ( Standard Level) have been set as an absolute minimum of **32** smokers per annum to ensure the pharmacy team maintain their skills to support smokers to quit. However, aspirational targets higher than this are set as Quality Indicators to enable monitoring and improvement interventions to be initiated to support pharmacies where recruitment of potential quitters is proving problematic.

3.6.2 Where business changes necessitate a change in the Governance Lead(s), the commissioner for the service should be notified. It is the responsibility of PH contract signatories for the pharmacy provider to be assured that processes for maintaining active Governance Leads are in place and followed.

## 4. Applicable Service Standards

### 4.1 Applicable national standards e.g. NICE

NICE guidance. The National Institute for Health and Care Excellence (NICE) produces public health guidance on the promotion of good health and the prevention of ill health for those working in the NHS, local authorities and the wider public and voluntary sectors. All of the following NICE guidance is directly related to smoking cessation and tobacco control and can be accessed from the NICE website.

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**Public health guidance**

- Brief interventions and referral for smoking cessation (PH1)
- Workplace interventions to support smoking cessation (PH5)
- Smoking cessation services (PH10)
- Preventing the uptake of smoking by children and young people (PH14)
- Identifying and supporting people most at risk of dying prematurely (PH15)
- School-based interventions to prevent smoking (PH23)
- Quitting smoking in pregnancy and following childbirth (PH26)
- Smokeless tobacco cessation (PH39)
- Tobacco harm reduction (PH45)
- Smoking cessation: acute, maternity and mental health services (PH48)
- Stop smoking interventions and services (NG92)

**Quality standards**

Smoking cessation: supporting people to stop smoking (QS43)

**Technical appraisals**

Smoking cessation: varenicline (TA123)

Smoking cessation: bupropion and nicotine replacement therapy (TA39, replaced by PH10)

The Provider at all times will comply with the law and any applicable quality requirements in relation to the service environment. Pharmacies should be operating to GPhC premises standards. This will of course include that the Service Environment is fit for the purpose of providing the Services and is clean, safe, suitable sufficient, adequate, functional, accessible (making reasonable adjustments where required) and effective.

The Public Health Shared service expects that each pharmacy will be aware of the Royal Pharmaceutical Society Professional Standards for Public Health Practice for Pharmacy and be able to demonstrate actively working towards meeting those standards.

**4.2 Applicable local standards**

Services should be delivered within the pharmacy setting. Where necessary consideration should be given to the requirement to maintain patient confidentiality by using a suitable consultation space if appropriate.

The Provider shall ensure that, as a minimum, premises meet requirements needed for the provision of advanced services within the national Community Pharmacy Contractual Framework. A copy of the self-declaration of suitability to provide these services may be requested.

Service monitoring data entry / documentation are required in accordance with the DH requirements and originals of paperwork or electronic templates will be provided by the commissioned specialist Stop Smoking Service provider. Good care should be taken, with the emphasis on suitable training, to ensure that data recorded and submitted quality of such returns is managed

**Both the Pharmacy Initiated NRT Voucher pathway and the Varenicline Pharmacy PGD pathway should be both considered to be dispensary-led activity due to the the requirement for a pharmacist clinical check and labelling requirements.**

**4.2.1 Accreditation Requirements**

A pharmacy cannot provide this service unless accredited, approved and contracted by the relevant Local Authority.

As part of the accreditation process, before being issued a contract, the pharmacy provider must complete a Self-Assessment template

The pharmacy will

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- Nominate both a pharmacist and another member of non-pharmacist staff who will be service Governance Leads for this service and thereby take overall responsibility for ensuring the service is provided to the required standards. Where business changes necessitate a change in the Governance Lead(s), the named Health Improvement Commissioner should be notified and the self-assessment document updated. It is the responsibility of PH contract signatories for the pharmacy provider to be assured that processes for maintaining active Governance Leads are in place and followed.
- Have access to NHS mail and inform the local authority of any changes to the provider email address.
- Have access to Summary Care Records and ensure that relevant staff are trained and have access rights.
- Have suitable Standard Operating Procedures (SOP) to cover all processes involved in delivery of the service. Company policies are acceptable where they reflect the principles of the scheme. Service protocols should reflect national guidelines
- Agree to use Quitmanager for the purpose of data collation, monitoring and management of this service. The pharmacy will ensure good recording-keeping practice; records (including copies of vouchers and recommendation forms) are confidential and should be stored securely for a suitable length of time. All information Governance standards will be adhered to including the use of Quitmanager.
- Ensure that an organisational policy is in place manage any complaints arising from provision of this service.
- Ensure that an organisational policy is in place to manage any clinical incidents arising during provision of this service that will enable incidents to be suitably investigated and reported accordance with the local authority policies and national guidance.
- Ensure that they have appropriate indemnity arrangements in place.
- to co-operate with any locally agreed Local Authority or SSS-led assessment of service user experience
- agree to participate in an annual Local Authority organised audit of service provision and allow access to commissioners to undertake quality assurance/ contract monitoring visits as required
- have appropriate health promotional material available for the patient group and promote its uptake
- demonstrate on request that pharmacists and staff involved in the provision of the service have undertaken CPD relevant to this service; specifically:
- The Governance Lead pharmacist has completed the current CPPE CPD training including NCSCT Stop smoking NCSCT practitioners' assessment: knowledge and skills. The Governance Lead pharmacist must complete and maintain the CPPE Declaration of Competence for Stop Smoking services.
- Pharmacists supplying varenicline via PGD must be accredited in line with the requirements of the PGD
- The pharmacist governance lead and pharmacy staff who wish to be Intermediate Adviser must attend local scheme implementation and any service update training as provided or commissioned and advised by the local authority in conjunction with the local commissioned Stop Smoking Service provider. Currently locally the Intermediate Adviser training is an initial 1 day course with an annual ½ day update session each year. The governance lead and appropriate staff must also complete shadowing opportunities and competency assessment as part of the requirements before service delivery can commence.
- Pharmacies should have a minimum of two accredited Stop Smoking Advisors. In the instance that Stop Smoking Advisors leave the Pharmacy, the Specialist Stop Smoking Service should be informed immediately in order to remove Quitmanager access, in line with Information Governance processes.
- It is the responsibility of the nominated Governance Lead to have taken steps to be assured that all staff (including support staff and locum pharmacists) are adequately trained in the operation of the service, and remain competent to meet the requirements of the service at all times. It is recommended that any locum or relief pharmacists that are known to be employed in the pharmacy (or any number of pharmacies offering this service) on a regular basis should be encouraged to undertake suitable CPD (including CPPE/ NCSCT online training and the CPPE Declaration of Competence) and be accredited to undertake varenicline supply via PGD
- All staff in the pharmacy should be able to have access to a copy of this service specification, protocols and guidance and any relevant updates. Governance leads should take steps to ensure

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that locum pharmacists are made aware of their responsibilities in relation to the service, including clinical checks, within their competence.

- It is the responsibility of the nominated Governance Lead to take steps to ensure that the commissioned service is available – reporting by exception to the stop smoking service manager if for any reason the service cannot be provided in accordance with the contract terms for more than 7 working days. In exceptional circumstances clients can be referred to the stop smoking service for continuation of supply following discussion with the stop smoking service manager

Unless provided otherwise in the relevant Specification, the Provider shall at all times and at its own cost, provide all Equipment necessary to provide the Services in accordance with the Law and any necessary Consent. For the purpose of this agreement, this clause relates specifically to all equipment and resources with the exception of those outlined below:

- CO monitors (these will be distributed by the commissioned specialist Stop Smoking Service provider). Pharmacies must provide auditable calibration records. Pharmacies are responsible for purchasing consumables such as mouth pieces and T-pieces. Pharmacies must adhere to the relevant infection control protocols.

### 5. Location of Provider Premises

The Provider's Premises address is the pharmacy as shown on the main Public Health Contract.

### 6. Required Insurances

As per Public Health Contract Terms and Conditions.

### 7. Quality Outcome Indicators

Quality Requirement	Threshold	Method of Measurement	Consequence of breach
Total no. of intermediate assessments	8 per quarter;	Quarterly submission of data	Remedial action plan
4 week quit rate equal to or in excess of National quality thresholds	≥35%	<u>Numerator:</u> Number of people quitting at 4 weeks <u>Denominator:</u> Number of people setting a quit date Monitored via quarterly performance reports supplied by the Specialist Stop Smoking Service or extracted from QuitManager	Remedial action plan
Min. CO validation rate for those quitting at 4 weeks; CO reading below 10ppm	≥80%	Monitored via monthly remuneration or Quit Manager	Remedial action plan
Complete and accurate submission of the required (mandatory) data set	100%	Monitored via monthly data entry on Quit Manager	Non payment
Loss to follow up	maximum 25% LTFU	Monitored via monthly remuneration or Quit Manager	Remedial action plan

### Additional Quality Standards

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Usual standards of good dispensary practice apply. The service should be adequately resourced in the pharmacy such that requests for smoking cessation support may be efficiently managed. This includes sufficient governance and administrative support for general organisation, service-user contact processes and data reporting.

Clients should have their NRT voucher or Champix® Recommendation Form processed and product dispensed with reasonable promptness, where the pharmacist is satisfied that they have enough information to safely do so.

The pharmacy service should be objectively audited at least annually to ensure that the dispensing service provided is of acceptable quality.

The pharmacy service should ensure that data is appropriately and accurately collated in-line with the Gold Standard Monitoring documentation on QuitManager and in accordance with NHS Records Management policy and practice. The accurate and timely completion of the Gold Standard Monitoring documentation is a pre-requisite for payment under this contract. It is the responsibility of the pharmacy to ensure that Quitmanager records are made contemporaneously alongside the consultation and should be completed within two days of the consultation. For payments made via QuitManager, data must be entered on the system in line with agreed payment schedules.

### **Performance Standards**

Services should meet the minimum annual thresholds of activity outlined.

Pharmacies should be seeking to achieve a minimum 35% 4-week quit rate.

Aspirational target; achievement of a minimum 80% CO validation rates for service-users successfully quitting at 4 weeks, determined by a CO reading of less than 10 ppm

Lost-to-follow-up rates should be lower than 25%\*

100% of service users should be seen within one working week and/or referred to an alternative provider

100% of pregnant service users should be offered an appointment within two working days of request, (but within one week is acceptable) and/or referred to an alternative provider

*\*Lost-to-follow-up status applies to those service users with no recorded quit status 4-weeks post-quit, either through face-to-face validation and/or telephone follow-up.*

### **Client follow up is the responsibility of the pharmacy**

## **8. Charges**

Reimbursement for services delivered will be paid under a combination of Payment by Results tariff and fees for making a dispensed supply of NRT and re-imburement of product costs according to an agreed formulary and payment schedule.

Assuming QuitManager records are completed accurately and submitted in a timely manner (see section 7.1 of the Service Specification for further information), the following payments will apply:

<u>Payment Trigger</u>	<u>Payment Value</u>	<u>Criteria for Payment</u>
<u>Completion of initial assessment (active recruitment patients only)</u>	<u>£10</u>	Secure return of fully completed Gold-Standard monitoring on paper to the Specialist Stop Smoking Hub within two working days of completion or on QuitManager
<u>ANY 4-week quit</u>	<u>£25</u>	Secure return of fully completed Gold Standard monitoring via QuitManager;

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		<ul style="list-style-type: none"> <li>Smoker has not smoked within the third and fourth week of quit date set (established via phone and/or face-to-face);</li> <li>Smoking status has been established between 25 and 42 days post quit date set;</li> <li>Monitoring is completed on QuitManager within two working days of established quit.</li> </ul>
<u>CO verification @ 4 weeks (additional payment to 4 week quit payment shown above)</u>	<u>£25</u>	<p>Secure return of fully completed Gold Standard monitoring via QuitManager; indicating a successful 4 week quit with the following criteria adhered to:</p> <ul style="list-style-type: none"> <li>Smoker has not smoked within the third and fourth week of quit date set;</li> <li>Smoking status has been verified by CO validation with a reading of &lt;10 ppm;</li> <li>Smoking status has been established between 25 and 42 days post quit date set;</li> <li>Monitoring is completed on QuitManager within two working days of established quit.</li> </ul>
<u>CO verified 12-week quit</u>	<u>£40</u>	<p>Secure return of fully completed Gold Standard monitoring via QuitManager; indicating a successful 12 week quit with the following criteria adhered to:</p> <ul style="list-style-type: none"> <li>Smoker has had a successful smoking outcome at 4-weeks;</li> <li>Smoking status has been verified by CO validation with a reading of &lt;10 ppm;</li> <li>Smoking status has been established between 77 and 98 days post quit date set;</li> </ul>

**Pharmacy NRT Dispensing Activity**

Standard Intermediate Stop Smoking Pharmacy Provider Payment Trigger	Condition	Amount
Initial 5 Week Pharmacy Voucher	Once only fee inclusive of all dispensing throughout the 5-week period (1 week, 2 week and 2 week). To be paid once the voucher is closed either by virtue of all dispensing completed or client LTF two weeks after the last possible dispensing date	£10
Subsequent 8 Week Pharmacy Dispensing Voucher Fee	Once only Fee inclusive of all dispensing throughout the remainder of the 12/13 week pathway (2 week, 2 week, 2 week and 2 week). To be claimed once the voucher is either closed by virtue of all dispensing completed or client LTF two weeks after last possible dispensing date	£5

**Pharmacy varenicline dispensing activity**

Initial Clinical Check & Dispensing		£12.50
Dispensing Fee (maximum two week supply)	Up to a maximum of 12 weeks product dispensed	£2.50

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(Subsequent clinical check fees are incorporated into the dispensing fee)			
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**9. Product Costs**

For NRT and Champix® supplied by voucher / Champix® recommendation Form the local Authority reimburses pharmacies for the cost of drugs supplied and for VAT (currently at 5%). Prices paid are agreed with the LPC at regular intervals. A pricing schedule is available on request and will normally be available on QuitManager.

QuitManager will generate of invoices for activity from the previous month on the 11th working day of the following month. For example, it will only be possible to generate invoices for May 2019 on and after the 11th working day of June 2019. In determining the working days in a month, bank holidays will NOT be counted.

Providers do not need to send these invoices to the Local Authority; the Local Authority will receive the invoices via quit manager. The Local Authority will process the invoices on the 13th working day of the month. This will allow 2 days for you to raise any queries about the invoice generated by QuitManager. It is the responsibility of the provider to report any discrepancies to the named Commissioner by the 13th working day of the month. The invoice will be submitted for payment if contact is not made by the 13th day. If any queries are made after this time, reconciliation will take place at a later date.

**References**

Department of Health, 2009. *Healthy Lives Healthy People: A Tobacco Control Plan for England*, s.l.: Department of Health.

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Department of Health, 2013. *Public Health Outcomes Framework 2013-2016 and technical updates*, s.l.: Department of Health.